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4-13-04

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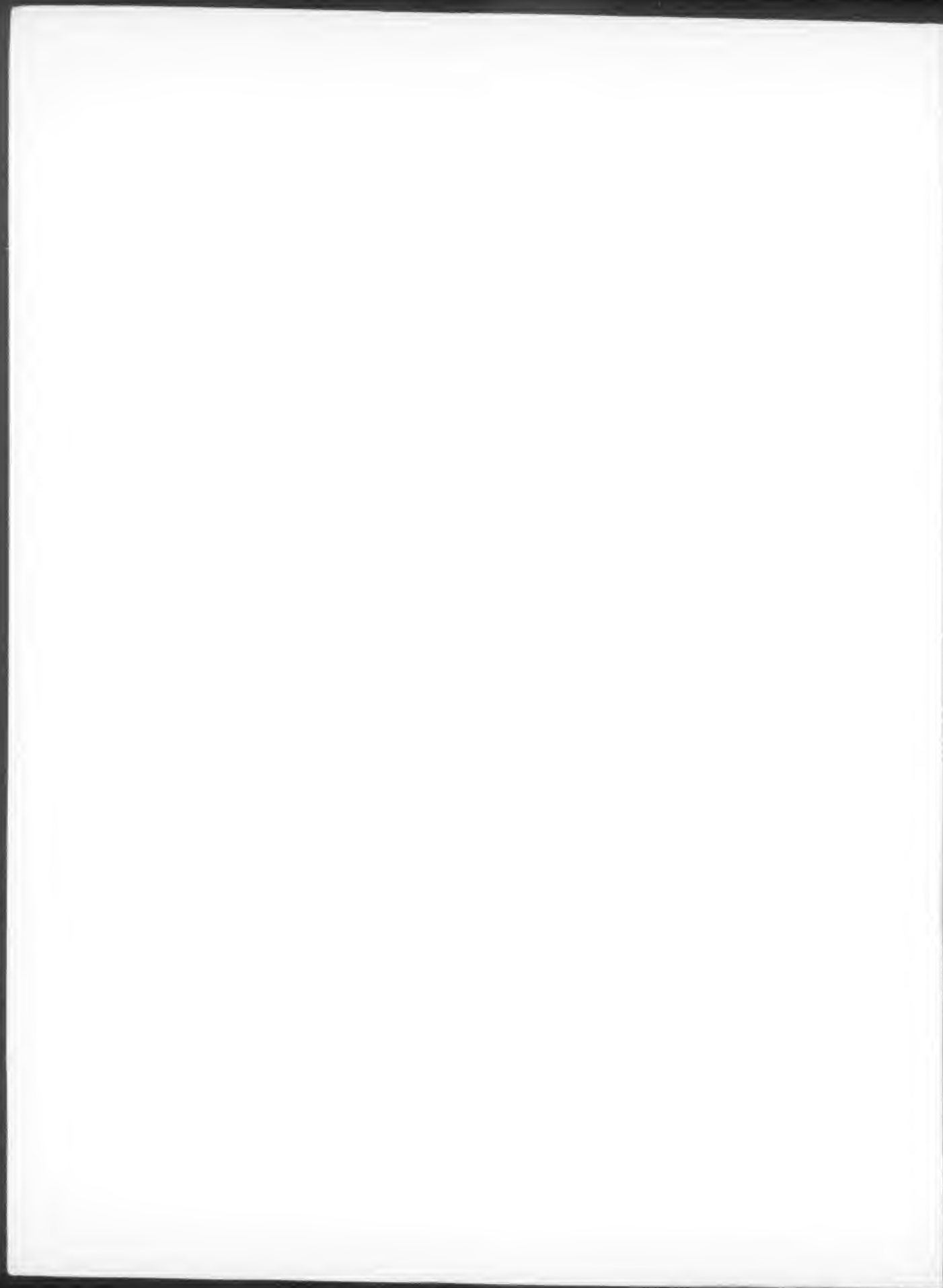
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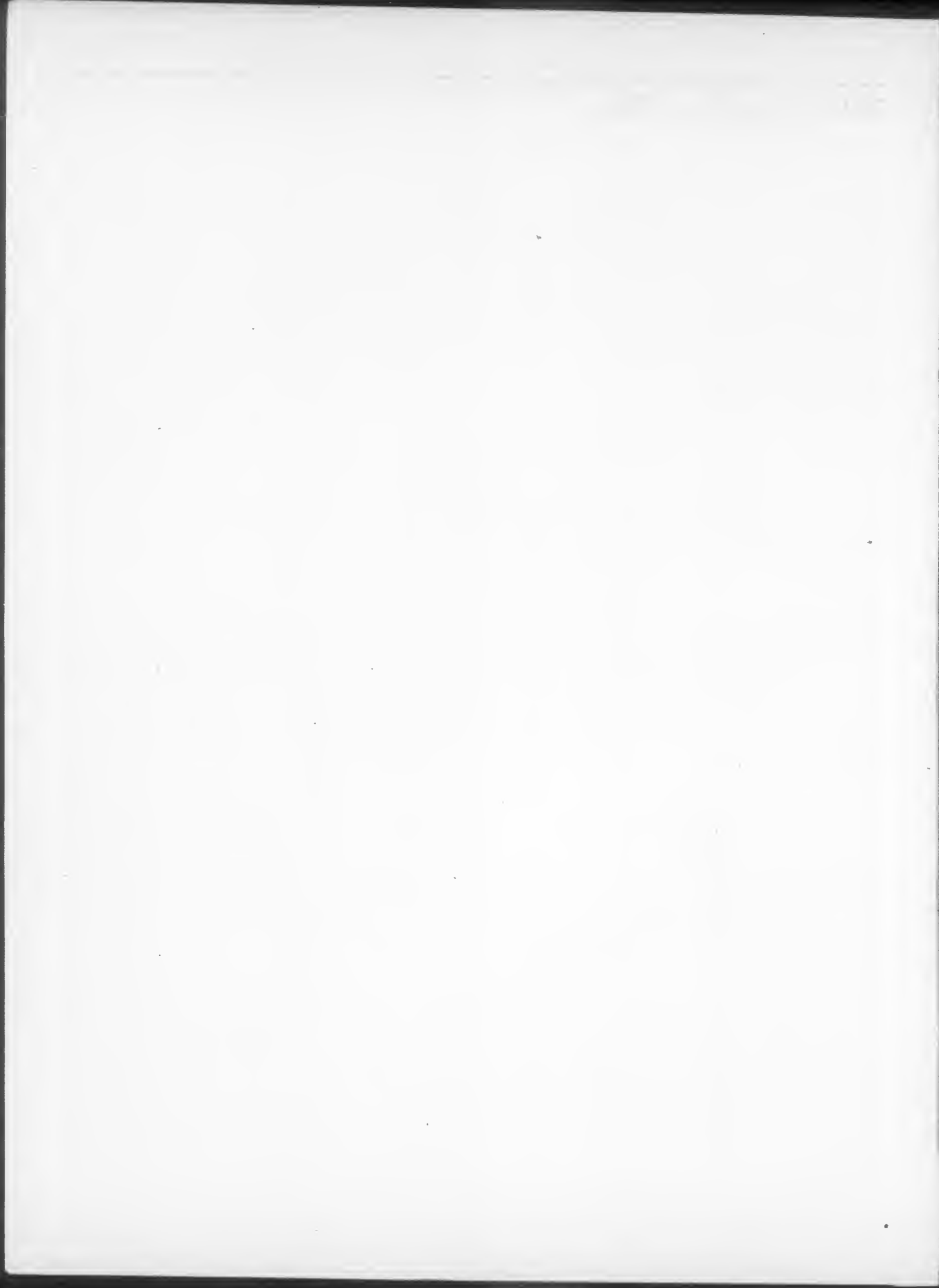
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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 25

[Docket No. NM276, Special Conditions No. 25-259-SC]

#### Special Conditions: Learjet Models 24 and 25 Airplanes; High Intensity Radiated Fields (HIRF)

**AGENCY:** Federal Aviation Administration (FAA) DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for Learjet Models 24 B/D/E/F and 25 B/C/D/F airplanes, modified by Flight Test Associates, Incorporated. These modified airplanes will have novel and unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The modification incorporates the installation of a dual Innovative Systems and Support Air Data Display Unit system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

**DATES:** The effective date of these special conditions is March 31, 2004. Comments must be received on or before May 13, 2004.

**ADDRESSES:** Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM-113), Docket No. NM276, 1601 Lind Avenue SW.,

Renton, Washington, 98055-4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: Docket No. NM276.

**FOR FURTHER INFORMATION CONTACT:** Mr. Steve Edgar, FAA, Standardization Branch, ANM-113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055-4056; telephone (425) 227-2025; facsimile (425) 227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

The FAA has determined that the notice and opportunity for prior public comment is impracticable because these procedures would significantly delay certification of the airplane and delivery of the affected airplane. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance; however, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

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

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

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped

postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

##### Background

On August 22, 2003, Flight Test Associates, Incorporated, Mojave, California, applied to the FAA, Los Angeles Aircraft Certification Office, for a supplemental type certificate (STC) to modify Learjet Models 24 B/D/E/F and 25 B/C/D/F airplanes. The proposed modification incorporates the installation of a dual Innovative Systems and Solution Air Data Display Unit (ADDU) system as primary altimeters. The information presented is flight critical. The ADDU systems installed in this airplane have the potential to be vulnerable to HIRF.

##### Type Certification Basis

Under the provisions of 14 CFR 21.101, Flight Test Associates, Incorporated, must show that the airplane, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A10CE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis."

The regulations incorporated by reference in Type Certificate No. A10CE include 14 Code of Federal Regulations (CFR) part 25, as amended by Amendments 25-2 through 25-18.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 25, as amended) do not contain adequate or appropriate safety standards for the modified Learjet Models 24 B/D/E/F and 25 B/C/D/F airplanes, because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Learjet Models 24 B/D/E/F and 25 B/C/D/F airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101.



Special conditions are initially applicable to the model for which they are issued. Should Flight Test Associates, Incorporated, apply at a later date for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under the provisions of § 21.101.

#### Novel or Unusual Design Features

The modified Learjet Models 24 B/D/E/F and 25 B/C/D/F will incorporate new dual primary altimeters that will perform critical functions. These systems may be vulnerable to HIRF external to the airplane.

#### Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive avionics/electronics and electrical systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Learjet Models 24 B/D/E/F and 25 B/C/D/F. These special conditions require that new primary altimeters that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

#### High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications coupled with electronic command and control of the airplane, the immunity of critical digital avionics/electronics and electrical systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1 or 2 below:

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the field strengths indicated in the following table for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz-100 kHz	50	50
100 kHz-500 kHz	50	50
500 kHz-2 MHz	50	50
2 MHz-30 MHz	100	100
30 MHz-70 MHz	50	50
70 MHz-100 MHz	50	50
100 MHz-200 MHz	100	100
200 MHz-400 MHz	100	100
400 MHz-700 MHz	700	50
700 MHz-1 GHz	700	100
1 GHz-2 GHz	2000	200
2 GHz-4 GHz	3000	200
4 GHz-6 GHz	3000	200
6 GHz-8 GHz	1000	200
8 GHz-12 GHz	3000	300
12 GHz-18 GHz	2000	200
18 GHz-40 GHz	600	200

The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

#### Applicability

As discussed above, these special conditions are applicable to Learjet Models 24 B/D/E/F and 25 B/C/D/F series airplanes. Should Aircraft Systems & manufacturing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well as under the provisions of 14 CFR 21.101.

#### Conclusion

This action affects only certain novel or unusual design features on the Learjet

Models 24 B/D/E/F and 25 B/C/D/F airplanes modified by Flight Test Associates, Incorporated. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of the special conditions for these airplanes has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. Because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

#### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

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

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

#### The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the modified Learjet Models 24 B/D/E/F and 25 B/C/D/F airplanes modified by Flight Test Associates, Incorporated.

1. *Protection From Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies:

*Critical Functions:* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.



Issued in Renton, Washington, on March 31, 2004.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04-8355 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2002-NM-174-AD; Amendment 39-13483; AD 2004-04-03

RIN 2120-AA64

#### Airworthiness Directives; Boeing Model 737-300, -400, and -500 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects a typographical error that appeared in airworthiness directive (AD) 2004-04-03 that was published in the **Federal Register** on February 18, 2004 (69 FR 7565). The typographical error resulted

in a reference to an incorrect effective date in the compliance time specified in Table 1 of the AD for Group 1 airplanes. This AD is applicable to certain Boeing Model 737 series airplanes. This AD requires a one-time general visual inspection of the seat locks and seat tracks of the flightcrew seats to ensure that the seats lock in position and to verify that lock nuts and bolts of adequate length are installed on the rear track lock bracket, and corrective action, if necessary.

**DATES:** Effective March 24, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Shannon Lennon, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM-150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 917-6436; fax (425) 917-6590.

**SUPPLEMENTARY INFORMATION:**

Airworthiness Directive (AD) 2004-04-03, amendment 39-13483, applicable to certain Boeing Model 737 series airplanes, was published in the **Federal Register** on February 18, 2004 (69 FR 7565). That AD requires a one-time general visual inspection of the seat locks and seat tracks of the flightcrew

seats to ensure that the seats lock in position and to verify that lock nuts and bolts of adequate length are installed on the rear track lock bracket, and corrective action, if necessary.

As published, that final rule incorrectly specifies "September 26, 2001" as the effective date for AD 2000-10-21 in the compliance time specified for Group 1 airplanes in Table 1 of that final rule. The correct effective date of AD 2000-10-21 is "June 12, 2000." It was the FAA's intent that operators use June 12, 2000, to determine the compliance time for Group 1 airplanes as specified in Table 1 of that final rule, as evidenced by the explanatory parenthetical reference "(the effective date of AD 2000-10-21, amendment 39-11745)."

Since no other part of the regulatory information has been changed, the final rule is not being republished in the **Federal Register**.

The effective date of this AD remains March 24, 2004.

**§ 39.13 [Corrected]**

On page 7566, the second column of Table 1 of AD 2004-04-03 is corrected to read as follows:

\* \* \* \* \*

TABLE 1.—COMPLIANCE TIME/SERVICE BULLETIN

Airplanes—	Compliance time—	Service bulletin—
For Group 1 airplanes listed in Boeing Alert Service Bulletin 737-25A1363, Revision 1, dated March 28, 2002.	Within 90 days after June 12, 2000 (the effective date of AD 2000-10-21, amendment 39-11745).	Boeing Alert Service Bulletin 737-25A1363, dated November 5, 1998.
For Group 2 airplanes listed in Boeing Alert Service Bulletin 737-25A1363, Revision 1, dated March 28, 2002.	Within 90 days after the effective date of this AD.	Boeing Alert Service Bulletin 737-25A1363, Revision 1, dated March 28, 2002.

\* \* \* \* \*

Issued in Renton, Washington, on April 1, 2004.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04-8296 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2004-NM-03-AD; Amendment 39-13514; AD 2004-05-19]

RIN 2120-AA64

#### Airworthiness Directives; Boeing Model 737-600, -700, -700C, -800, and -900 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects an error that appeared in airworthiness directive (AD) 2004-05-19 that was published in the **Federal Register** on March 9, 2004 (69 FR 10921). The error resulted in the omission of the phrase "whichever occurs first" in a certain

grace period for the initial compliance time. This AD is applicable to all Boeing Model 737-600, -700, -700C, -800, and -900 series airplanes. This AD requires an inspection of the rear spar attach pins and front spar attach bolts that attach the horizontal stabilizers to the horizontal stabilizer center section for damage; and follow-on or corrective actions, as applicable.

**DATES:** Effective March 24, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 917-6440; fax (425) 917-6590.

**SUPPLEMENTARY INFORMATION:**

Airworthiness Directive (AD) 2004-05-19, amendment 39-13514, applicable to all Boeing Model 737-600, -700, -700C, -800, and -900 series airplanes, was

published in the **Federal Register** on March 9, 2004 (69 FR 10921). That AD requires an inspection of the rear spar attach pins and front spar attach bolts that attach the horizontal stabilizers to the horizontal stabilizer center section for damage; and follow-on or corrective actions, as applicable.

As published, in the second row of the "Grace Period" column of Table 1 of AD 2004-05-19, the phrase "whichever occurs first" was inadvertently omitted. The correct grace period should have read, "For airplanes on which Boeing Service Bulletin 737-55-1074, dated August 15, 2002, has been done as of the effective date of this AD: Within 24 months or 6,000 flight cycles since accomplishment of the service bulletin, whichever occurs first."

Since no other part of the regulatory information has been changed, the final rule is not being republished in the **Federal Register**.

The effective date of this AD remains March 24, 2004.

**§ 39.13 [Corrected]**

On page 10922, in the third column, and on page 10933, in the first column, Table 1 of paragraph (a) of AD 2004-05-19 is corrected to read as follows:

\* \* \* \* \*  
(a) \* \* \*

**TABLE 1.—INITIAL COMPLIANCE TIME**

Threshold	Grace period
Prior to the accumulation of 15,000 total flight cycles or 60 months since the date of issuance of the original Airworthiness Certificate or the date of issuance of the Export Certificate of Airworthiness, whichever occurs first.	For airplanes on which Boeing Service Bulletin 737-55-1074, dated August 15, 2002, has not been done as of the effective date of this AD: Within 90 days after the effective date of this AD.
	For airplanes on which Boeing Service Bulletin 737-55-1074, dated August 15, 2002, has been done as of the effective date of this AD: Within 24 months or 6,000 flight cycles since accomplishment of the service bulletin, whichever occurs first.

\* \* \* \* \*

Issued in Renton, Washington, on April 6, 2004.

**Kevin M. Mullin,**  
*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*  
[FR Doc. 04-8297 Filed 4-12-04; 8:45 am]  
BILLING CODE 4910-13-P

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Docket No. FAA-2004-17341; Airspace Docket No. 02-ASO-4]

**Establishment of Class D Airspace; Greenville Donaldson Center, SC, Amendment of Class E Airspace; Greer, Greenville-Spartanburg Airport, SC, and Amendment of Class E Airspace; Greenville, SC**

**AGENCY:** Federal Aviation Administration (FAA), DOT.  
**ACTION:** Final rule; confirmation of effective date.

**SUMMARY:** This action confirms the new effective date for the establishment of Class D airspace at Greenville Donaldson Center, SC, the amendment of Class E2 airspace at Greer, Greenville-Spartanburg Airport, SC, and the amendment of Class E5 airspace at Greenville, SC. The construction of a new federal contract tower with a weather reporting system was delayed; therefore, the effective date of the establishment of Class D and E2 airspace and amendment of Class E5 airspace was also delayed.

**EFFECTIVE DATE:** The effective date of November 28, 2002, published on May 1, 2002, (67 FR 21575), and subsequently delayed indefinitely (67 FR 65872), is now 0901 UTC, August 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5586.

**SUPPLEMENTARY INFORMATION:**

**History**

Airspace Docket No. 02-ASO-04, published in the **Federal Register** on May 1, 2002 (67 FR 21575), established Class D airspace at Greenville Donaldson Center, SC, amended Class E2 airspace at Greer, Greenville-Spartanburg Airport, SC, and amended Class E5 airspace at Greenville, SC. The construction of a federal contract tower with a weather reporting system at Donaldson Center Airport made this

action necessary. This action was originally scheduled to become effective on November 28, 2002; however, an unforeseen delay in beginning construction on the tower required the effective date of this action to be delayed. Construction is now nearing completion.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (Air).

**Confirmation of Effective Date**

■ The effective date on Airspace Docket No. 02-ASO-4 is hereby confirmed to be August 5, 2004.

**Authority:** 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

\* \* \* \* \*

Issued in College Park, Georgia, on March 24, 2004.

**Jeffrey U. Vincent,**  
*Acting Manager, Air Traffic Division, Southern Region.*

[FR Doc. 04-8360 Filed 4-12-04; 8:45 am]  
BILLING CODE 4910-13-M

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Docket No. FAA-2004-16861; Airspace Docket No. 04-ASO-1]

**Amendment of Class D and E4 Airspace; Homestead, FL**

**AGENCY:** Federal Aviation Administration (FAA), DOT.  
**ACTION:** Final rule.

**SUMMARY:** This action amends Class D and E4 airspace at Homestead, FL. The name of the airport has changed from Dade County—Homestead Regional

Airport to Homestead Air Reserve Base (ARB). As a result of an evaluation, it has been determined a modification should be made to the Homestead, FL, Class D and E4 airspace areas to contain the Tactical Air Navigation (TACAN) or Instrument Landing System (ILS) Runway (RWY) 5, Standard Instrument Approach Procedure (SIAP) to the Homestead ARB. Additional surface area airspace is needed to contain the SIAP.

**EFFECTIVE DATE:** 0901 UTC, June 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5627.

**SUPPLEMENTARY INFORMATION:**

**History**

On February 19, 2004, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending Class D and E4 airspace at Homestead ARB, FL (69 FR 7713). This action provides adequate Class D and E4 airspace for IFR operations at Homestead ARB, FL. Designations for Class D airspace areas extending upward from the surface of the earth and Class E airspace designations for airspace designated as surface areas are published in Paragraphs 5000 and 6004 respectively, of FAA Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR part 71.1. The Class D and E designations listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

**The Rule**

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends Class D and E4 airspace at Homestead ARB, FL.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant

preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (Air).

**Adoption of the Amendment**

■ In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 5000 Class D Airspace*

\* \* \* \* \*

**ASO FL D Homestead, FL [Revised]**

Homestead ARB, FL

(Lat. 25°29'18" N., long. 80°23'01" W.)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 5.5-mile radius of Homestead ARB.

\* \* \* \* \*

*Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area*

\* \* \* \* \*

**ASO FL E4 Homestead, FL [Revised]**

Homestead ARB, FL

(Lat. 25°29'18" N., long. 80°23'01" W.)

That airspace extending upward from the surface within 1.5 miles each side of the 50° bearing and the 230° bearing from Homestead ARB extending from the 5.5-mile radius to 7 miles northeast and southwest of the airport.

\* \* \* \* \*

Issued in College Park, Georgia on March 31, 2004.

**Jeffrey U. Vincent,**

*Acting Manager, Air Traffic Division, Southern Region.*

[FR Doc. 04-8357 Filed 4-12-04; 8:45 am]

**BILLING CODE 4910-13-M**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Docket No. FAA-2004-16904; Airspace Docket No. 04-ASO-2]

**Establishment of Class E5 Airspace; Jamestown, KY; Correction**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Correcting amendment.

**SUMMARY:** This document contains a correction to the final rule (FAA-2004-16904; 04-ASO-2), which was published in the *Federal Register* on March 23, 2004, (69 FR 13470), establishing Class E5 airspace at Jamestown, KY. This action corrects an error in the legal description for the Class E5 airspace at Russell County Airport, KY.

**EFFECTIVE DATE:** Effective 0901 UTC, June 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5627.

**SUPPLEMENTARY INFORMATION:**

**Background**

Federal Register Document 04-6453, Docket No. FAA-2004-16904; Airspace Docket 04-ASO-2, published on March 23, 2004, (69 FR 13470), establishes Class E5 airspace at Russell County Airport, KY. An error was discovered in the legal description, describing the Class E5 airspace area. The word "mile" was inadvertently omitted after 6.5 and before the word radius. This action corrects the error.

Designations for 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 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, 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.

**Need for Correction**

As published, the final rule contains an error, which inadvertently omits the word "mile". Accordingly, pursuant to the authority delegated to me, the legal description for the Class E5 airspace area at Jamestown, KY, incorporated by reference at § 71.1, 14 CFR 71.1, and published in the *Federal Register* on March 23, 2004, (69 FR 16904), is corrected by making the following correcting amendment.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

■ In consideration of the foregoing, the Federal Aviation Administration corrects the adopted amendment, 14 CFR Part 71, by making the following correcting amendment:

**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 [Corrected]**

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows: Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

\* \* \* \* \*

**ASO KY 5E Jamestown, KY [Corrected]**

Russell County Airport, KY  
(Lat. 37°00'32" N., long. 85°06'10" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Russell County Airport.

\* \* \* \* \*

Issued in College Park, Georgia on March 31, 2004.

**Jeffrey U. Vincent,**

*Acting Manager, Air Traffic Division,  
Southern Region.*

[FR Doc. 04–8359 Filed 4–12–04; 8:45 am]

**BILLING CODE 4910–13–M**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA–2004–17295; Airspace Docket No. 04–AEA–02]

**Amendment of Class E Airspace;  
District of Columbia, Maryland,  
Virginia, and West Virginia**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final Rule; request for comments.

**SUMMARY:** This action removes the description of the Class E airspace designated for Andrews Air Force Base, MD; Lee Airport, MD; Baltimore Washington International Airport, MD; Martin State Airport, MD; College Park Airport, MD; Maryland State Police Heliport, Ft. McHenry, MD; Tipton Airport, MD; Frederick Municipal Airport, MD; Potomac Airport, MD; Montgomery County Airport, MD; Freeway Airport, MD; Bay Bridge Airport, MD; Cowley Shock Trauma Center Heliport, Baltimore, MD; Carroll County Airport, MD; Clearview Airpark, MD; Maryland Airport, MD; Davison Army Airfield, Ft. Belvoir, VA; Birch Hollow, VA; Washington Dulles International Airport, VA; Leesburg Executive Airport, VA; Manassas Municipal/Harry P. Davis Airport, VA; Mobile Business Resources Corporation Heliport, VA; Upperville Airport, VA; Eastern West Virginia Regional/Shepherd Field Airport, WV. The affected Class E–5 airspace for the airports included in these descriptions will be consolidated into the amended Washington, DC airspace description contained in Docket No. FAA–2004–17295; Airspace Docket No. 04–AEA–01, effective August 5, 2004.

**DATES:** *Effective date:* August 5, 2004.

*Comment Date:* Comments must be received on or before June 30, 2004.

**ADDRESSES:** Send comments on the rule 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–2004–17295; Airspace Docket No. 04–AEA–02 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 rule, any comments received, and any final disposition in person in the Docket Office between 9 a.m. and 5 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.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4890.

**FOR FURTHER INFORMATION CONTACT:** Mr. Francis Jordan, Airspace Specialist, Airspace Branch, AEA–520, Aviation Plaza, Jamaica, NY 11434–4809, telephone: (718) 553–4521.

**SUPPLEMENTARY INFORMATION:** Although this action is a final rule, which involves the amendment of Class E airspace within District of Columbia, Maryland, Virginia, and West Virginia, by consolidating that airspace into one description, and was not preceded by notice and public procedure, comments are invited on the rule. This rule will become effective on the date specified in the **DATES** section. However, after the review of any comments, if the FAA finds that further changes are appropriate, it will initiate rulemaking proceedings to extend the effective date or to amend the regulation.

Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule, and in determining whether additional rulemaking is required. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the rule which might suggest the need to modify the rule.

**The Rule**

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) amends the description of Class E airspace in the Washington, DC area by removing the airspace designations for Andrews Air Force Base, MD; Lee Airport, MD; Baltimore Washington International Airport, MD; Martin State Airport, MD; College Park Airport, MD; Maryland State Police Heliport, Ft. McHenry, MD; Tipton Airport, MD; Frederick Municipal Airport, MD; Potomac Airport, MD; Montgomery County Airpark, MD; Freeway Airport, MD; Bay Bridge Airport, MD; Cowley Shock Trauma Center Heliport, Baltimore, MD; Carroll County Airport, MD; Clearview Airpark, MD; Maryland Airport, MD; Davison Army Air Field, Ft. Belvoir, VA; Birch Hollow, VA; Washington Dulles International Airport, VA; Leesburg Executive Airport, VA; Manassas Municipal/Harry P. Davis Airport, VA; Mobil Business Resources Corporation Heliport, VA;

Upperville Airport, VA; Eastern West Virginia Regional/Shepherd Field Airport, WV. It consolidates those airspace areas into the amended Washington, DC description. The proliferation of airports with Instrument Flight Rule (IFR) operations within the Washington, DC metropolitan area has resulted in the overlap of numerous Class E airspace areas that complicate the chart depictions. This action clarifies the airspace and diminishes the scope and complexity of charting. The IFR airports within those areas will be incorporated into the Washington, DC Class E airspace area. Accordingly, since this action merely consolidates these airspace areas into one airspace designation and has inconsequential impact on aircraft operations in the area, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Class E airspace designations for airspace extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, 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 FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation it is certified that this rule will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporated by reference, Navigation (air).

#### Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

#### PART 71—[AMENDED]

■ 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 the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003 and effective September 16, 2003, is amended as follows:

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

*	*	*	*	*
AEA MD E5	Annapolis, MD	[Removed]		
AEA MD E5	Baltimore, MD	[Removed]		
AEA MD E5	College Park, MD	[Removed]		
AEA MD E5	Edgewood, MD	[Removed]		
AEA MD E5	Fort McHenry, MD	[Removed]		
AEA MD E5	Fort Meade, MD	[Removed]		
AEA MD E5	Frederick, MD	[Removed]		
AEA MD E5	Friendly, MD	[Removed]		
AEA MD E5	Gaithersburg, MD	[Removed]		
AEA MD E5	Indian Head, MD	[Removed]		
AEA MD E5	Mitchellville, MD	[Removed]		
AEA MD E5	Stevensville, MD	[Removed]		
AEA MD E5	University of Maryland, Baltimore, MD	[Removed]		
AEA MD E5	Westminster Carroll County Airport, MD	[Removed]		
AEA MD E5	Westminster Clearview Airport, MD	[Removed]		
AEA VA E5	Birch Hollow, VA	[Removed]		
AEA VA E5	Chantilly, VA	[Removed]		
AEA VA E5	Fairfax, VA	[Removed]		
AEA VA E5	Upperville, VA	[Removed]		
AEA WVA E5	Martinsburg, WV	[Removed]		
*	*	*	*	*

Issued in Jamaica, New York, on April 5, 2004.

**John G. McCartney,**

*Assistant Manager, Air Traffic Division, Eastern Region.*

[FR Doc. 04–8363 Filed 4–12–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA 2003–16214; Airspace Docket 02–ANM–11]

#### Revision of Class E Airspace; Kalispell, MT

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This final rule will revise Class E airspace at Kalispell, MT. An increase in Area Navigation (RNAV) Global Position System (GPS) Standard Instrument Approach procedures (SIAP) operations at Glacier Park International Airport, Kalispell, MT, makes it

necessary to increase the area controlled airspace. This additional controlled airspace extending upward from 1,200 feet above the surface of the earth is necessary for the containment and safety of Instrument Flight Rules (IFR) aircraft transitioning to/from the en route environment and executing these SIAP procedures.

**EFFECTIVE DATE:** 0901 UTC, August 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Ed Haesecker, Federal Aviation Administration, Air Traffic Division, 1601 Lind Avenue SW., Renton, WA 98055–4056; telephone (425) 227–2527.

#### SUPPLEMENTARY INFORMATION:

#### History

On October 21, 2003, the FAA proposed to amend Title 14 Code of Federal Regulations part 71 (CFR part 71) to modify Class E airspace at Kalispell, MT (68 FR 60049). An increase in RNAV GPS SIAP operations at Glacier Park International Airport, Kalispell, MT, makes it necessary to increase the area controlled airspace. This additional controlled airspace is necessary for the containment and safety of IFR aircraft transitioning to/from the en route environment and executing these SIAP procedures.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9L dated September 02, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

#### The Rule

This amendment to 14 CFR part 71 revises Class E airspace at Kalispell, MT. An increase in RNAV GPS SIAP operations at Glacier Park International Airport, Kalispell, MT, makes it necessary to increase the area controlled airspace. This additional controlled airspace extending upward from 1,200 feet above the surface of the earth is for the containment and safety of IFR aircraft transitioning to/from the en route environment and executing these SIAP procedures.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "significant regulatory action"



under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### Adoption of the Amendment

■ In consideration of the foregoing, 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; ROUTES; AND REPORTING POINTS.

■ 1. The authority citation for 14 CFR 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 part 71.1 of the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 02, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 6005 Class E Airspace area extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

#### ANM MT E5 Kalispell, MT [Revised]

Kalispell/Glacier Park International Airport, MT

(Lat. 48°18'41"N., long. 114°15'18"W.);  
Smith Lake Non Directional Beacon (NDB)  
(Lat. 48°06'30"N., long. 114°27'40"W.)

That airspace extending upward from 700 feet above the surface of the earth within a 7 mile radius of Kalispell/Glacier Park International Airport, and within 4.8 miles each side of the 035° and 215° bearings from the Smith Lake NDB extending from the 7 mile radius to 10.5 miles southwest of the NDB; that airspace extending upward from 1,200 feet above the surface of the earth bounded by a line from lat. 47°30'00"N., long. 112°37'30"W.; to lat. 47°43'30"N., long. 112°37'30"W.; to lat. 48°07'30"N., long. 113°30'00"W., to lat. 48°30'00"N., long. 113°30'00"W., to lat. 48°30'00"N., long. 116°03'35"W.; to lat. 47°30'00"N., long. 114°54'23"W.; thence to point of origin; excluding Kalispell/Glacier Park

International Airport Class D airspace, Class E2 airspace, and that airspace within Federal Airways.

\* \* \* \* \*

Issued in Seattle, Washington, on April 2, 2004.

Carla J. Mawhorter,  
Acting Manager, Air Traffic Division,  
Northwest Mountain Region.

[FR Doc. 04-8361 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2003-16266; Airspace Docket 01-ANM-11]

#### Amendment to Class E Airspace; Yakima, WA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment modifies the Class E airspace at Yakima, WA. New radar directed missed approach procedures have been developed at Yakima Air Terminal/McAllister Field, Yakima, WA, making it necessary to increase the area of controlled airspace. This additional controlled airspace extending upward from the surface of the earth is necessary for the safety of Instrument Flight Rules (IFR) aircraft executing new radar detected missed approach procedures.

**EFFECTIVE DATE:** 0901 UTC, August 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Ed Haeseker, Air Traffic Division, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, Washington 98055-4556; telephone (425) 227-2527.

**SUPPLEMENTARY INFORMATION:** On August 23, 2001, the FAA proposed to amend Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by modifying the airspace at Yakima, WA (66 FR 44327). This proposal would modify controlled airspace extending upward from the surface of the earth to contain IFR operations within controlled airspace when executing radar missed approach procedures. The published missed approach procedure for Instrument Landing System (ILS) Runway 27 at the Yakima Air Terminal/McAllister Field Airport requires a course reversal. Application of radar missed approach procedures introduces alternative radar directed courses and will eliminate conflicts with subsequent Runway 27 arrivals. Radar vector

missed approach procedures will increase airport efficiency during peak arrival periods.

Interested parties were invited to participate in this rule making proceeding by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in FAA Order 7400.9L dated September 02, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

#### The Rule

This amendment to 14 CFR part 71 will modify the Class E airspace at Yakima, WA, to accommodate aircraft executing the radar missed approach procedures. The radar missed approach procedures for ILS Runway 27 requires a course reversal that makes it necessary to increase the area of controlled airspace at the Yakima Air Terminal/McAllister Field Airport, Yakima, WA. This additional Class E airspace extending upward from the surface of the earth is necessary for the containment and safety of aircraft executing these procedures.

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

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### Adoption of the Amendment

■ In consideration of the foregoing, 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 14 CFR 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 part 71.1 of the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 6004 Class E airspace areas designated as an extension to a Class D surface area.*

\* \* \* \* \*

**ANM WA E4 Yakima, WA [Revised]**

Yakima Air Terminal/McAllister Field Airport

(Lat. 46°34'05.4"N., long. 120°32'38.6"W.)

That airspace extending upward from the surface within 2.5 miles each side of the 287° bearing from the Yakima Air Terminal extending from the 4.2 mile radius of Yakima Air Terminal to 9 miles northwest of the airport, and within 3.5 miles northeast and 1.8 miles southwest of the 107° bearing from the airport extending from the 4.2 mile radius of the airport to 11.2 miles southeast of the airport.

\* \* \* \* \*

■ 3. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

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

\* \* \* \* \*

**ANM WA E5 Yakima, WA [Revised]**

Yakima Air Terminal/McAllister Field Airport

(Lat. 46°34'05.4"N., long. 120°32'38.6"W.)

Yakima VORTAC

(Lat. 46°34'13.0"N., long. 120°26'40.6"W.)

That airspace extending upward from 700 feet above the surface within a 7.5 mile radius of the Yakima Air Terminal, and within 4.5 miles northeast and 9.5 miles southwest of the Yakima VORTAC 094° bearing extending from the 7.5 mile radius of the airport to 21 miles southeast of the VORTAC, and within 4.0 miles north and 5 miles south of the 287° bearing from the Yakima Air Terminal extending from the 7.5 mile radius of the airport to 16 miles northwest of the airport; that airspace extending upward from 1,200 feet above the

surface bounded by a line beginning at lat. 46°10'00"N., long. 119°45'00"W.; thence to lat. 46°10'00"N., long. 121°00'00"W.; to lat. 46°50'00"N., long. 121°00'00"W.; to lat. 46°50'00"N., long. 119°45'00"W.; thence to the point of origin, excluding that airspace within Federal Airways and the Ellensburg, WA, Class E airspace area.

\* \* \* \* \*

Issued in Seattle, Washington, on April 2, 2004.

Carla J. Mawhorter,

Acting Manager, Air Traffic Division,  
Northwest Mountain Region.

[FR Doc. 04–8356 Filed 4–12–04; 8:45 am]

BILLING CODE 4910–13–M

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 71**

[Docket No. FAA–2004–17081; Airspace Docket No. 04–AEA–01]

**Amendment of Class E Airspace; Washington, DC**

**AGENCY:** Federal Aviation Administration [FAA], DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends Class E airspace at Washington, DC. The development of multiple area navigation (RNAV) Standard Instrument Approach Procedures (SIAP) and the proliferation of airports within the metropolitan Washington, DC area with approved Instrument Flight Rules (IFR) operations and the resulting overlap of designated Class E–5 airspace have made this action necessary. This action consolidates the Class E–5 airspace designations for twenty four airports and results in the rescission of twenty Class E–5 descriptions through separate rulemaking action. The area will be depicted on aeronautical charts for pilot reference.

**EFFECTIVE DATE:** 0901 UTC August 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mr. Francis Jordan, Airspace Specialist, Airspace Branch, AEA–520, Air Traffic Division, Eastern Region, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, New York 11434–4809, telephone: (718) 553–4521.

**SUPPLEMENTARY INFORMATION:**

**History**

On February 25, 2004, a notice proposing to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by consolidating existing Class E–5 airspace designations in the Washington, DC metropolitan area and

incorporating those areas into the Washington, DC description was published in the *Federal Register* (69 FR 8581–8582). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. The rule is adopted as proposed.

The coordinates for this airspace docket are based on North American Datum 83. Class E airspace area designations for airspace extending upward from the surface are published in paragraph 6005 of FAA Order 7400.9L, dated September 2, 2003 and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be amended in the order.

**The Rule**

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) provides controlled Class E airspace extending upward from 700 ft above the surface for aircraft conducting IFR operations within the Washington, DC Class E–5 airspace description.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation it is certified that this rule will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**Adoption of the Amendment**

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

**PART 71—[AMENDED]**

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

**§ 71.1 [Amended]**

The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 ft above the surface of the earth.*

\* \* \* \* \*

**AEA DC E5 Washington, DC (Revised)**

That airspace extending upward from 700 feet above the surface within an area bounded by a line beginning at lat. 38°55'19" N., long. 76°12'28" W., to lat. 38°27'18" N., long. 77°03'51" W., to lat. 38°36'30" N., long. 77°15'17" W., to lat. 38°35'12" N., long. 77°37'06" W., to lat. 38°57'17" N., long. 78°02'29" W., to lat. 39°30'00" N., long. 78°09'00" W., to lat. 39°44'36" N., long. 77°36'08" W., to lat. 39°43'28" N., long. 77°00'00" W., to lat. 39°36'08" N., long. 76°28'38" W., to lat. 39°19'38" N., long. 76°04'04" W., to the point of beginning excluding the airspace that coincides with the Aberdeen, MD, Hagerstown, MD, Winchester, VA, Midland, VA Class E airspace areas and P-56A, P-56B, P-73, P-40, R-4009, R-4001A, R-4001B, R-6608A, R-6608B and R-6608C when they are in effect.

\* \* \* \* \*

Issued in Jamaica, New York, on April 5, 2004.

**John G. McCartney,**

*Assistant Manager, Air Traffic Division,  
Eastern Region.*

[FR Doc. 04-8364 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-M

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**Food and Drug Administration**
**21 CFR Part 573**

[Docket No. 1995F-0221]

**Food Additives Permitted in Feed and  
Drinking Water of Animals; Natamycin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of natamycin in broiler chicken feeds. Natamycin will be added to broiler chicken feed at a level of 11 parts per million (ppm) to retard the growth of *Aspergillus parasiticus* in the feed for up to 14 days after the

addition of natamycin. This action is in response to a food additive petition filed by Arkion Life Sciences of Wilmington, DE.

**DATES:** This rule is effective April 13, 2004. Submit written objections and requests for a hearing by June 14, 2004.

**ADDRESSES:** Submit written objections and requests for a hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:**

Karen Ekelman, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6653, e-mail: [kekelman@cvm.fda.gov](mailto:kekelman@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**
**I. Background**

In a notice published in the *Federal Register* of September 20, 1995 (60 FR 48715), FDA announced that a food additive petition (animal use) (FAP 2234) had been filed by DuCoc L.P., P. O. Box 219, Highland, IL 62249-1105. The petition proposed that part 573—*Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) be amended to provide for the safe use of natamycin in broiler chicken feeds, at the rate of 11 ppm, for retarding growth of *A. parasiticus*, *Penicillium rubrum*, and *Fusarium moniliforme*. The notice of filing of FAP 2234 provided for a 60-day comment period. No comments have been received.

On June 6, 1996, the Center for Veterinary Medicine (CVM) denied the petition because data submitted in support of some sections (utility, proposed purposes and amounts, proposed regulation, and proposed label) of the petition were determined to be inadequate. At that time, CVM informed DuCoc L.P., that the company could either amend the petition by submitting additional data to address concerns expressed in the letter, or withdraw the petition as provided for in § 571.7 (21 CFR 571.7).

On July 31, 2001, the sponsor amended the petition to seek approval for the use of natamycin in broiler chicken feeds, at a level of 11 ppm to retard the growth of *A. parasiticus* in the feeds for up to 14 days.

In a letter that CVM received from the petitioner on March 20, 2003, the petitioner informed FDA that sponsorship of natamycin for the intended use had been transferred from DuCoc L.P., Highlands, IL, to Arkion

Life Sciences, 3521 Silverside Rd., Wilmington, DE 19810. The transfer of sponsorship was announced in the *Federal Register* of May 22, 2003 (68 FR 28010). Data submitted by the sponsor in support of the petition permit an independent evaluation of the ability of natamycin to achieve the intended purpose in a safe manner. The sponsor submitted data that show that this level of natamycin will not present a human food safety concern. The petition also includes satisfactory information about the chemical identity of natamycin and indicates that natamycin will achieve its intended effect in a manner that is safe to broiler chickens consuming the treated feed.

**II. Conclusion**

FDA concludes that the data establish the safety and utility of natamycin (CAS No. 7681-93-8) for use as proposed and that the regulations should be amended as set forth in this document.

**III. Public Disclosure**

In accordance with § 571.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at CVM (see **ADDRESSES**) by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

**IV. Environmental Impact**

The agency has determined under 21 CFR 25.32(r) 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.

**V. Objections and Hearing Requests**

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall



include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

■ 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 573 is amended as follows:

#### PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 573.685 is added to read as follows:

##### § 573.685 Natamycin.

The food additive natamycin (CAS No. 7681-93-8) may be safely used in broiler chicken feeds in accordance with the following specifications:

(a) The additive is a stereoisomer of 22-[(3-amino-3,6-dideoxy-B-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.0<sup>5</sup>,7] octacosane-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula C<sub>33</sub>H<sub>47</sub>NO<sub>13</sub>.

(b) The additive shall conform to U.S.P. specifications.

(c) The additive (as part of a premix composed of calcium carbonate, natamycin, and lactose) is used for retarding the growth of *Aspergillus parasiticus* in broiler chicken feeds for up to 14 days after the addition of natamycin.

(d) Each pound (454 grams (g)) of the premix shall contain 434 (g) of calcium carbonate, 10 g of natamycin activity, and 10 g of lactose. The premix shall be mixed into broiler chicken feed at the rate of 1 pound (0.454 kilograms-(kg)) per ton (908 kg) of feed to provide natamycin at a level of 11 parts per million (ppm). The premix shall be thoroughly mixed into the dry

components of the broiler chicken feed before adding the liquid components. Broiler feeds to which the natamycin premix is added shall be used within 4 weeks of addition of the premix.

(e) To assure the safe use of the additive, the label or labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name and CAS number of the additive, and its purpose.

(2) A listing of ingredients consisting of calcium carbonate, the additive, and lactose and their proportions in the premix as prescribed under paragraph (d) of this section.

(3) Adequate directions for use to ensure a broiler chicken feed that is in compliance with the limitations prescribed in paragraph (d) of this section.

(4) An appropriate cautionary statement: "Caution: Store in a tightly-closed, light-resistant container in a cool, dry place."

(5) An expiration date of 1 year from the date of manufacture.

(6) A contact address and telephone number for reporting adverse reactions experienced by users, or to request a copy of the Material Safety Data Sheet for natamycin.

Dated: March 24, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04-8249 Filed 4-12-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 931

[NM-043-FOR]

#### New Mexico Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

**SUMMARY:** We are approving a proposed amendment to the New Mexico regulatory program (the "New Mexico program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). New Mexico proposed revisions to rules about definitions of permit modification, permit revision, and temporary cessation of operations; permit fees; administrative review of decisions; review of permits; requirements for

permit modifications; public hearings for permit modifications; and additional requirements for temporary cessation of operations. New Mexico revised its program to provide additional safeguards, clarify ambiguities and improve operational efficiency.

**EFFECTIVE DATE:** April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Willis L. Gainer, Telephone: 505-248-5096, Internet address: [wgainer@osmre.gov](mailto:wgainer@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the New Mexico Program
- II. Submission of the Proposed Amendment
- III. Office of Surface Mining Reclamation and Enforcement's (OSM's) Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision
- VI. Procedural Determinations

#### I. Background on the New Mexico Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the New Mexico program on December 31, 1980. You can find background information on the New Mexico program, including the Secretary's findings, the disposition of comments, and conditions of approval in the December 31, 1980, **Federal Register** (45 FR 86459). You can also find later actions concerning New Mexico's program and program amendments at 30 CFR 931.10, 931.11, 931.13, 931.15, 931.16 and 931.30.

#### II. Submission of the Proposed Amendment

By letter dated October 27, 2003, New Mexico sent us an amendment to its program (Administrative Record No. NM-869) under SMCRA (30 U.S.C. 1201 *et seq.*). New Mexico sent the amendment to include the changes made at its own initiative.

We announced receipt of the proposed amendment in the December 19, 2003, **Federal Register** (68 FR 70749). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's

adequacy (Administrative Record No. NM-871). We did not hold a public hearing or meeting because no one requested one. The public comment period ended on January 20, 2004. We received comments from one Federal agency.

### III. OSM's Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment.

#### A. Minor Revisions to New Mexico's Rules

New Mexico proposed minor editorial changes to the following previously-approved rules:

19.8.13.1301.A(4) New Mexico Annotated Code (NMAC) (30 CFR 774.13(b)(2)), concerning permit revisions, and

19.8.13.1301.E(1) NMAC (30 CFR 774.13(b)(2)), concerning public hearing and notice requirements.

Because these changes are minor, we find that they will not make New Mexico's rules less effective than the corresponding Federal regulations.

#### B. Revisions to New Mexico's Rules That Have the Same Meaning as the Corresponding Provisions of the Federal Regulations or SMCRA

New Mexico proposed revisions to the following rules containing language that is the same as or similar to the corresponding sections of the Federal regulations or statute:

19.8.12.1200.A NMAC (30 CFR 775.11(a)), concerning the permittee's or interested party's opportunity to request a hearing after the decision on a permit modification, and

19.8.13.1300.B NMAC (30 CFR 774.10(a)), concerning the authority of the New Mexico Program Director to require revision or modification of an approved permit.

Because these proposed rules contain language that is the same as or similar to the corresponding Federal regulations, we find that they are no less effective than the corresponding Federal regulations.

#### C. Revisions to New Mexico's Rules That Are Not the Same as the Corresponding Provisions of the Federal Regulation(s)

1. *Permit and Exploration Fees.* New Mexico proposed to revise 19.8.5.506.A, B, D, E, F, and G NMAC to raise the existing permit and exploration fees. New Mexico proposed to increase all fees collected from operators. New Mexico proposed to (1) increase the original permit filing fee to \$2,500 plus

\$25 per acre for the estimated area to be disturbed during the first year of mining, (2) increase the maximum limit for an annual permit fee to \$17,500 and include a formula for the annual fee based on a charge of \$25 per disturbed acre, (3) increase the fee for a permit transfer to \$1000, (4) increase the fee for a permit revision that adds disturbed acreage to \$4,000 plus \$25 per acre for the estimated area to be disturbed during the first year of mining in the expanded area, (5) add a flat fee of \$4000 to cover revisions with limited or no surface disturbance (e.g., changing the method of mining from surface stripping to underground or highwall mining), and (6) increase the fees for filing a notice of intention to explore and an application for exploration of greater than 250 tons of coal to, respectively, \$100 and \$200.

Section 507(a) of SMCRA states that each application for a surface coal mining and reclamation permit, pursuant to an approved State program or a Federal program, shall be accompanied by a fee as determined by the regulatory authority and that this fee may be less than but shall not exceed the actual or anticipated cost of reviewing, administering, and enforcing permits issued. This section also provides that the regulatory authority may develop procedures so as to enable the cost of the fee to be paid over the term of the permit. (The Federal regulation at 30 CFR 736.25 sets forth permitting fees for Federal programs implemented by OSM.)

New Mexico has increased fees that were part of the approved New Mexico program. New Mexico explained that just over half of the cost of administering the New Mexico program is covered by collected fees (including the proposed fee increases); the remaining cost is covered by a Federal grant.

The Director of OSM (Director) finds that New Mexico's proposed revisions to increase the fees collected for permitting exploration and surface coal mining and reclamation operations are in accordance with and no less stringent than Section 507(a) of SMCRA. Therefore, the Director approves New Mexico's proposed revisions at 19.8.5.506.A, B, D, E, F, and G NMAC.

2. *Permit Modifications and Revisions.* New Mexico proposed to add definitions of "permit modification" and "permit revision," at, respectively, 19.8.1.7.P(8) and (9) NMAC. New Mexico also proposed to revise 19.8.13.1301.B, C, and E(2) NMAC to (1) clarify that 19.8.13.1301.A NMAC defines when a permit revision is required and to require that a permit

modification be obtained for all other changes to a permit not classified as a permit revision; (2) to state that the operator may not implement any permit revision or permit modification before obtaining the written approval of the New Mexico Program Director; and (3) state that (a) within 10 days after the filing of a complete application for a permit modification, the Director of the New Mexico Program shall issue a decision approving or denying the application in whole or in part and promptly provide a written copy of the decision to the permittee and other interested parties and (b) within 30 days after the decision notification concerning the permit modification, the permittee or any person may request a formal hearing in regard to the New Mexico Program Director's decision, in accordance with 19.8.12.1200 NMAC.

The Federal regulations at 30 CFR 774.13(b)(2) require that the regulatory authority establish the scale or extent of revisions for which all permit application information requirements and procedures shall apply (including the public notice, public participation, and notice of decision requirements of 30 CFR 773.6, 773.19(b)(1) and (3) and 778.21). Such requirements and procedures shall apply at a minimum to all significant revisions.

Although the Federal regulations do not contain a definition of "significant revisions" or revisions that are not significant, New Mexico's program has been revised to clarify that "permit revisions" are the same as revisions that are termed "significant" in the Federal regulations. New Mexico's existing program contains all procedural requirements required by the Federal regulation at 30 CFR 774.13(b)(2) for significant revisions. Therefore, New Mexico's proposed definitions of "permit revision" and "permit modification" at 19.8.1.7.P(8) and (9) NMAC and clarification of the procedures that apply to "permit revisions" are consistent with the Federal regulations at 30 CFR 774.13(b)(2).

New Mexico added procedural requirements concerning permit modifications. The Federal regulation does not specify the procedures that apply to non-significant revisions, only that established procedures for revisions shall apply at a minimum to all significant revisions; this Federal regulation clearly allows the regulatory authority to establish procedures for non-significant revisions. Therefore, the Director finds that New Mexico's proposed procedures at 19.8.13.1301.B, C, and E(2) NMAC for "permit modifications" are also consistent with

the Federal regulations at 30 CFR 774.13(b)(2).

Based on the above discussion, the Director finds that the proposed New Mexico rules at 19.8.1.7.P(8) and (9) NMAC and 19.8.13.1301.B, C, and E(2) NMAC are no less effective than the Federal regulation at 30 CFR 774.13(b)(2) and approves them.

2. *Temporary Cessation of Operations.* New Mexico proposed to add a definition of "temporary cessation of operations" at 19.8.1.7.T(2) NMAC to mean the cessation of mining or reclamation operations for more than thirty days and where a reasonable expectation of the continuation of mining can be demonstrated by the permittee. New Mexico also proposed to revise 19.8.20.2073 NMAC, concerning temporary cessation of operations, by adding new C, D, E, and F, to state (1) at the New Mexico Program Director's discretion, the permittee may be directed to take other reasonable actions consistent with 19.8 NMAC to ensure the protection of public safety and the environment while the operation is under temporary cessation; (2) that no temporary cessation of mining and reclamation operations shall extend beyond the current permit term, unless the Director of the New Mexico Program approves an extension of the temporary cessation during the permit renewal process conducted in accordance with 19.8.13 NMAC; (3) that to continue under a temporary cessation beyond an existing permit term, the permittee must demonstrate that the mining operation has a reasonable expectation of continuing operations; and (4) that a temporary cessation may not be used to justify a lengthy delay to final reclamation or to preserve facilities beyond what may be considered appropriate for their use in association with an existing permit.

There is no Federal definition of "temporary cessation of operations." The Federal regulation at 30 CFR 816.131(a) requires that each person who conducts surface mining activities shall effectively secure surface facilities in areas in which there are no current operations but in which operations are to be resumed under an approved permit and states that temporary abandonment shall not relieve a person of their obligation to comply with any provisions of the approved permit. The Federal regulation at 30 CFR 816.131(b) states that before temporary cessation of mining and reclamation operations for a period of thirty days or more, or as soon as it is known that a temporary cessation will extend beyond 30 days, persons who conduct surface mining activities shall submit to the regulatory

authority a notice of intention to cease or abandon mining and reclamation operations. This regulation specifies that the notice shall include a statement of the exact number of acres which will have been affected in the permit area, prior to such temporary cessation, the extent and kind of reclamation of those areas which will have been accomplished, and identification of the backfilling, regrading, revegetation, environmental monitoring, and water treatment activities that will continue during the temporary cessation.

New Mexico's proposed definition of "temporary cessation of operations" includes the same 30 day period, beyond which an operator must declare a temporary cessation of operations, that is in the Federal regulation at 30 CFR 816.131(b). New Mexico's inclusion in its definition and/or in the performance standards of the requirements that the operator demonstrate "a reasonable expectation for the continuation of mining following temporary cessation" and not use temporary cessation as a means to "justify a lengthy delay to final reclamation or to preserve facilities beyond what may be considered appropriate for their use", is implicit though not stated in the Federal regulations; the Federal regulation at 30 CFR 816.131(a) describes temporary cessation, in part, as those situations "in which operations are to be resumed under an approved permit".

Section 505(b) of SMCRA provides for provisions of State law or rules that provide for more stringent environmental controls and regulations of surface coal mining and reclamation operations than do the provisions of SMCRA or the Federal regulations.

Therefore, New Mexico has the authority to adopt the proposed additional safeguards concerning the discretion of the Director of the New Mexico Program to require other reasonable actions to ensure the protection of public safety and the environment, and the relationship between temporary cessation and the permit term.

Based on the discussion above, the Director finds that New Mexico's proposed rules concerning temporary cessation of operations at 19.8.1.7.T(2) and 19.8.20.2073.C, D, E, and F are in accordance with Section 505(b) of SMCRA and no less effective than the Federal regulations at 30 CFR 816.131(a) and (b) and approves them.

#### IV. Summary and Disposition of Comments

##### Public Comments

We asked for public comments on the amendment (Administrative Record No. NM-870), but did not receive any.

##### Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the New Mexico program (Administrative Record No. NM-870).

The U.S. Fish and Wildlife Service (FWS), commented by letter dated December 29, 2003 (Administrative Record No. NM-872). FWS stated that it supported the changes to the New Mexico program and commended the New Mexico Mining Commission for taking proactive steps to revise its program and improve safeguards for the people and environment of New Mexico. FWS further commented, "[w]hile we are not aware of any problems with birds becoming trapped and or killed by ponded waters at coal mines in New Mexico, this has been, and continues to be a significant problem for hard rock mining operations and oil and gas facilities. We encourage you and your staff to keep in mind the potential for bird (and other wildlife) entrapment and exposure to hazardous chemicals in open waters, and would appreciate your support in eliminating these hazards. The Service has experience in dealing with hazardous, ponded waters, and general potential sources of impacts to migratory birds (e.g., power poles, towers), and can provide you and your staff with approaches to protect migratory birds and other wildlife. We would rather prevent the loss of migratory birds before more formal legal actions are necessary under the Migratory Bird Treaty Act (MBTA), which prohibits the taking of migratory birds, nests, and eggs, except as permitted by the Service. If your staff becomes aware of an actual or potential hazard to birds or other wildlife, please contact us and we can work with you and/or the company to ameliorate these hazards."

New Mexico's existing rules at 19.8.809.A and B NMAC require that an application for a permit to mine coal include a study of fish and wildlife and their habitats within the proposed permit area and the portions of the adjacent areas where effects on such resources may reasonably be expected to occur, and, that the applicant must consult with the appropriate State and

Federal fish and wildlife management, conservation, or land management agencies having responsibilities for fish and wildlife or their habitats, to determine the level of detail and the areas for such studies. In addition, New Mexico's rules at 19.8.9.905.A and B NMAC require that each application contain a fish and wildlife plan demonstrating how the applicant will minimize disturbances and adverse impacts on fish and wildlife, and, that the applicant describe methods the applicant will utilize to protect or enhance threatened or endangered species of plants or animals and their critical habitats; species such as eagles, migratory birds or other animals protected by State or Federal Law and their habitats, or other species identified through the consultation process pursuant to 19.8.8.809 NMAC; or habitats of unusually high value for fish and wildlife.

New Mexico did not propose revisions to these or other rules concerning fish and wildlife in this amendment. New Mexico's approved program provides, through the consultation and application requirements described above, the coordination requested in the FWS comment. The Director is not requiring New Mexico to further revise its program in response to these comments.

*Environmental Protection Agency (EPA) Concurrence and Comments*

Under 30 CFR 732.17(h)(11)(i) and (ii), we are required to get concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that New Mexico proposed to make in this amendment pertains to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. Under 30 CFR 732.17(h)(11)(i), OSM requested comments on the amendment from EPA (Administrative Record No. NM-870). EPA did not respond to our request.

*State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)*

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On December 2, 2003, we requested comments on New Mexico's amendment (Administrative Record No. NM-870), but neither responded to our request.

**V. OSM's Decision**

Based on the above findings, we approve New Mexico's October 27, 2003, amendment.

To implement this decision, we are amending the Federal regulations at 30 CFR Part 931, which codify decisions concerning the New Mexico program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrates that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

**VI. Procedural Determinations**

*Executive Order 12630—Takings*

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

*Executive Order 12866—Regulatory Planning and Review*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

*Executive Order 12988—Civil Justice Reform*

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

*Executive Order 13132—Federalism*

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the

purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

*Executive Order 13175—Consultation and Coordination With Indian Tribal Governments*

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian Tribes and have determined that the rule does not have substantial direct effects 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. The rule does not involve or affect Indian Tribes in any way.

*Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy*

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

*National Environmental Policy Act*

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

*Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

**Regulatory Flexibility Act**

The Department of the Interior certifies that this rule 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.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

**Small Business Regulatory Enforcement Fairness Act**

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: a. does not have an annual effect on the economy of \$100 million; b. will not cause a major increase in

costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and c. does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

**Unfunded Mandates**

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a

determination made that the Federal regulation did not impose an unfunded mandate.

**List of Subjects in 30 CFR Part 931**

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 15, 2004.

**Allen D. Klein,**  
*Regional Director, Western Regional Coordinating Center.*

■ For the reasons set out in the preamble, 30 CFR part 931 is amended as set forth below:

**PART 931—NEW MEXICO**

■ 1. The authority citation for part 931 continues to read as follows:

**Authority:** 30 U.S.C. 1201 *et seq.*

■ 2. Section 931.15 is amended in the table by adding a new entry in chronological order by "Date of Final Publication" to read as follows:

**§ 931.15 Approval of New Mexico regulatory program amendments.**

\* \* \* \* \*

Original amendment submission date	Date of final publication	Citation/description
October 27, 2003	April 13, 2004	19.8.1.7.P(8) and (9); 19.8.1.7.T(2); 19.8.5.506.A, B, D, E, F, and G; 19.8.12.1200.A; 19.8.13.1300.B; 19.8.13.1301.A(1), B, C, and E(1) and E(2); 19.8.20.2073 (C), (D), (E), and (F) NMAC

[FR Doc. 04-8381 Filed 4-12-04; 8:45 am]  
BILLING CODE 4310-05-P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 117**

[CGD08-04-014]

**Drawbridge Operation Regulations; Gulf Intracoastal Waterway—Bayou Boeuf, Amelia, LA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the BNSF RR Swing Bridge across Bayou Boeuf, mile 10.2, at Amelia, St. Mary Parish, LA. This deviation allows the bridge to remain closed to navigation for six hours. The deviation is necessary to

repair and replace damaged portions of the bridge.

**DATES:** This deviation is effective from 8 a.m. until 2 p.m. on Thursday, April 29, 2004.

**ADDRESSES:** Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 500 Poydras Street, New Orleans, Louisiana 70130-3310 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589-2965. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

**FOR FURTHER INFORMATION CONTACT:** David Frank, Bridge Administration Branch, telephone (504) 589-2965.

**SUPPLEMENTARY INFORMATION:** The BNSF RR has requested a temporary deviation in order to remove and replace damaged portions of the Bayou Boeuf Swing Bridge across Bayou Boeuf, mile 10.2, at Amelia, St. Mary Parish, LA. The repairs

are necessary to ensure the safety of the bridge. This temporary deviation will allow the bridge to remain in the closed-to-navigation position from 8 a.m. until 2 p.m. on Thursday, April 29, 2004.

As the bridge has no vertical clearance in the closed-to-navigation position, vessels will not be able to transit through the bridge site when the bridge is closed. Navigation at the site of the bridge consists mainly of tows with barges and some recreational pleasure craft. Due to prior experience, as well as coordination with waterway users, it has been determined that this closure will not have a significant effect on these vessels. An alternate route is available by using the GIWW, Morgan City to Port Allen Alternate Route.

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: April 6, 2004.

Marcus Redford,  
Bridge Administrator.

[FR Doc. 04-8318 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD05-04-066]

RIN 1625-AA00

#### Security Zone; Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and Its Tributaries

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing 500-yard temporary security zones throughout the Captain of the Port Philadelphia's area of responsibility around escorted passenger vessels in transit and 100-yard security zones around moored or anchored passenger vessels. The security zones are needed to ensure public safety and the safe transit of the passenger vessels in the Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries. The temporary moving security zones prohibit vessels from entering within a 500-yard radius of the escorted passenger vessels while in transit, and within a 100-yard radius of passenger vessels while moored or anchored, unless authorized by the Captain of the Port, Philadelphia, Pennsylvania, or his designated representative. These security zones are limited in duration and affect only certain passenger vessels and a small area at any given time.

**DATES:** This rule is effective from April 2, 2004, through September 1, 2004.

**ADDRESSES:** Documents as indicated in this preamble are available as part of docket CGD05-04-066 and are available for inspection or copying at Coast Guard Marine Safety Office Philadelphia, One Washington Avenue, Philadelphia, Pennsylvania, 19147, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Junior Grade Kevin Sligh or Ensign Jill Munsch, Coast Guard Marine Safety Office/Group Philadelphia, at (215) 271-4889.

**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 a NPRM. Publishing a NPRM and delaying the effective date would be contrary to the public interest, since immediate action is needed to continue to protect the public, ports and waterways of the United States.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing a NPRM and delaying the effective date would be contrary to the public interest, since immediate action is needed to continue to protect the public, ports and waterways of the United States. The Coast Guard was notified on March 29, 2004, of scheduled port calls by passenger vessels, making it impracticable for the safety of passenger vessels and mariners to delay publishing this security zone.

The Coast Guard plans to publish a NPRM proposing a permanent rule for security zones around passenger vessels and requesting public comment.

### Background and Purpose

The terrorist attacks of September 11, 2001 highlighted the need for heightened security measures at United States seaports. The President has found, pursuant to law, including the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950 (50 U.S.C. 191 *et seq.*), that the security of the United States is and continues to be endangered following the attacks. The Captain of the Port of Philadelphia has determined that security zones are necessary to protect the public, the waterway, and passenger vessels from potential subversive acts.

### Discussion of the Regulation

This temporary rule establishes 100-yard security zones around moored or anchored passenger vessels and 500-yard security zones around escorted passenger vessels while transiting the Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries. The Captain of the Port, Philadelphia, Pennsylvania's zone extends out in the Atlantic Ocean from the shoreline to 12 miles. For purposes of this rule, "passenger vessel" is defined as a vessel greater than 100 feet in length, over 100 gross tons, and that is authorized to carry 500 or more passengers, making voyages lasting more than 24 hours, except for a ferry. No vessels or persons may come within

a 500-yard radius of an underway, escorted passenger vessel, nor come or remain within a 100-yard radius of a moored or anchored passenger vessel without the permission of the Captain of the Port, Philadelphia, Pennsylvania or his designated representative.

These zones will be enforced around moving escorted passenger vessels and stationary passenger vessels while they are within the Captain of the Port of Philadelphia zone. A Broadcast Notice to Mariners will be issued to notify mariners to aid them in making alternate plans for transiting the affected waterway.

### 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).

The primary impact of this rule will be on vessels wishing to transit the affected waterway in the vicinity of passenger vessel security zone. Although this rule restricts traffic from freely transiting portions of the Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries, the restrictions are limited in duration and affect only a limited area.

### 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 may affect the following entities, some of which may be small entities: owners or operators of vessels wishing to transit the affected waterways of the Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries.

The rule will not have a significant impact on a substantial number of small entities for the following reasons: the restrictions are limited in duration and

affect only a limited area. A broadcast notice to mariners will be issued to notify mariners to make alternate plans for transiting the affected waterway.

#### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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).

#### 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 expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### Taking of Private Property

This rule will not effect 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 Security Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to security 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.

#### Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(g), of Commandant Instruction M16475.1D, from further environmental documentation.

A final "Environmental Analysis Checklist" and a final "Categorical Exclusion Determination" will be

available in the docket where indicated under ADDRESSES.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and 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. Chapters 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. From April 2, 2004, through September 1, 2004, add § 165.T05-066.

#### § 165.T05-066 Security Zone; Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries.

(a) *Location.* All navigable waters within 500 yards of escorted passenger vessels when they are in the Captain of the Port, Philadelphia zone, as established in 33 CFR 3.25-05.

(b) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones in § 165.33 of this part.

(2) The 500-yard moving security zones prohibit a person or a vessel from transiting or remaining within a 500-yard radius of an escorted passenger vessel while the passenger vessel is transiting in the Captain of the Port Philadelphia area of responsibility, unless authorized by the Captain of the Port Philadelphia, PA or designated representative.

(3) No person or vessel may come within 100 yards of a moored or anchored passenger vessel, unless authorized by the Captain of the Port Philadelphia, PA, or designated representative.

(4) Any person or vessel authorized to enter a security zone must operate in strict conformance with any directions given by the Captain of the Port Philadelphia, PA or designated representative and leave the security zone immediately if the Captain of the Port Philadelphia, PA or designated representative so orders.

(5) When a passenger vessel approaches within 500 yards of any moored or anchored stationary vessel, the stationary vessel must remain moored or anchored. The 500-yard security zone around the passenger

vessel will remain in effect while the passenger vessel is transiting near the stationary vessel. The stationary vessel must remain moored or anchored unless it is either ordered by or given permission by the Captain of the Port, Philadelphia or designated representative to do otherwise.

(6) The Coast Guard official enforcing this section can be contacted on VHF Marine Band Radio, channels 13 and 16. The Captain of the Port can be contacted at (215) 271-4807.

(c) *Maneuver-restricted vessels.* When conditions permit, the on-scene official patrol or Captain of the Port, or designated representative may:

(1) Permit vessels constrained by their navigational draft or restricted in their ability to maneuver to pass within the 500-yard zone around the transiting passenger vessel in order to ensure safe passage in accordance with the Navigation Rules as seen in 33 CFR chapter I, subchapters D and E; and

(2) Permit vessels constrained by their navigational draft or restricted in their ability to maneuver that must transit via a navigable channel or waterway to pass within 100 yards of an anchored passenger vessel.

(d) *Definitions.* As used in this section—

*Captain of the Port* means the Commanding Officer of the Coast Guard Marine Safety Office/Group Philadelphia or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act as a designated representative on his behalf.

*Passenger vessel* means a vessel greater than 100 feet in length, over 100 gross tons, and is authorized to carry 500 or more passengers, making voyages lasting more than 24 hours, except for a ferry.

Dated: April 2, 2004.

**Jonathan D. Sarubbi,**

*Captain, U.S. Coast Guard, Captain of the Port Philadelphia.*

[FR Doc. 04-8350 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-15-P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 04-782, MM Docket No. 01-293, RM-10302, RM-10547]

**Radio Broadcasting Services; Apache, Ardmore, Bennington, OK; Bonham, Bridgeport, TX; Cache, OK; Crowell, TX; Elk City, Lawton, OK; Palestine, Ranger, Stephenville, Wellington, TX**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document grants a counterproposal to upgrade Station KBOC(FM), Bridgeport, TX, from Channel 252A to Channel 252C0. To accommodate this upgrade, six other changes to the FM Table of Allotments are being made. The document also dismisses a mutually exclusive proposal to allot Channel 250C3 at Crowell, TX, and approves a settlement agreement between the parties. See 66 FR 53755, October 24, 2001. See also

**SUPPLEMENTARY INFORMATION.**

**DATES:** Effective May 10, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Andrew J. Rhodes, Media Bureau, (202) 418-2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's *Report and Order*, MM Docket 01-293, adopted March 24, 2004, and released March 26, 2004. The full text of this decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-863-2893, facsimile 202-863-2898, or via e-mail [qualexint@aol.com](mailto:qualexint@aol.com).

The reference coordinates for Channel 250C0 at Bridgeport, TX, are 33-26-13 and 97-29-05. To accommodate this upgraded allotment, the document (1) reallocates and changes the community of license for Station KCUB(FM) from Channel 252A at Stephenville, TX, to Channel 253A at Ranger, TX, at reference coordinates 32-22-55 and 98-45-55; (2) downgrades Station KYYK(FM), Palestine, TX, from Channel 252C2 to Channel 252C3 at reference coordinates 31-46-17 and 95-37-54; (3) downgrades, reallocates, and changes the community of license for Station KFYZ(FM) from Channel 252C3 at Bonham, TX, to Channel 251A at

Bennington, OK, at reference coordinates 34-04-00 and 95-59-52; (4) reallocates and changes the community of license for Station KACO(FM) from Channel 253C3 at Ardmore, OK, to Channel 253C3 at Apache, OK, at reference coordinates 34-53-34 and 98-14-01; (5) downgrades Station KTJJ(FM), Elk City, OK, from Channel 253C to Channel 295C1 at reference coordinates 35-15-36 and 99-33-08; and (6) substitutes Channel 253C3 for vacant Channel 298C3 at Wellington, TX, at reference coordinates 34-49-13 and 100-14-29. The FM Table of Allotments currently lists Channel 253A at Ardmore, Oklahoma. In 1997, the Audio Division granted Station KACO(FM) a construction permit to specify operation on Channel 253C3 in lieu of Channel 253A, BMPH-970307IC, to which a license was granted to cover this construction permit in 1998, BPH-19971010KI.

### List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

### PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

#### § 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by adding Apache, Channel 253C3, by removing Channel 253A at Ardmore, by adding Bennington, Channel 251A, by adding Cache, Channel 250A, by removing Channel 253C and adding Channel 295C1 at Elk City, and by removing Channel 251C1 at Lawton.

■ 3. Section 73.202(b), the Table of FM Allotments under Texas, is amended by removing Bonham, Channel 252C3, by removing Channel 252A and adding Channel 252C0 at Bridgeport, by removing Channel 252C2 and adding Channel 252C3 at Palestine, by adding Ranger, Channel 253A, by removing Stephenville, Channel 252A, and by removing Channel 298C3 and adding Channel 253C3 at Wellington.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 04-8330 Filed 4-12-04; 8:45 am]

BILLING CODE 6712-01-P



## DEPARTMENT OF STATE

48 CFR Parts 601, 602, 603, 604, 605, 606, 609, 611, 612, 613, 616, 617, 619, 622, 623, 625, 626, 628, 630, 632, 636, 637, 642, 651, 652, and 653

[Public Notice 4685]

RIN 1400-AB06

**Department of State Acquisition Regulation (DOSAR)**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** This rule makes final a proposed rule published for comment on November 13, 2003 amending the Department of State Acquisition Regulation (DOSAR). No public comments were received. The proposed rule is therefore adopted as final. This final rule also contains three miscellaneous amendments not published on November 13, 2003, as outlined below.

**EFFECTIVE DATE:** This rule is effective April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Gladys Gines, Procurement Analyst, Department of State, Office of the Procurement Executive, 2201 C Street, NW., Suite 603, State Annex Number 6, Washington, DC 20522-0602; telephone (703) 516-1691; e-mail address: [ginesgg@state.gov](mailto:ginesgg@state.gov). Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at: <http://www.regulations.gov/index.cfm>.

**SUPPLEMENTARY INFORMATION:** On November 13, 2003 (Public Notice 4525 at 68 FR 64297), the Department of State proposed numerous amendments to the DOSAR to reflect recent changes in the Federal Acquisition Regulation (FAR), as well as organizational and other policy changes within the Department. The rule was discussed in detail in Public Notice 4525, as were the Department's reasons for the changes to the regulation. The Department is now promulgating a final rule with the following minor changes from the proposed rule:

- DOSAR 601.603-70 is further revised to delete one more acquisition office (the Diplomatic Telecommunications Service—Program Office). The acquisition responsibilities of this office have been transferred to the Office of Acquisition Management.
- DOSAR 605.202-70 (a) is revised to delete the last sentence. This sentence established an end date (March 12, 2004) for the waiver for synopsising foreign acquisitions in the

Governmentwide Point of Entry (GPE). Since this waiver is extended periodically, it makes sense to not publish the actual date. This will ease administration of the regulation so that changes do not have to be published each time the date changes.

- DOSAR 605.202-70(d) is revised to state that the GPE waiver authority also does not apply to any contracts exceeding \$5 million. The proposed rule limited this to only construction contracts. A decision has been made that all contracts exceeding \$5 million must be synopsisized in the GPE.

These amendments do not affect the public, and therefore good cause exists to publish them without first soliciting public comment because prior public comment is unnecessary.

**Regulatory Findings**

*Administrative Procedure Act*

The Department is publishing this rule as a final rule after it was published as a proposed rule on November 13, 2003 (see **SUPPLEMENTARY INFORMATION**).

*Regulatory Flexibility Act*

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Act of 1995*

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$1 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

*Executive Order 12866*

The Office of Management and Budget has reviewed this rule under Executive Order 12866.

*Paperwork Reduction Act*

Information collection requirements have been approved under the Paperwork Reduction Act of 1980 by OMB, and have been assigned OMB Control Number 1405-0050. The Department is currently seeking approval for the information collection requirements associated with Form DS-4053, Department of State Mentor-Protégé Program Application.

**List of Subjects in 48 CFR Parts 601, 602, 603, 604, 605, 606, 609, 611, 612, 613, 616, 617, 619, 622, 623, 625, 626, 628, 630, 632, 636, 637, 642, 651, 652, and 653**

Department of State Acquisition Regulation.

- Accordingly, for the reasons set forth in the preamble, title 48, chapter 6 of the Code of Federal Regulations is amended as follows:

- 1. The authority citation for 48 CFR parts 601, 602, 603, 604, 605, 606, 609, 611, 612, 613, 616, 617, 619, 622, 623, 625, 626, 628, 630, 632, 636, 637, 642, 651, 652, and 653 continues to read as follows:

**Authority:** 40 U.S.C. 486(c); 22 U.S.C. 2658.

**Subchapter A—General**

**PART 601—DEPARTMENT OF STATE ACQUISITION REGULATION**

- 2. Section 601.105-3 is revised to read as follows:

**601.105-3 Copies.**

The DOSAR is available through the Department's Intranet system at <http://aope.a.state.gov>, or through the Internet from A/OPE's Acquisition Web site. The Internet address is: <http://www.statebuy.state.gov/>.

**601.106 [Amended]**

- 3. Section 601.106 is amended by removing from the last sentence "225,302 hours" and inserting "225,503 hours" in its place.

- 4. Section 601.603-1 is added to read as follows:

**601.603-1 General.**

Details of the Department's acquisition career management program are described in 6 FAH-6, the Acquisition Career Management Program Handbook, which is available on the Intranet from the A/OPE Web site (see 601.105-3 for address).

■ 5. Section 601.603-3 is amended by revising paragraph (d) to read as follows:

**601.603-3 Appointment.**

\* \* \* \* \*

(d) *Personal services agreements.* Individuals who may sign personal services agreements (PSAs) are limited to the following:

- (1) The Human Resources Officer;
- (2) The Human Resources/Financial Management Officer; or,
- (3) The Management Officer or an American Foreign Service Officer designated to perform human resource functions.

■ 6. In section 601.603-70, paragraph (a) is revised and a sentence is added at the end of paragraph (b)(6) to read as follows:

**601.603-70 Delegations of authority.**

(a) *Delegations.* As stated in 601.603-3(a), there is no contracting officer authority conferred by virtue of position. Pursuant to 601.602-1(b), the Procurement Executive has designated the following as contracting activities as defined in FAR 2.101. These authorities are not redelegable. In addition, specific individuals are designated as heads of contracting activities (HCAs) (see FAR 2.101):

(1) *Overseas posts.* Each overseas post shall be regarded as a contracting activity to enter into and administer contracts for the expenditure of funds involved in the acquisition of supplies, equipment, publications, and services. The Principal Officer, the Management Officer, or the Supervisory General Services Officer are designated as HCAs; provided, that he/she has a contracting officer's warrant issued by the Procurement Executive. The Procurement Executive (or authorized A/OPE staff) may delegate to a contracting officer, on a case-by-case basis, the authority to award a contract or modification which exceeds the contracting officer's warrant level.

(i) No authority is delegated to enter into cost-reimbursement, fixed-price incentive, or fixed-price redeterminable contracts. Design/build solicitations and contracts may only be entered into with the written approval of A/OPE and OBO. Proposed construction contracts exceeding \$500,000 and any related architect-engineer contracts must have prior A/OPE approval.

(ii) When expressly authorized by a U.S. Government agency which does not have a contracting officer at the post, the officers named in paragraph (a)(1) introductory text of this section may enter into contracts for that agency. Use of this authority is subject to the

statutory authority of that agency and any special contract terms or other requirements necessary for compliance with any conditions or limitations applicable to the funds of that agency. The agency's authorization shall cite the statute(s) and state any special contract terms or other requirements with which the acquisition so authorized must comply. In view of the contracting officer's responsibility for the legal, technical, and administrative sufficiency of contracts, questions regarding the propriety of contracting actions that the post is required to take pursuant to this authority may be referred to the Department for resolution with the headquarters of the agency concerned.

(2) *Office of Logistics Management; Office of Acquisition Management (A/LM/AQM).* The authority to enter into and administer contracts for the expenditure of funds involved in the acquisition of supplies and services, including construction, is delegated to the Director or designee as the HCA.

(3) *Foreign Service Institute.* The authority to enter into and administer contracts pursuant to Chapter 7, Title I, of the Foreign Service Act of 1980, as amended (22 U.S.C. 4021 *et seq.*), is delegated to the Director of the Foreign Service Institute, the Executive Director, the Deputy Executive Director, and the Supervisory Contracting Officer as the HCA.

(4) *Office of Foreign Missions.* The authority to enter into and administer contracts pursuant to Title II of the State Department Basic Authorities Act of 1956, as amended (22 U.S.C. 4301 *et seq.*), is delegated to the Director, Office of Foreign Missions, and the Administrative Officer as the HCA.

(5) *U.S. Mission to the United Nations.* The authority to enter into and administer contracts pursuant to the United Nations Participation Act of 1945, as amended (22 U.S.C. 287), is delegated to the Counselor for Administration as the HCA.

(6) *Regional Procurement Support Offices.* The authority to enter into and administer contracts for the expenditure of funds involved in the acquisition of supplies, equipment, publications, and services on behalf of overseas posts is delegated to each Director, Regional Procurement Support Office (RPSO) as the HCA at the following locations:

- (i) RPSO Frankfurt in conjunction with Consulate General Frankfurt; and
- (ii) RPSO Florida in conjunction with the Florida Regional Center.

(b) \* \* \*

(6) \* \* \* These authorities extend to any acquisition performed by any

Department of State contracting activity on behalf of INL.

\* \* \* \* \*

**PART 602—DEFINITIONS OF WORDS AND TERMS**

■ 7. Section 602.101-70 is amended by adding, in alphabetical order, a definition of "Chief of Mission"; and, by revising the definition of "Despatch Agency", as follows:

**602.101-70 DOSAR definitions.**

\* \* \* \* \*

*Chief of Mission* means the principal officer in charge of a diplomatic mission of the United States or of a United States office abroad which is designated by the Secretary of State as diplomatic in nature, including any individual assigned under section 502(c) of the Foreign Service Act of 1980 (Public Law 96-465) to be temporarily in charge of such a mission or office.

\* \* \* \* \*

*Despatch Agency* means the office responsible for the transportation of supplies between the U.S. and posts within its specific geographic area as assigned by the Office of Logistics Operations. There are six Despatch Agencies, one each in Iselin, New Jersey; Baltimore, Maryland; Miami, Florida; Seattle, Washington; Brownsville, Texas; and the European Logistics Support Office in Antwerp, Belgium.

\* \* \* \* \*

**PART 603—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST**

■ 8. Section 603.104-5 is redesignated as section 603.104-4.

■ 9. Section 603.104-10 is redesignated as section 603.104-7. New section 603.104-7 is amended in paragraph (d)(2)(ii)(B) by correcting the citation at the end of the paragraph to read "FAR 3.104-7(d)(2)(ii)(B)."

■ 10. Section 603.204 is amended by revising paragraph (b) to read as set forth below, and by removing paragraph (c):

**603.204 Treatment of violations.**

\* \* \* \* \*

(b) Upon completion of the investigation and/or prosecution or with the consent of the U.S. Department of Justice, the Assistant Inspector General for Investigations shall provide to the Procurement Executive a report, together with all pertinent documentation, concerning the suspected violation. The Office of the Procurement Executive shall provide to

the contractor a written notice by certified mail, return receipt requested, presenting the findings, and shall establish a schedule, including location, for an investigative hearing for the purposes described in FAR 3.204(b).

\* \* \* \* \*

■ 11. Section 603.601 is amended by adding the following sentence to the end of paragraph (a):

#### 603.601 Policy.

(a) \* \* \* This policy also applies to individuals hired under personal services agreements and personal services contracts.

■ 12. A new Subpart 603.8, consisting of section 603.804, is added to read as follows:

#### Subpart 603.8—Limitations on the Payment of Funds To Influence Federal Transactions

##### 603.804 Policy

(b) The contracting officer shall forward a copy of all contractor disclosures furnished pursuant to the clause at FAR 52.203-12 to the Office of the Legal Adviser, Employment Law, Senior Ethics Counsel (L/EMP/Ethics).

#### PART 604—ADMINISTRATIVE MATTERS

■ 13. Subpart 604.5 is revised to read as follows:

#### Subpart 604.5—Electronic Commerce in Contracting

##### 604.502 Policy.

(b) The Assistant Secretary of State for Administration is the head of the agency for the purpose of FAR 4.502(b).

(1)(i) *Posting solicitations for domestic contracting activities.* Contracting officers at domestic contracting activities shall post all open market competitive, unclassified Requests for Proposals and Invitations for Bids exceeding the simplified acquisition threshold on the Internet, unless an exception has been approved by the head of the contracting activity. Contracting officers may post Requests for Quotations and noncompetitive acquisitions if desired. Solicitations shall be posted through the Statebuy Interactive Platform (SIP) at <https://state.monmouth.army.mil/>. If the SIP is temporarily unavailable (due either to problems with the SIP system or the Internet connections), the solicitation shall be posted on the Governmentwide point of entry (GPE), and immediately posted on the SIP when the SIP again becomes available.

(ii) *Materials not in automated format.* For solicitations containing

drawings or other materials that are not in an automated format, the contracting officer shall:

(A) Post as much of the solicitation as possible on the Internet; and,

(B) Make hard copies available for those parts of the solicitation that are not in an automated format.

(iii) *Posting solicitations for overseas contracting activities.* Contracting officers at overseas contracting activities shall post competitive local guard solicitations on the Internet using the Statebuy Interactive Platform if U.S. firms may be competing. Posting of other solicitations is optional.

#### Subchapter B—Competition and Acquisition Planning

#### PART 605—PUBLICIZING CONTRACT ACTIONS

■ 14. Section 605.202-70 is amended—

■ (a) By removing “CBD” in the first sentence of paragraph (a);

■ (b) By adding the words “in the Governmentwide point of entry (GPE)” after the word “notices” in the first sentence of paragraph (a);

■ (c) By removing “CBD” and inserting “GPE” in its place in the second sentence of paragraph (a);

■ (d) By removing the last sentence of paragraph (a);

■ (e) By removing “CBD” and inserting “GPE” in its place in paragraph (b); and,

■ (f) By revising paragraph (d) to read as follows:

##### 605.202-70 Foreign acquisitions.

\* \* \* \* \*

(d) *Policy exclusions.* GPE waiver authority does not apply to local guard service contracts exceeding \$250,000, or any contracts exceeding \$5 million. Local guard service contracts that exceed \$250,000 and other contracts that exceed \$5 million shall be published in the GPE. Option year prices shall be included when computing the applicability of this threshold.

■ 15. Section 605.207-70 is amended by removing the word “synopsis” and inserting the word “notice” in its place.

##### 605.303 [Amended]

■ 16. Section 605.303 is amended by removing the word “Office” and inserting the word “Bureau” in its place in the first sentence of paragraph (a).

#### PART 606—COMPETITION REQUIREMENTS

##### 606.302 [Amended]

■ 17. Section 606.302-6 is amended—

■ (a) By removing the words “*Commerce Business Daily*” and inserting “GPE” in their place in paragraph (c)(1)(i);

■ (b) By removing the words “CBD synopsis” and inserting “GPE notice” in their place in paragraph (c)(1)(ii); and,

■ (c) By removing the words “*Commerce Business Daily*” and inserting “GPE” in their place in paragraph (c)(2).

##### 606.370 [Amended]

■ 18. Section 606.370 is amended by removing the word “Administrative” and inserting the word “Management” in its place in the third sentence of paragraph (b).

■ 19. Section 606.501 is amended by inserting the following sentence after the first sentence in paragraph (b):

##### 606.501 Requirement.

\* \* \* \* \*

(b) \* \* \* A/LM/AQM’s competition advocate is also designated the contracting activity competition advocate for the Regional Procurement Support Offices. \* \* \*

##### 606.501-70 [Amended]

■ 20. Section 606.501-70 is amended by removing the word “Administrative” and inserting the word “Management” in its place.

#### PART 609—CONTRACTOR QUALIFICATIONS

■ 21. A new section 609.404-70 is added to read as follows:

##### 609.404-70 Specially Designated Nationals List.

Contracting officers shall not award to any of the entities listed on the Specially Designated Nationals (SDN) List, available on the Department of Treasury’s Office of Foreign Assets Control Web site at <http://www.treas.gov/ofac/>. Contracting officers shall consult this list prior to award for any dollar amount. This list may also be accessed through the EPLS Web site at <http://epls.arnet.gov>.

■ 22. Section 609.405 is amended—

■ (a) By removing paragraphs (d) introductory text and (d)(1)(i);

■ (b) By adding a new paragraph (d)(3) to read as indicated below; and,

■ (c) By removing paragraphs (d)(4)(i) and (d)(4)(ii).

##### 609.405 Effect of listing.

\* \* \* \* \*

(d)(3) The Procurement Executive is the agency head’s designee for the purposes of FAR 9.405(d)(3).

■ 23. Section 609.406-3 is amended by revising the last two sentences of paragraph (a)(1) to read as follows:

##### 609.406-3 Procedures.

(a)(1) \* \* \* The Office of the Inspector General shall investigate the

matter, as appropriate, and provide a copy of its investigation report to the Procurement Executive for consideration of debarment action, if and when appropriate. The contracting officer shall provide to the Procurement Executive and the Office of the Inspector General a copy of his or her intended actions in response to the Office of the Inspector General report.

\* \* \* \* \*

#### **PART 611—DESCRIBING AGENCY NEEDS**

■ 24. A new subpart 611.6 is added to read as follows:

##### **Subpart 611.6—Priorities and Allocations**

Sec.

611.600 Scope of subpart.

611.602 General.

611.603 Procedures.

##### **Subpart 611.6—Priorities and Allocations**

###### **611.600 Scope of subpart.**

On September 18, 2001, the Department of Commerce (DOC) authorized the Department of State to use the Defense Priorities and Allocations System (DPAS). This authority expires on October 1, 2006. The Department of Defense has approved the Department's Embassy Security Protection Program (DOSESPP) as a national defense program eligible for the priorities support under the DPAS.

###### **611.602 General.**

(c)(1) Authority to use the DPAS is limited to the following circumstances:

(i) The contract or order must be placed with a U.S. firm; and,

(ii) The contract or order must be in support of the DOSESPP, which consists of work involving the security of overseas posts. The DOSESPP includes a wide range of elements of both physical and technical security, such as:

(A) New Embassy/Consulate Compound (NEC/NCC) Program. This program involves the construction of new secure Embassies, Consulates, and related facilities, as well as renovations of newly acquired buildings when used as alternatives to the construction of new secure buildings.

(B) Physical security upgrade. This includes installation of forced entry/ballistic resistant (FE/BR) windows and doors, walls/fences, active anti-ram barriers, bollards (concrete and steel barriers), and related items.

(C) Forced entry/ballistic resistant (FE/BR) components. This includes

doors, windows, and related facilities and items that can provide the necessary time to protect Government personnel from attack.

(D) Armored vehicles. This includes passenger vehicles with appropriate armoring.

(E) Entry control and building surveillance equipment. This includes walk-through metal detectors, X-ray equipment, surveillance cameras, explosive detection equipment, and other features to enhance the protection of Government personnel and facilities.

(2) DOC has assigned the following priority rating to DOSESPP contracts or orders: DO-H8.

###### **611.603 Procedures.**

(f) Department of State contracting officers are authorized to sign DO-H8 rated contracts or orders. It is the responsibility of the requirements office to determine which contracts or orders should be rated. All contracts with U.S. firms under the DOSESPP will not necessarily need to be assigned a priority rating.

(g) The contracting officer should place a DO-H8 rating on any contract or order if there is any doubt as to whether a contractor doing work for Embassy security protection will be able to deliver on time. If an unrated contract or order is not completed on time, the contracting officer may modify the contract or order to add the rating; however, the rating shall only be effective for the newly established delivery date, not the original delivery date.

(1) DOC can provide special assistance to implement the DPAS program in specific cases. For example, the Department may request a higher priority rating, or request that DOC issue a written directive to a contractor that is not complying with the DPAS regulations. In addition, although the DPAS program normally applies only to U.S. firms, if the Department has a prime contract with a foreign firm that will be awarding subcontracts with U.S. firms, the Department may request from DOC authorization to place a rating on the prime contract.

(2) Contracting officers or requirements offices who wish to request special assistance from DOC must complete DOC Form BXA-999, *Request for Special Priorities Assistance*, and submit it to A/OPE, which will arrange for submission of the request to DOC.

#### **PART 612—ACQUISITION OF COMMERCIAL ITEMS**

■ 25. A new part 612, consisting of subpart 612.3 and section 612.302, is added to subchapter B as follows:

##### **PART 612—ACQUISITION OF COMMERCIAL ITEMS**

###### **Subpart 612.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Items**

###### **612.302 Tailoring of provisions and clauses for the acquisition of commercial items.**

(c) The head of the contracting activity shall approve any request for a waiver to tailor a clause or otherwise include any additional terms or conditions in a solicitation or contract in a manner that is inconsistent with customary commercial practice.

###### **Subchapter C—Contracting Methods and Contract Types**

#### **PART 613—SIMPLIFIED ACQUISITION PROCEDURES**

■ 26. Section 613.303-5 is amended by adding a new paragraph (b) to read as follows:

###### **613.303-5 Purchases under BPAs.**

(b) Individual purchases under BPAs for commercial items may exceed the simplified acquisition threshold; however, the higher threshold must be consistent with the requirements of FAR 13.303-5(b)(1) and (2).

\* \* \* \* \*

#### **PART 616—TYPES OF CONTRACTS**

##### **616.505 [Amended]**

■ 27. Section 616.505 is amended by correcting the paragraph designation of "(b)(4)" to read "(b)(5)".

#### **PART 617—SPECIAL CONTRACTING METHODS**

■ 28. Section 617.204 is amended by adding the following sentence to the end of paragraph (e):

##### **617.204 Contracts.**

(e) \* \* \* The Procurement Executive may delegate this approval authority to individuals within the Office of the Procurement Executive.

■ 29. Section 617.504-70 is amended by adding the words "and Bureau Executive Directors" after the words "deputy assistant secretaries" in paragraph (a) and by removing the parenthetical "(illustrated in part 653)" in the first sentence of paragraph (b).

**Subchapter D—Socioeconomic Programs****PART 619—SMALL BUSINESS PROGRAMS**

■ 30. Section 619.201 is revised to read as follows:

**619.201 General policy.**

(a) The Operations Director, Office of Small and Disadvantaged Business Utilization (A/SDBU), is responsible for performing all functions and duties prescribed in FAR 19.201(c) and (d).

(b) In addition to the requirements of FAR 19.201(b), each head of the contracting activity, or designee, is responsible for establishing in coordination with the A/SDBU Operations Director annual goals for the DOS small business program.

(c) The Assistant Secretary of State for Administration is the agency head for the purposes of FAR 19.201(c).

(d) Pursuant to FAR 19.201(d), each Small and Disadvantaged Business Utilization Specialist (SDBUS) is responsible for—

(1) Maintaining a program to locate capable small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business sources to fulfill DOS acquisition requirements;

(2) Coordinating inquiries and requests for advice from small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns on DOS contracting and subcontracting opportunities and other acquisition matters;

(3) Advising contracting activities on new or revised small business policies, regulations, procedures, and other related information;

(4) Assuring that small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns are provided adequate specifications or drawings by initiating, in writing, with appropriate technical and contracting personnel to ensure that all necessary specifications or drawings for current and future acquisitions, as appropriate, are available;

(5) Reviewing all proposed acquisitions in excess of the simplified acquisition threshold, including commercial items using the simplified acquisition procedures of FAR Subpart 13.5, and task and delivery orders under

multiple award contracts exceeding \$2 million, to assure that small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns will be afforded an equitable opportunity to compete and, as appropriate, initiating recommendations for small business, 8(a), or HUBZone set-asides. This includes proposed contract modifications for new or additional requirements that do not fall within the original scope of the contract and which exceed the simplified acquisition limitation. This does not include the exercising of contract options;

(6) Assuring that contract financing available under existing regulations is offered when appropriate and that requests by small business concerns for such financing are not treated as a handicap in the award of contracts;

(7) Providing assistance to the contracting officer in making determinations concerning responsibility of prospective contractors whenever small business concerns are involved;

(8) Participating in the evaluation of a prime contractor's small, small disadvantaged, woman-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business subcontracting plans;

(9) Assuring that the participation of small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns is accurately reported;

(10) Attending, as appropriate, debriefings to unsuccessful small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns to assist those firms in understanding requirements for responsiveness and responsibility so that the firm may be able to qualify for future awards;

(11) Making available to SBA copies of solicitations when so requested;

(12) When a bid or offer from a small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business has been rejected for non-responsiveness or non-responsibility, upon request, aid, counsel, and assist that firm in understanding requirements for responsiveness and responsibility so

that the firm may be able to qualify for future awards;

(13) Participating in Government-industry conferences to assist small business concerns, including Business Opportunity/Federal Acquisition Conferences, Minority Business Enterprise Acquisition Seminars and Business Opportunity Committee meetings;

(14) Maintaining a list of supplies and services that have been placed as repetitive small business set-asides;

(15) Participating in the development, implementation, and review of automated source systems to assure that the interests of small business concerns are included;

(16) Advising potential sources how they can obtain information about competitive acquisitions;

(17) Providing small business, small disadvantaged business, women-owned small business, HUBZone small business, veteran-owned small business, and service-disabled veteran-owned small business concerns information regarding assistance available from Federal agencies such as the Small Business Administration, Minority Business Development Agency, Bureau of Indian Affairs, Economic Development Administration, National Science Foundation, Department of Labor and others, including State agencies and trade associations; and

(18) Participating in interagency programs relating to small business matters as authorized by the A/SDBU Operations Director.

(f)(1) The Procurement Executive is the agency designee for the purposes of FAR 19.201(f)(1). The written determination shall be forwarded to the Procurement Executive through the A/SDBU Operations Director.

■ 31. A new section 619.202, and subsection 619.202-70 are added to read as follows:

**619.202 Specific policies.****619.202-70 The Department of State Mentor-Protégé Program.**

(a) *Purpose.* The Mentor-Protégé Program is designed to motivate and encourage firms to assist small businesses with business development, including small disadvantaged businesses, women-owned small businesses, HUBZone small businesses, veteran-owned small businesses and service-disabled veteran-owned small businesses. The program is also designed to improve the performance of DOS contracts and subcontracts, foster the establishment of long-term business relationships between small businesses and prime contractors, and increase the



overall number of small businesses that receive DOS contract and subcontract awards. The program is limited to non-commercial item acquisitions.

(b) *Definitions.* The definitions of small business (SB), HUBZone small business concern (HUBZone), small disadvantaged business (SDB), women-owned small business (WOSB), veteran-owned small business (VOSB), and service-disabled veteran-owned small business (SDVOSB) are the same as found in FAR 2.101.

*Mentor* means a prime contractor that elects to promote and develop small business subcontractors by providing developmental assistance designed to enhance the business success of the protégé.

*Protégé* means a small business, HUBZone small business, small disadvantaged business, women-owned small business, veteran-owned small business, or service-disabled veteran-owned small business that is the recipient of developmental assistance pursuant to a mentor-protégé program.

(c) *Non-affiliation.* For purposes of the Small Business Act, a protégé firm is not considered an affiliate of a mentor firm solely because the protégé firm is receiving developmental assistance from the mentor firm under the program.

(d) *General policy.* (1) Eligible business prime contractors not included on the "List of Parties Excluded from Federal Procurement and Nonprocurement Programs" that are approved as mentor firms may enter into agreements with eligible protégé.

(2) A firm's status as a protégé under a DOS contract shall not have an effect on the firm's ability to seek other prime contracts or subcontracts.

(e) *Incentives for prime contractor participation.* (1) Under the Small Business Act (15 U.S.C. 637(d)(4)(E)), DOS is authorized to provide appropriate incentives to encourage subcontracting opportunities for small businesses consistent with the efficient and economical performance of the contract. This authority is limited to negotiated acquisitions.

(2) Before awarding a contract that requires a subcontracting plan, the existence of a mentor-protégé arrangement, and performance, if any, under an existing arrangement, may be considered by the contracting officer in:

(i) Evaluating the quality of a proposed subcontracting plan under FAR 19.704-5; and,

(ii) Assessing the prime contractor's compliance with the subcontracting plans submitted in previous contracts as a factor in determining contractor responsibility under FAR 19.705-5(a)(1).

(3) A non-monetary award may be presented annually (or as often as appropriate) to the mentoring firm providing the most effective developmental support of a protégé. The Mentor-Protégé Program Manager will recommend an award winner to the Operations Director, A/SDBU.

(f) *Measurement of program success.* The success of the DOS Mentor-Protégé Program will be measured by:

(1) The increase in the number and dollar value of contracts awarded to protégé firms under DOS contracts from the date the protégé enters the program;

(2) The increase in the number and dollar value of contracts and subcontracts awarded to the protégé under other Federal agencies and commercial contracts; and,

(3) The developmental assistance provided by the mentor firm and the resulting increase in the technical, managerial, financial or other capabilities of the protégé firm, as reported by the protégé.

(g) *Eligibility of mentor firms.* A mentor firm:

(1) May be either a large or small business;

(2) Must be eligible for award of U.S. Government contracts;

(3) Must be able to provide developmental assistance that will enhance the ability of protégé to perform as subcontractors; and,

(4) Will be encouraged to enter into arrangements with protégé and firms with whom they have established business relationships.

(h) *Eligibility of protégé firms.* (1) A protégé firm must be:

(i) A SB, HUBZone, SDB, WOSB, VOSB, or SDVOSB as those terms are defined in FAR 2.101;

(ii) Small in the NAICS code for the services or supplies to be provided by the protégé to the mentor; and,

(iii) Eligible for award of U.S. Government contracts.

(2) Except for SDB and HUBZone firms, a protégé firm may self-certify to a mentor firm that it meets the requirements set forth in paragraph (h)(1) of this subsection. Mentors may rely in good faith on written representations by potential protégé that they meet the specified eligibility requirements. SDB status eligibility and documentation requirements are determined by FAR 19.304. HUBZone status eligibility and documentation requirements are determined by FAR 19.1303.

(3) Protégé may have multiple mentors. Protégé participating in mentor-protégé programs in addition to DOS's program should maintain a system for preparing separate reports of

mentoring activity for each agency's program.

(i) *Selection of protégé firms.* (1) Mentor firms are solely responsible for selecting protégé firms. The mentor is encouraged to identify and select a broad base of protégé firms whose core competencies support DOS's mission. (2) Mentors may have multiple protégé.

(3) The selection of protégé firms by mentor firms may not be protested, except that any protest regarding the size or eligibility status of an entity selected by a mentor shall be handled in accordance with FAR and SBA regulations.

(j) *Application and agreement process for mentor-protégé teams to participate in the program.* (1) Firms interested in becoming a mentor firm shall apply in writing to A/SDBU. The application (Form DS-4053, Department of State Mentor-Protégé Program Application), shall be evaluated by the nature and extent of technical and managerial support proposed as well as the extent of financial assistance in the form of equity investment, loans, joint-venture support, and traditional subcontracting support proposed.

(2) A proposed mentor shall submit the application form and associated information to A/SDBU.

(k) *A/SDBU review of application.* (1) A/SDBU shall review the information to ensure the mentor and protégé are eligible and the information provided is complete. A/SDBU shall consult with the contracting officer on the adequacy of the proposed mentor-protégé arrangement, and its review shall be complete no later than 30 calendar days after receipt of the application by A/SDBU.

(2) Upon completion of the review, A/SDBU will advise the mentor if its application is acceptable. The mentor may then implement the developmental assistance program in accordance with the approved agreement.

(3) The agreement defines the relationship between the mentor and protégé firms only. The agreement itself does not create any privity of contract between the mentor or protégé and the DOS.

(1) *Developmental assistance.* The forms of developmental assistance a mentor can provide to a protégé include:

(i) Management guidance relating to:  
(i) Financial management;  
(ii) Organizational management;  
(iii) Overall business management/ planning;

(iv) Business development; and,  
(v) Technical assistance.

(2) Loans;

(3) Rent-free use of facilities and/or equipment;

(4) Property;

(5) Temporary assignment of personnel to protégé for purpose of training; and,

(6) Any other types of permissible, mutually beneficial assistance.

(m) *Obligation.* (1) A mentor or protégé firm may voluntarily withdraw from the program. However, in no event shall such withdrawal impact the program mission and contractual requirements under the prime contract.

(2) Mentor and protégé firms shall submit to A/SDBU annual reports on program progress of the mentor-protégé agreements. Large business mentors may submit these reports as part of their SB, HUBZone, SDB, WOSB, VOSB, and SDVOSB plan submission in accordance with the due date on the SF-295. DOS shall consider the following in evaluating these reports:

(i) Specific actions taken by the contractor, during the evaluation period, to increase the participation of protégés as suppliers to the U.S. Government and to commercial entities;

(ii) Specific actions taken by the mentor, during the evaluation period, to develop the technical and corporate administrative expertise of a protégé as defined in the agreement;

(iii) To what extent the protégé has met the developmental objectives in the agreement; and,

(iv) To what extent the mentor firm's participation in the Mentor-Protégé Program resulted in the protégé receiving contract(s) and subcontract(s) from private firms and agencies other than the DOS.

(3) The DOS A/SDBU shall submit the annual reports to the cognizant contracting officer regarding participating prime contractor(s) performance in the program.

(4) Mentor and protégé firms shall submit an evaluation to the A/SDBU at the conclusion of the mutually agreed upon program period, the conclusion of the contract, or the voluntary withdrawal by either party from the program, whichever comes first.

(n) *Internal controls.* (1) A/SDBU shall oversee the program and shall work with the cognizant contracting officer to achieve program objectives.

(2) DOS may rescind approval of an existing Mentor-Protégé agreement if it determines that such an action is in the Department's best interest. The rescission shall be in writing and sent to the mentor and protégé firms after approval by the A/SDBU Operations Director. Rescission of an agreement does not change the terms of the subcontract between the mentor and the protégé or the prime contractor's obligations under its subcontracting plan.

(o) *Solicitation provision and contract clause.* (1) The contracting officer shall insert the provision at 652.219-72, Department of State Mentor-Protégé Program, in all unrestricted solicitations exceeding \$500,000 (\$1,000,000 for construction) that offer subcontracting opportunities.

(2) The contracting officer shall insert the clause at DOSAR 652.219-73, Mentor Requirements and Evaluation, in all contracts where the prime contractor has signed a Mentor-Protégé Agreement with the Department of State.

■ 32. Subpart 619.7 is amended by revising the subpart heading to read as follows:

**Subpart 619.7—The Small Business Subcontracting Program**

■ 33. Section 619.705-1 is revised to read as follows:

**619.705-1 General support of the program.**

It is the Department's policy to incorporate its current fiscal year goals as negotiated with the SBA into all pertinent Department solicitations, in addition to the standard subcontract clauses. Incorporation of the goals does not require that large prime contractors must subcontract, but does require that to the extent they plan to subcontract, specific goals be established for doing business with small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business firms. Where funds are available, an incentive clause such as that found in FAR 52.219-10, Incentive Subcontracting Program, is encouraged.

■ 34. Section 619.705-3 is revised to read as follows:

**619.705-3 Preparing the solicitation.**

To further promote the use of small, disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business firms by large prime contractors, contracting officers are encouraged to consider the adequacy of the subcontracting plans, and/or past performance in achieving negotiated subcontract goals, as part of the overall evaluation of the technical proposals.

■ 35. Section 619.705-4 is revised to read as follows:

**619.705-4 Reviewing the subcontracting plan.**

A/SDBU shall review subcontracting plans to determine if small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned

small business concerns are afforded the maximum practicable opportunity to participate as subcontractors. A/SDBU shall recommend to the contracting officer changes needed to subcontracting plans found to be deficient.

■ 36. Section 619.705-6-70 is amended by revising the first sentence in paragraph (b) to read as follows:

**619.705-6-70 Reporting responsibilities.**

\* \* \* \* \*

(b) Contracting officers shall collect subcontracting data from contractors required to establish subcontracting plans in support of small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business concerns. \* \* \*

**619-708-70 [Amended]**

■ 37. Section 619.708-70 is amended by removing the words "and Small Disadvantaged Business".

**619.801 [Removed]**

■ 38. Section 619.801 is removed.

■ 39. Section 619.805-2 is amended by adding a new paragraph (a)(2) to read as follows:

**619.805-2 Procedures.**

(a) \* \* \*

(2) In accordance with a waiver approved by SBA, contract actions for services exceeding \$3 million and supplies exceeding \$5 million that supplement the security of U.S. diplomatic posts and protect the lives of Department personnel may be awarded non-competitively. Contracting officers do not need to compete 8(a) acquisitions as stated when those acquisitions exceed the 8(a) competition thresholds. This waiver is in effect for the duration of the national state of emergency as declared by the President of the United States. If a contracting officer has a question as to whether a particular action falls under this waiver, the contracting officer should contact A/SDBU.

\* \* \* \* \*

**PART 622—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITION**

■ 40. Subpart 622.13 is amended by revising the subpart heading to read as follows:

**Subpart 622.13—Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans**

■ 41. Section 622.1303 is redesignated as section 622.1305. Newly designated

622.1305 is amended by revising the citation "FAR 22.1303" at the end of the sentence to read "FAR 22.1305."

■ 42. Section 622.1308 is redesignated as section 622.1310. Newly designated 622.1310 is amended by revising the citation "FAR 22.1308(a)(2) and (c)" at the end of the sentence to read "FAR 22.1310(a)(1)(ii) and (a)(2)."

■ 43. A new subpart 622.15, consisting of section 622.1503, is added to read as follows:

**Subpart 622.15—Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor**

**622.1503 Procedures for acquiring end products on the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor.**

(e) The contracting officer shall refer to the DOS Inspector General for Investigation any instances where the contracting officer has reason to believe that forced or indentured child labor was used to mine, produce, or manufacture an end product furnished pursuant to a contract awarded subject to the certification required in FAR 22.1503(c).

**PART 623—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE**

■ 44. Part 623 is amended by revising the heading to read as set forth above.

**Subpart 623.1 [Removed]**

■ 45. Subpart 623.1, consisting of sections 623.104 and 623.107, is removed.

**623.400 [Amended]**

■ 46. Section 623.400 is amended by removing the words "made and/or performed" and inserting the word "awarded" in their place in the second sentence.

■ 47. Section 623.404 is revised to read as follows:

**623.404 Agency affirmative procurement programs.**

(a) The Department's affirmative procurement program has been established by A/OPE. It is available on the A/OPE Internet and Intranet Web sites at <http://www.statebuy.state.gov/green.htm> and <http://aope.a.state.gov/green2.htm>, respectively.

**PART 625—FOREIGN ACQUISITION**

**625.102 [Removed]**

■ 48. Section 625.102 is removed.

■ 49. A new section 625.103 is added to read as follows:

**625.103 Exceptions.**

(a) The authority to make the determination prescribed in FAR 25.103(a) is delegated, without power of redelegation, to the head of the contracting activity.

■ 50. Section 625.105 is revised to read as follows:

**625.105 Determining reasonableness of cost.**

(a)(1) The authority to make the determinations prescribed in FAR 25.105(a)(1) is delegated, without power of redelegation, to the head of the contracting activity.

**625.108 [Removed]**

■ 51. Section 625.108 is removed.

■ 52. Section 625.202 is revised to read as follows:

**625.202 Exceptions.**

(a)(1) The authority to make the determination prescribed in FAR 25.202(a)(1) is delegated, without power of redelegation, to the head of the contracting activity.

**625.203 [Removed]**

■ 53. Section 625.203 is removed.

■ 54. Section 625.204 is revised to read as follows:

**625.204 Evaluating offers of foreign construction material.**

(b) The head of the contracting activity is the agency head for the purposes of FAR 25.204(b).

**Subpart 625.3 [Removed]**

■ 55. Subpart 625.3, consisting of sections 625.300, 625.300-70, 625.302, and 625.304 is removed.

**Subpart 625.7 [Removed]**

■ 56. Subpart 625.7, consisting of section 625.703, is removed.

**PART 626—OTHER SOCIOECONOMIC PROGRAMS**

■ 57. Part 626, consisting of subpart 626.2 and section 626.200-70, is removed.

**Subchapter E—General Contracting Requirements**

**PART 628—BONDS AND INSURANCE**

**628.203 [Amended]**

■ 58. Section 628.203 is amended in paragraph (g) by removing the words "Office of the Inspector General" and inserting the words "Assistant Inspector General for Investigations" in their place.

**Subpart 628.70 [Removed]**

**628.7001 [Removed]**

■ 59. Subpart 628.70, consisting of section 628.7001, is removed.

**PART 630—COST ACCOUNTING STANDARDS ADMINISTRATION**

■ 60. A new part 630 is added to read as follows:

**PART 630—COST ACCOUNTING STANDARDS ADMINISTRATION**

**Subpart 630.2—CAS Program Requirements**

**630.201 Contract requirements.**

**630.201-5 Waiver.**

(a) The Procurement Executive is the head of the agency for the purposes of FAR 30.201-5(a) and (b).

**PART 632—CONTRACT FINANCING**

**632.006-2 [Amended]**

■ 61. Section 632.006-2 is amended by removing the words "Assistant Inspector General for Investigations" and inserting the words "Procurement Executive" in their place.

■ 62. Subpart 632.4 is amended by revising the Subpart heading to read as follows:

**Subpart 632.4—Advance Payments for Non-Commercial Items**

**632.903 [Removed]**

■ 63. Section 632.903 is removed.

■ 64. A new section 632.906 is added to read as follows:

**632.906 Making payments.**

(a) *General.* The authority to make the determination prescribed in FAR 32.906(a) is delegated, without power of redelegation, to the head of the contracting activity. Before making this determination, the head of the contracting activity shall consult with the appropriate financial office.



## Subchapter F—Special Categories of Contracting

### PART 636—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

■ 65. Section 636.101–70 is revised to read as follows:

#### 636.101–70 Exception.

Contracts for overseas construction, including capital improvements, alterations, and major repairs, may be excepted where necessary from the provisions of the FAR (48 CFR Chapter 1) under the authority of section 3 of the Foreign Service Buildings Act of 1926, as amended (22 U.S.C. 294). The Director/Chief Operating Officer of the Bureau of Overseas Buildings Operations is authorized to approve such exceptions.

■ 66. Sections 636.104, 636.104–70 and 636.104–71, are added to read as follows:

#### 636.104 Policy.

#### 636.104–70 Foreign Service Buildings Act of 1926, as amended.

(a) *Policy.* Section 11 of the Foreign Service Buildings Act of 1926, as amended (22 U.S.C. 302) limits competition for the construction, alteration, or repair of buildings or grounds abroad exceeding \$5 million to:

(1) American-owned firms; or  
(2) Firms from countries which permit or agree to permit substantially equal access to American firms for comparable diplomatic and consular building projects.

(b) *Limitation.* This participation may be permitted by or limited to:

(1) Host-country firms where required by international agreement; or  
(2) By the laws of the host country; or  
(3) Where determined by the Secretary of State to be necessary in the interest of bilateral relations or necessary to carry out the construction project.

(c) *Evaluation preference.* For purposes of determining competitive status, American-owned firms shall receive a ten (10) percent price preference reduction, provided that two prospective responsible bidders/offers submit a bid/offer.

#### 636.104–71 Omnibus Diplomatic Security and Antiterrorism Act.

(a) *Preference for United States contractors.* The Omnibus Diplomatic Security and Antiterrorism Act of 1986 (Public Law 99–399; 22 U.S.C. 4852) limits certain construction projects abroad to United States persons or qualified United States joint venture persons. The Omnibus Diplomatic

Security and Antiterrorism Act of 1986 applies to the following, as determined by the Assistant Secretary for Diplomatic Security:

(1) Diplomatic construction or design projects abroad exceeding \$10 million; or,

(2) Diplomatic construction projects abroad at any dollar amount that involve technical security, unless the project involves low-level technology.

(b) *Exception.* This preference shall not apply with respect to any diplomatic construction or design project in a foreign country whose statutes prohibit the use of United States contractors on such projects.

(c) *Subcontracting limitation.* With respect to a diplomatic construction project, a prime contractor may not subcontract more than 50 percent of the total value of the contract for that project.

■ 67. Section 636.202 is added to read as follows:

#### 636.202 Specifications.

(d) The Director/Chief Operating Officer of the Bureau of Overseas Building Operations is the head of the agency for the purposes of FAR 36.202(d)(3) and (4).

■ 68. Section 636.513 is amended by adding the following sentence to the end of paragraph (a):

#### 636.513 Accident prevention.

(a) \* \* \* The contracting officer shall confer with OBO/OM/SHEM if there are any questions on any factors listed in paragraph (4) of the clause, or if the contracting officer has any questions regarding construction safety issues.

■ 69. Section 636.570 is added to read as follows:

#### 636.570 Additional DOSAR provisions.

(a) The contracting officer shall insert the provision at 652.236–71, Foreign Service Buildings Act, As Amended, in all contracts exceeding \$5,000,000 for the construction, alteration, or repair of buildings and grounds overseas, unless:

(1) An international agreement with or laws of the host country government permits or limits the participation to host-country firms; or,

(2) The Secretary of State determines that it is necessary to the interest of bilateral relations or to carry out the project to either permit or limit the participation to host-country firms; or,

(3) The provision at DOSAR 652.236–72 applies.

(b) The contracting officer shall insert the provision at 652.236–72, Statement of Qualifications for the Omnibus Diplomatic Security and Antiterrorism Act, in all diplomatic construction or

design solicitations exceeding \$10 million; or, diplomatic construction projects abroad at any dollar amount that involve technical security, unless the project involves low-level technology, as determined by the Assistant Secretary of Diplomatic Security.

#### 636.602–4 [Removed]

■ 70. Section 636.602–4 is removed.

### PART 637—SERVICE CONTRACTING

■ 71. Section 637.102 and section 637.102–70 are added to read as follows:

#### 637.102 Policy.

#### 637.102–70 Special requirements for the acquisition of local guard services overseas.

(a) *Policy.* Section 136 of the Foreign Relations Authorization Act, Fiscal Years 1990 and 1991 (22 U.S.C. 4864) encourages the participation of United States persons and qualified United States joint venture persons in local guard contracts overseas under diplomatic security programs.

(b) *Evaluation preference.* For purposes of determining competitive status, proposals of United States persons and qualified United States joint venture persons shall receive a ten (10) percent price preference reduction.

#### 637.104–70 [Amended]

■ 72. Section 637.104–70 is amended by removing the words “Office of Foreign Buildings” and inserting the words “Bureau of Overseas Buildings Operations” in their place, and by removing the words “and the Moscow Embassy Buildings Control Office” in paragraph (f).

■ 73. Section 637.110 is amended by adding a new paragraph (d) to read as follows:

#### 637.110 Solicitation provisions and contract clauses.

\* \* \* \* \*

(d) The contracting officer shall insert the provision at 652.237–73, Statement of Qualifications for Preference as a U.S. Person, in all overseas local guard solicitations.

■ 74. A new Subpart 637.6, consisting of section 637.601, is added to read as follows:

#### Subpart 637.6—Performance-Based Contracting

##### 637.601 General.

It is the Department's policy that all new service contracts be performance-based, with clearly defined deliverables and performance standards. Any

deviations from this policy shall be fully justified in writing and approved by the Departmental Competition Advocate.

#### Subchapter G—Contract Management

### PART 642—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 75. Section 642.271 is redesignated as section 642.272. A new section 642.271 is added to read as follows:

#### 642.271 Government Technical Monitor (GTM).

(a) *Policy.* The contracting officer may appoint a Government Technical Monitor (GTM) to assist the Contracting Officer's Representative (COR) in monitoring a contractor's performance. The contracting officer may appoint a GTM because of physical proximity to the contractor's work site, or because of special skills or knowledge necessary for monitoring the contractor's work. The contracting officer may also appoint a GTM to represent the interests of another requirements office or post concerned with the contractor's work. A GTM shall be a direct-hire U.S. Government employee.

■ 76. Subpart 642.15, consisting of sections 642.1503 and 642.1503-70, is added to read as follows:

#### Subpart 642.15—Contractor Performance Information 642.1503 Procedures.

#### 642.1503-70 Contractor Performance System (CPS).

(a) The Department of State subscribes to the Contractor Performance System (CPS) maintained by the National Institutes of Health. CPS is an Internet-based tool allowing contracting officers to input past performance information and view past performance information input by other contracting officers in other locations and agencies.

(b) All DOS contracting officers with access to the Internet shall use CPS to evaluate contractor's past performance for all contracts exceeding \$100,000, including options. Contracting officers shall also use the CPS to evaluate the past performance of offerors on all competitive negotiated acquisitions exceeding \$100,000, including options, unless the contracting officer documents in the contract file why past performance is not an appropriate evaluation factor. The CPS may also be used for evaluating acquisitions not exceeding \$100,000 to conform to the general principle of considering past performance in all acquisitions.

(c) Form DS-1771, *Contractor Past Performance Evaluation*, shall be used only:

(1) When the CPS is temporarily unavailable. When the CPS becomes available, data from any DS-1771 created in the interim shall be promptly entered into the CPS; or

(2) At overseas locations where access to the Internet is not practicable.

(d) Heads of contracting activities shall send a list of the names, work addresses, and phone numbers of all acquisition personnel whom they wish to have access to the CPS to A/LM/AQM.

### PART 651—USE OF GOVERNMENT SOURCES BY CONTRACTORS

#### 651.701 [Amended]

■ 77. Section 651.701 is amended by removing the last sentence of paragraph (c).

#### Subchapter H—Clauses and Forms

### PART 652—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 78. Section 652.216-70 is amended by revising the clause date and by revising paragraph (b) to read as follows:

#### 652.216-70 Ordering—Indefinite-Delivery Contract.

\* \* \* \* \*

#### Ordering—Indefinite-Delivery Contract (APR 2004)

\* \* \* \* \*

(b) The DS-2076, Purchase Order, Receiving Report and Voucher, and DS-2077, Continuation Sheet.

■ 79. Section 652.219-70 is revised to read as follows:

#### 652.219-70 Department of State Subcontracting Goals.

As prescribed in 619.708-70, insert a provision substantially the same as follows:

#### Department of State Subcontracting Goals (APR 2004)

(a) The offeror shall provide a Small, Small Disadvantaged, Woman-Owned Small, HUBZone Small, and Service-Disabled Veteran-Owned Small Enterprise Subcontracting Plan that details its approach to selecting and using Small, Small Disadvantaged, Woman-Owned Small, HUBZone Small, and Service-Disabled Veteran-Owned Small Business Enterprises.

(b) For the fiscal year [insert appropriate fiscal year], the Department's subcontracting goals are as follows:

(1) Goal for subcontracting to SB:

(2) Goal for subcontracting to SDB:

(3) Goal for subcontracting to SWB:

(4) Goal for subcontracting to HUBZone Firms:

(5) Goal for subcontracting to SDVO:

(6) Omnibus goals (if applicable):

(i) 10% to minority business

(ii) 10% to small business

(End of provision)

■ 80. Section 652.219-72 is added to read as follows:

#### 652.219-72 Department of State Mentor-Protégé Program.

As prescribed in 619.202-70(o)(1), insert the following provision:

#### Department of State Mentor-Protégé Program (APR 2004)

(a) Large and small businesses are encouraged to participate in the Department of State Mentor-Protégé Program. Mentor firms provide eligible small business protégés with developmental assistance to enhance their business capabilities and ability to obtain Federal contracts.

(b) Mentor firms are large prime contractors or eligible small businesses capable of providing developmental assistance. Protégé firms are small businesses, as defined in 13 CFR parts 121, 124, and 126.

(c) Developmental assistance is technical, managerial, financial, and other mutually beneficial assistance that aids protégés. Firms interested in participating in the program are encouraged to contact the Department of State OSDBU for further information. (End of provision)

■ 81. Section 652.219-73 is added to read as follows:

#### 652.219-73 Mentor Requirements and Evaluation.

As prescribed in 619.202-70(o)(2), insert the following clause:

#### Mentor Requirements and Evaluation (APR 2004)

(a) Mentor and protégé firms shall submit an evaluation to the Department of State's OSDBU at the conclusion of the mutually agreed upon program period, the conclusion of the contract, or the voluntary withdrawal by either party from the program, whichever occurs first. At the conclusion of each year in the mentor-protégé program, the prime contractor and protégé will formally brief the Department of State Mentor-Protégé Program Manager regarding program accomplishments under their mentor-protégé agreement.

(b) A mentor or protégé shall notify the OSDBU and the contracting officer, in writing, at least 30 calendar days in advance of the effective date of the firm's withdrawal from the program. A mentor firm shall notify the OSDBU and the contracting officer upon receipt of a protégé's notice of withdrawal from the program. (End of clause)

#### 652.226-70 [Removed]

■ 82. Section 652.226-70 is removed.

**652.228-70 [Removed and Reserved]**

- 83. Section 652.228-70 is removed and reserved.
- 84. Section 652.236-70 is amended—
  - (a) By revising the date of the clause;
  - (b) By revising paragraph (a)(4) to read as set forth below; and,
  - (c) By revising paragraph (d)(1) to read as set forth below:

**652.236-70 Accident Prevention.**

\* \* \* \* \*

**Accident Prevention (APR 2004)**

- (a) \* \* \*
- (4) For overseas construction projects, the contracting officer shall specify in writing additional requirements regarding safety if the work involves:
  - (i) Scaffolding;
  - (ii) Work at heights above two (2) meters;
  - (iii) Trenching or other excavation greater than one (1) meter in depth;
  - (iv) Earth moving equipment;
  - (v) Temporary wiring, use of portable electric tools, or other recognized electrical hazards. Temporary wiring and portable electric tools require the use of a ground fault circuit interrupter (GFCI) in the affected circuits; other electrical hazards may also require the use of a GFCI;
  - (vi) Work in confined spaces (limited exits, potential for oxygen less than 19.5 percent or combustible atmosphere, potential for solid or liquid engulfment, or other hazards considered to be immediately dangerous to life or health such as water tanks, transformer vaults, sewers, cisterns, etc.);
  - (vii) Hazardous materials—a material with a physical or health hazard including but not limited to, flammable, explosive, corrosive, toxic, reactive or unstable, or any operations which creates any kind of contamination inside an occupied building such as dust from demolition activities, paints, solvents, etc.; or
  - (viii) Hazardous noise levels.

\* \* \* \* \*

- (d) \* \* \*
- (1) Submit a written plan to the contracting officer for implementing this clause. The plan shall include specific management or technical procedures for effectively controlling hazards associated with the project; and,

- 85. Section 652.236-71 is added to read as follows:

**652.236-71 Foreign Service Buildings Act, as Amended.**

As prescribed in 636.570(a), insert the following provision:

**Foreign Service Buildings Act, as Amended (APR 2004)**

- (a) This solicitation is subject to Section 11 of the Foreign Service Buildings Act of 1926, as amended (22 U.S.C. 302). This statute limits competition under this solicitation to:
  - (1) American-owned firms, as described in paragraph (b) of this provision; and,
  - (2) Firms from countries that permit or agree to permit substantially equal access to

American firms for comparable diplomatic and consular building projects.

(b) To qualify as an American-owned firm for purposes of this solicitation, the bidder/offeror must demonstrate evidence of:

- (1) Performance of similar construction work in the United States; and
- (2) Either—
  - (i) Ownership in excess of 50% by U.S. citizens or permanent residents; or
  - (ii) Incorporation in the United States for more than three (3) years and employment of U.S. citizens or permanent residents in more than half of the company's permanent full-time professional and managerial positions in the United States.

(c) For purposes of determining competitive status, offers submitted by American-owned firms shall be reduced by ten (10) percent, provided that two responsible bidders/offerors submit a bid/offer.

(d) *Evidence of qualification.* (1) Performance of similar construction work in the United States. The bidder/offeror must describe below one or more similar projects completed in the United States. For each project, provide the following information:

Location: \_\_\_\_\_  
 (City and State) \_\_\_\_\_  
 Complexity: \_\_\_\_\_

(Office building, etc.) \_\_\_\_\_  
 Type of construction: \_\_\_\_\_  
 Value of project: \_\_\_\_\_  
 Location: \_\_\_\_\_  
 (City and State) \_\_\_\_\_  
 Complexity: \_\_\_\_\_

(Office building, etc.) \_\_\_\_\_  
 Type of construction: \_\_\_\_\_  
 Value of project: \_\_\_\_\_  
 Location: \_\_\_\_\_  
 (City and State) \_\_\_\_\_  
 Complexity: \_\_\_\_\_

(Office building, etc.) \_\_\_\_\_  
 Type of construction: \_\_\_\_\_  
 Value of project: \_\_\_\_\_

If the bidder/offeror's participation was as a partner or co-venture, indicate the percentage of the project performed by the bidder/offeror: \_\_\_\_\_ %

- (2) Corporate location or ownership.
  - (i) The bidder/offeror certifies that it  is  is not owned in excess of fifty (50) percent by United States citizens or permanent residents.

(ii) The bidder/offeror certifies that it  has not been incorporated in the United States for more than three years and that it  employs  does not employ United States citizens or permanent residents in more than half of its permanent full-time professional and managerial positions in the United States.

(e) By signing this bid/offer, the bidder/offeror certifies to the best of its knowledge, all of the representations and certifications provided in this provision are accurate, current and complete. (End of provision)

- 86. Section 652.236-72 is added to read as follows:

**652.236-72 Statement of Qualifications for the Omnibus Diplomatic Security and Antiterrorism Act.**

As prescribed in 636.570(b), insert the following provision:

**Statement of Qualifications for the Omnibus Diplomatic Security and Antiterrorism Act (APR 2004)**

(a) This solicitation is subject to Section 402 and Section 406(c) of the Omnibus Diplomatic Security and Antiterrorism Act of 1986 (P.L. 99-399; 22 U.S.C. 4852). The Act limits certain construction projects abroad to United States persons or United States joint venture persons, and excludes organizations that have business arrangements with Libya. This Statement of Qualifications shall be used to determine if a bidder/offeror meets the definition of a "United States person" or a "United States joint venture person" and whether they have any business arrangements with Libya that may disqualify them from participating in this solicitation.

(b) *Definition.* As used in this provision—  
*U.S. person* means a company, partnership, or joint venture that the Government determines, after consideration of all available information, including but not limited to that provided by the bidder/offeror in response to this solicitation, to be qualified pursuant to Section 402.

(c) *Representation.* The bidder/offeror represents as part of its bid/offer that it  does  does not meet the qualifications as a U.S. person as set forth in Section 402 of the Act.

[Complete a Statement of Qualifications for Purposes of Determining Status as a U.S. Person if the offeror represents that it is eligible. See paragraph (d) of this provision.]

*Warning:* Any material misrepresentation made in the Statement of Qualifications may be the basis for disqualification of a bidder/offeror and reference for consideration of suspension or debarment or for prosecution under Federal law (cf. 18 U.S.C. 1001). Bidder/offeror qualifications will be determined primarily on the basis of information submitted in the Statement of Qualifications, including attachments thereto, but the Government may, at its discretion, rely on information contained elsewhere in the bidder's/offeror's bid/proposal or obtained from other sources.

(d) *Statement of Qualifications for Purposes of Determining Status as a U.S. Person* (22 U.S.C. 4852). A bidder/offeror that represents that it is a U.S. person must provide the following information.

Statement of Qualifications for Purposes of Determining Status as a U.S. Person (22 U.S.C. 4852)  
 Name and address of U.S. person organization providing this information:

\_\_\_\_\_

*Introduction.* Section 402 of the Omnibus Diplomatic Security and Antiterrorism Act (Public Law 99-399) provides that a "United States person" or a "qualified United States joint venture" must meet certain requirements, listed in sections 402(c)(2) and (3) of the Act, to be eligible to compete. To assist business entities to determine whether

they qualify as a U.S. person or U.S. joint venture person, guidance is hereby provided. For ease of reference, the statutory language is quoted immediately before the definitions that apply to it. Space for the required information is provided immediately following each definition.

Note: The Statement of Qualifications shall provide information correctly applicable to the U.S. person whose qualifications are being certified, and shall not include information pertaining to corporate affiliates or subsidiaries. Organizations that wish to use the experience or financial resources of any other legally dependent organization or individual, including parent companies, subsidiaries, or other related organizations, must do so by way of a joint venture. A prospective bidder/offeree may be an individual organization or firm, a formal joint venture in which the co-venturers have reduced their arrangement to writing, or a de facto joint venture where no formal agreement has been reached, but the offering entity relies upon the experience of a related U.S. firm that guarantees performance. To be considered a "qualified United States joint venture person," the joint venture must have at least one firm or organization that itself meets all the requirements of a U.S. person listed in Section 402. By signing this bid/proposal, the U.S. person co-venturer agrees to be individually responsible for performance of the contract, notwithstanding the terms of any joint venture agreement.

1. *Section 402(c)(2)(A)*: "The term 'United States person' means a person which—(A) is incorporated or legally organized under the laws of the United States, including the District of Columbia, and local laws."

Definitions for purposes of Section 402 determinations of eligibility—

*Incorporated* means the successful de jure incorporation of a business organization pursuant to the laws of any United States jurisdiction or component thereof.

*Legally organized* means the legally recognized existence of an organization other than a de jure corporation (e.g., a partnership) under the laws of any United States jurisdiction or component thereof. Only organizations that have a legal status, including the right to bring suit, to sign contracts, and to hold property under the law of the jurisdiction where they are doing business will qualify as legally organized. A natural person who is a United States citizen acting in his or her entrepreneurial capacity will be deemed to be a "person legally organized" within the scope of this definition, provided that the prospective bidder/offeree holds all required licenses to do business in the jurisdiction where he or she is located.

*United States* means any jurisdiction that is one of the fifty States, the District of Columbia, a United States territory, a United States possession, or the Commonwealths of Puerto Rico and the Northern Mariana Islands.

*Question 1*. The organization seeking eligibility under Section 402 is  incorporated or is  legally organized under the laws of what jurisdiction?

2. *Section 402(c)(2)(B)*: "The term 'United States person' means a person which—(B) has its principal place of business in the United States."

Definitions for purposes of Section 402 determinations of eligibility—

*Principal place of business* means the main location of the prospective bidder/offeree. For purposes of this section, a prospective bidder/offeree shall identify only one principal place of business, and such location shall include at least the offices of the chief operating officer and headquarters staff. The named location must be a United States jurisdiction from which a tax return has been filed or will be filed during the calendar year in which the prospective bidder/offeree submits this bid/offeree.

*United States* means any jurisdiction that is one of the fifty States, the District of Columbia, a United States territory, a United States possession, or the Commonwealths of Puerto Rico and the Northern Mariana Islands.

*Question 2(a)*. The organization seeking eligibility has its principal place of business in what city and state?

*Question 2(b)*. What kind of tax return was or will be filed, and in what jurisdiction, during the current calendar year?

- (i) Jurisdiction: \_\_\_\_\_  
(e.g., federal, state, city)
- (ii) Type of return (e.g., income tax, franchise tax, etc.). Include all that apply: \_\_\_\_\_

3. *Section 402(c)(2)(C)*: "The term 'United States person' means a person which has been incorporated or legally organized in the United States—

(i) for more than 5 (five) years before the issuance date of the invitation for bids or request for proposals with respect to a construction project under subsection (a)(1); and,

(ii) for more than 2 (two) years before the issuance date of the invitation for bids or request for proposals with respect to a construction or design project abroad that involves technical security under subsection (a)(2)."

Definitions for purposes of Section 402 determinations of eligibility—

*Has been incorporated or legally organized* means that the organization can show continuity as an ongoing business. Organizations that have changed only their names meet the continuity requirement of this subsection. Organizations that have been bought, sold, merged, or otherwise substantially altered or enlarged their principal business activities will have the burden of proving that there have been ongoing operations by the same business entity for the required period of time. If the successor entity has acquired all of the assets and liabilities of the predecessor business and the predecessor business has no further existence, the successor may claim the incorporation date of the predecessor. In any other circumstance, the prospective bidder/offeree must show that the law of the jurisdiction in which it operates regards the prospective bidder/offeree as the complete successor in interest of the predecessor

business for purpose of contractual obligations.

*Issuance date* means the date in Block 3 of the Standard Form 1442 accompanying this solicitation.

*Years* means calendar years measured from day of the month to day of the month. For example, January 1, 2002 through December 31, 2002 is one calendar year, as is July 1, 2002 through July 1, 2003.

*Question 3*:

(i) On what date was the organization seeking eligibility incorporated or legally organized? \_\_\_\_\_

(ii) If this date is less than the required number of years before the issuance date, on the basis of what documentation does the organization seeking eligibility claim that it has been in business for the requisite period of time? \_\_\_\_\_ (Identify, and forward copies as an Attachment to this Statement. This material may include such items as certificates of incorporation, partnership agreements, resolutions of boards of directors, etc.).

4. *Section 402(c)(2)(D)*: "The term 'United States person' means a person which has performed within the United States or at a United States diplomatic or consular establishment abroad administrative and technical, professional, or construction services similar in complexity, type of construction, and value to the contract being bid."

Definitions for purposes of Section 402 determination of eligibility—

*Administrative and technical, professional, or construction services* means the kind of work in which the prospective bidder/offeree is interested. If the proposed contract is for construction management services, the prospective bidder/offeree will be expected to demonstrate construction management expertise. In general, "administrative" means the capacity or ability to manage; "technical" means the specific skills peculiar to the type of work required; "professional" means expert services resulting from advanced training in the type of work required; and "construction" experience if it has not directly performed all of the actual construction activities. Thus, an entity whose only construction work experience was performed by its legally distinct subsidiary or parent will not be considered to have construction experience.

*Complexity* means the physical size and technical size and demands of the project. "Performed" means projects that have been fully completed by the prospective bidder/offeree and accepted by the owner or other party to the transaction. Projects still in progress have not yet been performed for purposes of this definition.

*Type of construction* means the overall nature of the facilities to be built, including the kinds of materials to be used. Thus, if the contract will require the construction of a multi-story office building, the prospective bidder/offeree will be expected to demonstrate experience with facilities of this type.

*Value* means the total contract price of the project, not to the profit or loss to the bidder/offeree.

*Within the United States* means a United States jurisdiction that is the place where the



subject matter of the contract or other arrangement was in fact completed. It does not mean the place where the contract or other arrangement was negotiated or signed. The term "United States" means any jurisdiction that is one of the 50 states, the District of Columbia, a United States territory, a United States possession, or the Commonwealth of Puerto Rico and the Northern Mariana Islands.

**Question 4:** List on this page, and an attachment (if necessary), one or more similar projects completed by the prospective bidder/offeree. For each project, provide the following information:

Location:  
(City and State, or Country)

Type of service:  
(administrative, etc.)

Complexity:  
(office building, etc.)

Type of construction:

Value of project:

If the prospective bidder/offeree's participation was as a partner or co-venturer, indicate the percentage of the project performed by the prospective offeror: \_\_\_\_\_ %

5. **Section 402(c)(2)(E):** "The term 'United States person' means a person which—with respect to a construction project under subsection (a)(1)—has achieved a total business volume equal to or greater than the value of the project being bid in 3 years of the 5-year period before the date specified in subparagraph (C)(i)."

Definitions of purposes of Section 402 determination of eligibility—  
3 years of the 5-year period before the date specified in subparagraph (C)(i) means the three to five calendar year period immediately preceding the issuance date of this solicitation.

**Total business volume** means the U.S. dollar value of the gross income or receipts reported by the prospective bidder/offeree on its annual federal income tax returns.

**Years** means the business year of the prospective bidder/offeree, as reflected on its annual federal income tax returns.

**Question 5:** Please complete the information below for at least three of the five listed years.

The gross receipts for the business year:  
(list year and amount).

The gross receipts for the business year:  
(list year and amount).

The gross receipts for the business year:  
(list year and amount).

The gross receipts for the business year:  
(list year and amount).

The gross receipts for the business year:  
(list year and amount).

6. **Section 402(c)(2)(F):** "The term 'United States person' means a person which—(i) employs United States citizens in at least 80 percent of its principal management positions in the United States; (ii) employs United States citizens in more than half of its permanent, full-time positions in the United States; and (iii) will employ United States

citizens in at least 80 percent of the supervisory positions on the foreign buildings office project site."

Definitions for purposes of Section 402 determinations of eligibility—

**In the United States** refers to those positions that the prospective bidder/offeree maintains within all jurisdictions which are one of the 50 states, the District of Columbia, a United States territory, a United States possession, or the Commonwealths of Puerto Rico and the Northern Mariana Islands.

**Permanent, full-time positions** means positions with the prospective bidder/offeree that are intended to be indefinite, as opposed to limited, seasonal, or project-duration periods. The term 'full-time' refers to positions in which the occupants are expected to and ordinarily work 40 hours a week. The term 'permanent, full-time positions' covers the portion of the prospective bidder's/offeree's workforce that continues to be employed without regard to the fluctuating requirements of production or projects.

**Principal management positions** refers to chief operating officer and those management officials reporting directly to him or her. In the case of a partnership, the term refers to every general partner. In the case of a corporation, the term refers to those officers of the corporation who are active in running its day-to-day operations. Members of corporation boards of directors who do not have operational responsibilities do not occupy "principal management positions" simply by virtue of their service on the board. In all cases, the term "principal management positions" also includes the position or positions held by the individual or individuals who will have primary corporate management oversight responsibility for this contract if the prospective bidder/offeree is awarded the contract. Each prospective bidder/offeree is responsible for listing all of its principal management positions and identifying their current occupants by name and citizenship.

**Supervisory positions** means all positions with significant authority to direct the work of others as well as those for which access to classified or controlled documents is required. Such positions will be identified in each contract.

**United States citizen** means natural persons with United States citizenship by virtue either of birth or of naturalization.

**Question 6(a):** The bidder/offeree has the following staff:

(i) Principal management positions in the United States:

Chief Operating Officer:

(name)

(citizenship)

(ii) For each individual reporting directly to the above-named Chief Operating Officer, list position, name, and citizenship:

Position:

Name:

Citizenship:

(iii) Individual(s) expected to have primary management oversight responsibility for contract if it is awarded:

(name)

(citizenship)

**Question 6(b):** Number of permanent, full-time positions in the United States:

**Question 6(c):** Number of United States citizens currently employed in permanent, full-time positions in the United States:

**Question 6(d):** Certification of intent to employ U.S. citizens in a minimum of 80 percent of the supervisory positions identified by the Government on this project:  
I so certify:  
(signature)

(name typed or printed)

(position)

(date)

7. **Section 402(c)(2)(G):** "The term 'United States person' means a person which has the existing technical and financial resources in the United States to perform this contract."

Definitions for purposes of Section 402 determinations of eligibility—

**Existing technical and financial resources** means the capability of the prospective bidder/offeree to mobilize adequate staffing and monetary arrangements from within the United States sufficient to perform the contract. Adequate staffing levels may be demonstrated by presenting the resumes of current United States citizens and resident aliens with skills and expertise necessary for the work in which the prospective bidder/offeree is interested or some other indication of available United States citizen or permanent legal resident human resources. Demonstration of adequate financial resources must be issued by entities that are subject to the jurisdiction of United States courts and have agents located within the United States for acceptance of service of process.

**Question 7:** Submit, as an Attachment to this Statement, materials demonstrating existing technical and financial resources in the United States.

8. **Section 402(c)(3):** "The term 'qualified United States joint venture person' means a joint venture in which a United States person or persons owns at least 51 percent of the assets of the joint venture."

Definitions for purposes of Section 402 determinations of eligibility—

**Assets** means tangible and intangible things of value conveyed or made available to the joint venture by the co-venturers.

**Joint venture** means a formal or *de facto* arrangement by and through which two or more persons or entities associate for the purpose of carrying out the prospective contract. Prospective bidders/offerees are advised that a joint venture may not be acceptable to projects requiring a Department of Defense facility security clearance because each co-venturer may post particular problems in obtaining security clearances. To be acceptable, all members of a joint venture must be individually and severally liable for



the full performance of and resolution of any and all matters arising out of the contract, notwithstanding any provision of the joint venture agreement of law of the jurisdiction under which the joint venture was created.

**Question 8(a):** The bidder/offeree  is  is not a joint venture.

**Question 8(b):** If the bidder/offeree is a joint venture, the U.S. person participant is:

(name)

(address)

**Question 8(c):** If the bidder/offeree is a joint venture, the names and countries of citizenship for all co-venturers are as follows:

(name)

(citizenship)

(name)

(citizenship)

(name)

(citizenship)

**Question 8(d):** If the bidder/offeree is a joint venture, the U.S. person will own at least 51 percent of the assets of the joint venture.

I so certify:

(signature)

(name typed printed)

(position)

(title)

9. *Libya*. Section 406(c) states "No person doing business with Libya may be eligible for any contract awarded pursuant to this Act."

Definitions for purposes of Section 406 eligibility—

*Contract awarded* establishes a time frame for the bar on doing business with Libya. The time during which a relationship with Libya is prohibited begins on the date the Section 406 information is submitted. For bidders/offerees not selected for contract award, the prohibition ceases on the date of award. For the bidder/offeree that is awarded the contract, the bar continues through the life of the contract, ending on the date of final acceptance of the work.

*Doing business* means all transactions of any kind agreed to or performed after the earlier of the date on which a bid/proposal is submitted to the Department of State under this solicitation or on which the contract, subcontract, program, or other arrangement with the Department of State is awarded or becomes effective. Any transaction commenced prior to the date of submittal or award and not yet completed must be reported. Transactions that call for continued or future performance shall be disqualifying. Transactions that have been completely performed but for which payment has not yet been made must be reported, but shall not be disqualifying unless any event other than payment of a previously-agreed upon sum occurs. Examples of disqualifying actions include any pending litigation arising out of business transactions with Libya,

renegotiation of the terms of a loan, and refinancing an amount owed or owing.

*Person* means any individual or legal entity, whether U.S. or foreign. Subcontractors and others who do not have a direct contractual relationship with the United States are not covered by this section.

*With Libya* means transactions between any person and the Government of Libya, government entities of Libya, or any other organization wholly owned or effectively controlled by the Government of Libya. It is the responsibility of the entity submitting Section 406 information to disclose existing relationships with the entities that it has reasonable grounds to believe are or may be Libyan. In case of doubt or dispute, the Department of State shall determine, at its sole discretion, whether any organization is a governmental entity of Libya, wholly owned by the Government of Libya, or effectively controlled by the Government of Libya.

#### Certification

Based on the foregoing, I hereby certify on behalf of this organization that it  is  is not doing business with Libya as those terms are used in Section 406(c) of the Omnibus Diplomatic Security and Antiterrorism Act of 1986.

(e) *Signature*: By signing this document, the offeror indicates that to the best of his or her knowledge, all of the representations and certifications provided in response to the questions contained in this Statement of Qualifications are accurate, current, and complete and that the offeror is aware of the penalty prescribed in 18 U.S.C. 1001 for making false statements.

(End of provision)

■ 87. Section 652.237-71 is revised to read as follows:

#### 652.237-71 Identification/Building Pass.

As prescribed in 637.110(b), insert the following clause.

##### Identification/Building Pass (APR 2004)

(a) *Contractors working in domestic facilities who already possess a security clearance.*

(1) The contractor shall obtain a Department of State building pass for all employees performing under this contract who require frequent and continuing access to Department of State facilities. The Bureau of Diplomatic Security, Office of Domestic Facilities Protection, shall issue passes. They shall be used for the purpose of facility access only, and shall not be used for any other purpose.

(2) The contractor shall submit a Visitor Authorization Request (VAR) Letter to the Bureau of Diplomatic Security, Information Security Programs Division, Industrial Security Branch (DS/ISP/INB) on its cleared employees containing the following information:

- (i) Contractor employee's full name, social security number, and date of birth;
- (ii) Contractor's company name;
- (iii) Security clearance level;
- (iv) Date the clearance was granted;
- (v) Name of the contractor's Facility Security Officer;

(vi) Contracting Officer's Representative (COR); and,

(vii) Contract number.

(3) DS/ISP/INB shall process and approve the VAR letter, if appropriate. The approved VAR letter shall be forwarded to the contractor for their records.

(4) The contractor employee shall hand-carry the following documentation to the Building Pass Office, Department of State, 520 23rd Street, courtyard of Columbia Plaza, Washington, DC:

(i) A Department of State sponsorship letter from the COR, addressing the following:

- (A) The purpose for which the pass is being requested;
- (B) The employee's valid security clearance level (reflected on the VAR);
- (C) Contract number and period of performance;
- (D) Type of access (24/7, normal business hours, escort authority or no escort authority granted); and
- (E) Expiration date of building pass (1 year or 3 years);

(ii) Letter on company letterhead to accompany the application, containing the following information:

- (A) The purpose for which the pass is being requested;
- (B) Verification of employment;
- (C) The employee's valid security clearance level; and,
- (D) Contract number and period of performance;
- (iii) The DS-1838, *Request for Building Pass Identification Card*.

(b) *Contractors working in domestic facilities where security clearances are not required.*

(1) The contractor shall obtain a Department of State building pass for all employees performing under this contract who require frequent and continuing access to Department of State facilities. The Bureau of Diplomatic Security, Office of Domestic Facilities Protection, shall issue passes. They shall be used for the purpose of facility access only, and shall not be used for any other purpose.

(2) The contractor shall submit the following paperwork, in original, to the Bureau of Diplomatic Security, Information Security Programs Division, Industrial Security Branch (DS/ISP/INB):

- (i) SF-85P, *Questionnaire for Public Trust Positions*;
- (ii) SF-85P/S, *Supplemental Questionnaire for Selected Positions*; and,
- (iii) DOS Credit Release, which may be obtained from DS/ISP/INB via mail or facsimile.

(3) DS/ISP/INB shall conduct a preliminary background check. If the background check is favorable, DS/ISP/INB will forward a letter to the company Facility Security Officer (FSO) notifying them that the individual may proceed to the Building Pass Office to continue the badging process. DS/ISP/INB will forward a copy of this letter to the Building Pass Office.

(4) When a contractor employee is approved to receive a building pass, he/she shall hand-carry the following documentation to the Contractor Building Pass Office, Department of State, 520 23rd

Street, NW., courtyard of Columbia Plaza, NW., Washington, DC.:

(i) A Department of State sponsorship letter from the COR, addressing the following:

(A) The purpose for which the pass is being requested;

(B) Whether or not the employee has a valid security clearance;

(C) Contract number and period of performance;

(D) Type of access (24/7, normal business hours, escort authority or no escort authority granted); and

(E) Expiration date of building pass (1 year or 3 years);

(ii) DS Form 1838, *Request for Building Pass Identification Card*;

(iii) Letter on company letterhead to accompany the application, containing the following information:

(A) The purpose for which the pass is being requested;

(B) Verification of employment;

(C) Whether or not the applicant has a valid security clearance; and,

(D) Contract number and period of performance;

(iv) Original SF-85P or a copy of the SF-85P, with an original signature and current date;

(v) Original SF-85P/S or a copy of the SF-85P/S, with an original signature and current date;

(vi) Copy of the DOS Credit Release, with an original signature and current date; and,

(vii) Original proof of U.S. citizenship, such as a birth certificate or valid U.S. passport. Non-U.S. citizens must submit a valid photo Immigration and Naturalization Service Employment Authorization Document (INS EAD).

(5) Applicants shall be fingerprinted at the Building Pass Office and the process for a building pass shall be initiated. The approval process shall take at least 48 hours. Applicants shall not return to the Building Pass Office until they receive notification from DS/ISP/INB that the process is complete. Once DS/ISP/INB receives notification from the Building Pass Office that a building pass can be issued, DS/ISP/INB shall notify the FSO and the COR that the applicant has been approved for initial contract performance.

(c) *Contractors working in overseas facilities.* Contractors shall submit appropriate documentation to obtain building passes as specified in the contract.

(d) All contractor employees, both domestic and overseas, shall wear the passes in plain sight at all times while in Department of State buildings. All contractor employees shall show their passes, where appropriate, when entering these buildings and upon request of uniformed guards or any other authorized personnel.

(e) All passes shall be returned to the COR upon separation of the employee, or expiration or termination of the contract. Final payment under this contract shall not be made until all passes are returned to the COR.

(End of clause)

■ 88. Section 652.237-72 is amended by revising the date of the clause to read

“(APR 2004)” and by removing the words “the preceding Friday is observed; when any such day falls on a Sunday” and by inserting the words “or Sunday” in their place in the first sentence of paragraph (b).

■ 89. Section 652.237-73 is added to read as follows:

**652.237-73 Statement of Qualifications for Preference as a U.S. Person.**

As prescribed in 637.110(d), insert the following provision:

**Statement of Qualifications for Preference as a U.S. Person (APR 2004)**

(a) This solicitation is subject to Section 136 of the Foreign Relations Authorization Act, Fiscal Years 1990 and 1991 (22 U.S.C. 4864). The Act encourages the participation of United States persons and qualified United States joint venture persons in the provision of local guard services overseas, and provides for a preference for eligible offers.

(b) *Definitions.* As used in this provision—  
*Eligible offer* means an offer that (1) is otherwise responsive to the solicitation; and (2) contains a fully prepared Statement of Qualifications (see paragraph (d) of this provision), which upon review is determined by the Government to meet the requirements of Section 136 for assignment of preference as a U.S. person.

*Preference* means subtraction by the Government of ten percent (10%) from the total evaluated price of an offer.

*U.S. person* means a company, partnership, or joint venture that the Government determines, after consideration of all available information, including but not limited to that provided by the offeror in response to the solicitation, to be qualified for assignment of preference pursuant to Section 136.

(c) *Representation.* The offeror represents as part of its offer that it  is,  is not eligible for preference as a U.S. person. [Complete a Statement of Qualifications for Purposes of Obtaining Preference as a U.S. Person if the offeror represents that it is eligible. See paragraph (d) of this provision.]

*Warning:* Any material misrepresentation made in the Statement of Qualifications may be the basis for disqualification of an offeror and reference for consideration of suspension or debarment or for prosecution under Federal law (cf. 18 U.S.C. 1001). The Government will determine offeror qualifications primarily on the basis of information submitted in the Statement of Qualifications, including Attachments thereto, but the Government may, at its discretion, rely on information contained elsewhere in the offeror's proposal or obtained from other sources.

(d) *Statement of Qualifications for Purposes of Obtaining Preference as a U.S. Person (22 U.S.C. 4864).* An offeror that represents that it is eligible for preference as a U.S. person must provide the following information. This Statement of Qualifications must be a complete and certified document, and submitted as a separate Volume 5, with all necessary attachments, as defined in Section L of this solicitation.

Statement of Qualifications for Purposes of Obtaining Preference as a U.S. Person (22 U.S.C. 4864)

Name and address of U.S. person or organization providing this information:

*Introduction.* Section 136 of the Foreign Relations Authorization Act for Fiscal Years 1990 and 1991, Public Law 101-246 (22 U.S.C. 4864), as amended, provides that a “United States person” or a “qualified United States joint venture” must meet certain requirements, listed in the Act, to be eligible for the statutory preference. To assist business entities to determine whether they qualify as a U.S. person or U.S. joint venture person entitled to preference under Section 136, guidance is hereby provided. Only those prospective offerors submitting a properly completed and certified Volume 5 with their initial proposals will be considered in the determination of eligibility for assignment of preference as a U.S. person or U.S. joint venture person. For ease of reference, statutory language is quoted immediately before the definitions that apply to it. Space for the required information is provided immediately following each definition.

*Note:* The Statement of Qualifications shall provide information correctly applicable to the U.S. person whose qualifications are being certified, and shall not include information pertaining to corporate affiliates or subsidiaries. Organizations that wish to use the experience or financial resources of another organization or individual, including parent companies, subsidiaries, or local, national or offshore organizations, must do so by way of a joint venture. The contract resulting from this solicitation shall not allow subcontracting. A prospective offeror may be a sole proprietorship, a formal joint venture in which the co-venturers have reduced their arrangement to writing, or a de facto joint venture with no written agreement. To be considered a “qualified joint venture person,” the joint venture must have at least one firm or organization that itself meets all the requirements of a U.S. joint venture person listed in Section 136. By signing this proposal, the U.S. person co-venturer agrees to be individually responsible for performance of the contract, notwithstanding the terms of any joint venture agreement.

1. *Section 136(d)(1):* “The term ‘United States person’ means a person which—(A) is incorporated or legally organized under the laws of the United States, including the laws of any State, locality, or the District of Columbia.”

*Definitions for purposes of Section 136 determinations of eligibility—*

*Incorporated* means the state of legal recognition as an artificial person that may be afforded to a business entity pursuant to the laws of any United States jurisdiction or component thereof.

*Legally organized* means the state of legal recognition that may be afforded to a business entity that is other than a corporation pursuant to the laws of any United States jurisdiction or component thereof. This is the least form of legal

recognition that will qualify an offeror for this preference. Only those prospective offerors that have legal status, including the right to bring suit, to sign contracts, and to hold property under the law of the jurisdiction under which they are doing business will qualify as legally organized. A natural person who is a United States citizen acting in his or her entrepreneurial capacity will be deemed to be a "person legally organized" within the scope of this definition, provided that the prospective offeror holds all required licenses to do business in the jurisdiction where he or she is located.

*United States* means any jurisdiction that is one of the fifty States, the District of Columbia, a United States territory, a United States possession, or the Commonwealth of Puerto Rico and the Northern Mariana Islands.

**Question 1.** The organization seeking eligibility under Section 136 is  incorporated or is  legally organized under the laws of what jurisdiction?

2. *Section 136(d)(1)*: "The term 'United States person' means a person that—(B) has its principal place of business in the United States."

Definitions for purposes of Section 136 determinations of eligibility—

*Principal place of business* means the geographic location of the main office or seat of management of the prospective offeror. For purposes of this Statement, a prospective offeror shall identify only one principal place of business, and such location shall include at least the offices of the chief operating officer and headquarters staff. The named location must be a United States jurisdiction in which the prospective offeror may bring suit and be sued and in which service of process shall be accepted.

**Question 2(a).** The organization seeking eligibility has its principal office in what city and state?

**Question 2(b).** What kind of tax return was or will be filed, and in what jurisdiction, during the current calendar year? The jurisdiction identified herein need not be the same jurisdiction identified in Question 2(a).

(i) Jurisdiction:

(ii) Type of return (e.g., income tax, franchise tax, etc.). Include all that apply:

3. *Section 136(d)(1)*: "The term 'United States person' means a person which—(C) has been incorporated or legally organized in the United States—(i) for more than 2 (two) years before the issuance date of the invitation for bids or request for proposals with respect to the contract under subsection (c) of this section."

Definitions for purposes of Section 136 determinations of eligibility—

*Has been incorporated or legally organized* means that the organization can show continuity as an ongoing business. Organizations that have changed only their names meet the continuity requirement of this subsection. Organizations that have been bought, sold, merged, or otherwise

substantially altered or enlarged their principal business activities will have the burden of proving that there have been ongoing operations by the same business entity for the required period of time. If the successor entity has acquired all of the assets and liabilities of the predecessor entity and the predecessor entity has no further existence, the successor may claim the incorporation or legal organization date of the predecessor. In any other circumstance, the prospective offeror must show that the law of the jurisdiction in which it operates regards the prospective offeror as the complete successor in interest of the predecessor entity for purpose of contractual obligations.

*Issuance date* means the date in Block 5 of the Standard Form 33 accompanying this solicitation.

*Years* means calendar years measured from day of the month to day of the month. For example, January 1, 2002 through December 31, 2002 is one calendar year, as is July 1, 2002 through July 1, 2003.

**Question 3:**

(i) On what date was the organization seeking eligibility incorporated or legally organized?

(ii) If this date is less than two years before the issuance date, on the basis of what documentation does the organization seeking eligibility claim that it has been in business for the requisite period of time?

(Identify, and forward copies as an Attachment to this Statement).

4. *Section 136(d)(1)*: "The term 'United States person' means a person which—(D) has performed within the United States or overseas security services similar in complexity to the contract being bid."

Definitions for purposes of Section 136 determination of eligibility—

*Complexity* means the physical size or extent of the effort, as described in Section B and Exhibit A of this solicitation; combined with the required quality of the effort as described in Sections C and H of this solicitation.

*Overseas* means within any jurisdiction that is not a part of the United States as defined below.

*Performed* means contracts that have been fully completed by the prospective offeror and accepted by the other party to the transaction. Contracts still in progress have been performed for purposes of this definition if performance in complexity to the contract being bid has been ongoing for at least one year. Contracts need not have been with the U.S. Government.

*Security services* means work of a kind as to fall within or compare closely with those described in the Statement of Work in Section C of this solicitation. An entity whose only security services experience was performed by its legally distinct parent or subsidiary organization will not be considered to have security services experience.

*Within the United States* means within the legal geographic boundaries of a United States jurisdiction that is the place where the subject matter (e.g., services) of the contract

or other arrangement was in fact completed. The place where the contract or other arrangement was negotiated or signed is not relevant to this definition.

**Question 4:** Describe in an Attachment to this Statement (see L.1.3.5), the qualifying similar contracts or other arrangements performed by the prospective offeror. Provide required information on a sufficient number of arrangements to show that similar services have been performed overseas or in the United States. The description must consist of the following information on each arrangement, which shall be submitted as an Attachment to this Statement:

*Location:* (city and state or country).

*Type of service:* (for example, stationary guards, roving patrol, quick-reaction force, etc.).

*Complexity:* (type of facilities guarded, and number or extent of facilities, number of guards, etc.).

5. *Section 136(d)(1)*: "The term 'United States person' means a person which—(E) with respect to the contract under subsection (c) of this section, has achieved a total business volume equal to or greater than the value of the project being bid in 3 years of the 5-year period before the date specified in subparagraph (C)."

Definitions of purposes of Section 136 determination of eligibility—

*3 years of the 5-year period before the date specified in subparagraph (C)* means the three to five calendar year period immediately preceding the issuance date of this solicitation.

*Total business volume* means the U.S. dollar value of the gross income or receipts reported by the prospective offeror on its annual federal income tax returns.

*Years* means calendar years.

**Question 5:** Describe in an Attachment to this Statement (see L.1.3.5), for at least three of the five twelve-month income tax periods (fiscal years) defined below, the gross receipts of the organization seeking eligibility.

(i) The fiscal year ending during the calendar year that includes the date of this solicitation.

(ii) The fiscal year ending in the calendar year immediately prior to the calendar year that includes the date of this solicitation.

(iii) The fiscal year ending in the calendar year two years before the calendar year that includes the date of this solicitation.

(iv) The fiscal year ending in the calendar year three years before the calendar year that includes the date of this solicitation.

(v) The fiscal year ending in the calendar year four years before the calendar year that includes the date of this solicitation.

An entity will be deemed to have met this requirement if the total cumulative business volume for the three years presented exceeds the contract price at time of award under this solicitation for the full term for which prices are solicited, including any option periods.

6. *Section 136(d)(1)*: "The term 'United States person' means a person which—(F)(i) employs United States citizens in at least 80 percent of its principal management positions in the United States; and (F)(ii) employs United States citizens in more than half of its permanent full-time positions in the United States."

Definitions for purposes of Section 136 determinations of eligibility—

*Full-time* (positions) means those personnel positions in which the occupants are expected to and ordinarily work for 40 or more hours per week.

*In the United States* refers to those personnel positions that are encumbered as of the date of this solicitation and that the prospective offeror maintains in geographic locations within the jurisdictions defined above as constituting the United States.

*Permanent* (positions) means personnel positions that are intended to be indefinite as to length of employment, as opposed to limited, seasonal, or project-length personnel appointments.

*Permanent, full-time positions* means that portion of the prospective offeror's workforce that continues to be employed without regard to the ordinary fluctuations of production or projects.

*Principal management positions* means those personnel positions including at least the chief executive officer (if any) and the chief operating officer (whether by title or by function) of the organization seeking eligibility, together with all those management officials who constitute the highest levels of management authority within the organization. In the case of a partnership, all general partners are deemed to hold principal management positions. In the case of a corporation, those officers of the corporation who are principally responsible for the day-to-day operation of the corporation. Members of corporation boards of directors do not occupy "principal management positions" simply by virtue of their service on the board. In all cases, the term "principal management positions" also includes the position or positions held by the individual or individuals in the United States who will have primary corporate management oversight responsibility for this contract if the prospective contractor is awarded the contract.

*United States citizen* means natural persons with United States citizenship by virtue either of birth or of naturalization.

**Question 6(a):** The organization seeking eligibility shall list all of its principal management positions and identify the current occupant of each listed position by name and citizenship. Provide the information as an Attachment to this Statement in the following format:

(i) Principal management positions in the United States:  
Chief Executive Officer (if any):

(name)

(citizenship)

Chief Operating Officer:

(name)

(citizenship)

(ii) For each additional corporate officer having principal responsibility for the day-to-day operations of the corporation, list position, name, and citizenship.

Position:

Name:

Citizenship:

(iii) Individual(s) in the United States expected to have primary management oversight responsibility for contract if it is awarded:

(name)

(citizenship)

**Question 6(b):** Number of permanent, full-time, currently encumbered personnel positions that are located in the United States (good faith estimates acceptable):

**Question 6(c):** Number of United States citizens currently employed in permanent, full-time positions that are located in the United States (good faith estimates acceptable):

**7. Section 136(d)(1):** "The term 'United States person' means a person which—(G) has the existing technical and financial resources in the United States to perform the contract."

Definitions for purposes of Section 136 determinations of eligibility—

*Existing technical and financial resources* means technical and financial capability within the United States to mobilize adequate staffing, equipment and organizational arrangements to perform the contract. Adequate technical resources may be demonstrated by presenting an organization chart, and résumés of current officers and employees in the United States who possess skills and expertise necessary to provide management and oversight of the work. Other indicia will be considered if offered to demonstrate that the prospective offeror has available resources in the United States adequate to provide home office management and oversight of the work. Adequate financial resources may be demonstrated by proof of possession of a combination of net worth, bank lines of credit, or bank guarantees. If lines of credit or bank guarantees are used to demonstrate adequate financial resources, they must be from entities within the United States.

**Question 7:** Submit, as an Attachment to this Statement, materials demonstrating existing technical and financial resources in the United States (see L.1.3.5).

**8. Section 136(d)(2):** "The term 'qualified United States joint venture person' means a joint venture in which a United States person or persons owns at least 51 percent of the assets of the joint venture."

Definitions for purposes of Section 136 determinations of eligibility—

*Assets* means tangible and intangible things of value conveyed or made available to the joint venture by the co-venturers. To be qualified for U.S. preference, 51 percent of the assets of the joint venture must be owned by the U.S. person co-venturer(s).

*Joint venture* means a formal or de facto association of two or more persons or entities to carry out a single business enterprise for profit, for which purpose they combine their property, money, effects, skills, and knowledge. To be acceptable, all members of a joint venture must be jointly and severally liable for full performance and resolution of matters arising out of the contract.

**Question 8(a):** The prospective offeror  is  is not a joint venture.

**Question 8(b):** If the prospective offeror is a joint venture, the U.S. person participant is:

(name)

(address)

**Question 8(c):** If the prospective offeror is a joint venture, the names and countries of citizenship for all co-venturers are as follows:

(name)

(citizenship)

(name)

(citizenship)

(name)

(citizenship)

**Question 8(d):** If the prospective offeror is a joint venture, the U.S. person will own at least 51 percent of the assets of the joint venture.

I so certify: (name)

(position)

(title)

(e) *Signature:* By signing this document, the offeror indicates that to the best of his or her knowledge, all of the representations and certifications provided in response to the questions contained in this Statement of Qualifications are accurate, current, and complete and that the offeror is aware of the penalty prescribed in 18 U.S.C. 1001 for making false statements.

(End of provision)

#### 652.242-70 [Amended]

■ 90. Section 652.242-70 is amended by removing "642.271" and inserting "642.272(a)" in its place in the clause prescription.

#### 652.242-73 [Amended]

■ 91. Section 652.242-73 is amended by removing "642.271(b)" and inserting "642.272(b)" in its place in the clause prescription and in Alternate 1.

### PART 653—FORMS

#### 653.101-70 [Amended]

■ 92. Section 653.101-70 is amended by adding a sentence at the end reading as follows: "The State Department forms are available through the Department's Intranet Web site at <http://arpsdir.a.state.gov/efrms.html>."

■ 93. Section 653.219-71 is added to read as follows:

#### 653.219-71 DOS form DS-4053, Department of State Mentor-Protégé Program Application.

As prescribed in 619.102-70(i), DS-4053 is prescribed for use in applying



for an agreement under the Department of State Mentor-Protégé Program.

#### Subpart 653.3 [Removed]

■ 94. Subpart 653.3, consisting of sections 653.000 and 653.303, is removed.

Dated: March 11, 2004.

Corey M. Rindner,

Procurement Executive, Bureau of Administration, Department of State.

[FR Doc. 04-8107 Filed 4-12-04; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 622

[Docket No. 001005281-00369-02; I.D. 040704B]

#### Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS closes the commercial hook-and-line fishery for king mackerel in the exclusive economic zone (EEZ) in the southern Florida west coast subzone. This closure is necessary to protect the Gulf group king mackerel resource.

**DATES:** Effective 12:01 a.m., local time, April 9, 2004, through June 30, 2004.

**FOR FURTHER INFORMATION CONTACT:** Mark Godcharles, telephone: 727-570-5727, fax: 727-570-5583, e-mail: [Mark.Godcharles@noaa.gov](mailto:Mark.Godcharles@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on April 30, 2001 (66 FR 17368, March 30, 2001), NMFS implemented a commercial quota of 2.25 million lb (1.02 million kg) for the eastern zone (Florida) of the Gulf migratory group of king mackerel. That quota is further divided into separate quotas for the Florida east coast subzone and the northern and southern Florida west coast subzones. On April 27, 2000, NMFS implemented the final rule (65 FR 16336, March 28, 2000) that divided the Florida west coast subzone of the eastern zone into northern and southern subzones, and established their separate quotas. The quota implemented for the southern Florida west coast subzone is 1,040,625 lb (472,020 kg). That quota is further divided into two equal quotas of 520,312 lb (236,010 kg) for vessels in each of two groups fishing with hook-and-line gear and run-around gillnets (50 CFR 622.42(c)(1)(i)(A)(2)(i)).

Under 50 CFR 622.43(a), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification at the Office of the Federal Register. NMFS has determined that the commercial quota of 520,312 lb (236,010 kg) for Gulf group king mackerel for vessels using hook-and-line gear in the southern Florida west coast subzone was reached on April 6, 2004. Accordingly, the commercial hook-and-line fishery for king mackerel in the southern Florida west coast subzone is closed effective 12:01 a.m., local time, April 9, 2004, through June 30, 2004, the end of the fishing year.

The Florida west coast subzone is that part of the eastern zone south and west of 25°20.4' N. lat. (a line directly east from the Miami-Dade County, FL boundary). The Florida west coast subzone is further divided into northern and southern subzones. The southern subzone is that part of the Florida west coast subzone which from November 1 through March 31 extends south and west from 25°20.4' N. lat. to 26°19.8' N. lat. (a line directly west from the Lee/Collier County, FL boundary), i.e., the area off Collier and Monroe Counties. From April 1 through October 31, the southern subzone is that part of the Florida west coast subzone which is between 26°19.8' N. lat. and 25°48' N. lat. (a line directly west from the Monroe/Collier County, FL boundary), i.e., the area off Collier County.

NMFS previously determined that the commercial quota for king mackerel from the western zone of the Gulf of Mexico was reached and closed that segment of the fishery on September 24,

2003 (68 FR 55554, September 26, 2003). Subsequently, NMFS determined that the commercial quota for Gulf group king mackerel in the northern Florida west coast subzone was reached and closed that segment of the fishery on November 13, 2003 (68 FR 64820; November 17, 2003). Thus, with this closure, all commercial fisheries for Gulf group king mackerel in the EEZ are closed from the U.S./Mexico border through the southern Florida west coast subzone through June 30, 2004, except for vessels fishing with run-around gillnets in the southern Florida west coast subzone.

Except for a person aboard a charter vessel or headboat, during the closure, no person aboard a vessel for which a commercial permit for king mackerel has been issued may fish for Gulf group king mackerel in the EEZ in the closed zones or subzones. A person aboard a vessel that has a valid charter vessel/headboat permit for coastal migratory pelagic fish may continue to retain king mackerel in or from the closed zones or subzones under the bag and possession limits set forth in 50 CFR 622.39(c)(1)(ii) and (c)(2), provided the vessel is operating as a charter vessel or headboat. A charter vessel or headboat that also has a commercial king mackerel permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, king mackerel from the closed zones or subzones taken in the EEZ, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to trade in king mackerel from the closed zones or subzones that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B), as such prior notice and opportunity for public comment is unnecessary and contrary to the public interest. Such procedures would be unnecessary because the rule itself already has been subject to notice and comment, and all that remains is to notify the public of the closure. Allowing prior notice and opportunity



for public comment is contrary to the public interest because of the need to immediately implement this action in order to protect the fishery since the capacity of the fishing fleet allows for rapid harvest of the quota. Prior notice and opportunity for public comment will require time and would potentially result in a harvest well in excess of the established quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30 day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

This action is taken under 50 CFR 622.43(a) and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 8, 2004.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[Docket No. 031125288-4102-02; I.D. 110303A]

RIN 0648-AR35

#### Fisheries Off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Amendment 16-2

**AGENCY:** National Marine Fisheries Service, National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement Amendment 16-2 to the Pacific Coast Groundfish Fishery Management Plan (FMP). Amendment 16-2 amended the FMP to include overfished species rebuilding plans for lingcod, canary rockfish, darkblotched rockfish, and Pacific ocean perch (POP) within the FMP. This final rule adds two rebuilding parameters to the Code of Federal Regulations (CFR) for each overfished stock, the target year for rebuilding and the harvest control rule.

Amendment 16-2 addressed the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to protect and rebuild overfished species managed under a Federal FMP. Amendment 16-2 also responded to a Court order, in which NMFS was ordered to provide Pacific Coast groundfish rebuilding

plans as FMPs, FMP amendments, or regulations, per the Magnuson-Stevens Act.

**DATES:** Effective May 13, 2004.

**ADDRESSES:** Copies of Amendment 16-2 and the final environmental impact statement/regulatory impact review/initial regulatory flexibility analysis (FEIS/RIR/IRFA) are available from Donald McIsaac, Executive Director, Pacific Fishery Management Council (Council), 7700 NE Ambassador Place, Portland, OR 97220, phone: 503-820-2280. These documents are also available online at the Council's website at <http://www.pcouncil.org>.

**FOR FURTHER INFORMATION CONTACT:** Becky Renko (Northwest Region, NMFS), phone: 206-526-6150; fax: 206-526-6736 or; e-mail: [becky.renko@noaa.gov](mailto:becky.renko@noaa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access

The proposed and final rules for this action are accessible via the Internet at the Office of the Federal Register's website at <http://www.gpoaccess.gov/fr/index.html>. Background information and documents are available at the NMFS Northwest Region website at <http://www.nwr.noaa.gov/1sustfsh/gdfsh01.htm> and at the Council's website at <http://www.pcouncil.org>.

##### Background

Amendment 16-2 revised the FMP to include overfished species rebuilding plans for lingcod, canary rockfish, darkblotched rockfish, and POP. This final rule implements Amendment 16-2 by adding two rebuilding parameters, the target year in which the stock would be rebuilt under the adopted rebuilding plan ( $T_{TARGET}$ ) and the harvest control rule, to the CFR at 50 CFR 660.370 for each overfished stock.

Amendment 16-2 addressed the requirements of the Magnuson-Stevens Act to protect and rebuild overfished species managed under a Federal FMP. Amendment 16-2 also responded to a Court order in *Natural Resources Defense Council, Inc. v. Evans*, 168 F. Supp. 2d 1149 (N.D. Cal 2001.), in which NMFS was ordered to provide Pacific Coast groundfish rebuilding plans as FMPs, FMP amendments, or regulations, per the Magnuson-Stevens Act.

A Notice of Availability for Amendment 16-2 was published on November 7, 2003 (68 FR 63053). NMFS requested comments on the amendment under the Magnuson-Stevens Act FMP amendment review provisions for a 60-day comment period, ending January 6, 2004. A proposed rule was published on

December 5, 2003 (68 FR 67998), requesting public comment through January 5, 2004. During the Amendment 16-2 and proposed rule comment period, NMFS received four letters of comment. These letters are addressed later in the preamble to this final rule. The preamble to the proposed rule for this action provides additional background information on the fishery and on this final rule. Further detail on Amendment 16-2 also appears in the FEIS/RIR/IRFA for this action which was prepared by the Council.

After consideration of the public comments received on the amendment, NMFS approved Amendment 16-2 on January 30, 2004. As required by the standards established by Amendment 16-1, the rebuilding plans adopted under Amendment 16-2 for lingcod, canary rockfish, darkblotched rockfish, and POP specified the following rebuilding parameters in the FMP: unfished biomass ( $B_0$ ) and target biomass ( $B_{MSY}$ ), the year the stock would be rebuilt in the absence of fishing ( $T_{MIN}$ ), the year the stock would be rebuilt if the maximum time period permissible under national standard guidelines were applied ( $T_{MAX}$ ), and the target year in which the stock would be rebuilt under the adopted rebuilding plan ( $T_{TARGET}$ ). Other information relevant to rebuilding was also included. The estimated rebuilding parameters will serve as management benchmarks in the FMP and the FMP will not be amended if the values for these parameters change after new stock assessments and rebuilding analyses are completed, as is likely to happen.

Amendment 16-1 specified two rebuilding parameters,  $T_{TARGET}$  and the harvest control rule for the rebuilding period, that are to be codified in Federal regulations for each individual species rebuilding plan. This final rule adds these rebuilding parameters to the CFR at 50 CFR 660.370 for lingcod, canary rockfish, darkblotched rockfish, and POP.  $T_{TARGET}$  is the year in which there is a 50-percent likelihood that the stock will have been rebuilt with a given mortality rate. The harvest control rule expresses a given fishing mortality rate that is to be used over the course of rebuilding. These parameters will be used to establish the optimum yields (OYs-harvest specifications) for species with rebuilding plans. Conservation and management goals defined in the FMP require the Council and NMFS to manage to the appropriate OY for each species or species groups, including those OYs established for rebuilding overfished species. The OYs and management measures will be set on an

annual or biennial basis, and will address the fisheries as a whole. Regulations implemented through the harvest specifications and management measures are based on the most recently available scientific information and are intended to address all of the fisheries that take groundfish and to keep the total catch of groundfish, including overfished species, within their respective OYs. The FMP addresses how the fisheries as a whole are to be managed, whereas rebuilding plans are species-specific and define the parameters that govern the rebuilding of a particular species.

If, after a new stock assessment, the Council and NMFS conclude that either or both of the parameters defined in regulation should be revised, the revision will be implemented through the Federal rulemaking process, and the updated values codified in the Federal regulations. NMFS believes that the FMP with the newly added rebuilding plans will be sufficient "to end overfishing in the fishery and to rebuild affected stocks of fish" (16 U.S.C. 1854(e)(3)(A)).

Amendment 16-2 will be followed by Amendment 16-3. A notice of intent to prepare an Environmental Impact Statement (EIS) was published on September 12, 2003 (68 FR 53712) for Amendment 16-3. If approved, Amendment 16-3 will contain rebuilding plans for bocaccio, cowcod, widow rockfish and yelloweye rockfish. The Council is scheduled to take final action on the Amendment 16-3 rebuilding plans at its April 5-9, 2004 meeting. The notice of availability of the Draft EIS is scheduled for publication in June 2004.

#### Comments and Responses

NMFS received four letters of comment on the proposed rule to implement Amendment 16-2: three letters were received from environmental advocacy organizations, and one letter was received from the U.S. Department of the Interior. These comments are addressed here:

*Comment 1:* The proposed target dates for rebuilding Amendment 16-2 species are inconsistent with the Magnuson-Stevens Act because the target rebuilding dates are not as short as possible.

*Response:* NMFS believes that the specified rebuilding time periods for the four overfished species are consistent with the legal requirements of the Magnuson-Stevens Act and with the national standard guidelines. The Magnuson-Stevens Act does not state that rebuilding must be completed in the shortest time possible, rather it

requires the time for rebuilding to be as short as possible, taking into account certain factors. The Magnuson-Stevens Act, section 304 (e)(4)(A), and the national standard guidelines at 50 CFR 600.310 (e)(4)(A) recognize the following factors that enter into the specification of a time period for rebuilding: the status and biology of the stock or stock complex; interactions between stocks or stock complexes and the marine ecosystem; the needs of fishing communities; recommendations of international organizations in which the U.S. is a participant; and management measures under an international agreement in which the U.S. participates.

According to the national standard guidelines at 50 CFR 600.310(e)(ii)(B)(2), if the year the stock would be rebuilt in the absence of fishing ( $T_{MIN}$ ) is 10 years or less, then the specified time period for rebuilding may be adjusted upward to the extent warranted by the needs of fishing communities and recommendations of international organizations in which the U.S. is a participant. However, the rebuilding period may not exceed 10 years unless international agreements, which the United States is a party to, dictate otherwise.

Of the four overfished stocks affected by this rulemaking, lingcod was the only species in which  $T_{MIN}$  was estimated to be 10 years or less. As permitted by the Magnuson-Stevens Act and the national standard guidelines, the needs of the fishing community were taken into consideration when the rebuilding period for lingcod was established that would rebuild the stock by 2009. It should be noted, that the difference between the  $T_{MIN}$  rebuilding year of 2007 (the Maximum Conservation Alternative) and the rebuilding year of 2009 under Council's preferred alternative was 2 years.

Lingcod are caught in wide range of commercial and recreational fisheries both on the continental shelf and nearshore areas. To achieve rebuilding by  $T_{MIN}$ , management measures would need to be designed to prohibit the catch of lingcod until the stock was rebuilt. Any fishery in which bycatch occurs would need to be curtailed or eliminated to completely prevent bycatch of lingcod. The Maximum Conservation Alternative which would have achieved rebuilding by  $T_{MIN}$ , was expected to result in a significant adverse socioeconomic impact due to the reduction in profits, personal income, and employment. NMFS believes that choosing the Council-preferred alternative, which results in a target year for rebuilding of 2009, was

a reasonable accommodation to meet the needs of the fishing communities.

According to the national standard guidelines at 50 CFR 600.310(e)(ii)(B)(3), if  $T_{MIN}$  is 10 years or greater, "then the specified-time period for rebuilding  $T_{TARGET}$  may be adjusted upward to the extent warranted by the needs of fishing communities and recommendations by international organizations in which the U.S. participates, except that no such upward adjustment can exceed the rebuilding period calculated in the absence of fishing mortality, plus one mean generation time or equivalent period based on the species' life-history characteristics ( $T_{MAX}$ ).". All of the rebuilding periods for canary rockfish, darkblotched rockfish and POP are less than  $T_{MAX}$ .

The rebuilding probabilities ( $P_{MAX}$ , which are estimated probabilities of rebuilding the stock by  $T_{MAX}$ ) for canary rockfish, darkblotched rockfish and POP range between 60 percent and 80 percent. This represents a better than 50 percent likelihood that each of these stocks will be rebuilt (reach the  $B_{MSY}$  biomass) by  $T_{MAX}$ , while allowing sufficient access to overfished stocks, so that healthy groundfish stocks that co-occur with overfished species can be harvested. Canary rockfish are relatively unproductive but occur in a wide range of fisheries. The Council chose a  $T_{TARGET}$  closer to  $T_{MAX}$  (reflected in the relatively lower 60-percent rebuilding probability) in order to allow some bycatch in all of the various fisheries. The EIS for this amendment has further information regarding the reasons for the adopted rebuilding periods.

*Comment 2:* Rebuilding target dates for lingcod and canary rockfish are based upon a 60 percent probability of achieving rebuilding within  $T_{MAX}$ . This low probability results in target rebuilding dates that are close to  $T_{MAX}$ , which leaves little room for uncertainties in stock status, recruitment success, accounting and management of fishing mortality and other factors. The rebuilding probabilities for Amendment 16-2 species should be closer to those suggested by the *Technical Guidance on the Use of the Precautionary Approaches to Implementing National Standard 1 of the Magnuson-Stevens Fishery Conservation and Management Act* (Technical Guidance).

*Response:* As explained above in the response to comment 1, if  $T_{MIN}$  is 10 years or greater, the national standard guidelines at 50 CFR 600.310(e)(ii)(B)(3), allow  $T_{TARGET}$  to be adjusted upward to the extent warranted by the needs of fishing communities and

recommendations by international organizations in which the U.S. participates, except that no such upward adjustment can exceed  $T_{MAX}$ . The Technical Guidance recommends that  $T_{TARGET}$  be set no higher than the midpoint between  $T_{MIN}$  and  $T_{MAX}$ .

Adopting the midpoint as a binding criterion in all cases would not be consistent with the Magnuson-Stevens Act because it would not allow the factors in the Act at section 304(e)(4) and the national standard guidelines at 50 CFR 600.310(e)(4)(ii), which include the needs of fishing communities, to be taken into account. The Technical Guidance is not a binding regulation that must be followed; the Technical Guidance itself acknowledges that it deals only with biological issues, and not with socioeconomic issues, which fishery management councils must consider, per the Magnuson-Stevens Act.

Canary rockfish and lingcod are caught in a wide range of commercial and recreational fisheries both on the continental shelf and nearshore areas. The Council recognized the socioeconomic importance of the fisheries for co-occurring species to harvesters and communities and recommended target rebuilding periods that would allow the harvest of the healthy stocks while providing a strong likelihood the overfished stocks will recover within the targeted time period. NMFS agrees with the Council's recommended rebuilding goals.

*Comment 3:* The groundfish fishery suffers from a variety of factors that create uncertainty in the rebuilding process. While estimates of catch have improved over time for the commercial fishery, the recreational fishery catch estimates remain problematic. Inadequate enforcement means some catch is never recorded. A standardized reporting methodology to assess the amount and type of bycatch in each West Coast fishery is incomplete. Without adequate enforcement and data collection methods, it is unlikely that the total mortality of the four overfished species will be consistent with the limits necessary to rebuild these species.

*Response:* Many recent improvements have been made to the information systems used to manage the groundfish fishery. The improvements that are expected to reduce the types of uncertainty identified by the commenter include: the implementation of a West Coast Groundfish Observer Program (WCGOP) to collect commercial fishery data to improve discard and total catch estimates in the commercial fishery; the development of a new bycatch model to

better estimate fleetwide impacts; replacement of the old Marine Recreational Fishery Statistical Survey (MRFSS) with new and more accurate statistical surveys; and the implementation of a vessel monitoring program to monitor compliance with depth-based management measures. NMFS believes that these data collection methods and enforcement mechanisms, which are discussed below, improve the agency's ability to monitor and enforce the harvest management measures specified for the fishery, and thereby keep the overfished species within the harvest levels established for rebuilding.

NMFS recognizes that effective bycatch accounting and control mechanisms are necessary for staying within the total catch OYs established for rebuilding. NMFS agrees with the commenter that estimates of catch have improved over time for the commercial fishery. Since the inception of the WCGOP in August 2001, substantial improvements have been made in the data and models used to estimate fleetwide discards in commercial fisheries. Following the release of the first year of WCGOP data in January 2003, NMFS incorporated observer program data on the bycatch of overfished species into the bycatch model. The Council began to use observer data to inform inseason groundfish management at its April 2003 meeting. For the 2004 fishing year, NMFS has further revised the bycatch model to incorporate discard rates on both overfished and targeted species, as generated by observer data. Because the second year of the WCGOP increased coverage of the limited entry nontrawl fleet, NMFS plans to further modify the 2004 bycatch model to incorporate nontrawl data once it has been compiled into a usable form. The agency expects that data from the second year of the WCGOP will be incorporated into inseason groundfish fisheries management by the April 2004 Council meeting, and will be used in the development of 2005–2006 management measures. [For further information on the bycatch model, see the preamble to the 2003 and 2004 proposed rules to implement specifications and management measures, 68 FR 936, January 7, 2003, and 69 FR 1380, January 8, 2004.]

Recreational catch data are compiled in the Recreational Fisheries Information Network (RecFIN) database. The types of data compiled in RecFIN include sampled biological data, estimates of landed catch plus discards, and economic data. The MRFSS, which includes field surveys and a random-daily phone survey, has been part of the

RecFIN database system. The MRFSS was not initially designed for the purpose of estimating catch and effort at the level of precision needed for management or assessment, rather it was designed to provide a broad picture look of national fisheries. Comparisons with independent and more precise estimation procedures has shown wide variance in catch estimates. Inseason management of recreational fisheries using MRFSS has been complicated by large inseason variance of catch estimates. Washington and Oregon have used the MRFSS system as a supplement to the port sampling programs from which most of their recreational catch estimates are derived. Because California has had a greater dependence on MRFSS in estimating their recreational catch, catch estimates of California recreational catch have varied considerably.

In recent years, many efforts have been made to improve the MRFSS system. In 2001 the Pacific States Marine Fisheries Commission (PSMFC), with support from NMFS, began a new survey to estimate party/charter boat (CPFV) fishing effort in California. This survey differed from the traditional MRFSS telephone survey of anglers to determine CPFV trips by 2-month period. The survey sampled 10 percent of the active CPFV fleet each week to determine the number of trips taken and the anglers carried on each trip. This 10-percent sample was then expanded to make estimates of total angler trips for Southern California and Northern California. However, increased sampling coverage is needed to improve the precision in estimates necessary for managing for the low OYs of overfished species like canary rockfish and bocaccio. In any statistical sampling program, a greater sample size is needed to more accurately predict rare events such as the catch of overfished species. Therefore, the Council and West Coast states requested a different system to replace MRFSS on the West Coast. NMFS agreed, and a new catch and effort estimation system is being developed.

The MRFSS has been or is being phased out on the West Coast. Changes listed below are expected to result in improved recreational catch estimates. Beginning in January 2004, the MRFSS and State of California State Ocean Salmon Project were replaced by one all inclusive survey, the California Recreational Survey which will sample all fisheries and fishing modes. Since July 2003, Oregon has continued to use its Oregon Recreational Boat Survey and replaced MRFSS with a new inland boat and shore survey using the state's angler

licenses to estimate effort. Since July 2003, Washington MRFSS has maintained its Ocean Sampling Program and replaced Puget Sound MRFSS boat and shore sampling with a new Puget Sound Boat Survey. The State's angler licenses will be used to estimate angler effort in the Puget Sound. Shore sampling was discontinued in July 2003. RecFIN funds formerly used to conduct MRFSS in the three states have been redirected to support, along with state funding, the cost of these new programs.

In January 2004, NMFS implemented a vessel monitoring program to monitor compliance with closed and restricted areas, including the rockfish conservation areas. The Pacific Coast vessel monitoring program consists of declaration reports and a vessel monitoring system (VMS). The declaration reports, which aid enforcement in identifying vessels operating in a closed or restricted area, are reports sent by fishermen before leaving port on a fishing trip. The purpose of the declaration report is to identify their intent to legally fish within a Rockfish Conservation Area (RCA -large-scale depth-related areas where low overfished rockfish species are commonly found), the gear that will be used, and the fishery they are participating in. The VMS is used to track an individual vessel's geographic position through a satellite communication system. VMS transceiver units are required aboard all vessels registered to limited entry permits and will be used to track vessel activity in relation to closed areas within 200 nautical miles along the Pacific coast.

NMFS expects that, taken together, these various improvements to commercial and recreational fisheries monitoring and sampling methodologies should greatly improve estimates of total mortality of overfished and other species.

*Comment 4:* Amendment 16-2 does not contain management measures to rebuild overfished species. To ensure rebuilding goals are met, rebuilding plans need to include management measures to (1) ensure rebuilding targets are met, (2) account for and reduce bycatch, (3) reduce impacts of current fishing on habitats that are important to the overfished stocks and their prey species, and (4) aid in the enforcement of the management measures.

*Response:* West Coast groundfish fisheries are multi-species fisheries and the FMP covers over 80 species of fish. The four overfished species affected by this action co-occur with many other more abundant stocks. Because of this

commingling of overfished and more abundant stocks, the varied fisheries that take groundfish all tend to have some effect on at least one of the nine species that has been declared overfished.

The FMP addresses how the fisheries as a whole are to be managed, whereas rebuilding plans are species-specific and define the parameters that govern the rebuilding of a particular species. The harvest specifications and management measures, on an annual or biennial basis, address the fisheries as a whole. Regulations implemented through the harvest specifications and management measures are intended to address all of the fisheries that take groundfish and include measures to implement rebuilding plans for overfished species. Management measures in these regulatory packages are based on the most recently available scientific information on the status of the various groundfish stocks and fisheries.

In managing a multi-species fishery, it is not necessary or practical to include all of the management measures that will be used to rebuild a particular overfished species in that species' rebuilding plan. Rebuilding plans will provide the specific time period and fishing mortality rate that management measures implemented under the authority of the FMP be consistent with. It is important for the FMP as a whole to provide the structure to implement a variety of different management measures to rebuild overfished stocks, and to manage the fisheries as a whole in accordance with the Magnuson-Stevens Act. Relying on the whole FMP to protect overfished stocks within a multi-species fishery, does not violate the Magnuson-Stevens Act.

The FMP and its rebuilding plans are sufficient "to end overfishing in the fishery and to rebuild affected stocks of fish" (16 U.S.C. 1854(e)(3)(A)). They are neither vague nor meaningless. This Amendment 16 1 sets out the required elements for a rebuilding plan. The FMP states in section 4.6.1.5. that "OY recommendations will be consistent with established rebuilding plans and achievement of their goals and objectives. . . . (b) In cases where a stock or stock complex is overfished, Council action will specify OY in a manner that complies with rebuilding plans developed in accordance with Section 4.5.2." The Plan further states at 5.1.4 "For any stock the Secretary has declared overfished or approaching the overfished condition, or for any stock the Council determines is in need of rebuilding, the Council will implement such periodic management measures as

are necessary to rebuild the stock by controlling harvest mortality, habitat impacts, or other effects of fishing activities that are subject to regulation under the biennial process. These management measures will be consistent with any approved rebuilding plan." Most management measures used in the fishery are described in section 6 of the FMP. The existing emergency rule for groundfish for January and February 2004, (69 FR 13222; January 8, 2004), implements the first four rebuilding plans, and the interim rebuilding strategies for the remaining overfished species for January and February. The proposed rule for groundfish for 2004 (69 FR 1380; January 8, 2004), proposes ABCs/OYs and management measures that implement the rebuilding plans. The management of overfished species for 2004 is summarized at 69 FR 1380.

The FMP as a whole provides direction on rebuilding overfished species in several places and includes, in Chapter 6, management measures and regulatory programs the Council uses and intends to use to meet its varied fishery management responsibilities. Section 6.1 describes a series of management measures that the Council uses to control fishing mortality, including but not limited to: permits, licenses and endorsements; restrictions on trawl mesh size; landing limits and trip frequency limits; quotas, including individual transferable quotas; escape panels or ports for pot gear or trawl or other net gear; size limits; bag limits; time/area closures; other forms of effort control including input controls on fishing gear such as restrictions on trawl size or longline length or number of hooks or pots; and allocation of species or species groups between fishing sectors. Section 6.2 among other things authorizes the Council to close fishing seasons, either as time/area closures set pre-season or inseason, in order to protect overfished species. Section 6.3 of the FMP deals with bycatch management and measures the Council has taken in recent years to reduce bycatch. Essential fish habitat (EFH) is addressed in section 6.6. As described below in the response to this comment, NMFS is in the process of reviewing the FMP's approach to EFH. Nonetheless, it is the FMP as a whole that sets the Council's management philosophies and practices for all groundfish species and protects overfished species, not just the specific rebuilding plans for those species.

The Magnuson-Stevens Act at section 303(a) describes the required provisions of any Federal fishery management plan. Sub-paragraph 303(a)(7) requires that the FMP describe and identify



essential fish habitat and "minimize to the extent practicable adverse effects on such habitat caused by fishing..." Sub-paragraph 303(a)(11) requires that the FMP "establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery, and include conservation and management measures that, to the extent practicable and in the following priority: (A) minimize bycatch; and (B) minimize the mortality of bycatch which cannot be avoided."

Amendment 11 to the FMP provided a description within the FMP of EFH for West Coast groundfish. Amendment 11 was challenged in *American Oceans Campaign v. Daley* 183 F. Supp. 2d1 (D.C.C. 2000), along with challenges to fisheries managed by the Caribbean, Gulf of Mexico, New England, and North Pacific Fishery Management Councils. For West Coast groundfish, the Court found that NMFS had not conducted an adequate National Environmental Policy Act (NEPA) analysis on the effects of fishing on groundfish EFH. NMFS is in the midst of drafting an EIS on groundfish EFH and plans to release the draft EIS for public review in February 2005. Further information on this EIS is available at: [http://www.nwr.noaa.gov/1sustfsh/groundfish/eis\\_efh/efh/](http://www.nwr.noaa.gov/1sustfsh/groundfish/eis_efh/efh/).

Amendment 11 described EFH for West Coast groundfish based on information that was available in 1998, when the amendment was completed. Since that time, there have been notable increases in funding for EFH research and improvements in ocean habitat mapping technologies. These research and mapping improvements are informing the drafting of the new EFH DEIS. Until the completion of that DEIS, Amendment 11's descriptions of EFH for each of the overfished species must serve to characterize species-specific EFH and to inform management measures intended to rebuild those species. For example, the EFH appendix to Amendment 11 (online at <http://www.nwr.noaa.gov/1sustfsh/efhappendix/page1.html>) provides descriptions of the habitats used by the 80+ species in the FMP, including the ocean depths where those species are commonly found. The Council used these habitat descriptions in the development of Rockfish Conservation Areas (RCAs), which are intended to protect the suite of continental and slope overfished species in waters where they are commonly found. RCAs are primarily intended to protect overfished stocks from being incidentally harvested by vessels targeting more abundant species. Closure of these areas, however, also

protects habitat within the RCAs from the effects of groundfish fishing gear. NMFS anticipates that the new EFH EIS will allow the Council to incorporate more data-rich descriptions of the EFH of individual groundfish species into its groundfish fishery management planning. Section 303(a) of the Magnuson-Stevens Act requires that the FMP as a whole include a description of EFH and EFH protection measures. It does not require that each amendment to the FMP describe EFH and provide EFH protection measures.

Amendment 13 to the FMP addressed bycatch in the West Coast groundfish fisheries and was also challenged in Court, *Pacific Marine Conservation Council, Inc. v. Evans*, 200 F. Supp. 2d1194 (N.D. Calif. 2002). The Court held that Amendment 13 failed to establish an adequate bycatch reporting methodology, did not comply with the duty to minimize bycatch and bycatch mortality, and violated NEPA because NMFS did not take "hard look" at the environmental consequences of Amendment 13, and failed to consider a reasonable range of alternatives and their environmental consequences. In particular, the Court concluded that Amendment 13 failed to establish a standardized reporting methodology because it failed to establish either a mandatory or an adequate observer program. Further, it failed to minimize bycatch and bycatch mortality because it failed to include all practicable management measures in the FMP itself. The Court also found a lack of reasoned decisionmaking because four specific bycatch reduction measures (fleet size reduction, marine reserves, vessel incentives, and discard caps) were rejected without consideration on their merits. With respect to NEPA, the EA prepared for Amendment 13 failed to address adequately the ten criteria for an action's significance set forth in the Council on Environmental Quality regulations at 40 CFR 1508.27(b), and also failed to analyze reasonable alternatives, particularly the immediate implementation of an adequate at-sea observer program and bycatch reduction measures.

NMFS is in the process of drafting an EIS to address the Court's requirement for a new NEPA analysis on bycatch in the groundfish fisheries and is scheduled to release the draft EIS for public review through the Environmental Protection Agency on February 27, 2004. The draft EIS on bycatch provides information necessary to further improve the bycatch reduction program for West Coast groundfish fisheries. Further information on this EIS is available at:

[http://www.nwr.noaa.gov/1sustfsh/groundfish/eis\\_efh/pseis/](http://www.nwr.noaa.gov/1sustfsh/groundfish/eis_efh/pseis/).

NMFS has implemented numerous bycatch reduction measures since the Council's approval of Amendment 13 in 2000. Through the issuance of exempted fishing permits (EFPs), the agency has supported the collection of data needed to assess the feasibility of full retention measures in the following fisheries: Pacific whiting, arrowtooth flounder, yellowtail rockfish, nearshore flatfish, and the dogfish fishery. NMFS has also supported the use of EFPs to test the effectiveness of flatfish selective trawl gears. Shorter-than-year-round fishing seasons have been set for various species and sectors of the groundfish fleet in order to protect different overfished groundfish species. Amendment 14 to the FMP implemented a permit stacking program for the limited entry fixed gear fleet that reduced the number of vessels participating in the primary sablefish fishery by about 40 percent. In 2003, NMFS implemented a buyback of limited entry trawl vessels and their permits, reducing the groundfish trawl fleet by about one-third. NMFS has implemented gear modification requirements that restrict the use of trawl gear in rocky habitat and that constrain the catching capacity of recreational fishing gear. Higher groundfish landings limits have been made available for trawl vessels using gear or operating in areas where overfished species are less likely to be taken.

Implementation of the NMFS WCGOP in August 2001 addressed the Court's order that NMFS implement an adequate bycatch assessment methodology, which uses a standardized reporting methodology. NMFS believes that the WCGOP comprises an adequate reporting methodology for estimating the amount and type of bycatch occurring in the fishery. Amendment 16-1 added provisions to the FMP that made this program mandatory.

In 2002, a bycatch model was first used to examine species-to-species landings limit ratios. Data from this observer program, from historic observer programs, and from fishery-dependent data are used in the bycatch model for West Coast groundfish fisheries. WCGOP data are used in analyzing where and when different sectors of the groundfish fleet have targeted and may target groundfish. Each intervening year since 2002, the bycatch model has been modified to incorporate new WCGOP data. The bycatch model has been used in the development of Rockfish Conservation Areas (RCAs - large time/



area closures that affect the entire West Coast and are specifically designed to reduce the incidental catch of overfished groundfish species in fisheries targeting more abundant stocks) which were implemented through 50 CFR 660.304 and the harvest specifications and management measures.

*Comment 5:* NMFS should, at a minimum, include measures to compare total mortality estimates at the end of each year with that year's OY values to determine if any overages have occurred. If so, an adjustment should be made in the following year's OY as early in that year as possible to compensate for the overages. Such measures would be consistent with recommendations in the Technical Guidance to make downward adjustments of subsequent year fishing mortality rates in response to OY overages for overfished species.

*Response:* The Magnuson-Stevens Act requires NMFS to annually report to Congress on the status of the fisheries and to identify those fisheries that are overfished or approaching a condition of being overfished. Each year, NMFS prepares *The Annual Report to Congress on the Status of the Fisheries* which provides the mandated information and also identifies any stocks for which overfishing has occurred. Overfishing occurs when a stock or stock complex is subjected to a rate of fishing mortality that jeopardizes the stock's ability to produce maximum sustainable yield (MSY) on a continuing basis. For West Coast groundfish, the ABC is set at FMSY and exceeding the ABC is overfishing.

When looking at whether ABC values have been exceeded, NMFS also notes whether OY values have been exceeded and works with the Council to revise management measures so as to reduce the likelihood that OYs for the same species will be exceeded in subsequent years. Management measures for healthy stocks are intended to achieve OYs without exceeding them, unless the achievement of a particular species' OY would negatively affect the rebuilding of a co-occurring overfished species. In such a case, management measures would be designed to keep the harvest under the OY of the healthy stock in order to rebuild the overfished stock. NMFS will continue to monitor whether the fisheries have exceeded acceptable biological catches (ABCs) or OYs and will continue to work with the Council to make inseason adjustments to management measures to prevent the fisheries from continually exceeding OY target levels.

NMFS, the state fisheries agencies, and the Council monitor fisheries

landings inseason. Commercial fisheries landings are monitored by a fish ticket system managed by the three states. State fish ticket data is compiled by the Pacific States Marine Fisheries Commission (PSMFC). Estimated commercial landings amounts are provided to the agencies and the public via the Pacific Fisheries Information Network (PacFIN). Depending on state funding and staffing levels, groundfish landings may be recorded in PacFIN anywhere from several days to a few months after the landings have been made. For this reason, fishery managers must estimate current landings levels of a particular species by extrapolating what we know has already been landed out to an estimate based on several different variables, such as past harvest rates in particular months, number of vessels participating in the fishery in those months, etc. With the time delays in this landings monitoring system, the Council does not have fully up-to-date landings information when making its inseason adjustments or ABC/OY recommendations.

The state fish ticket system and PacFIN monitor commercial fisheries landings. These systems do not include fish taken at sea and lost or discarded. While NMFS monitors total catch levels through at-sea observer sampling programs, the agency does not have the staff, funding, or technology to monitor the thousands of trawl tows and trap and longline hauls that result in the fishery's total commercial catch. Instead, NMFS monitors a portion of the commercial fleet through observers and uses a model based on the observer data with fish ticket and other data to estimate total catch for the fleet.

In the preamble to the proposed rule for the 2004 Annual Specifications and Management Measures (January 8, 2004, 69 FR 1380), NMFS described a bycatch model that is used both pre-season to develop management measures and inseason to modify management measures. This model is a "total catch" model, i.e. it calculates the total expected catch, not just fish that are actually landed. The model is updated annually with new WCGOP data. Observer data from the 2001–2002 fisheries was used to develop 2004 management measures and discard estimates. NMFS just completed its analysis of 2002–2003 WCGOP data (<http://www.nwfsc.noaa.gov/research/divisions/fram/observers/>), and that analysis will be available to the Council for the development of the 2005–2006 fishery specifications and management measures.

As with the commercial fisheries, PSMFC maintains a database for

recreational fisheries, the Recreational Fisheries Information Network (RecFIN). Estimates of recreational fisheries catch and landings are available on the internet at <http://www.recfin.org/>. All three states deploy port samplers for at-dock sampling of recreational groundfish fisheries. Even more so than in commercial fisheries, recreational fisheries data may not be available to fisheries managers until several months after the subject fishing trips have occurred. Because the states of Washington and Oregon have smaller coastlines and smaller populations than California, they tend to directly sample a much greater proportion of their recreational fisheries catch than California does.

In past years, California has relied on NMFS' MRFSS for its estimates of recreational fisheries catch. MRFSS uses a telephone survey of the general population to determine which persons in the population are anglers, and, of the anglers, how much of which species they are catching and landing. MRFSS was initially designed as an annual sampling program that would provide a snapshot of an entire year's harvest of different recreational species. Because MRFSS was the only tool for estimating recreational catch, the Council has used it for inseason management in recent years.

Recreational fisheries data needs have increased notably since the Council first began managing the fisheries to rebuild overfished stocks in 2000. All three states, the Council, and NMFS have been concerned that data generated from MRFSS was not accurate or timely enough to support inseason management of recreational fisheries. Over 2002–2003, the agencies met through the PSMFC's RecFIN Data Committee and worked together to update their monitoring programs so as to better meet the coastwide need for improved recreational fisheries catch data. PSMFC reported to the Council on the planned changes to recreational fisheries data gathering in the three states at the Council's November 2003 meeting. All three states have eliminated MRFSS as a sampling tool, focusing instead on at-dock sampling and angler interviews. While California will continue to use telephone interviews as one of its data-gathering methods, its survey population will be licensed California anglers, not the entire population of the State of California. California will also be increasing its at-dock sampling presence and providing some on-board observation of charterboats. Oregon and Washington will also be replacing their MRFSS general-population surveys with

surveys specific to licensed anglers; and with increased at-dock and at-sea monitoring.

The Technical Guidance at section 3.4 states that "...Stock rebuilding should be monitored closely so that adjustments can be made when rebuilding milestones are not being met for whatever reason. For example, if target rebuilding fishing mortality rates are exceeded due to quota over-runs, subsequent target fishing mortality rates should typically be adjusted downwards to put the stock back on the rebuilding time table." NMFS makes adjustments to OYs after conducting a stock assessment of the population of a particular species; these assessments occur every 2-4 years. (Previously, NMFS had been on a 3-year stock assessment cycle. With the adoption of Amendment 17, the science and management cycle has shifted from annual to biennial management. Under the biennial management cycle, stock assessments will be conducted every 2-4 years.) The decisions on which stock assessments to do which year will depend on the status of the stocks, and the availability of data and stock assessment personnel. In the years between assessments, NMFS and the Council address over- and under-harvests by adjusting management measures to try to achieve, but not exceed, OYs of several of the more abundant stocks will, of necessity, not be achieved in order to protect co-occurring overfished species.

Stock assessments take harvest overages and underages into account in evaluating the status of a stock and whether rebuilding milestones are being met. New fishing mortality rates set subsequent to each new stock assessment will keep the stock on its rebuilding trajectory. NMFS does not plan to adopt a policy of regularly adjusting ABCs and OYs either inseason or annually to account for catch overages or underages from the previous year. Such a policy, if carried out over a period of several years, could result in wild fluctuations in harvest levels, further de-stabilizing fishing communities. Overages or underages will continue to be incorporated into new stock assessments and the appropriate adjustments to fishing mortality rates to remain on the rebuilding trajectories will be made at that time. As the Technical Guidance notes in several places, its guidance is intended to address the biological aspects of national standard 1 and does not incorporate the socio-economic considerations addressed by the Magnuson-Stevens Act and the other national standards.

*Comment 6:* In the preamble to the proposed rule, NMFS states that the target year for rebuilding should only be changed in unusual circumstances, such as if, based on new information, the rebuilding target is greater than the maximum allowable time frame ( $T_{MAX}$ ) and if socio-economic reasons dictate otherwise. These are inappropriate reasons for changing the target rebuilding date because: (1) Shortening the rebuilding period to account for a revised  $T_{MAX}$  provides no assurance that the species will be rebuilt in as short a time as possible, and (2) target rebuilding dates have already been lengthened for socio-economic reasons, further lengthening target rebuilding periods for socio-economic reasons will prevent rebuilding of the overfished populations.

*Response:* NMFS believes that the specified rebuilding time periods for the four overfished species need to be consistent with the legal requirements of the Magnuson-Stevens Act and with the national standard guidelines. If a new stock assessment and rebuilding analysis result in a  $T_{MAX}$  being a shorter duration than that previously predicted, NMFS would be required to keep  $T_{TARGET}$  below  $T_{MAX}$ . Discussion on setting target rebuilding dates can be found in the responses to Comment 1 and Comment 2, where we explain the Magnuson-Stevens Act and the national standard guideline requirements regarding rebuilding duration and factors that may affect the rebuilding period, as well as the Technical Guidance recommendations.

*Comment 7:* The proposed rule presents the status of each Amendment 16-2 stock when it was declared overfished, but omits the status of those species as of their most recent stock assessments. Those stock statuses should be shown, since the rebuilding parameters provided in the regulations reflect information from the most recent stock assessments.

*Response:* The proposed rule reflects the rebuilding parameters that were adopted by the Council in June 2003. These parameters were based on the most recent stock assessments that were available at that time. Since June 2003, new stock assessments and rebuilding analyses were prepared and approved by the Council for POP and darkblotched rockfish. The most recent status of each overfished species can be found in the overfished species section of the preamble to the proposed rule for the 2004 harvest specifications and management measures January 8, 2004 (69 FR 1380). It is NMFS's intention to provide the most recent stock assessment and rebuilding analysis

results with the preamble discussions in future proposed rules to implement the harvest specifications and management measures. The harvest specifications and management measures is a Federal rulemaking with a notice and comment period. This information will also be available within the annual Stock Assessment and Fishery Evaluation (SAFE) document. As explained earlier in this document under "changes from the proposed rule," this final rule implements the most up-to-date rebuilding parameters for the four Amendment 16-2 overfished species. Any changes to these rebuilding parameters will be through a notice-and-comment rulemaking.

*Comment 8:* Amendment 16-2 should be brought into compliance with the Magnuson-Stevens Act requirement at 304(e)(3)(a) that a rebuilding plan be designed "to end overfishing in the fishery and to rebuild affected stocks of fish." To do so, rebuilding plans should include specific conservation and management measures designed to rebuild each species. The EIS for Amendment 16-2 should have included a range of management measures alternatives necessary to achieve the proposed rebuilding targets and time periods.

*Response:* The rebuilding plans for the four overfished species are consistent with the Magnuson-Stevens Act requirements at 304(e)(3)(a) and, when considered as part of the FMP as a whole, are sufficient to "to end overfishing in the fishery and to rebuild affected stocks of fish."

The FMP is the Council's policy vehicle for addressing how the fisheries as a whole are to be managed, whereas rebuilding plans are species-specific and are intended to define the parameters the Council will use to govern the rebuilding of a particular species. The harvest specifications and management measures, on an annual or biennial basis, address the fisheries as a whole. Regulations implemented through the harvest specifications and management measures are intended both to address all of the fisheries that take groundfish and to implement the requirements of rebuilding plans. Management measures in these regulatory packages are based on the most recently available scientific information on the status of the various groundfish stocks and fisheries. The response to Comment 4 further describes the components of the FMP that can be used to manage the fishery and rebuild overfished stocks.

*Comment 9:* Accounting mechanisms must be established to accurately count bycatch of overfished species and other

marine life such as the use of an observer program with adequate coverage, Federal permit or licensing requirements, or other appropriate data collection methods. Bycatch accounting measures must also ensure that all sources of mortality data are made available to the public and incorporated into the annual specifications process in a timely manner.

*Response:* At 16 U.S.C. 1853(a)(11), the Magnuson-Stevens Act requires that FMPs, among other things, "establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery..." Adequate bycatch accounting is necessary for managing a fishery, and for keeping total catch within specified OYs.

An observer program is one means for obtaining bycatch information in commercial fisheries. In August 2001, NMFS implemented the WCGOP which uses a standardized bycatch reporting methodology. The availability of the WCGOP observer coverage plan was announced on January 10, 2002 (67 FR 1329) and is available via the internet at: <http://www.nwfsc.noaa.gov/research/divisions/fram/observers/>.

In the first year of the WCGOP (August 2001–August 2002,) NMFS focused observer coverage largely on the non-whiting groundfish trawl fleet, with some pilot effort in the nontrawl limited entry and open access fleets. Observer coverage for the nontrawl fleet, particularly for limited entry vessels with sablefish endorsements, expanded during the second year of the observer program (September 2002–August 2003). In September 2003, NMFS reported to the Council on bycatch modeling and observer data developments.

WCGOP has focused its coverage on the limited entry trawl fleet because that fleet annually makes greater than 95 percent (by weight) of West Coast commercial groundfish landings coastwide (PacFIN, 1999–2003). Under the WCGOP coverage plan, the program has a goal of 10 percent coverage of trawl landings in any one year. With its 30–40 observers available each year, the WCGOP has been able to select each trawl fleet participant for coverage for at least one cumulative limit period in each year. The observer coverage levels are dependent upon the number of vessels actively participating in the fishery and on available program funding. Data from the first year of the observer program are available on the WCGOP site, mentioned earlier in this paragraph. NMFS is evaluating data from the second year of observer coverage and plans to release a data report on the WCGOP activities over

September 2002–August 2003 in early 2004.

Following the release of the first year of WCGOP data in January 2003, NMFS incorporated WCGOP data on the bycatch of overfished species into the bycatch model. The Council began to use observer data to inform inseason groundfish management at its April 2003 meeting. For the 2004 fishing year, NMFS has further revised the bycatch model to incorporate discard rates on both overfished and targeted species, as generated by observer data. Because the second year of the WCGOP increased coverage of the limited entry nontrawl fleet, NMFS plans to further modify the 2004 bycatch model to incorporate nontrawl data. The agency expects that data from the second year of the WCGOP will be incorporated into inseason groundfish fisheries management by the April 2004 Council meeting, and will be used in the development of 2005–2006 management measures. Amendment 16–1 of the FMP added language that made the WCGOP a mandatory program for the groundfish fishery. The commenter also wishes the FMP to discuss the scope and adequacy of an observer program, whereas the FMP defers the design of the WCGOP to NMFS.

Over the past year, NMFS has been reviewing the agency's approach to standardized bycatch monitoring programs for all federally managed fisheries. The report, "Evaluating Bycatch: A National Approach to Standardized Bycatch Monitoring Programs," is available on the internet at: <http://www.nmfs.noaa.gov/bycatch.htm>. Also available at that website is the "NOAA Fisheries Objectives, Protocol, and Recommended Precision Goals for Standardized Bycatch Reporting Methodologies." This latter report addresses the question of the adequacy of an observer program or other standardized reporting methodology by setting "precision goals" for monitoring programs. According to this report, the levels of precision NMFS strives to achieve for fishery resources caught as bycatch in a fishery, excluding species protected under the ESA or MMPA, is a 20–30 percent CV [coefficient of variation] for estimates of total discards (aggregated over all species) for the fishery; or if total catch cannot be divided into discards and retained catch then the recommended goal for estimates of total catch is a CV of 20–30 percent." In setting these precision goals, NMFS recognizes that "(1) there are intermediate steps in increasing precision which may not immediately achieve the goals; (2) there are

circumstances in which higher levels of precision may be desired, particularly when management is needed on fine spatial or temporal scales; (3) there are circumstances under which meeting the precision goal would not be an efficient use of public resources; and (4) there may be significant logistical constraints to achieving the goal."

The "Evaluating Bycatch" report characterizes the WCGOP as a "developing" observer program, meaning that it is a program "in which an established stratification design has been implemented and alternative allocation schemes [for observer coverage] are being evaluated to optimize sample allocations by strata to achieve the recommended goals of precision of bycatch estimates for the major species of concern." The next step beyond a developing observer program is a "mature" program "in which some form of an optimal sampling allocation scheme has been implemented. The program is flexible enough to achieve the recommended goals of precision of bycatch estimates for the major species of concern considering changes in the fishery over time."

As discussed above, NMFS will be releasing the second year of observer data in January 2004. Because observer coverage in the groundfish fishery has been largely focused on the trawl fishery, NMFS expects that it will have achieved the NMFS precision goals of 20–30 percent CV for estimates of total discards in the trawl fishery and of 20–30 percent CV for estimates of species-specific discards of those overfished species that are commonly taken in the trawl fishery. For overfished species that are either not commonly taken in the trawl fishery, such as yelloweye rockfish, or species that are unavailable to the fisheries because of large area closures, such as cowcod, NMFS expects that the current trawl-focused sampling program will not achieve the 20–30 percent CV precision goal. As it works toward becoming a mature observer program, the WCGOP will likely increase observer coverage of nontrawl vessels in order to get a more precise estimate of yelloweye rockfish bycatch. For cowcod, a rare event species with large portions of its habitat closed to fishing, evaluation of annual mortality may have to take some form other than a fishery observation program.

At section 6.3.3, the FMP identifies the management need for an observer program or other bycatch measurement program as an aid for the Council to "better identify and prioritize the bycatch problems in the groundfish fishery, based on the expected benefits

to the U.S. and on the practicality of addressing these problems." The Council has used data from WCGOP to re-shape its landings limits and time/area closures. The Council has also used WCGOP data to evaluate species-to-species landings limit ratios, as well as species-to-species catch ratios in the bycatch model. NMFS expects that the WCGOP will continue to meet the Council's need to identify and prioritize bycatch problems in the groundfish fishery, and that WCGOP data will continue to directly inform both annual and inseason management measures.

In January 2004, NMFS implemented a vessel monitoring program to monitor compliance with closed areas, including the groundfish conservation areas. The Pacific Coast vessel monitoring program consists of declaration reports and VMS. With VMS, vessels registered to limited entry trawl vessels are required to install and use a mobile transceiver unit whenever the vessel is used to fish in state or Federal waters off the west coast. The VMS equipment records the vessel's geographic position and sends it to NMFS through a satellite communication system where it is stored in a database. VMS position data can be used in combination with observer data to better understand total fishing effort, shifts in fishing effort, and potential bycatch levels.

*Comment 10:* Amendment 16-2 does not include provisions for the rebuilding plans of its subject species that would set standards for reviewing progress toward rebuilding for those species. This is a requirement of rebuilding plans according to Amendment 16-1. NMFS, as the agent of the Secretary of Commerce, has the duty to review rebuilding plans every two years to ensure adequate progress. Without established standards for determining adequacy of progress and triggers for modifying rebuilding parameters, there is a high probability that rebuilding plans will ultimately fail to achieve rebuilding.

*Response:* NMFS believes that the rebuilding plans under Amendment 16-2 are consistent with the requirements of the Magnuson-Stevens Act. The Magnuson-Stevens Act requires the Secretary to review rebuilding plans at intervals that may not exceed two years. During the Amendment 16-1 process, for the purpose of clarity, NMFS worked with the Council staff to add a sentence to the FMP at the end of section 4.5.3.6 to read, "Regardless of the Council's schedule for reviewing overfished species rebuilding plans, the Secretary of Commerce, through NMFS, is required to review the progress of overfished species rebuilding plans

toward rebuilding goals every two years, per the Magnuson-Stevens Act at 16 U.S.C. 304(e)(7)." NMFS's review of the adequacy of progress on rebuilding plans will be primarily be done through stock assessment updates and are expected to follow the schedule defined by the Magnuson-Stevens Act.

FMP Section 4.5.3.2, Contents of Rebuilding Plans, states that generally, "rebuilding plans will contain ... 4. The process, and any applicable standards, that will be used during periodic review to evaluate progress in rebuilding the stock to the target biomass." While adopting these rebuilding plans, the Council and NMFS realized that standards for measuring the progress of rebuilding needed to be refined. Therefore, at the Council's November 2003 meeting, NMFS asked the Council's SSC to review and develop standards for measuring the progress of rebuilding. NMFS also made this request to the Council in its letter of approval for Amendment 16-1 and reminded the Council of this request in its letter of approval for Amendment 16-2. In these letters, NMFS recommended that setting standards for measuring the progress of rebuilding plans be included in the SSC's Terms of Reference for the Stock Assessment Review (STAR) processes. By including the setting of rebuilding plan progress standards in the STAR processes for overfished species, the NMFS/Council process for developing and reviewing stock assessments would continue the link between stock assessments and rebuilding plans for overfished species. NMFS fully expects that these standards will be defined before the Secretary's review in January 2006 and the standards will be included in the Council's annual SAFE document.

*Comment 11:* Amendment 16-2 improperly opens the door for use of the mixed-stock exception, which is contrary to the requirements of the Magnuson-Stevens Act.

*Response:* Amendment 16-2 does not open the door for what the commenter allege is the "illegal use of the mixed-stock exception." Amendment 16-2 has no effect on the mixed-stock exception. Although the mixed-stock exception currently exists in the national standard guidelines, the Council has never exercised the exception. Amendment 16-2 makes no change in the condition of its possible application.

*Comment 12:* Marine sanctuaries are needed where fishing is prohibited. The rebuilding policy does not provide enough protection for fish stocks.

*Response:* Marine sanctuaries are defined under the National Marine Sanctuaries Act (16 U.S.C. 1431-1445)

as areas of the marine environment which have special conservation, recreational, ecological, historical, cultural, archeological, scientific, educational, or esthetic qualities that will improve the conservation, understanding, management, and wise and sustainable use of marine resources; enhance public awareness, understanding, and appreciation of the marine environment; and maintain for future generations the habitat, and ecological services, of the natural assemblage of living resources that inhabit these areas.

Section 303(a) of the Magnuson-Stevens Act requires that the FMP as a whole include a description of EFH and EFH protection measures, but does not provide authority to implement marine sanctuaries. Further, it does not require that each individual amendment to the FMP describe EFH and provide EFH protection measures such as marine protected areas. The commenter is correct in stating that Amendment 16-2 does not contain requirements for marine sanctuaries. However, the commenter is incorrect in then concluding that overfished species are not adequately protected by the FMP.

*Comment 13:* Commercial fisheries are causing stock depletion.

*Response:* NMFS agrees that commercial fishing results in fishing mortality, as does recreational fishing. Declines below the overfished levels in the 1990s were due in large part to harvest rate policies that were based on the best scientific information at the time, but were later discovered to not be sustainable. More recent stock assessments indicate that West Coast groundfish stocks likely have lower levels of productivity than other similar species worldwide. A retrospective analysis determined that harvest rate policies in the 1990s, though based on the best available information at the time, were too high to maintain stocks at BMSY.

A 2000 review of groundfish harvest rates by the Council's SSC showed that then-current scientific information indicated both lower than historically estimated recruitment levels for West Coast groundfish and a corresponding need for lower than historically used harvest rates. Since 2000, NMFS and the Council have set ABCs for groundfish species at more precautionary rates (F40% for flatfish, F50% for rockfish, and F45% for other groundfish such as sablefish and lingcod).

*Comment 14:* To ensure rebuilding, fishing mortality rates and rebuilding strategies should be upheld even when new information suggests that the stock



size is increasing more rapidly than expected.

**Response:** Rebuilding plans are expected to be revised only when reviews reveal a significant discrepancy between current stock status and that projected in the original rebuilding plan or in earlier reviews. It is NMFS's intention that any changes to rebuilding strategies be made during the annual or biennial setting of harvest specifications and management measures and be established through a Federal rulemaking with a notice and comment period.

#### Changes From the Proposed Rule

On January 8, 2004, NMFS published a proposed rule to implement the 2004 fishery specifications and management measures January 8, 2004 (69 FR 1380). This proposed rule contained revisions to the harvest control rules for POP and darkblotched rockfish that had originally been published in the Amendment 16-2 proposed rule. These revisions are now in place under the final 2004 fishery specifications and management measures that were published on March 9, 2004 at 69 FR 11064.

The POP rebuilding parameters in the Amendment 16-2 proposed rule were based on a 2000 stock assessment that had resulted in a target rebuilding year of 2027 and a harvest control rule of  $F=0.0082$ . The 2004 OY presented in the 2004 fishery specifications and management measures was based on a new stock assessment prepared in 2003. Because POP rebuilding parameters such as the unfished biomass and BMSY were updated with the new stock assessment, the POP harvest control rule in the final rule will be revised to  $F=0.0257$  from  $F=0.0082$ . However, the target rebuilding year (2027) will remain the same as was announced for POP in the Amendment 16-2 proposed rule.

Similarly, the darkblotched rockfish rebuilding parameters in the Amendment 16-2 proposed rule were based on a 2000 stock assessment that had resulted in a target rebuilding year of 2030 and a harvest control rule of  $F=0.027$ . The 2004 OY presented in the 2004 fishery specifications and management measures was based on a new stock assessment that was prepared in 2003 and results in the same target rebuilding year (2030) as was announced in the Amendment 16-2 proposed rule for the darkblotched rockfish rebuilding plan. However, because other rebuilding parameters such as the unfished biomass and BMSY were updated with the new stock assessment, the harvest control rule in

the final rule will be revised to  $F=0.032$  from  $F=0.027$ .

#### Classification

The Administrator, Northwest Region, NMFS, has determined that Amendment 16-2 is necessary for the conservation and management of the Pacific Coast groundfish fishery and that it is consistent with the Magnuson-Stevens Act and other applicable laws.

A Final Environmental Impact Statement (FEIS) for this action was filed with the Environmental Protection Agency on December 12, 2003. A notice of availability for the FEIS was published on December 19, 2003 (68 FR 70795). In approving Amendment 16-2, on January 30, 2004, NMFS issued a Record of Decision identifying the selected alternative (see ADDRESSES).

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

NMFS prepared a final regulatory flexibility analysis (FRFA) as part of the regulatory impact review. The FRFA incorporates the IRFA, the comments and responses to the proposed rule, and a summary of the analyses completed to support the action. A copy of this analysis is available from NMFS (see ADDRESSES).

During the comment period for the proposed rule, NMFS received four letters of comment, but none of these comments addressed the IRFA or impacts on small businesses. There are no recordkeeping, reporting, or other compliance issues forthcoming from this proposed rule. This rule does not duplicate, overlap, or conflict with other Federal rules.

This action is needed because the Magnuson-Stevens Act at 304 (e)(3) requires rebuilding plans for species that have been declared overfished. These plans must be in the form of FMPs, FMP amendments, or regulations. The objective of this proposed rule is to implement rebuilding parameters that will result in lingcod, canary rockfish, darkblotched rockfish and POP stocks returning to their MSY biomass levels.

Amendment 16-2 responds to a Court order in *Natural Resources Defense Council, Inc. v. Evans*, 168 F. Supp. 2d 1149 (N.D. Cal 2001.), in which NMFS was ordered to provide Pacific Coast groundfish rebuilding plans as FMPs, FMP amendments, or regulations, per the Magnuson-Stevens Act. On October 27, 2003, the Court ordered NMFS to approve rebuilding plans for lingcod, canary rockfish, darkblotched rockfish, and POP by January 31, 2004.

Amendment 16-2 follows the framework established by Amendment 16-1 and amends the FMP to include

rebuilding plans for canary rockfish, darkblotched rockfish, POP, and lingcod. For each overfished species rebuilding plan, the following parameters would be specified in the FMP: estimates of unfished biomass ( $B_0$ ) and target biomass ( $B_{MSY}$ ), the year the stock would be rebuilt in the absence of fishing ( $T_{MIN}$ ), the year the stock would be rebuilt if the maximum time period permissible under national standard guidelines were applied ( $T_{MAX}$ ) and the target year in which the stock would be rebuilt under the rebuilding plan ( $T_{TARGET}$ ). No new management measures are proposed in Amendment 16-2. Amendment 16-1 describes and authorizes the use of numerous types of management measures intended to achieve rebuilding. These management measures will be implemented through the biennial management process and will be used to constrain fishing to the targets identified in the rebuilding plans.

The FEIS/RIR/IRFA for this final rule defines six alternative actions that were considered for each of the four overfished species. The alternatives present a range of rebuilding strategies in terms of rebuilding probabilities for each species. The no action alternative would be based on the "40 10 harvest policy", which is the default rebuilding policy for setting OYs. Under the 40 10 harvest policy, stocks with biomass levels below B40% have OYs set in relation to the biomass level. At B40%, an OY may be set equal to the ABC. However, if a stock's spawning biomass declines below B40%, the OY is scaled downward until at 10 percent (B10%) the harvest OY is set at zero unless modified for a species-specific rebuilding plan. In comparison to the other alternatives, (except the maximum conservation alternative) the 40 10 policy can result in lower OYs in the short term, when a stock is at a low biomass level, but allow greater harvests when a stock is at higher biomass levels. For further information on the 40 10 policy see the preamble for the annual specifications and management measures published on January 8, 1999(64 FR 1316) or section 5.3 of the FMP.

The 40-10 policy alternative could require short-term reductions in OYs for stocks at lower biomass levels than would be required under the other alternatives, except the maximum conservation alternative. Such reductions could result in reduced profits, income, and employment in a wide range of groundfish fisheries over a longer period of time than would occur with the other alternatives. The maximum conservation alternative,



based on a harvest mortality rate of zero, would be in place for each stock until the individual stock was rebuilt, resulting in the target rebuilding period for each stock being equal to  $T_{MIN}$ . Each stock could be expected to rebuild fastest under this alternative, but at considerable socioeconomic cost. Because canary and darkblotched rockfish are caught in a wide range of other fisheries, a zero harvest mortality rate would likely result in the closure of other fisheries. The rebuilding of these stocks, even in the absence of fishing, is likely to result in many current participants in the commercial recreational fisheries as well as supporting businesses going out of business. The maximum harvest alternative for each overfished species was based on a 50-percent probability of rebuilding the stocks to their MSY biomass levels by  $T_{MAX}$ . This alternative would delay rebuilding for the longest period of time with the intent of keeping harvests at the highest allowable levels for the duration of rebuilding. As a result, this alternative would have the least socioeconomic impact, in the short term. Delaying the rebuilding period under the maximum harvest alternative can also be expressed as the level of increased risk to the overfished stocks. Further delay in rebuilding could have a greater socioeconomic impact than the other alternatives, if currently healthy stocks were overfished.

Intermediate alternatives were presented only as the rebuilding parameter values for the harvest rate,  $P_{MAX}$ , and  $T_{TARGET}$ . While keeping the number of alternatives manageable (recognizing that the five primary alternatives encompass the full range of reasonable alternatives) these additional alternatives were presented in the FEIS to support decision making and were structured around 10 percent increments in  $P_{MAX}$  between 60 percent and 80 percent for each of the four overfished stocks. The 90 percent  $P_{MAX}$  value was not evaluated because the effects were not significantly different from the Maximum Conservation Alternative.

The socioeconomic impacts of the intermediate values fall within the range of the other alternatives that were fully analyzed in the FEIS analysis. Quantifying the differences between these alternatives is difficult given the lack of detailed socioeconomic data. The mixed stock exception alternative would allow higher harvests of canary rockfish and could be combined with any of alternatives (except the no action alternative). Since the demands of rebuilding canary rockfish will affect a range of fisheries, (because it constrains

stocks), relaxing this constraint under any of the alternatives would allow a higher harvest level in some fisheries. However, fisheries with little or no canary rockfish bycatch, but with bycatch of other overfished species, would not necessarily benefit. This alternative was not considered for POP or lingcod, since they do not constrain stocks in fisheries where they are targeted or incidentally caught. The last set of alternatives considered were the Council's preferred alternatives for each species and are as follows: lingcod - 60-percent probability of rebuilding the stock to its MSY biomass by  $T_{MAX}$  with a  $T_{TARGET}$  of 2009 and a harvest rate of 0.0531 in the North and 0.0610 in the south; canary rockfish - 60-percent probability of rebuilding the stock to its MSY biomass by  $T_{MAX}$  with a  $T_{TARGET}$  of 2074 and a harvest rate of 0.0220, darkblotched rockfish - 80 percent probability of rebuilding the stock to its MSY biomass by  $T_{MAX}$  with a  $T_{TARGET}$  of 2030 and a harvest rate of 0.027, and POP - 70 percent probability of rebuilding the stock to its MSY biomass by  $T_{MAX}$  with a  $T_{TARGET}$  of 2027 and a harvest rate of 0.0082. The Council's preferred alternatives, were taken from the range of intermediate alternatives for each species.

Rebuilding parameters associated with  $P_{MAX}$  values less than 50 percent were considered, but rejected because they were not considered to be compliant with the requirements of the Magnuson-Stevens Act as interpreted in a 2000 Federal Court ruling (*Natural Resources Defense Council v. Daley, April 25, 2000, U.S. Court of Appeals for the District of Columbia Circuit,* ). A mixed stock exception alternative was considered for darkblotched rockfish, but was rejected because the Council indicated that it should not be applied to darkblotched rockfish.

A fish-harvesting business is considered a "small" business by the Small Business Administration (SBA) if it has annual receipts not in excess of \$3.5 million. The economic impacts of implementing these rebuilding plans will be shared among the participants. Approximately 1,560 vessels participate in the West Coast groundfish fisheries. Of those, about 410 vessels are registered to limited entry permits issued for either trawl, longline, or pot gear. About 1,150 vessels land groundfish against open access limits while either directly targeting groundfish or taking groundfish incidentally in fisheries directed at nongroundfish species. All but 10 20 of those vessels are considered small businesses by the SBA. Of the 450 groundfish buyers that regularly

purchase groundfish, 38 buyers purchased groundfish product in excess of \$1,000,000 in 2002. In the 2001 recreational fisheries, there were 106 Washington charter vessels engaged in salt water fishing outside of Puget Sound, 232 charter vessels active on the Oregon coast and 415 charter vessels active on the California coast. NMFS does not know the proportion of recreational charter vessel operations that would be considered large businesses, but the agency believes that the majority of these businesses would be considered "small" businesses by the SBA. This rule is not expected to yield disproportionate economic impacts between those small and large entities.

Implementation of specific rebuilding plans may entail substantial economic impacts on some groundfish buyers, commercial harvesters, and recreational operators. The Council preferred rebuilding alternatives specify annual OY levels for the overfished species that allow some harvest of healthy stocks to continue and are sufficient to mitigate some of the adverse economic impacts on these entities, while not compromising the statutory requirement for timely rebuilding.

This action was developed after meaningful consultation and collaboration with tribal representatives on the Council who have agreed with the provisions that apply to tribal vessels. This action is, therefore, compliant with Executive Order 13175 (Consultation and coordination with Indian tribal governments).

#### List of Subjects in 50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian Natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: April 6, 2004.

William T. Hogarth,  
Assistant Administrator for Fisheries,  
National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

#### PART 660—FISHERIES] OFF WEST COAST STATES AND IN THE WESTERN PACIFIC

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. Section 660.370, "Overfished species rebuilding plans" is revised to read as follows:

**§ 660.370 Overfished species rebuilding plans.**

(a) *Canary rockfish*. The target year for rebuilding the canary rockfish stock to  $B_{MSY}$  is 2074. The harvest control rule to be used to rebuild the canary rockfish stock is an annual harvest rate of  $F=0.022$ .

(b) *Darkblotched rockfish*. The target year for rebuilding the darkblotched rockfish stock to  $B_{MSY}$  is 2030. The harvest control rule to be used to rebuild the darkblotched rockfish stock is an annual harvest rate of  $F=0.032$ .

(c) *Lingcod*. The target year for rebuilding the lingcod stock to  $B_{MSY}$  is 2009. The harvest control rule to be used to rebuild the lingcod stock is an annual harvest rate of  $F=0.0531$  in the area north of  $40^{\circ}10' N$ . lat. and  $F=0.061$  for the area south of  $40^{\circ} 10' N$ . lat.

(d) *Pacific ocean perch (POP)*. The target year for rebuilding the POP stock to  $B_{MSY}$  is 2027. The harvest control rule to be used to rebuild the POP stock is an annual harvest rate of  $F=0.0257$ .

[FR Doc. 04-8382 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-22-S

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 031124287-4060-02; I.D. 040604B]

**Fisheries of the Exclusive Economic Zone Off Alaska; Alaska Plaice in the Bering Sea and Aleutian Islands**

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Alaska plaice in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2004 total allowable catch (TAC) of Alaska plaice in the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), April 10, 2004, until 2400 hrs, A.l.t., December 31, 2004.

**FOR FURTHER INFORMATION CONTACT:** Josh Keaton, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2004 TAC specified for Alaska plaice in the BSAI is 9,250 metric tons (mt) as established by the 2004 harvest specifications for groundfish of the BSAI (69 FR 9242, February 27, 2004).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2004 TAC specified for Alaska plaice will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 6,250 mt, and is setting aside the remaining 3,000 mt as bycatch to support other anticipated groundfish

fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Alaska plaice in the BSAI.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent the Agency from responding to the most recent fisheries data in a timely fashion and would delay the closure of Alaska plaice fishery in the BSAI.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: April 7, 2004.

**Alan D. Risenhoover,**  
*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 04-8353 Filed 4-8-04; 4:15 pm]

BILLING CODE 3510-22-S

## Proposed Rules

Federal Register

Vol. 69, No. 71

Tuesday, April 13, 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 71

[Docket No. FAA-2004-17345; Airspace Docket No. 04-ASO-5]

#### Proposed Amendment of Class D and E Airspace; Goldsboro, NC

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend Class D and E5 airspace at Goldsboro, NC. As a result of an evaluation, it has been determined a modification should be made to the Goldsboro, NC Class D and E5 airspace areas to contain the Tactical Air Navigation (TACAN) or Instrument Landing System (ILS) Standard Instrument Approach Procedures (SIAPs) to Seymour Johnson AFB. Additional surface area airspace is needed to contain the SIAPs.

**DATES:** Comments must be received on or before May 13, 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-2004-17345/Airspace Docket No. 04-ASO-5, 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 5 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.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation

Administration, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337.

#### FOR FURTHER INFORMATION CONTACT:

Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5586.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

Interested parties are invited to participate in this proposed 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-2004-17345/Airspace Docket No. 04-ASO-5." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

##### Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Document's Web page at <http://www.access.gpo.gov/nara>. Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic

Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

##### The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend Class D and E5 airspace at Goldsboro, NC. Class D airspace designations for airspace areas extending upward from the surface of the earth and Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraphs 5000 and 6005 respectively, of FAA Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves a established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

##### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

## The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

*Paragraph 5000 Class D Airspace.*

\* \* \* \* \*

#### ASO NC D Goldsboro, NC [REVISED]

Goldsboro, Seymour Johnson AFB, NC  
(Lat. 35°20'22" N., long. 77°57'38" W.)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 5.7-mile radius of Seymour Johnson AFB.

\* \* \* \* \*

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

#### ASO NC E5 Goldsboro, NC [REVISED]

Goldsboro, Seymour Johnson AFB, NC  
(Lat. 35°20'22" N., long. 77°57'38" W.)  
Seymour Johnson TACAN (Lat. 35°20'06" N., long. 77°58'18" W.)

Goldsboro-Wayne Municipal Airport  
(Lat. 35°27'38" N., long. 77°57'54" W.)

Mount Olive Municipal Airport  
(Lat. 35°13'20" N., long. 78°02'16" W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Seymour Johnson AFB and within 2.5 miles each side of the Seymour Johnson TACAN 265° radial extending from the 6.6-mile radius to 12 miles west of the TACAN; within a 5-mile radius of the Goldsboro-Wayne Municipal Airport and within a 5-mile radius of Mount Olive Municipal Airport.

\* \* \* \* \*

Issued in College Park, Georgia, March 24, 2004.

**Jeffrey U. Vincent,**  
*Acting Manager, Air Traffic Division,  
Southern Region.*

[FR Doc. 04–8358 Filed 4–12–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA–2004–17296; Airspace Docket No. 04–AEA–03]

#### Proposed Amendment to Class E Airspace; Lynchburg, VA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to amend the Class E airspace area at Lynchburg, VA. The development of a standard Instrument Approach Procedure (SIAP) based on area navigation (RNAV) to serve flights into Falwell Airport, Lynchburg, VA under Instrument Flight Rules (IFR) has made this proposal necessary. Controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain aircraft executing the approach. The area would be depicted on aeronautical charts for pilot reference.

**DATES:** Comments must be received on or before May 13, 2004.

**ADDRESSES:** Send comments on the 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–2004–17296; Airspace Docket No. 04–AEA–03 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 5 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.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809.

**FOR FURTHER INFORMATION CONTACT:** Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809, telephone: (718) 553–4521.

**SUPPLEMENTARY INFORMATION:**

## Comments Invited

Interested parties are invited to participate in this proposed 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, 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–2004–17296; Airspace Docket No. 04–AEA–03." The postcard will be date/time stamped and returned to the commenter.

## Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Documents Web page at <http://www.access.gpo.gov/nara>.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

## The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at Lynchburg, VA. The development of a SIAP to serve flights operating IFR into Falwell Airport make this action necessary. Controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs. Class E airspace designations for airspace areas extending upward from

700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

#### PART 71—[AMENDED]

1. The authority citation for 14 CFR 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 7400.9L, dated September 2, 2003, and effective September 16, 2003, is proposed to be amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

#### AEA VA E5 Lynchburg, VA (Revised)

Lynchburg Regional-Preston Glenn Field,  
Lynchburg, VA  
(lat. 37°19'36" N., long. 79°12'02" W.)  
Falwell Airport, Lynchburg, VA  
(lat. 37°22'41" N., long. 79°07'20" W.)  
Lynchburg VORTAC  
(lat. 37°15'17" N., long. 79°14'11" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Lynchburg Regional-Preston Glenn Field and within 2.7 miles each side of the Lynchburg VORTAC 200° radial extending from the 6.5-mile radius to 7.4 miles south of the VORTAC and within 3.1 miles each side of the Lynchburg VORTAC 022° radial extending from the 6.5-mile radius to 21.3 miles northeast of the VORTAC and within a 6-mile radius of Falwell Airport.

\* \* \* \* \*

Issued in Jamaica, New York, on April 5, 2004.

**John G. McCartney,**

*Assistant Manager, Air Traffic Division,  
Eastern Region.*

[FR Doc. 04–8362 Filed 4–12–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Parts 1917 and 1918

[Docket No. S–025A]

RIN 1218–AA56

#### Longshoring and Marine Terminals; Vertical Tandem Lifts

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Proposed rule; notice of hearing.

**SUMMARY:** OSHA is convening an informal public hearing to receive testimony and documentary evidence on Vertical Tandem Lifts.

**DATES:** *Informal public hearing.* The Agency will hold the informal public hearing in Washington, DC beginning July 29, 2004. The hearing will commence at 10 a.m. on the first day, and at 9 a.m. on the second and subsequent days, which will be scheduled, if necessary.

Notice of Intention to Appear to provide testimony at the informal public hearing. Parties who intend to present testimony at the informal public hearing must notify OSHA in writing of their intention to do so no later than May 13, 2004.

*Hearing testimony and documentary evidence.* Parties who are requesting 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 June 14, 2004.

**ADDRESSES:** *Informal public hearing.* The informal public hearing will be held in the Auditorium on the plaza

level of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

*Notice of Intention to Appear at the hearing.* Notices of Intention to Appear at the informal public hearing should be submitted in triplicate (3 copies) to the Docket Office, Docket No. S–025A, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. These notices also may be faxed to the Docket Office at (202) 693–1648, or submitted electronically 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.* Testimony and documentary evidence must be submitted in triplicate (3 copies) to the Docket Office at the above address. Testimony and documentary evidence totaling 10 or fewer pages may be faxed to the Docket Office at (202) 693–1648. Materials such as studies or journal articles may not be attached to faxed testimony or documentary evidence; instead, three copies of this material must be mailed to the Docket Office at the above address. Such material must identify clearly the name of the individual who is testifying, date, docket number, and subject so that OSHA can attach it to the appropriate faxed documents.

**FOR FURTHER INFORMATION CONTACT:** For general information and press inquiries, contact Ms. Layne Lathram, 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 Mr. Paul Rossi, Office of Maritime, Room N–3609, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone: (202) 693–2086; fax: (202) 693–1663). For hearing information, contact Ms. Veneta Chatmon, Office of Communications, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone: (202) 693–1999). For additional copies of this **Federal Register** notice, contact the Office of Publications, Room N–3103, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 (telephone: (202) 693–1888). Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's homepage at <http://www.osha.gov>.

**SUPPLEMENTARY INFORMATION:** OSHA published a proposed standard for Longshoring and Marine Terminals;



Vertical Tandem Lifts, in the **Federal Register** on September 16, 2003 (68 FR 54297). On December 10, 2003 (68 FR 68804), OSHA published a notice providing an additional sixty (60) days for the submission of comments and hearing requests, extending the comment period to February 13, 2004. During the comment period, OSHA received two requests for a public hearing (Exs. 40-13 and 43-1). OSHA is granting these requests. The Agency is placing the Notices of Intention to Appear, hearing testimony, and documentary evidence in the rulemaking docket, which will be available for inspection and copying at the OSHA Docket Office.

#### **Public Participation—Comments and Hearings**

OSHA encourages members of the public to participate in this rulemaking by providing oral testimony and documentary evidence at the informal public hearing. Accordingly, the Agency invites interested parties having knowledge of, or experience with, the issues raised in the Notice of Proposed Rulemaking (NPRM) to participate in this process, and welcomes any pertinent data that will provide the Agency with the best available evidence to use in developing the final rule. This section describes the procedures the public must use to schedule an opportunity to deliver oral testimony and to provide documentary evidence at the informal public hearing.

**Hearing arrangements.** Pursuant to section 6(b)(3) of the Occupational Safety and Health Act ("the Act"; 29 U.S.C. 655), members of the public must have an opportunity at the informal public hearing to provide oral testimony concerning the issues raised in the NPRM. An administrative law judge will preside over the hearing, and will resolve any procedural matters relating to the hearing on the first day.

**Purpose of the hearing.** The legislative history of Section 6 of the Act, as well as the Agency's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of the hearing is a judge and questions by interested parties are allowed on pertinent issues, the hearing is informal and legislative in purpose. Therefore, the hearing provides interested parties with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints that could impede or protract the rulemaking process. The hearing is not an adjudicative proceeding subject to the technical rules of evidence; instead, it is

an informal administrative proceeding convened for the purpose of gathering and clarifying information. The regulations that govern the hearing, and the pre-hearing guidelines issued for the hearing, will ensure that participants are treated fairly and have due process; this approach 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, procedures, and participation will be decided in favor of developing a complete record.

**Conduct of the hearing.** 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 judge who presides over the hearing makes no decision or recommendation on the merits of the NPRM or the final rule, the judge has the responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested parties receive a full and fair informal hearing, the judge has the authority and power to: Regulate the course of the proceedings; dispose of procedural requests, objections, and similar 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 questions. At the close of the hearing, the judge 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, and 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 hearings.** Hearing participants must file a Notice of Intention to Appear that provides the following information: The name, address, and telephone number of each individual who will provide testimony; the capacity (e.g., name of the establishment/organization the individual is representing; the individual's occupational title and position) in which the individual will testify; approximate amount of time requested for the individual's testimony; specific issues the individual will address, including a brief description 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.

OSHA emphasizes that, while the hearing is open to the public and interested parties are welcome to attend, only a party who files a proper Notice of Intention to Appear may ask questions and participate fully in the hearing. A party who did not file a Notice of Intention to Appear may be allowed to testify at the hearing if time permits, but this determination is at the discretion of the presiding judge.

**Hearing testimony and documentary evidence.** The Agency will review each submission and determine if the information it contains warrants the amount of time requested. OSHA then will allocate an appropriate amount of time to each presentation, and will notify the participants of the time allotted to their presentations. Prior to the hearing, the Agency will notify the participant if the allotted time is less than the requested time, and will provide the reasons for this action. OSHA may limit to 10 minutes the presentation of any participant who fails to comply substantially with these procedural requirements. The Agency may also request a participant to return for questions 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 judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. This record will consist of all of the written comments, oral testimony, documentary evidence, and other material received during the hearing. Following certification of the record, OSHA will review the proposed provisions in light of all the evidence received as part of the record, and then will issue the final determinations based on the entire record.

#### **Authority**

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, directed the preparation of this document. It is issued under sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Section 41 of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941), Secretary's Order 5-2002 (67 FR 65008), and 29 CFR part 1911.

Signed at Washington, DC on April 6, 2004.

**John L. Henshaw,**

*Assistant Secretary of Labor.*

[FR Doc. 04-8301 Filed 4-12-04; 8:45 am]

BILLING CODE 4510-26-M

## POSTAL SERVICE

### 39 CFR Part 111

#### Packaging Standards and General Mailability

**AGENCY:** Postal Service.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Postal Service™ is extending the comment period for the proposed rule titled "Packaging Standards and General Mailability" that was published on February 26, 2004, in the *Federal Register* (69 FR 8899-8905).

**DATES:** The comment period is extended through May 13, 2004.

**ADDRESSES:** Mail or deliver written comments to the Manager, Mailing Standards, Attn: Neil Berger, U.S. Postal Service, 1735 N. Lynn Street, Room 3025, Arlington, VA 22209-6038. Written comments may also be submitted via facsimile transmission to (703) 292-4058. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the Postal Service Headquarters Library, 475 L'Enfant Plaza, SW., 11th Floor North, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Neil Berger at (703) 292-3645, Mailing Standards, United States Postal Service.

**SUPPLEMENTARY INFORMATION:** On February 26, 2004, the Postal Service published a proposed rule containing minor changes and editorial reorganization to the *Domestic Mail Manual* (DMM™) in order to clarify and standardize packaging and closing requirements, types of acceptable mailing containers, and mailing requirements for certain articles processed on Postal Service sorting equipment.

This proposed rule would also update terminology and reorganize current standards for better reference and presentation. This proposed rule does not affect any of the current standards for the preparation of presort

destination packages of mailpieces prepared under DMM M020.

**Neva R. Watson,**

*Attorney, Legislative.*

[FR Doc. 04-8255 Filed 4-12-04; 8:45 am]

BILLING CODE 7710-12-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[FRL-7646-9]

#### National Priorities List for Uncontrolled Hazardous Waste Sites, Proposed Rule No. 40; Correction

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Environmental Protection Agency ("EPA" or "the Agency") published a proposed rule in the *Federal Register* of March 8, 2004 (69 FR 10646), proposing 11 sites to the National Priorities List (NPL). This document corrects the name of one of the sites.

**FOR FURTHER INFORMATION CONTACT:** Yolanda Singer, phone (703) 603-8835, State, Tribal and Site Identification Branch, Assessment and Remediation Division, Office of Superfund Remediation and Technology Innovation (Mail Code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW., Washington, DC 20460.

#### Correction

In the *Federal Register* of March 8, 2004, on page 10652, in Table 1, under the site name column, "Devil's Swamp—Ewell Property" is corrected to read "Devil's Swamp Lake."

Dated: April 7, 2004.

**Marianne Lamont Horinko,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

[FR Doc. 04-8315 Filed 4-12-04; 8:45 am]

BILLING CODE 6560-50-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[DA 04-765, MB Docket No. 04-78, RM-10866]

#### Digital Television Broadcast Service; Ponce, PR

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Siete Grande Television, Inc., licensee of station WSTE-TV, requesting the substitution of DTV channel 8c for WSTE's assigned DTV channel 66. DTV Channel 8c can be allotted to Ponce, Puerto Rico, at reference coordinates 18-02-52 N. and 66-39-16 W. with a power of 50, a height above average terrain HAAT of 88 meters.

**DATES:** Comments must be filed on or before May 24, 2004, and reply comments on or before June 8, 2004.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceeding involving petitions for rule making (except in broadcast allotment proceedings). See *Electronic Filing of Documents in Rule Making Proceedings*, GC Docket No. 97-113 (rel. April 6, 1998). Filings by paper can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. The Commission's contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Stuart A. Shorestein, Wolf, Block, Schorr & Solis-Cohen LLP, 250 Park Avenue, New York, New York 10177 (Counsel for Siete Grande Television, Inc.).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418-1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 04-78, adopted March 23, 2004, and released April 2, 2004. The full text of this document is available for public

inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 202-863-2893, facsimile 202-863-2898, or via e-mail [qualexint@aol.com](mailto:qualexint@aol.com).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

#### List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

#### PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

##### § 73.622 [Amended]

2. Section 73.622(b), the Table of Digital Television Allotments under Puerto Rico is amended by removing DTV channel 66 and adding DTV channel 8c at Ponce.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 04-8331 Filed 4-12-04; 8:45 am]

BILLING CODE 6712-01-P

#### FEDERAL COMMUNICATIONS COMMISSION

##### 47 CFR Part 73

[DA 04-781, MB Docket No. 02-126, RM-10448]

#### Radio Broadcasting Services; Wynnewood, OK

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule, dismissal.

**SUMMARY:** This document dismisses a pending petition for rulemaking to add an FM allotment in Wynnewood, Oklahoma. The Commission had requested comment on a petition filed by David Garland, proposing the allotment of Channel 266A at Wynnewood, Oklahoma. *Wynnewood, Oklahoma*, 17 FCC Rcd 9557 (MB 2002). The petitioner filed comments in support of the proposal. In addition, a counterproposal was filed by DFWU, Inc., proposing the alternative allotment of Channel 265A at Konawa, Oklahoma. Both the original proposal in this proceeding and the counterproposal were determined to be in conflict with, and outside the comment period for, proposals under consideration in MM Docket No. 01-180. *Holdenville, Oklahoma*, 16 FCC Rcd 14,912 (MM 2001). This document therefore dismisses the petition and counterproposal in this proceeding and terminates the proceeding.

**FOR FURTHER INFORMATION CONTACT:** Deborah A. Dupont, Media Bureau (202) 418-7072.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02-126, adopted March 24, 2004, and released March 26, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893.

The Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 04-8332 Filed 4-12-04; 8:45 am]

BILLING CODE 6712-01-P

#### DEPARTMENT OF THE INTERIOR

##### Fish and Wildlife Service

##### 50 CFR Part 17

RIN 1018-AT44

#### Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Santa Barbara County Distinct Population Segment of the California Tiger Salamander

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; reopening of comment period and public hearing announcement.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service) give notice of reopening the public comment period and scheduling one public hearing on the proposed critical habitat designation for the Santa Barbara County Distinct Vertebrate Population Segment (DPS) of the California tiger salamander (*Ambystoma californiense*).

**DATES:** The comment period for this proposal now closes on May 28, 2004. Any comments received by the closing date will be considered in the final decision on this proposal. One public hearing will be held on May 11, 2004, in Santa Maria from 1 p.m. to 3 p.m., and from 6 p.m. to 8 p.m.

**ADDRESSES:** The public hearing in Santa Maria will be held at the Radisson Hotel, 3455 Skyway Drive, Santa Maria CA 93455.

Written comments and materials may be submitted to us by any one of the following methods:

1. You may submit written comments and information to the Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003, or by facsimile 805/644-3958.

2. You may hand-deliver written comments to our Ventura Office, at the address given above.

3. You may send comments by electronic mail (e-mail) to [fw1CTSCH@r1.fws.gov](mailto:fw1CTSCH@r1.fws.gov).

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the Ventura Fish and Wildlife Office, at address given above (telephone 805/644-1766).

**FOR FURTHER INFORMATION CONTACT:** Carl Benz, at the above address (telephone 805/644-1766; facsimile 805/644-3958).

**SUPPLEMENTARY INFORMATION:**

**Public Comments Solicited**

We will accept written comments and information during this reopened comment period. We solicit comments on the original proposed critical habitat designation (January 22, 2004, 69 FR 3064). Of particular interest to us are comments on the criteria used to identify critical habitat, the special management considerations, and additional suggestions regarding the primary constituent elements identified for the California tiger salamander in this proposed rule. Please feel free to suggest other sources of information relevant to this species of which you may be aware.

An analysis of the economic impacts of proposing critical habitat for the California tiger salamander is being prepared. We will announce the availability of the draft economic analysis as soon as it is completed, at which time we will seek public review and comment. At that time, copies of the draft economic analysis will be available for downloading from the Internet at <http://ventura.fws.gov>, or by contacting the Ventura Fish and Wildlife Office directly (see **ADDRESSES** section).

Please submit electronic comments in an ASCII file format and avoid the use of special characters and encryption. Please also include "ttn: RIN 1018-AT44" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, please contact the Ventura Fish and Wildlife Office (see **ADDRESSES** section and **FOR FURTHER INFORMATION CONTACT**). In the event that our internet connection is not functional, please submit your comments by the alternate methods mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this prominently at the beginning of your comments. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of

organizations or businesses, available for public inspection in their entirety.

**Background**

On January 22, 2004, we published in the **Federal Register** a proposed critical habitat rule for the Santa Barbara DPS of California tiger salamander listed under the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*). Six critical habitat units, totaling approximately 13,920 acres (5,633 hectares), are proposed for designation for the Santa Barbara County DPS of California tiger salamander. The proposed critical habitat is located in Santa Barbara County, CA. For locations of these proposed units, please consult the proposed rule (69 FR 3064).

The comment period for the proposed critical habitat designation originally closed on March 22, 2004. We are now announcing one public hearing and are reopening the comment period to allow all interested parties to submit oral or written comments on the proposal. We are seeking comments or suggestions from the public, other concerned agencies, the scientific community, industry, or any other interested parties concerning the proposed rule. Comments already submitted on the proposed rule need not be resubmitted as they will be fully considered in the final determination.

Section 4(b)(5)(E) of the Act requires that a public hearing be held if it is requested within 45 days of the publication of a proposed rule. We received numerous requests for an extension of the comment period and for a public hearing. In response to these requests, we are reopening the public comment period and holding a public hearing on the date and at the address described in the **DATES** and **ADDRESSES** section.

Anyone wishing to make an oral statement for the record is encouraged to provide a written copy of their statement and present it to us at the hearing. In the event there is a large attendance, the time allotted for oral statements may be limited. Oral and written statements receive equal consideration. There are no limits to the length of written comments presented at the hearing or mailed to us.

Persons needing reasonable accommodations in order to attend and participate in the public hearing should contact Patti Carroll, Region 1, at 503/231-2080 as soon as possible. In order to allow sufficient time to process requests, please call no later than 1 week before the hearing date.

Information regarding this proposal is available in alternative formats upon request.

**Author**

The primary author of this notice is Katie Drexhage (see **ADDRESSES** section).

**Authority:** The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: April 5, 2004.

**Craig Manson,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 04-8328 Filed 4-12-04; 8:45 am]

BILLING CODE 4310-55-U

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 229**

[Docket No. 040407106-4106-01, I.D. 040104A]

RIN 0648-AS04

**List of Fisheries for 2004**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Proposed rule.

**SUMMARY:** The National Marine Fisheries Service (NMFS) is publishing the proposed List of Fisheries (LOF) for 2004, as required by the Marine Mammal Protection Act (MMPA). The proposed LOF for 2004 reflects new information on interactions between commercial fisheries and marine mammals. NMFS must categorize each commercial fishery on the LOF into one of three categories under the MMPA based upon the level of serious injury and mortality of marine mammals that occurs incidental to each fishery. The categorization of a fishery in the LOF determines whether participants in that fishery are subject to certain provisions of the MMPA, such as registration, observer coverage, and take reduction plan requirements.

**DATES:** Comments must be received by May 13, 2004.

**ADDRESSES:** Send comments to Chief, Marine Mammal Conservation Division, Attn: List of Fisheries, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Comments may also be sent via email to [2004LOF.comments@noaa.gov](mailto:2004LOF.comments@noaa.gov) or to the Federal eRulemaking portal: <http://www.regulations.gov> (follow instructions for submitting comments).



Comments regarding the burden-hour estimates, or any other aspect of the collection of information requirements contained in this proposed rule, should be submitted in writing to the Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910 and to David Rostker, OMB, by e-mail at [David\\_Rostker@omb.eop.gov](mailto:David_Rostker@omb.eop.gov) or by fax to 202-395-7285.

See **SUPPLEMENTARY INFORMATION** for information on how to obtain registration information, materials, and marine mammal reporting forms.

**FOR FURTHER INFORMATION CONTACT:**

Kristy Long, Office of Protected Resources, 301-713-1401; Kim Thounhurst, Northeast Region, 978-281-9328; Juan Levesque, Southeast Region, 727-570-5312; Cathy Campbell, Southwest Region, 562-980-4060; Brent Norberg, Northwest Region, 206-526-6733; Bridget Mansfield, Alaska Region, 907-586-7642. Individuals who use a telecommunications device for the hearing impaired may call the Federal Information Relay Service at 1-800-877-8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

**SUPPLEMENTARY INFORMATION:**

Registration information, materials, and marine mammal reporting forms may be obtained from the following regional offices:

NMFS, Northeast Region, One Blackburn Drive, Gloucester, MA 01930-2298, Attn: Marcia Hobbs;

NMFS, Southeast Region, 9721 Executive Center Drive North, St. Petersburg, FL 33702, Attn: Teletha Griffin;

NMFS, Southwest Region, Protected Species Management Division, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213, Attn: Don Peterson;

NMFS, Northwest Region, 7600 Sand Point Way NE, Seattle, WA 98115, Attn: Permits Office; or

NMFS, Alaska Region, Protected Resources, P.O. Box 22668, 709 West 9th Street, Juneau, AK 99802.

**What is the List of Fisheries?**

Section 118 of the MMPA requires that NMFS place all U.S. commercial fisheries into one of three categories based on the level of incidental serious injury and mortality of marine mammals that occurs in each fishery (16 U.S.C. 1387 (c)(1)). The categorization of a fishery in the LOF determines whether participants in that fishery may be required to comply with certain provisions of the MMPA, such as registration, observer coverage, and take

reduction plan requirements. NMFS must reexamine the LOF annually, considering new information in the Stock Assessment Reports, other relevant sources, and the LOF, and publish in the **Federal Register** any necessary changes to the LOF after notice and opportunity for public comment (16 U.S.C. 1387 (c)(3)).

**How Does NMFS Determine in which Category a Fishery is Placed?**

The definitions for the fishery classification criteria can be found in the implementing regulations for section 118 of the MMPA (50 CFR 229.2). The criteria are also summarized here.

*Fishery Classification Criteria*

The fishery classification criteria consist of a two-tiered, stock-specific approach that first addresses the total impact of all fisheries on each marine mammal stock, and then addresses the impact of individual fisheries on each stock. This approach is based on consideration of the rate, in numbers of animals per year, of incidental mortalities and serious injuries of marine mammals due to commercial fishing operations relative to the Potential Biological Removal (PBR) level for each marine mammal stock. The MMPA (16 U.S.C. 1362 (20)) defines the PBR level as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population. This definition can also be found in the implementing regulations for section 118 at 50 CFR 229.2

*Tier 1:* If the total annual mortality and serious injury across all fisheries that interact with a stock is less than or equal to 10 percent of the PBR level of the stock, all fisheries interacting with the stock would be placed in Category III. Otherwise, these fisheries are subject to the next tier (Tier 2) of analysis to determine their classification.

*Tier 2, Category I:* Annual mortality and serious injury of a stock in a given fishery is greater than or equal to 50 percent of the PBR level.

*Tier 2, Category II:* Annual mortality and serious injury of a stock in a given fishery is greater than 1 percent and less than 50 percent of the PBR level.

*Tier 2, Category III:* Annual mortality and serious injury of a stock in a given fishery is less than or equal to 1 percent of the PBR level.

While Tier 1 considers the cumulative fishery mortality and serious injury for a particular stock, Tier 2 considers fishery-specific mortality and serious injury for a particular stock. Additional

details regarding how the categories were determined are provided in the preamble to the final rule implementing section 118 of the MMPA (60 FR 45086, August 30, 1995).

Since fisheries are categorized on a per-stock basis, a fishery may qualify as one Category for one marine mammal stock and another Category for a different marine mammal stock. A fishery is typically categorized on the LOF at its highest level of classification (e.g., a fishery that qualifies for Category III for one marine mammal stock and for Category II for another marine mammal stock will be listed under Category II).

**Other Criteria That May Be Considered**

In the absence of reliable information indicating the frequency of incidental mortality and serious injury of marine mammals by a commercial fishery, NMFS will determine whether the incidental serious injury or mortality qualifies for Category II by evaluating other factors such as fishing techniques, gear used, methods used to deter marine mammals, target species, seasons and areas fished, qualitative data from logbooks or fisher reports, stranding data, and the species and distribution of marine mammals in the area, or at the discretion of the Assistant Administrator for Fisheries (50 CFR 229.2).

**How Do I Find Out if a Specific Fishery is in Category I, II, or III?**

This proposed rule includes two tables that list all U.S. commercial fisheries by LOF Category. Table 1 lists all of the fisheries in the Pacific Ocean (including Alaska). Table 2 lists all of the fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean.

**Am I Required to Register Under the MMPA?**

Owners of vessels or gear engaging in a Category I or II fishery are required under the MMPA (16 U.S.C. 1387(c)(2)), as described in 50 CFR 229.4, to register with NMFS and obtain a marine mammal authorization from NMFS in order to lawfully incidentally take a marine mammal in a commercial fishery. Owners of vessels or gear engaged in a Category III fishery are not required to register with NMFS or obtain a marine mammal authorization.

**How Do I Register?**

Fishers must register with the Marine Mammal Authorization Program (MMAP) by contacting the relevant NMFS Regional Office (see **ADDRESSES**) unless they participate in a fishery that has an integrated registration program (described below). Upon receipt of a



completed registration, NMFS will issue vessel or gear owners physical evidence of a current and valid registration that must be displayed or in the possession of the master of each vessel while fishing in accordance with section 118 of the MMPA (16 U.S.C. 1387(c)(3)(A)).

#### What is the Process for Registering in an Integrated Fishery?

For some fisheries, NMFS has integrated the MMPA registration process with existing state and Federal fishery license, registration, or permit systems and related programs. Participants in these fisheries are automatically registered under the MMPA and are not required to submit registration or renewal materials or pay the \$25 registration fee. Following is a list of integrated fisheries and a summary of the integration process for each Region. Fishers who operate in an integrated fishery and have not received registration materials should contact their NMFS Regional Office listed in the first paragraph of **SUPPLEMENTARY INFORMATION**.

#### Which Fisheries Have Integrated Registration Programs?

The following fisheries have integrated registration programs under the MMPA:

1. All Alaska Category II fisheries;
2. All Washington and Oregon Category II fisheries;
3. Northeast Regional fisheries for which a state or Federal permit is required. Individuals fishing in fisheries for which no state or Federal permit is required must register with NMFS by contacting the Northeast Regional Office (see **ADDRESSES**); and
4. All North Carolina, South Carolina, Georgia, and Florida Category I and II fisheries for which a state permit is required.

#### How Do I Renew My Registration Under the MMPA?

Regional Offices, except for the Northeast Region, annually send renewal packets to participants in Category I or II fisheries that have previously registered; however, it is the responsibility of the fisher to ensure that registration or renewal forms are completed and submitted to NMFS at least 30 days in advance of fishing. Individuals who have not received a renewal packet by January 1 or are registering for the first time should request a registration form from the appropriate Regional Office (see **ADDRESSES**).

#### Am I Required to Submit Reports When I Injure or Kill a Marine Mammal During the Course of Commercial Fishing Operations?

In accordance with the MMPA (16 U.S.C. 1387(e)) and 50 CFR 229.6, any vessel owner or operator, or fisher (in the case of non-vessel fisheries), participating in a Category I, II, or III fishery must report all incidental injuries or mortalities of marine mammals that occur during commercial fishing operations to NMFS. "Injury" is defined in 50 CFR 229.2 as a wound or other physical harm. In addition, any animal that ingests fishing gear or any animal that is released with fishing gear entangling, trailing, or perforating any part of the body is considered injured, regardless of the absence of any wound or other evidence of an injury, and must be reported. Instructions on how to submit reports can be found in 50 CFR 229.6.

#### Am I Required to Take an Observer Aboard My Vessel?

Fishers participating in a Category I or II fishery are required to accommodate an observer aboard vessel(s) upon request. Observer requirements can be found in 50 CFR 229.7.

#### Am I Required to Comply With Any Take Reduction Plan Regulations?

Fishers participating in a Category I or II fishery are required to comply with any applicable take reduction plans.

#### Sources of Information Reviewed for the Proposed 2004 LOF

NMFS reviewed the marine mammal incidental serious injury and mortality information presented in the Stock Assessment Reports (SARs) for all observed fisheries to determine whether changes in fishery classification were warranted. NMFS SARs are based on the best scientific information available at the time of preparation for the information presented in the SARs, including the level of serious injury and mortality of marine mammals that occurs incidental to commercial fisheries and the potential biological removal (PBR) levels of marine mammal stocks. NMFS also reviewed other sources of new information, including marine mammal stranding data, observer program data, fisher self-reports, and other information that is not included in the SARs. NMFS also took into account the discretion of the Assistant Administrator for Fisheries in developing the 2004 proposed LOF.

The information contained in the SARs is reviewed by regional scientific review groups (SRGs) representing Alaska, the Pacific (including Hawaii),

and the U.S. Atlantic, Gulf of Mexico, and the Caribbean. The SRGs were created by the MMPA to review the science that goes into the stock assessment reports, and to advise NMFS on population status and trends, stock structure, uncertainties in the science, research needs, and other issues.

The proposed LOF for 2004 was based, among other things, on information provided in the final SARs for 1996 (63 FR 60, January 2, 1998), the final SARs for 2001 (67 FR 10671, March 8, 2002), the final SARs for 2002 (68 FR 17920, April 14, 2003), and the draft SARs for 2003 (68 FR 51561, August 27, 2003).

#### Summary of Changes to the Proposed LOF for 2004

The following summarizes changes in fishery classification including fisheries listed on the LOF, the number of participants in a particular fishery, and the species and/or stocks that are incidentally killed or seriously injured in a particular fishery, that are proposed for the 2004 LOF. The placement and definitions of U.S. commercial fisheries proposed for 2004 are identical to those provided in the LOF for 2003 with the following exceptions.

#### Commercial Fisheries in the Pacific Ocean: Fishery Classification

*Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/ Set Line Fishery*

NMFS proposes to reclassify the Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/ Set Line Fishery (Hawaii longline fishery) as Category I under the MMPA primarily because of the level of incidental mortality and serious injury that occurs between this fishery and the Hawaiian stock of false killer whales (*Pseudorca crassidens*). However, NMFS also has information regarding incidental mortality and serious injury that occurs between this fishery and the Hawaiian stock of Risso's dolphins (*Grampus griseus*), Hawaiian stock of bottlenose dolphins (*Tursiops truncatus*), Hawaiian stock of spinner dolphins (*Stenella longirostris*), Hawaiian stock of pantropical spotted dolphins (*Stenella attenuata*), Hawaiian stock of short-finned pilot whales (*Globicephala macrorhynchus*), Hawaiian stock of Blainville's beaked whales (*Mesoplodon densirostris*), Hawaiian stock of sperm whales (*Physeter macrocephalus*) and the Central North Pacific stock of humpback whales (*Megaptera novaeangliae*).

In 2002, NMFS surveyed cetacean abundance, including the Hawaiian

stock of false killer whales, in waters where the Hawaii longline fishery operated, a survey that would allow for a better estimate of abundance and a more reliable PBR level and better estimates of mortality and serious injury in marine mammal stocks taken by this fishery. This survey addressed the limitations of the earlier survey data, discussed in the 2001 and 2003 LOFs (66 FR 42780, August 15, 2001; 68 FR 41725, July 15, 2003) and the need for these data was emphasized in the 2001 LOF. The 2002 Pacific and Alaska SARs provided data about these stocks of marine mammals and calculated a rate of interaction between the Hawaii longline fishery and each stock based on observer data. As a result, false killer whales (Hawaiian stock) were determined to be a strategic stock in 2002. However, the surveys were not completed prior to the 2002 LOF and these data were not completely analyzed prior to the completion of the 2003 LOF. Further, the abundance estimate on which the PBR was based was considered an underestimate because it was based on 1993–98 aerial surveys conducted only within approximately 25 nautical miles of the main Hawaiian Islands, not throughout the entire range of the false killer whale stock. For these reasons, NMFS left in place the fishery's classification as a Category III fishery in 2002 and 2003 based on the limitations of available information, and the need to review other relevant sources in 2004.

#### Information Available for the 2004 LOF That was Not Available for the 2003 LOF

**Abundance information:** The results of the 2002 surveys in the Hawaiian EEZ are now available (Barlow, 2003. Cetacean Abundance in Hawaiian Waters during Summer/Fall of 2002, referenced as PSRG-7), and these have been combined with the earlier aerial surveys within 25 nmi of the main Hawaiian Islands (Mobley *et al.* 2000) to produce an estimate of the abundance of false killer whales in the Hawaiian EEZ. The methods used in the surveys followed standard survey techniques and are described in the scientific papers cited above. The method for combining the results of the two surveys followed standard statistical procedures. The 2002 survey of the entire Hawaiian Islands Exclusive Economic Zone (EEZ) resulted in an abundance estimate for false killer whales (Hawaiian stock) of 268 individuals (based on the lower 85-percent confidence interval), a slight increase from the previous estimate.

**Mortality information:** The results of an expanded observer program in the Hawaiian longline fishery are now

available (Forney 2003. Estimates of Cetacean Mortality and Injury in the Hawaii Based Longline Fishery, 1994–2002. 11/4/2003). These mortality and serious injury estimates were based upon a long-term data set, with expanded observer coverage between 2000 and 2002 primarily in tuna-style fishing. These data allowed an evaluation of the suggestion that tuna-style fishing resulted in little to no (remote likelihood) injury or mortality of marine mammals. Since 1998, only one false killer whale has been observed killed in the Hawaiian EEZ.

As a result of these data, updated abundance and mortality estimates have been included in the 2004 draft stock assessment report for the Hawaiian stock of false killer whales (False Killer Whale (*Pseudorca crassidens*): Hawaiian stock, dated 11/15/2003). This report describes abundance, mortality and status of false killer whales and partitions serious injury and mortality of the stock within and outside the US EEZ. All of the above reports have been subjected to scientific review within NMFS and are the best scientific information available related to abundance and mortality of false killer whales in the area.

**New Management Regime and Effort Reduction for the Fishery:** NMFS approved a regulatory amendment under the Fishery Management Plan for the Pelagic Fisheries of the Western Pacific Region (FMP) submitted by the Western Pacific Fishery Management Council (Council), published a proposed rule on January 28, 2004, and issued a final rule on April 2, 2004 (69 FR 17329) to establish a number of conservation and management measures for the fisheries managed under the FMP in order to provide adequate protections for sea turtles. On February 23, 2004, NMFS concluded consultation and issued a biological opinion under section 7 of the Endangered Species Act on the pelagic fisheries of the western Pacific region as they would be managed under the measures implemented through this final rule. The biological opinion found that the fisheries are not likely to jeopardize the continued existence of any ESA-listed species under the jurisdiction of NMFS.

That final rule reopened the swordfish-directed component of the Hawaii-based longline fishery with annual fleet-wide limits on fishery interactions with leatherback and loggerhead sea turtles, and an annual fleet-wide limit on fishing effort. The final rule also requires that operators of general longline vessels annually complete a protected species workshop

and have on board a valid protected species workshop certificate.

To implement the regulatory amendment proposed by the Council, the final rule: (1) Establishes an annual effort limit on the amount of shallow-set longline fishing effort north of the equator that may be collectively exerted by Hawaii-based longline vessels (2,120 shallow-sets per year) and (2) divides and distributes this shallow-set annual effort limit each calendar year in equal portions to all holders of Hawaii longline-limited access permits. The interaction limits for leatherback and loggerhead sea turtles may also limit, albeit indirectly, interactions with other protected species, such as false killer whales, in the shallow-set component of the Hawaii-based longline fishery. Furthermore, under the ESA, when any of the incidental take limits is exceeded, NMFS reinitiates consultation under section 7 of the ESA, at which point the need for more restrictive measures would be considered. The terms and conditions of the incidental take statement in the 2004 biological opinion also mandate 100-percent observer coverage in the shallow-set component of the Hawaii-based longline fishery and at least 20-percent coverage in the deep-set component. NMFS intends to implement these levels of coverage. Given the relatively long history of the deep-set component and our understanding of patterns of fishing, catches, and interactions with protected species, NMFS has determined 20 percent to be a sufficient level of coverage in the deep-set component of the fishery.

#### Tier Evaluation

**Tier 1 Evaluation:** The Hawaii longline fishery is the only fishery known to interact with the Hawaiian stock of false killer whales. Based on the currently available data, total annual incidental mortality and serious injury across all fisheries (in this case, just the Hawaii longline fishery) is greater than or equal to 10 percent of the PBR level for the Hawaiian stock of false killer whales. Therefore, the Hawaii longline fishery is subject to Tier 2 analysis.

**Tier 2 Evaluation:** Based on extrapolations from the currently available data, total annual mortality and serious injury (4.4 animals) of the Hawaiian stock of false killer whales exceeds 50 percent of the PBR level (PBR=1.2). The continued take of false killer whales and other cetaceans, including endangered humpback and sperm whales, warrant recategorization of the fishery. Therefore, NMFS recommends elevating this fishery to Category I in the 2004 LOF.

### Justification for Category I Classification

A mathematical application of the regulations based on the currently available data indicates that the total annual mortality and serious injury (4.4 animals) of the Hawaiian stock of false killer whales exceeds 50 percent of the PBR level (PBR=1.2). Therefore, NMFS is proposing to reclassify this fishery to a Category I under the MMPA. However, as explained below, NMFS is concerned that such a categorization may not adequately reflect the impact of this fishery on false killer whales. Accordingly, during the public comment period for this proposed rule, the NMFS Pacific Island Region will convene a workshop to evaluate the information used in this proposed categorization. The workshop will consist of NMFS scientists and managers as well as other individuals knowledgeable in marine mammal population assessments and interactions with fishing gear. The workshop will provide guidance on the reliability and adequacy of available information, including information on mortality and serious injury, used in the tier analysis and subsequent categorization decision. NMFS will consider the results of the workshop and public comments received on this proposed rule in its decision to classify this fishery in the final LOF for 2004.

In the case of the Hawaii longline fishery, the classification is affected most by incidental mortality and serious injury of false killer whales. The mortality estimate is considered reliable in recent years because it is based upon a relatively high level of observer coverage in the fishery. The single mortality of a false killer whale in 1998 within the EEZ is the basis for the expanded mortality estimate. The average mortality used in the LOF comparisons to abundance are based on a 5-year average. So if no further mortalities occur in 2004, this single event will no longer be considered in the 5-year average in 2005.

The abundance estimate of 268 animals is currently the best available for this stock and represents a much better estimate for this stock inside the Hawaiian EEZ than estimates in previous years. However, the extent to which the abundance estimate may be lower than the actual abundance of false killer whales is unknown. As a result, the extent to which the PBR of 1.2 may also be considered an underestimate is unknown for this stock of false killer whales. The uncertainty in the abundance and PBR estimates likely overemphasizes the ratio between

mortality and significant injury in this fishery to PBR; therefore, the impact of this fishery on false killer whales may be overemphasized.

As noted above, the interaction limits for sea turtles may also limit, albeit indirectly, interactions with other protected species, including false killer whales, that occur in the shallow-set component of the Hawaii-based longline fishery. The extent to which these measures reduce interactions with marine mammal stocks is not known at this time.

In summary, the abundance (and subsequently, the PBR) of false killer whales in the North Pacific Ocean is currently considered the best available estimate. However, it remains a minimum estimate because the surveys upon which the abundance estimate are based were limited in scope to a portion of the range, the Hawaiian EEZ, of the false killer whale stock. It does indicate that the stock abundance is low within the Hawaiian Island EEZ. Mortality records indicate that false killer whales occupy international waters and the EEZ around Palmyra, areas outside the 2002 survey area. Clearly, the number of false killer whales in the North Pacific Ocean subject to injury and mortality by the longline fishery exceeds the minimum population estimate included in Barlow, 2003 but it is not known by how much it is an underestimate. Such a conclusion can be based simply upon the presence of false killer whales in international waters and in the EEZ surrounding Palmyra that were hooked and killed or seriously injured incidental to the longline fishery.

The proposed reclassification of the Hawaii Longline Fishery to a Category I is warranted based on the current information. However, NMFS intends to address the scientific bases for this conclusion at a workshop which will be held during the public comment period. As previously provided, NMFS will consider the results of this workshop and public comments received on this proposed rule in its decision to classify this fishery in the final LOF for 2004.

### Delineation of Alaska Fisheries

The List of Fisheries has included the Alaska groundfish fisheries as large combinations of fisheries since 1990. In the 2003 final LOF (68 FR 41725, July 15, 2003), NMFS indicated that it would review the existing fishery delineations in the LOF for Federal and state fisheries in Alaska. The decision to review Alaska fisheries was based, in part, on NMFS' recognition that the Bering Sea and Aleutian Islands (BSAI) groundfish trawl fishery is not a homogenous fishery, but rather, a

diverse group of fisheries that target different groundfish species over distinct geographic areas within the Bering Sea and during different seasons. Marine mammal interactions likely vary among BSAI groundfish trawl fisheries, based on gear type, time and area of operations, and target groundfish species.

NMFS also reviewed the Gulf of Alaska (GOA) Groundfish Trawl, Bering Sea and GOA Finfish Pot, AK Crustacean Pot, BSAI Groundfish Longline/Set Line (federally regulated waters, including miscellaneous finfish and sablefish), and GOA Groundfish Longline/Set Line (federally regulated waters, including miscellaneous finfish and sablefish) fisheries. Based on this review, NMFS proposes to delineate these fisheries by target species and gear type.

NMFS seeks to collect and analyze data in a manner that provides information that allows for the most effective management of living marine resources, including marine mammals. Marine mammal interactions vary among Alaska groundfish fisheries, based on time and area of operation, method of gear deployment, and target groundfish species. Therefore, this proposed delineation of fisheries operations is expected to allow for improved resolution of factors affecting incidental mortality and serious injury of marine mammals in these fisheries. The proposed newly delineated fisheries are currently listed within fisheries classified as Category III fisheries on the LOF. NMFS is completing an analysis of past incidental mortality and serious injury for each of the proposed newly delineated fisheries in accordance with the fishery classification criteria set forth in the implementing regulations of section 118 of the MMPA (50 CFR part 229). NMFS proposes these newly delineated fisheries be added to the LOF as Category III fisheries until completion of the analysis of serious injury and mortality for these new fisheries.

### Delineation of AK Bering Sea and Aleutian Islands Groundfish Trawl Fishery

NMFS proposes separating the BSAI groundfish trawl fishery into four fisheries based on target species. These four fisheries are: *AK Bering Sea and Aleutian Islands Atka Mackerel Trawl Fishery*, *AK Bering Sea and Aleutian Islands Flatfish Trawl Fishery*, *AK Bering Sea and Aleutian Islands Pacific Cod Trawl Fishery*, and *AK Bering Sea and Aleutian Islands Pollock Trawl Fishery*. These fisheries operate in generally different geographic areas and

seasons, although some overlap may occur. Where overlap occurs, NMFS is able to differentiate in which fishery a vessel is operating when incidental mortality and serious injury of a marine mammal occurs through a combination of catch data, vessel monitoring systems (VMS) information, and observer data, even when a vessel participates in more than one fishery on a given trip. These fisheries likewise are managed separately by NMFS and the North Pacific Fishery Management Council.

#### **Delineation of GOA Groundfish Trawl Fishery**

NMFS proposes separating the GOA groundfish trawl fishery into four fisheries based on target species. These four fisheries are: *AK Gulf of Alaska Flatfish Trawl Fishery*, *AK Gulf of Alaska Pacific Cod Trawl Fishery*, *AK Gulf of Alaska Pollock Trawl Fishery*, and *AK Gulf of Alaska Rockfish Trawl Fishery*.

#### **Delineation of Bering Sea and GOA Finfish Pot Fishery**

NMFS proposes separating the Bering Sea and GOA finfish pot fishery into four fisheries based on target species. These four fisheries are: *AK Aleutian Islands Sablefish Pot Fishery*, *AK Bering Sea Sablefish Pot Fishery*, *AK Bering Sea and Aleutian Islands Pacific Cod Pot Fishery*, and *AK Gulf of Alaska Pacific Cod Pot Fishery*.

#### **Delineation of Alaska Crustacean Pot Fishery**

NMFS proposes separating the Alaska crustacean pot fishery into four fisheries based on target species. These four fisheries are: *AK Southeast Alaska Shrimp Pot Fishery*, *AK Southeast Alaska Crab Pot Fishery*, *AK Gulf of Alaska Crab Pot Fishery*, and *AK Bering Sea and Aleutian Islands Crab Pot Fishery*.

#### **Delineation of BSAI Groundfish Longline/Set Line Fishery (Federally Regulated Waters, Including Miscellaneous Finfish and Sablefish)**

NMFS proposes separating the BSAI groundfish longline/set line fishery into four fisheries based on target species. These four fisheries are: *AK Bering Sea and Aleutian Islands Greenland Turbot Longline Fishery*, *AK Bering Sea and Aleutian Islands Pacific Cod Longline Fishery*, *AK Bering Sea and Aleutian Islands Rockfish Longline*, and *AK Bering Sea and Aleutian Islands Sablefish Longline Fishery*.

#### **Delineation of GOA Groundfish Longline/Set Line Fishery (Federally Regulated Waters, Including Miscellaneous Finfish and Sablefish)**

NMFS proposes separating the GOA groundfish longline/set line fishery into four fisheries based on target species. These four fisheries are: *AK Gulf of Alaska Sablefish Longline Fishery*, *AK Gulf of Alaska Pacific Cod Longline Fishery*, *AK Gulf of Alaska Flatfish Longline Fishery*, and *AK Gulf of Alaska Rockfish Longline*.

#### **Removal of Fisheries from the LOF**

NMFS proposes removing the *AK Bering Sea and Gulf of Alaska Finfish Pot Fishery*, *AK Crustacean Pot Fishery*, *AK Bering Sea and Aleutian Islands Groundfish Longline/Set Line Fishery (federally regulated waters, including miscellaneous finfish and sablefish)*, *AK Gulf of Alaska Groundfish Longline/Set Line Fishery (federally regulated waters, including miscellaneous finfish and sablefish)*, *AK Bering Sea and Aleutian Islands Groundfish Trawl Fishery*, and *AK Gulf of Alaska Groundfish Trawl Fishery* from the LOF. After reviewing these fisheries, NMFS is proposing to differentiate each fishery by target species and gear type, which more accurately reflect existing fishery management regimes in Alaska. Therefore, removing these fisheries will not negatively affect NMFS' ability to analyze and assess serious injury and mortality of marine mammals captured incidental to these fisheries. A description of the proposed delineation of these fisheries can be found above in the Fishery Classification section for the Pacific Ocean.

#### **Number of Vessels/Persons**

The estimated number of participants in the "OR Swordfish Floating Longline Fishery" is updated to 1 based on 2003 permit data.

The estimated number of participants in the "WA Puget Sound Region Salmon Drift Gillnet Fishery" is updated to 210 based on 2003 permit data.

#### **Commercial Fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean: Fishery Classification**

##### *Gulf of Mexico Blue Crab Trap/Pot Fishery*

In the 2003 LOF (68 FR 41725, July 15, 2003), NMFS provided that it would work with the Gulf States Marine Fisheries Commission (GSMFC) and the Sea Grant program to better monitor bottlenose dolphin takes in the "Gulf of Mexico Blue Crab Trap/Pot Fishery," to educate fishers about marine mammal interaction issues and ways to reduce

takes in the fishery, and to continue working on the derelict trap/pot removal program. The NMFS Southeast Regional Office has been working closely with the GSMFC and Sea Grant to develop outreach materials throughout the past year and anticipates distributing these materials in the near future. NMFS will continue to monitor strandings and communicate with fishers to determine the effectiveness of outreach efforts.

NMFS has been unable to conduct abundance surveys or analyze Gulf bottlenose dolphin stock structure due to budgetary constraints. Therefore, the bottlenose dolphin stock structure in the Gulf of Mexico is still not well defined at this time. Currently, the vast majority of NMFS' resources for bottlenose dolphin research is being expended in the Atlantic Ocean to satisfy needs of the Atlantic Bottlenose Dolphin Take Reduction Team. As the needs of this existing TRT are met, NMFS hopes to shift resources to the Gulf of Mexico to better define bottlenose dolphin stock structure in this area. NMFS will reevaluate classification of this fishery as relevant information becomes available. However, NMFS does not propose any change to the classification of this fishery because NMFS lacks adequate information at this time.

#### **List of Fisheries**

The following two tables list U.S. commercial fisheries according to their assigned categories under section 118 of the MMPA. The estimated number of vessels/participants is expressed in terms of the number of active participants in the fishery, when possible. If this information is not available, the estimated number of vessels or persons licensed for a particular fishery is provided. If no recent information is available on the number of participants in a fishery, the number from the most recent LOF is used.

The tables also list the marine mammal species and stocks that are incidentally killed or injured in each fishery based on observer data, logbook data, stranding reports, and fisher reports. This list includes all species or stocks known to experience injury or mortality in a given fishery, but also includes species or stocks for which there are anecdotal or historical, but not necessarily current, records of interaction. Additionally, species identified by logbook entries may not be verified. Not all species or stocks identified are the reason for a fishery's placement in a given category. There are a few fisheries that are in Category II that have no recently documented

interactions with marine mammals. Justifications for placement of these fisheries are by analogy to other gear types that are known to cause mortality or serious injury of marine mammals, as

discussed in the final LOF for 1996 (60 FR 67063, December 28, 1995), and according to factors listed in the definition of "Category II fishery" in 50 CFR 229.2.

Table 1 lists commercial fisheries in the Pacific Ocean (including Alaska); Table 2 lists commercial fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean.



Table 1 - List of Fisheries Commercial Fisheries in the Pacific Ocean

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
<b>Category I</b>		
<u>GILLNET FISHERIES:</u>		
CA angel shark/halibut and other species set gillnet (>3.5 in. mesh)	58	Harbor porpoise, Central CA Common dolphin, short-beaked, CA/OR/WA Common dolphin, long-beaked CA California sea lion, U.S. Harbor seal, CA Northern elephant seal, CA breeding Sea otter, CA
<u>LONGLINE/SET LINE FISHERIES:</u>		
HI swordfish, tuna, billfish, mahi mahi, wahoo, oceanic sharks longline/set line	140	Humpback whale, Central North Pacific False killer whales, HI Risso's dolphin, HI Bottlenose dolphin, HI Spinner dolphin, HI Short-finned pilot whale, HI Sperm whale, HI
<b>Category II</b>		
<u>GILLNET FISHERIES:</u>		
AK Bristol Bay salmon drift gillnet	1,903	Steller sea lion, Western U.S. Northern fur seal, Eastern Pacific Harbor seal, Bering Sea Beluga whale, Bristol Bay Gray whale, Eastern North Pacific Spotted seal, AK Pacific white-sided dolphin, North Pacific
AK Bristol Bay salmon set gillnet	1,014	Harbor seal, Bering Sea Beluga whale, Bristol Bay Gray whale, Eastern North Pacific Northern fur seal, Eastern Pacific Spotted seal, AK
AK Cook Inlet salmon drift gillnet	576	Steller sea lion, Western U.S. Harbor seal, GOA Harbor porpoise, GOA Dall's porpoise, AK Beluga whale, Cook Inlet
AK Kodiak salmon set gillnet	188	Harbor seal, GOA Harbor porpoise, GOA Sea otter, AK
AK Metlakatla/Annette Island salmon drift gillnet	60	None documented

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
AK Peninsula/Aleutian Islands salmon drift gillnet	164	Northern fur seal, Eastern Pacific Harbor seal, GOA Harbor porpoise, GOA Dall's porpoise, AK
AK Peninsula/Aleutian Islands salmon set gillnet	116	Steller sea lion, Western U.S. Harbor porpoise, Bering Sea
AK Prince William Sound salmon drift gillnet	541	Steller sea lion, Western U.S. Northern fur seal, Eastern Pacific Harbor seal, GOA Pacific white-sided dolphin, North Pacific Harbor porpoise, GOA Dall's porpoise, AK Sea Otter, AK
AK Southeast salmon drift gillnet	481	Steller sea lion, Eastern U.S. Harbor seal, Southeast AK Pacific white-sided dolphin, North Pacific Harbor porpoise, Southeast AK Dall's porpoise, AK Humpback whale, Central North Pacific
AK Yakutat salmon set gillnet	170	Harbor seal, Southeast AK Gray whale, Eastern North Pacific
CA/OR thresher shark/swordfish drift gillnet (≥ 14 in. mesh)	113	Steller sea lion, Eastern U.S. Sperm whale, CA/OR/WA Dall's porpoise, CA/OR/WA Fin whale, CA/OR/WA Gray whale, Eastern North Pacific Northern Pacific white-sided dolphin, CA/OR/WA Southern Pacific white-sided dolphin, CA/OR/WA Risso's dolphin, CA/OR/WA Bottlenose dolphin, CA/OR/WA offshore Short-beaked common dolphin, CA/OR/WA Long-beaked common dolphin, CA/OR/WA Northern right-whale dolphin, CA/OR/WA Short-finned pilot whale, CA/OR/WA Baird's beaked whale, CA/OR/WA Mesoplodont beaked whale, CA/OR/WA Cuvier's beaked whale, CA/OR/WA Pygmy sperm whale, CA/OR/WA California sea lion, U.S. Northern elephant seal, CA breeding Humpback whale, CA/OR/WA-Mexico Minke whale, CA/OR/WA Striped dolphin, CA/OR/WA Killer whale, CA/OR/WA Pacific coast Northern fur seal, San Miguel Island
CA yellowtail, barracuda, white seabass, and tuna drift gillnet fishery (mesh size > 3.5 inches and < 14 inches)	24	None documented

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
WA Puget Sound Region salmon drift gillnet (includes all inland waters south of US-Canada border and eastward of the Bonilla-Tatoosh line--Treaty Indian fishing is excluded)	210	Harbor porpoise, inland WA Dall's porpoise, CA/OR/WA Harbor seal, WA inland
<u>PURSE SEINE FISHERIES:</u>		
AK Southeast salmon purse seine	416	Humpback whale, Central North Pacific
CA anchovy, mackerel, tuna purse seine	150	Bottlenose dolphin, CA/OR/WA offshore California sea lion, U.S. Harbor seal, CA
CA squid purse seine	65	Short-finned pilot whale, CA/OR/WA
<u>TRAWL FISHERIES:</u>		
AK miscellaneous finfish pair trawl	2	None documented
<u>LONGLINE/SET LINE FISHERIES:</u>		
CA pelagic longline	30	California sea lion
OR swordfish floating longline	1	None documented
OR blue shark floating longline	1	None documented
Category III		
<u>GILLNET FISHERIES:</u>		
AK Cook Inlet salmon set gillnet	745	Steller sea lion, Western U.S. Harbor seal, GOA Harbor porpoise, GOA Dall's porpoise, AK Beluga whale, Cook Inlet
AK Kuskokwim, Yukon, Norton Sound, Kotzebue salmon gillnet	1,922	Harbor porpoise, Bering Sea
AK miscellaneous finfish set gillnet	3	Steller sea lion, Western U.S.
AK Prince William Sound salmon set gillnet	30	Steller sea lion, Western U.S. Harbor seal, GOA
AK roe herring and food/bait herring gillnet	2,034	None documented
CA set and drift gillnet fisheries that use a stretched mesh size of 3.5 in or less	341	None documented
Hawaii gillnet	115	Bottlenose dolphin, HI Spinner dolphin, HI
WA Grays Harbor salmon drift gillnet (excluding treaty Tribal fishing)	24	Harbor seal, OR/WA coast

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
WA, OR herring, smelt, shad, sturgeon, bottom fish, mullet, perch, rockfish gillnet	913	None documented
WA, OR lower Columbia River (includes tributaries) drift gillnet	110	California sea lion, U.S. Harbor seal, OR/WA coast
WA Willapa Bay drift gillnet	82	Harbor seal, OR/WA coast Northern elephant seal, CA breeding
<b><u>PURSE SEINE, BEACH SEINE, ROUND HAUL AND THROW NET FISHERIES:</u></b>		
AK Metlakatla salmon purse seine	10	None documented
AK miscellaneous finfish beach seine	1	None documented
AK miscellaneous finfish purse seine	3	None documented
AK octopus/squid purse seine	2	None documented
AK roe herring and food/bait herring beach seine	8	None documented
AK roe herring and food/bait herring purse seine	624	None documented
AK salmon beach seine	34	None documented
AK salmon purse seine (except Southeast Alaska, which is in Category II)	953	Harbor seal, GOA
CA herring purse seine	100	California sea lion, U.S. Harbor seal, CA
CA sardine purse seine	120	None documented
HI opelu/akule net	16	None documented
HI purse seine	18	None documented
HI throw net, cast net	47	None documented
WA (all species) beach seine or drag seine	235	None documented
WA, OR herring, smelt, squid purse seine or lampara	130	None documented
WA salmon purse seine	440	None documented
WA salmon reef net	53	None documented
<b><u>DIP NET FISHERIES:</u></b>		
CA squid dip net	115	None documented
WA, OR smelt, herring dip net	119	None documented
<b><u>MARINE AQUACULTURE FISHERIES:</u></b>		

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
CA salmon enhancement rearing pen	>1	None documented
OR salmon ranch	1	None documented
WA, OR salmon net pens	14	California sea lion, U.S. Harbor seal, WA inland waters
<b>TROLL FISHERIES:</b>		
AK North Pacific halibut, AK bottom fish, WA, OR, CA albacore, groundfish, bottom fish, CA halibut non-salmonid troll fisheries	1,530 (330 AK)	None documented
AK salmon troll	2,335	Steller sea lion, Western U.S. Steller sea lion, Eastern U.S.
American Samoa tuna troll	<50	None documented
CA/OR/WA salmon troll	4,300	None documented
Commonwealth of the Northern Mariana Islands tuna troll	50	None documented
Guam tuna troll	50	None documented
HI net unclassified	106	None documented
HI trolling, rod and reel	1,795	None documented
<b>LONGLINE/SET LINE FISHERIES:</b>		
AK Bering Sea, Aleutian Islands Greenland turbot longline	36	Killer whale, Eastern North Pacific resident Killer whale, Eastern North Pacific transient
AK Bering Sea, Aleutian Islands Pacific cod longline	114	None documented
AK Bering Sea, Aleutian Islands rockfish longline	17	None documented
AK Bering Sea, Aleutian Islands sablefish longline	63	None documented
AK Gulf of Alaska halibut longline	1302	None documented
AK Gulf of Alaska Pacific cod longline	440	None documented
AK Gulf of Alaska rockfish longline	421	None documented
AK Gulf of Alaska sablefish longline	412	None documented
AK halibut longline/set line (State and Federal waters)	3,079	Steller sea lion, Western U.S.
AK octopus/squid longline	7	None documented
AK state-managed waters groundfish longline/setline (including sablefish, rockfish, and miscellaneous finfish)	731	None documented



Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
WA, OR, CA groundfish, bottomfish longline/set line	367	None documented
WA, OR North Pacific halibut longline/set line	350	None documented
<b>TRAWL FISHERIES:</b>		
AK Bering Sea, Aleutian Islands Atka mackerel trawl	8	Steller sea lion, Western U.S.
AK Bering Sea, Aleutian Islands flatfish trawl	26	Steller sea lion, Western U.S. Killer whale, Eastern North Pacific resident Killer whale, Eastern North Pacific transient
AK Bering Sea, Aleutian Islands Pacific cod trawl	87	None documented
AK Bering Sea, Aleutian Islands pollock trawl	120	Steller sea lion, Western U.S. Killer whale, Eastern North Pacific resident Killer whale, Eastern North Pacific transient Humpback whale, Central North Pacific Humpback whale, Western North Pacific
AK Bering Sea, Aleutian Islands rockfish trawl	9	None documented
AK Gulf of Alaska flatfish trawl	52	None documented
AK Gulf of Alaska Pacific cod trawl	101	None documented
AK Gulf of Alaska pollock trawl	83	None documented
AK Gulf of Alaska rockfish trawl	45	None documented
AK food/bait herring trawl	3	None documented
AK miscellaneous finfish otter or beam trawl	6	None documented
AK shrimp otter trawl and beam trawl (statewide and Cook Inlet)	58	None documented
AK state-managed waters of Cook Inlet, Kachemak Bay, Prince William Sound, Southeast AK groundfish trawl	2	None documented
WA, OR, CA groundfish trawl	585	Steller sea lion, Western U.S. Northern fur seal, Eastern Pacific Pacific white-sided dolphin, Central North Pacific Dall's porpoise, CA/OR/WA California sea lion, U.S. Harbor seal, OR/WA coast
WA, OR, CA shrimp trawl	300	None documented
<b>POT, RING NET, AND TRAP FISHERIES:</b>		
AK Aleutian Islands sablefish pot	8	None documented

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
AK Bering Sea sablefish pot	6	Humpback whale, Central North Pacific Humpback whale, Western North Pacific
AK Bering Sea, Aleutian Islands Pacific cod pot	76	None documented
AK Bering Sea, Aleutian Islands crab pot	329	None documented
AK Gulf of Alaska crab pot	unknown	None documented
AK Gulf of Alaska Pacific cod pot	154	None documented
AK Southeast Alaska crab pot	unknown	None documented
AK Southeast Alaska shrimp pot	unknown	None documented
AK octopus/squid pot	72	None documented
AK snail pot	2	None documented
CA lobster, prawn, shrimp, rock crab, fish pot	608	Sea otter, CA
OR, CA hagfish pot or trap	25	None documented
WA, OR, CA crab pot	1,478	None documented
WA, OR, CA sablefish pot	176	None documented
WA, OR shrimp pot & trap	254	None documented
HI crab trap	22	None documented
HI fish trap	19	None documented
HI lobster trap	15	Hawaiian monk seal
HI shrimp trap	5	None documented
<b>HANDLINE AND JIG FISHERIES:</b>		
AK miscellaneous finfish handline and mechanical jig	100	None documented
AK North Pacific halibut handline and mechanical jig	93	None documented
AK octopus/squid handline	2	None documented
American Samoa bottomfish	<50	None documented
Commonwealth of the Northern Mariana Islands bottomfish	<50	None documented
Guam bottomfish	<50	None documented
HI aku boat, pole and line	54	None documented
HI deep sea bottomfish	434	Hawaiian monk seal

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
HI inshore handline	650	Bottlenose dolphin, HI
HI tuna	144	Rough-toothed dolphin, HI Bottlenose dolphin, HI Hawaiian monk seal
WA groundfish, bottomfish jig	679	None documented
<b><u>HARPOON FISHERIES:</u></b>		
CA swordfish harpoon	228	None documented
<b><u>POUND NET/WEIR FISHERIES:</u></b>		
AK herring spawn on kelp pound net	452	None documented
AK Southeast herring roe/food/bait pound net	3	None documented
WA herring brush weir	1	None documented
<b><u>BAIT PENS:</u></b>		
WA/OR/CA bait pens	13	None documented
<b><u>DREDGE FISHERIES:</u></b>		
Coastwide scallop dredge	108 (12 AK)	None documented
<b><u>DIVE, HAND/MECHANICAL COLLECTION FISHERIES:</u></b>		
AK abalone	1	None documented
AK clam	156	None documented
WA herring spawn on kelp	4	None documented
AK dungeness crab	3	None documented
AK herring spawn on kelp	363	None documented
AK urchin and other fish/shellfish	471	None documented
CA abalone	111	None documented
CA sea urchin	583	None documented
HI coral diving	2	None documented
HI fish pond	10	None documented
HI handpick	135	None documented
HI lobster diving	6	None documented
HI squidding, spear	267	None documented

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
WA, CA kelp	4	None documented
WA/OR sea urchin, other clam, octopus, oyster, sea cucumber, scallop, ghost shrimp hand, dive, or mechanical collection	637	None documented
WA shellfish aquaculture	684	None documented
<u>COMMERCIAL PASSENGER FISHING VESSEL (CHARTER BOAT) FISHERIES:</u>		
AK, WA, OR, CA commercial passenger fishing vessel	>7,000 (1,107 AK)	None documented
HI "other"	114	None documented
<u>LIVE FINFISH/SHELLFISH FISHERIES:</u>		
CA finfish and shellfish live trap/hook-and-line	93	None documented

List of Abbreviations Used in Table 1: AK - Alaska; CA - California; GOA - Gulf of Alaska; HI - Hawaii; OR - Oregon; WA - Washington

Table 2 - List of Fisheries Commercial Fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Category I		
<u>GILLNET FISHERIES:</u>		
Mid-Atlantic coastal gillnet	>655	Humpback whale, Gulf of Maine Minke whale, Canadian east coast Bottlenose dolphin, WNA offshore Bottlenose dolphin, WNA coastal Harbor porpoise, GME/BF Harbor seal, WNA Harp seal, WNA Long-finned pilot whale, WNA Short-finned pilot whale, WNA White-sided dolphin, WNA Common dolphin, WNA

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Northeast sink gillnet	341	North Atlantic right whale, WNA Humpback whale, WNA Minke whale, Canadian east coast Killer whale, WNA White-sided dolphin, WNA Bottlenose dolphin, WNA offshore Harbor porpoise, GME/BF Harbor seal, WNA Gray seal, WNA Common dolphin, WNA Fin whale, WNA Spotted dolphin, WNA False killer whale, WNA Harp seal, WNA
<b><u>LOONGLINE FISHERIES:</u></b>		
Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline	<200	Humpback whale, WNA Minke whale, Canadian east coast Risso's dolphin, WNA Long-finned pilot whale, WNA Short-finned pilot whale, WNA Common dolphin, WNA Atlantic spotted dolphin, WNA Pantropical spotted dolphin, WNA Striped dolphin, WNA Bottlenose dolphin, WNA offshore Bottlenose dolphin, GMX Outer Continental Shelf Bottlenose dolphin, GMX Continental Shelf Edge and Slope Atlantic spotted dolphin, Northern GMX Pantropical spotted dolphin, Northern GMX Risso's dolphin, Northern GMX Harbor porpoise, GME/BF Pygmy sperm whale, WNA
<b><u>TRAP/POT FISHERIES:</u></b>		
Northeast/Mid-Atlantic American lobster trap/pot	13,000	North Atlantic right whale, WNA Humpback whale, WNA Fin whale, WNA Minke whale, Canadian east coast Harbor seal, WNA
<b><u>TRAWL FISHERIES:</u></b>		
Atlantic squid, mackerel, butterfish trawl	620	Common dolphin, WNA Risso's dolphin, WNA Long-finned pilot whale, WNA Short-finned pilot whale, WNA White-sided dolphin, WNA
Category II		
<b><u>GILLNET FISHERIES:</u></b>		



Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Gulf of Mexico gillnet	724	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal Bottlenose dolphin, Eastern GMX coastal Bottlenose dolphin, GMX Bay, Sound, and Estuarine
North Carolina inshore gillnet	94	Bottlenose dolphin, WNA coastal
Northeast anchored float gillnet	133	Humpback whale, WNA White-sided dolphin, WNA Harbor seal, WNA
Northeast drift gillnet	unknown	None documented
Southeast Atlantic gillnet	779	Bottlenose dolphin, WNA coastal
Southeastern U.S. Atlantic shark gillnet	6	Bottlenose dolphin, WNA coastal North Atlantic right whale, WNA Atlantic spotted dolphin, WNA
<u>TRAWL FISHERIES:</u>		
Atlantic herring midwater trawl (including pair trawl)	17	Harbor seal, WNA
<u>TRAP/POT FISHERIES:</u>		
Atlantic blue crab trap/pot	>16,000	Bottlenose dolphin, WNA coastal West Indian manatee, FL
Atlantic mixed species trap/pot	unknown	Fin whale, WNA Humpback whale, Gulf of Maine Minke whale, Canadian east coast Harbor porpoise, GM/BF
<u>PURSE SEINE FISHERIES:</u>		
Gulf of Mexico menhaden purse seine	50	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal
<u>HAUL/BEACH SEINE FISHERIES:</u>		
Mid-Atlantic haul/beach seine	25	Bottlenose dolphin, WNA coastal Harbor porpoise, GME/BF
North Carolina long haul seine	33	Bottlenose dolphin, WNA coastal
<u>STOP NET FISHERIES:</u>		
North Carolina roe mullet stop net	13	Bottlenose dolphin, WNA coastal
<u>POUND NET FISHERIES:</u>		
Virginia pound net	187	Bottlenose dolphin, WNA coastal
Category III		
<u>GILLNET FISHERIES:</u>		

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Caribbean gillnet	>991	Dwarf sperm whale, WNA West Indian manatee, Antillean
Chesapeake Bay inshore gillnet	45	Harbor porpoise, GME/BF
Delaware Bay inshore gillnet	60	Humpback whale, WNA Bottlenose dolphin, WNA coastal Harbor porpoise, GME/BF
Long Island Sound inshore gillnet	20	Humpback whale, WNA Bottlenose dolphin, WNA coastal Harbor porpoise, GME/BF
Rhode Island, southern Massachusetts (to Monomoy Island), and New York Bight (Raritan and Lower New York Bays) inshore gillnet	32	Humpback whale, WNA Bottlenose dolphin, WNA coastal Harbor porpoise, GME/BF
<b><u>TRAWL FISHERIES:</u></b>		
Calico scallops trawl	12	None documented
Crab trawl	400	None documented
Georgia, South Carolina, Maryland whelk trawl	25	None documented
Gulf of Maine, Mid-Atlantic sea scallop trawl	215	None documented
Gulf of Maine northern shrimp trawl	320	None documented
Gulf of Mexico butterflyfish trawl	2	Atlantic spotted dolphin, Eastern GMX Pantropical spotted dolphin, Eastern GMX
Gulf of Mexico mixed species trawl	20	None documented
Mid-Atlantic mixed species trawl	>1,000	None documented
North Atlantic bottom trawl	1,052	Long-finned pilot whale, WNA Short-finned pilot whale, WNA Common dolphin, WNA White-sided dolphin, WNA Striped dolphin, WNA Bottlenose dolphin, WNA offshore
Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl	>18,000	Bottlenose dolphin, WNA coastal
U.S. Atlantic monkfish trawl	unknown	Common dolphin, WNA
<b><u>MARINE AQUACULTURE FISHERIES:</u></b>		
Finfish aquaculture	48	Harbor seal, WNA
Shellfish aquaculture	unknown	None documented
<b><u>PURSE SEINE FISHERIES:</u></b>		

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Gulf of Maine Atlantic herring purse seine	30	Harbor porpoise, GME/BF Harbor seal, WNA Gray seal, WNA
Gulf of Maine menhaden purse seine	50	None documented
Florida west coast sardine purse seine	10	Bottlenose dolphin, Eastern GMX coastal
Mid-Atlantic menhaden purse seine	22	Bottlenose dolphin, WNA coastal Humpback whale, WNA
U.S. Atlantic tuna purse seine	5	None documented
U.S. Mid-Atlantic hand seine	>250	None documented
<u>LONGLINE/HOOK-AND-LINE FISHERIES:</u>		
Gulf of Maine tub trawl groundfish bottom longline/ hook-and-line	46	Harbor seal, WNA Gray seal, Northwest North Atlantic Humpback whale, WNA
Gulf of Maine, U.S. Mid-Atlantic tuna, shark swordfish hook-and-line/harpoon	26,223	Humpback whale, WNA
Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean snapper-grouper and other reef fish bottom longline/hook-and-line	>5,000	None documented
Southeastern U.S. Atlantic, Gulf of Mexico shark bottom longline/hook-and-line	<125	None documented
Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean pelagic hook-and-line/harpoon	1,446	None documented
<u>TRAP/POT FISHERIES</u>		
Caribbean mixed species trap/pot	>501	None documented
Caribbean spiny lobster trap/pot	>197	None documented
Florida spiny lobster trap/pot	2,145	Bottlenose dolphin, Eastern GMX coastal
Gulf of Mexico blue crab trap/pot	4,113	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal Bottlenose dolphin, Eastern GMX coastal Bottlenose dolphin, GMX Bay, Sound, & Estuarine West Indian manatee, FL
Gulf of Mexico mixed species trap/pot	unknown	None documented
Southeastern U.S. Atlantic, Gulf of Mexico golden crab trap/pot	10	None documented
Southeastern U.S. Atlantic, Gulf of Mexico stone crab trap/pot	4,453	None documented

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally killed/injured
U.S. Mid-Atlantic eel trap/pot	>700	None documented
<b><u>STOP SEINE/WEIR/POUND NET FISHERIES:</u></b>		
Gulf of Maine herring and Atlantic mackerel stop seine/weir	50	North Atlantic right whale, WNA Humpback whale, WNA Minke whale, Canadian east coast Harbor porpoise, GME/BF Harbor seal, WNA Gray seal, Northwest North Atlantic
U.S. Mid-Atlantic crab stop seine/weir	2,600	None documented
U.S. Mid-Atlantic mixed species stop seine/weir/pound net (except the North Carolina roe mullet stop net)	751	None documented
<b><u>DREDGE FISHERIES:</u></b>		
Gulf of Maine mussel	>50	None documented
Gulf of Maine, U.S. Mid-Atlantic sea scallop dredge	233	None documented
U.S. Mid-Atlantic/Gulf of Mexico oyster	7,000	None documented
U.S. Mid-Atlantic offshore surf clam and quahog dredge	100	None documented
<b><u>HAUL/BEACH SEINE FISHERIES:</u></b>		
Caribbean haul/beach seine	15	West Indian manatee, Antillean
Gulf of Mexico haul/beach seine	unknown	None documented
Southeastern U.S. Atlantic, haul/beach seine	25	None documented
<b><u>DIVE, HAND/MECHANICAL COLLECTION FISHERIES:</u></b>		
Atlantic Ocean, Gulf of Mexico, Caribbean shellfish dive, hand/mechanical collection	20,000	None documented
Gulf of Maine urchin dive, hand/mechanical collection	>50	None documented
Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean cast net	unknown	None documented
<b><u>COMMERCIAL PASSENGER FISHING VESSEL (CHARTER BOAT) FISHERIES:</u></b>		
Atlantic Ocean, Gulf of Mexico, Caribbean commercial passenger fishing vessel	4,000	None documented

List of Abbreviations Used in Table 2: FL - Florida; GA - Georgia; GME/BF - Gulf of Maine/Bay of Fundy; GMX - Gulf of Mexico; NC - North Carolina; SC - South Carolina; TX - Texas; WNA - Western North Atlantic

### Classification

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule would not have a significant economic impact on a substantial number of small entities. For convenience, the factual basis leading to the certification is repeated below.

Under existing regulations, all fishers participating in Category I or II fisheries must register under the MMPA, obtain an Authorization Certificate, and pay a fee of \$25. Additionally, fishers may be subject to a take reduction plan and requested to carry an observer. The Authorization Certificate authorizes the taking of marine mammals incidental to commercial fishing operations. NMFS has estimated that approximately 41,600 fishing vessels, most of which are small entities, operate in Category I or II fisheries, and therefore, are required to register. However, registration has been integrated with existing state or Federal registration programs for the majority of these fisheries so that the majority of fishers do not need to register separately under the MMPA. Currently, approximately 5,800 fishers register directly with NMFS under the MMPA authorization program.

This rule proposes to elevate the Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/Set Line Fishery to Category I in the LOF. Therefore participants in this fishery (140 participants) would be required to register under the MMPA.

Though this proposed rule would affect a number of small entities, the \$25 registration fee, with respect to anticipated revenues, is not considered a significant economic impact. If a vessel is requested to carry an observer, fishers will not incur any economic costs associated with carrying that observer. As a result of this certification, an initial regulatory flexibility analysis was not prepared. In the event that reclassification of a fishery to Category I or II results in a take reduction plan, economic analyses of the effects of that plan will be summarized in subsequent

rulemaking actions. Further, if a vessel is requested to carry an observer, fishers will not incur any economic costs associated with carrying that observer.

This proposed rule contains collection-of-information requirements subject to the Paperwork Reduction Act. The collection of information for the registration of fishers under the MMPA has been approved by the Office of Management and Budget (OMB) under OMB control number 0648-0293 (0.25 hours per report for new registrants and 0.15 hours per report for renewals). The requirement for reporting marine mammal injuries or mortalities has been approved by OMB under OMB control number 0648-0292 (0.15 hours per report). These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these reporting burden estimates or any other aspect of the collections of information, including suggestions for reducing burden, to NMFS and OMB (see ADDRESSES).

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

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

An environmental assessment (EA) was prepared under the National Environmental Policy Act (NEPA) for regulations to implement section 118 of the MMPA (1995 EA). The 1995 EA concluded that implementation of those regulations would not have a significant impact on the human environment. This proposed rule would not make any

significant change in the management of reclassified fisheries, and therefore, this proposed rule is not expected to change the analysis or conclusion of the 1995 EA. If NMFS takes a management action, for example, through the development of a Take Reduction Plan (TRP), NMFS will first prepare an environmental document as required under NEPA specific to that action.

This proposed rule would not affect species listed as threatened or endangered under the Endangered Species Act (ESA) or their associated critical habitat. The impacts of numerous fisheries have been analyzed in various biological opinions, and this proposed rule will not affect the conclusions of those opinions. The classification of fisheries on the LOF is not considered to be a management action that would adversely affect threatened or endangered species. If NMFS takes a management action, for example, through the development of a TRP, NMFS would conduct consultation under section 7 of the ESA for that action.

This proposed rule would have no adverse impacts on marine mammals and may have a positive impact on marine mammals by improving knowledge of marine mammals and the fisheries interacting with marine mammals through information collected from observer programs or take reduction teams.

This proposed rule would not affect the land or water uses or natural resources of the coastal zone, as specified under section 307 of the Coastal Zone Management Act.

Dated: April 8, 2004.

**William T. Hogarth,**

*Assistant Administrator for Fisheries,  
National Marine Fisheries Service.*

[FR Doc. 04-8383 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-22-S



## Notices

Federal Register

Vol. 69, No. 71

Tuesday, April 13, 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

#### Forest Service

#### Siskiyou County Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Siskiyou County Resource Advisory Committee will meet in Yreka, California, April 19, 2004. The meeting will include routine business including a discussion of larger scale projects and a RAC Web site.

**DATES:** The meeting will be held April 19, 2004, from 4:30 p.m. until 6:30 p.m.

**ADDRESSES:** The meeting will be held at the Yreka High School Library, Preece Way, Yreka, California.

**FOR FURTHER INFORMATION CONTACT:** Don Hall, RAC Coordinator, Klamath National Forest, (530) 841-4468 or electronically at [donaldhall@fs.fed.us](mailto:donaldhall@fs.fed.us).

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public. Public comment opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: April 5, 2004.

**Margaret J. Boland,**  
*Designated Federal Official.*

[FR Doc. 04-8290 Filed 4-12-04; 8:45 am]

BILLING CODE 3410-11-M

### DEPARTMENT OF AGRICULTURE

#### Natural Resources Conservation Service

#### Cavalry Creek Watershed Site 6, Washita County, OK

**AGENCY:** Natural Resources Conservation Service, USDA.

**ACTION:** Notice of availability of record of decision.

**SUMMARY:** M. Darrel Dominick, responsible Federal official for projects administered under the provisions of Public Law 106-472, in the State of Oklahoma, is hereby providing notification that a record of decision to proceed with the installation of the Cavalry Creek Watershed Site 6 project is available. Single copies of this record of decision may be obtained from M. Darrel Dominick at the address shown below.

**FOR FURTHER INFORMATION CONTACT:** M. Darrel Dominick, State Conservationist, Natural Resources Conservation Service, State Office, 100 USDA Suite 206, Stillwater, Oklahoma 74074-2655; telephone (405) 742-1227.

Dated: April 7, 2004.

**M. Darrel Dominick,**  
*State Conservationist.*

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials).

[FR Doc. 04-8329 Filed 4-12-04; 8:45 am]

BILLING CODE 3410-16-P

### DEPARTMENT OF COMMERCE

#### Foreign-Trade Zones Board

[Docket 14-2004]

#### Proposed Foreign-Trade Zone— Auburn, Maine; Application and Public Hearing

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Lewiston-Auburn Economic Growth Council (a Maine not-for-profit corporation), to establish a general-purpose foreign-trade zone in Auburn (Androscoggin County), Maine, within the Portland Customs port of entry. The FTZ application was submitted pursuant to the provisions of the FTZ Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on April 5, 2004. The applicant is authorized to make the proposal under Maine Revised Code 13062(D).

The proposed zone consists of 760 acres located principally at the Auburn/Lewiston Municipal Airport/Industrial Park complex, on Lewiston Junction Road in Auburn. In addition to the

airport, the complex includes the Auburn Intermodal facility, as well as land planned for industrial park development. An additional site is located at 123 Rodman Road. The complex is owned by public and private companies, and the City of Auburn is in the process of acquiring the land needed to promote industrial development. The Rodman Road site is a privately-owned site.

The application indicates a need for zone services in the Lewiston-Auburn region. Several firms have indicated an interest in using zone procedures for warehousing/distribution activities. Specific manufacturing approvals are not being sought at this time. Requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

As part of the investigation, the Commerce examiner will hold a public hearing on May 11, 2004, at 1 p.m., Auburn City Hall, Council Chambers, 45 Spring Street, Auburn, ME 04210.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submissions via Express/Package Delivery Services: Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099-14th Street NW., Washington, DC 20005; or
2. Submissions via the U.S. Postal Service: Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Avenue NW., Washington, DC 20230.

The closing period for their receipt is June 14, 2004. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to June 28, 2004).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the Lewiston-Auburn Economic Growth Council, 95 Park Street, Suite 411, Lewiston, Me 04243.

Dated: April 5, 2004.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 04-8378 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### Information Systems Technical Advisory Committee; Notice of Partially Closed Meeting

The Information Systems Technical Advisory Committee (ISTAC) will meet on April 28 and 29, 2004, 9 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Pennsylvania Avenue and Constitution Avenue, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to information systems equipment and technology.

#### April 28

##### Public Session

1. Opening remarks and introductions.
2. Comments or presentations by the public.
3. Update on graphics processors.
4. Discussion on developments in cryptography.
5. Discussion on system software and encryption.
6. Discussion on wireless technology and standards.
7. Discussion on semiconductors and technology.
8. Discussion on crypto in networking.
9. Discussion on classification and crypto for management.

#### April 29

##### Closed Session

10. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2--§§ 10(a)(1) and 10(a)(3).

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that public presentation materials or comments be forwarded before the meeting to the address listed below: Ms. Lee Ann Carpenter, Advisory Committees MS: 1009D, U.S. Department of Commerce,

14th St. & Constitution Ave., NW., Washington, DC 20230.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on March 23, 2004, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of this meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2--§§ 10(a)(1) and 10 (a)(3).

For more information, contact Lee Ann Carpenter on 202-482-2583.

Dated: April 7, 2004.

Lee Ann Carpenter,

Committee Liaison Officer.

[FR Doc. 04-8304 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-JT-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-549-817]

#### Certain Hot-Rolled Carbon Steel Flat Products From Thailand: Final Results and Partial Rescission of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce ("the Department") has conducted an administrative review of the antidumping duty order on certain hot-rolled carbon steel flat products from Thailand produced and/or exported by Sahaviriya Steel Industries Public Company Limited ("SSI"), Nakornthai Strip Mill Public Co., Ltd. ("Nakornthai"), and Siam Strip Mill Public Co., Ltd. ("Siam Strip"). The period of review ("POR") is May 3, 2001, through October 31, 2002. Based on our analysis of comments received, these final results remain unchanged from the Preliminary Results. The final results are listed below in the "Final Results of Review" section.

**EFFECTIVE DATE:** April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Helen Kramer at (202) 482-0405 or Ann Barnett-Dahl at (202) 482-3833, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave, NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

## Background

On December 8, 2003, the Department published the preliminary results and partial rescission of its administrative review of the antidumping duty order on certain hot-rolled carbon steel flat products from Thailand. See *Certain Hot-Rolled Steel from Thailand: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review*, 68 FR 68336 (December 8, 2003) ("Preliminary Results").

We invited parties to comment on the Preliminary Results. On January 8, 2003, we received case briefs from SSI and Nucor Corporation ("the Petitioner"). On January 12, 2003, we received rebuttal briefs from SSI and the Petitioner. A hearing was not requested.

## Partial Rescission

In our preliminary results, we announced our preliminary decision to rescind the review with respect to Nakornthai and Siam Strip because these companies had no entries of hot-rolled steel from Thailand during the POR. See *Preliminary Results*. We have received no new information contradicting the decision. Therefore, we are rescinding the administrative review with respect to Nakornthai and Siam Strip.

## Scope of the Antidumping Duty Order

The products covered by this antidumping duty order are certain hot-rolled carbon steel flat products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths, of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness. Universal mill plate (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1250 mm, and of a thickness of not less than 4.0 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of this order.

Specifically included within the scope of this order are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, and the substrate for motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium or niobium (also commonly referred to as

columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum.

Steel products to be included in the scope of this order, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products in which: (i) Iron predominates, by weight, over each of the other contained elements; (ii) the carbon content is 2 percent or less, by weight; and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium, or 0.15 percent of vanadium, or 0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of this review unless otherwise excluded. The following products, by way of example, are outside or specifically excluded from the scope of this order:

- Alloy hot-rolled steel products in which at least one of the chemical elements exceeds those listed above (including, e.g., American Society for Testing and Materials (ASTM) specifications A543, A387, A514, A517, A506).
- Society of Automotive Engineers (SAE)/American Iron & Steel Institute (AISI) grades of series 2300 and higher.
- Ball bearing steels, as defined in the HTSUS.
- Tool steels, as defined in the HTSUS.
- Silico-manganese (as defined in the HTSUS) or silicon electrical steel with a silicon level exceeding 2.25 percent.
- ASTM specifications A710 and A736.
- USS abrasion-resistant steels (USS AR 400, USS AR 500).
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).
- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping

and which have assumed the character of articles or products classified outside chapter 72 of the HTSUS.

The merchandise subject to this review is classified in the HTSUS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90. Certain hot-rolled carbon steel flat products covered by this review, including: Vacuum degassed fully stabilized; high strength low alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00.

Although the HTSUS subheadings are provided for convenience and CBP purposes, the written description of the merchandise is dispositive.

#### Analysis of Comments Received

The Department has received comments from SSI and the Petitioner, all of which are addressed in the "Issues and Decision Memorandum" from Joseph A. Spetrini, Deputy Assistant Secretary, Import Administration, to James J. Jochum, Assistant Secretary, Import Administration, dated April 6, 2004 ("Decision Memorandum"), which is hereby adopted by this notice. Attached to this notice as an Appendix is a list of the issues that SSI and the Petitioner have raised and to which we have responded in the *Decision Memorandum*. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in the Department's Central Records Unit, located at 14th Street and Constitution Avenue, NW., Room B-099. In addition, a complete version of the Decision

Memorandum can be accessed directly on the Import Administration Web site at <http://ia.ita.doc.gov/> under the heading **Federal Register Notices**. The paper copy and electronic version of the Decision Memorandum are identical in content.

#### Changes Since the Preliminary Results

Based on our analysis of comments received and findings at verification, our preliminary results remain unchanged.

#### Final Results of

Review We determine that the following dumping margins exist for the period May 3, 2001 through October 31, 2002:

Manufacturer/Exporter	Margin (percent)
SSI .....	0.00

All other entries of the subject merchandise during the POR will be liquidated at the antidumping duty rate in place at the time of entry. The Department will issue appropriate assessment instructions directly to the U.S. Customs and Border Protection ("CBP") within 15 days of publication of these final results of review.

#### Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) For the companies named above, the cash deposit rates will be the rates for these firms shown above, except that, for exporters with *de minimis* rates (i.e., less than 0.5 percent) no deposit will be required; (2) for previously-reviewed producers and exporters with separate rates, the cash deposit rate will be the company-specific rate established for the most recent period for which they were reviewed; and (3) for all other producers and exporters, the rate will be 3.86 percent, the "all others" rate established in the less than fair value investigation (66 FR 49622, September 28, 2001). These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant

entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 6, 2004.

**James J. Jochum,**  
Assistant Secretary for Import  
Administration.

#### Appendix

##### List of Comments and Issues in the Decision Memorandum

1. Date of Sale
2. Home Market Duty Drawback
3. Margin Adjustment for Export Subsidy
4. Slab Costs
5. Income Offsets to the General and Administrative Expenses
6. Financial Expense Offset

[FR Doc. 04-8373 Filed 4-12-04; 8:45 am]

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#### DEPARTMENT OF COMMERCE

##### International Trade Administration

[A-570-890]

#### Notice of Postponement of Preliminary Determination of Antidumping Duty Investigation of Wooden Bedroom Furniture from the People's Republic of China

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of Postponement of Preliminary Determination of Antidumping Duty Investigation.

**EFFECTIVE DATE:** April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Catherine Bertrand or Robert Bolling, Import Administration, International Trade Administration, U.S. Department

of Commerce, 14th Street and Constitution Avenue, N.W., Washington, DC 20230; telephone: (202) 482-3207, (202) 482-3434, respectively.

**SUMMARY:** The Department of Commerce ("Department") is postponing the preliminary determination in the antidumping duty investigation of wooden bedroom furniture from the People's Republic of China ("PRC") from April 28, 2004, until no later than June 17, 2004. This postponement is made pursuant to section 733(c)(1)(A) of the Tariff Act of 1930, as amended ("the Act").

#### SUPPLEMENTARY INFORMATION:

##### Postponement of Preliminary Determination

On December 17, 2003, the Department published the initiation of the antidumping duty investigation of imports of wooden bedroom furniture from the PRC. See Initiation of Antidumping Duty Investigation: Wooden Bedroom Furniture from the People's Republic of China, 68 FR 70228 (December 17, 2003). The notice of initiation stated that we would make our preliminary determination for this antidumping duty investigation no later than 140 days after the date of issuance of the initiation.

On March 31, 2004, Petitioners<sup>1</sup> made a timely request pursuant to 19 CFR §351.205(e) for a fifty-day postponement of the preliminary determination, or until June 17, 2004. Petitioners requested postponement of the preliminary determination because it believes additional time is necessary to allow Petitioners to review the responses to the supplemental questionnaires and submit comments to the Department, and also to allow the Department time to analyze thoroughly the respondents' data and to seek additional information, if necessary.

For the reasons identified by the Petitioners, and because there are no compelling reasons to deny the request, we are postponing the preliminary determination under section 733(c)(1) of the Act. Therefore, the preliminary determination is now due no later than June 17, 2004. The deadline for the final determination will continue to be 75 days after the date of the preliminary determination.

<sup>1</sup> Petitioners are: American Furniture Manufacturers Committee for Legal Trade and its individual members; the Cabinet Makers, Millmen and Industrial Carpenters Local 721; UBC Southern Council of Industrial Workers Local Union 2305; United Steel Workers of America Local 193U; Carpenters Industrial Union Local 2093; and Teamsters, Chauffeurs, Warehouseman and Helpers Local 991.

This notice is issued and published pursuant to sections 733(f) and 777(i) of the Act.

Dated: April 6, 2004.

**James J. Jochum,**  
Assistant Secretary for Import  
Administration.

[FR Doc. 04-8374 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-DS-S

#### DEPARTMENT OF COMMERCE

##### International Trade Administration

[A-489-812]

#### Light-Walled Rectangular Pipe and Tube from Turkey; Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of preliminary determination of sales at less than fair value and postponement of final determination.

**EFFECTIVE DATE:** April 13, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Paige Rivas (Guven) at (202) 482-0651; Timothy Finn or Drew Jackson (MMZ) at (202) 482-0065, and (202) 482-4406, respectively; and Mark Manning (Ozborsan) at (202) 482-5253, AD/CVD Enforcement Office IV, Group II, 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

The Department of Commerce (the Department) preliminarily determines that light-walled rectangular pipe and tube (LWRPT) from Turkey is being sold, 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 September 9, 2003, the Department received a petition for the imposition of antidumping duties on LWRPT from Mexico and Turkey, filed in proper form by California Steel and Tube, Hannibal Industries, Inc., Leavitt Tube Company, LLC, Maruichi American Corporation, Northwest Pipe Company, Searing Industries, Inc., Vest

Inc., and Western Tube and Conduit Corporation (collectively, the petitioners). See Letter from petitioners to Secretary Evans of the Department and Secretary Abbott of the U.S. International Trade Commission (ITC), "Petition for the Imposition of Antidumping Duties: Light-Walled Rectangular Pipe and Tube from Mexico and Turkey," dated September 9, 2003 (Petition). The Department initiated the antidumping investigation of LWRPT from Turkey on September 29, 2003. See *Notice of Initiation of Antidumping Investigations: Light-Walled Rectangular Pipe and Tube from Mexico and Turkey*, 68 FR 57667 (October 6, 2003) (*Initiation Notice*). Since the initiation of this investigation, the following events have occurred.

On October 14 and 15, 2003, the Department issued a shortened version of section A<sup>1</sup> of the antidumping questionnaire to eighteen pipe and tube producers in Turkey, in which each company was asked to provide the quantity and value of its shipments of subject merchandise to the United States during the period of investigation (POI). The Department received responses from these companies during the period October 24, 2003 through November 10, 2003.

On October 17, 2003, the Department issued to interested parties a set of proposed physical product characteristics that it intends to use to make its fair value comparisons. The Department received comments on its proposed physical product characteristics from MMZ Onur Boru Profil Uretim San. Ve. Tic. A.S. (MMZ) and Noksel Celik Boru Sanayi A.S. (Noksel) on October 28, 2003. The Department received rebuttal comments from the petitioners and Yucel Boru Ve Profil A.S. (Yucel Boru) on November 4, 2003.

On October 24, 2003, the ITC preliminarily determined that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of LWRPT from Mexico and Turkey that are alleged

to be sold in the United States at LTFV. See *Light-Walled Rectangular Pipe and Tube from Mexico and Turkey*, 68 FR 61829 (October 30, 2003).

On November 14, 2003, the Department selected Guven Boru Ve. Profil San. Ve. Tic. Ltd. Sti. (Güven), MMZ, Ozborsan Boru San. Ve. Tic. (Ozborsan) (collectively, respondents), as mandatory respondents in this investigation. See Memorandum from Mark Manning, Senior Import Compliance Specialist, to Thomas F. Futtner, Acting Office Director, "Selection of Respondents for the Antidumping Investigation of Light-Walled Rectangular (LWR) Pipe and Tube from Turkey," dated November 14, 2003, (Respondent Selection Memo).

On November 21, 2003, the Department issued sections A-E of its antidumping questionnaire to the respondents, which included the Department's final physical product characteristics to be used to make fair value comparisons. Section D of the questionnaire included special instructions on how to report costs of production in an economy experiencing high inflation.

We received responses to section A of the questionnaire from MMZ and Ozborsan on December 17, 2003, and from Guven on January 12, 2004. We received responses to sections B, C, and D of the questionnaire from MMZ and Ozborsan in January 2004, and from Guven in February 2004. We issued supplemental questionnaires, pertaining to sections A through D of the questionnaire, to the respondents from January through March 2004. Respondents replied to these supplemental questionnaires in February and March 2004. Ozborsan filed its response and supplemental responses to the Department's questionnaires on a joint basis with its sister company, Onur Metal (Onur).

On January 28, 2004, petitioners submitted a letter in support of the postponement of the preliminary determination. On February 5, 2004, pursuant to section 733(c)(1)(B) of the Act, the Department postponed the preliminary determination of this investigation by 50 days, from February 16, 2004, until April 6, 2004. See *Light-Walled Pipe and Tube from Mexico and Turkey: Notice of Postponement of Preliminary Antidumping Duty Determinations*, 69 FR 5487 (February 5, 2004).

On February 19, 2004, the Department issued the antidumping duty questionnaire to Ozdemir Boru Profil San. Ve. Tic. Ltd. Sti. (Ozdemir) in order to examine its relationship with certain other Turkish respondents. The

Department requested that Ozdemir submit its response to section A of the questionnaire by March 12, 2004. On March 17, 2004, the Department notified Ozdemir that its response to section A of the questionnaire was past due and requested that Ozdemir notify the Department by March 22, 2004, if it had encountered unexpected difficulties in submitting its response. On March 18, 2004, Ozdemir sent a letter to the Department in which it requested a two week extension of the deadline for submitting its section A response. On March 22, 2004, Ozdemir provided an incomplete response to section A of the Department's questionnaire. Furthermore, Ozdemir did not provide a response to sections B, C, and D of the questionnaire, which were due on March 26, 2004, nor did it request an extension of this deadline.

#### Postponement of the Final Determination

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, 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 March 19, 2004, Ozborsan/Onur requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until 135 days after the publication of the preliminary determination. Ozborsan/Onur also included a request to extend the period for any provisional measures from a period of four months to not more than six months after the publication of the preliminary determination. Accordingly, since we have made an affirmative preliminary determination, and the requesting parties account for a significant proportion of exports of the subject merchandise, we have postponed the final determination until not later than 135 days after the date of the publication of the preliminary determination.

<sup>1</sup> Section A of the questionnaire requests general information concerning a company's corporate structure and business practices, the merchandise under investigation, and the manner in which it sells that merchandise in all of its markets. Section B requests a complete listing of all of the company's home market sales of foreign like product or, if the home market is not viable, of sales of the foreign like product in the most appropriate third-country market (this section is not applicable to respondents in non-market economy cases). Section C requests a complete listing of the company's U.S. sales of subject merchandise. Section D requests information on the cost of production of the foreign like product and the constructed value of the merchandise under investigation. Section E requests information on further manufacturing.



### Period of Investigation

The POI is July 1, 2002, through June 30, 2003. See 19 CFR 351.204(b)(1).

### Scope Comments

In accordance with the preamble to the Department's regulations (see *Antidumping Duties; Countervailing Duties*, 62 FR 27296, 27323 (May 19, 1997)), we set aside a period of time for parties to raise issues regarding product coverage of the scope of the investigation and encouraged all parties to submit comments on product coverage within 20 calendar days of publication of the *Initiation Notice* (see 68 FR 57668). As noted above, no comments were submitted to the record of this investigation. However, certain Mexican producers and the petitioners provided comments regarding the scope of these investigations. See the preliminary determination of the antidumping investigation on LWRPT from Mexico.

### Scope of Investigation

The merchandise covered by this investigation is LWRPT from Turkey, which are welded carbon-quality pipe and tube of rectangular (including square) cross-section, having a wall thickness of less than 0.156 inch. These LWRPT have rectangular cross sections ranging from 0.375 x 0.625 inches to 2 x 6 inches, or square cross sections ranging from 0.375 to 4 inches, regardless of specification. LWRPT are currently classifiable under item number 7306.60.5000 of the Harmonized Tariff System of the United States (HTSUS). The HTSUS item number is provided for convenience and customs purposes only. The written product description of the scope is dispositive.

The term "carbon-quality" applies to products in which (i) iron predominates, by weight, over each of the other contained elements, (ii) the carbon content is 2 percent or less, by weight, and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated: 1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium (also called columbium), or 0.15 percent of vanadium, or 0.15 percent of zirconium.

### Selection of Respondents

Section 777A(c)(1) of the Act directs the Department to calculate weight-

average 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 from the exporting country that can reasonably be examined. As guidance in selecting respondents, the petitioners provided a copy of the chapter on Turkish companies from the 14th edition of *Iron and Steel Works of the World*, published by Metal Bulletin Books, in addition to a list of Turkish steel tube manufacturers. See Petition at Exhibit 7B. U.S. Customs and Border Protection (CBP) import statistics identify eighteen exporters/producers of subject merchandise during the POI. However, due to limited resources, we determined that we could investigate only the three Turkish producers/exporters that accounted for the largest volume of exports to the United States during the POI. See Respondent Selection Memo. Therefore, we selected Guven, MMZ, and Ozborsan as mandatory respondents in this investigation.

### Collapsing

Section 771(33)(A) of the Act states that affiliated persons include, "{m}embers of a family, including brothers and sisters (whether by the whole or half blood), spouse, ancestors, and lineal descendants." In addition, section 771(33)(F) of the Act states that, "two or more persons directly or indirectly controlling, controlled by, or under common control with, any person," shall be considered to be affiliated. Furthermore, under 19 CFR 351.401(f), we will treat "two or more affiliated producers as a single entity where those producers (1) Have production facilities for similar or identical products that would not require substantial retooling of either facility in order to restructure manufacturing priorities and (2) the Secretary concludes that there is significant potential for the manipulation of price or production" based on factors such as: (a) The level of common ownership; (b) the extent to which managerial employees or board members of one firm sit on the board of the other firm; and (c) whether operations are intertwined (e.g., through sharing of sales information,

involvement in production and pricing decisions, sharing facilities/employees, and/or significant transactions between the two affiliated producers).

Guven, Ozborsan, and Ozdemir are owned by three brothers, each of which owns the largest percentage of shares in his respective company. In addition, the brother who owns the largest percentage of shares of Ozborsan is also a significant shareholder of Ozborsan's sister company, Onur. The Department considers these three brothers to be "affiliated persons" pursuant to section 771(33)(A) of the Act. See *Final Results of Antidumping Duty Administrative Review: Certain Welded Carbon Steel Pipes and Tubes from Thailand*, 62 FR 53808 (October 16, 1997).

Further, the Department considers Guven, Onur, Ozborsan, and Ozdemir to be affiliated according to section 771(33)(F) of the Act ("two or more persons directly or indirectly, controlled by, or under common control with, any person," shall be considered to be affiliated).

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." Although this section of the statute uses the singular phrase "any person," the Court of International Trade (CIT) has recognized that "the singular word 'person' can be interpreted to encompass a 'family' in order to carry out the intent of the statute." See *Ferro Union, Inv. v. United States*, 44 F. Supp. 2d at 1326 citing *St. Louis v. Missouri*, 263 U.S. 640, 657, 68 L. Ed. 486, 44 S. Ct. 213 (1924), ("words importing the singular may {not} extend and be applied to several persons or things \* \* \* except where it is necessary to carry out the evident intent of the statute (emphasis added).") (*Ferro Union*). As the CIT noted in *Ferro Union*, "the intent of 19 U.S.C. 1677(33) was to identify control exercised through 'corporate or family groupings.' SAA {Statement of Administrative Action} at 838. By interpreting 'family' as a control person, Commerce was giving effect to this intent." See *Ferro Union*, 44 F. Supp. 2d at 1325; see also, 19 CFR 351.102(b) ("{i}n determining whether control over another person exists, within the meaning of section 771(33) of the Act, the Secretary will consider the following factors, among others: corporate or family groupings \* \* \*"). Additionally, in past cases involving control through corporate or family groupings, the Department has noted that the control factors of individual members of the group (e.g., stock ownership, management

positions, board membership) are considered in the aggregate. See *Certain Cold-Rolled Flat-Rolled Carbon-Quality Steel Products From Brazil; Notice of Final Determination of Sales at Less Than Fair Value*, 65 FR 5554, 5566 (February 4, 2000).

With respect to Ozborsan and Onur, the brother who owns Ozborsan is also a significant shareholder in Onur. Moreover, Ozborsan stated that Onur has the same management structure as Ozborsan (see Exhibit A-2 of Ozborsan's December 17, 2003, submission and Ozborsan/Onur's March 29, 2004, submission at 2). The management chart that Ozborsan provided in Exhibit A-2 indicates that the brother who owns the largest percent of shares in Ozborsan is also Ozborsan's "Head of Company." Thus, this person is both a significant shareholder in Onur and is also the "Head of Company" for Onur. Furthermore, the brother who owns the largest percentage of shares in Guven is also the President of Guven. The third brother, who owns the largest percentage of shares in Ozdemir, is also the founder and Managing Director of Ozdemir.

The brothers' leadership positions within these companies, as well as the fact that the brothers own the largest percentage of shares in their respective companies, puts these brothers in a position to directly or indirectly control Guven, Onur, Ozborsan, and Ozdemir, thus satisfying the requirements of affiliation under section 771(33)(F) of the Act. Based on the Department's practice of considering companies or corporate groups under family control to be affiliated under section 771(33)(A) and (F) of the Act, the Department considers Guven, Onur, Ozborsan, and Ozdemir to be affiliated. See Memorandum from Thomas F. Futtner, Acting Office Director, to Holly A. Kuga, Acting Deputy Assistant Secretary, "Decision Memorandum: Whether to Collapse Certain Turkish Pipe and Tube Producers Into A Single Entity," dated April 6, 2004 (Collapsing Memorandum).

Regarding the first collapsing criterion listed in 19 CFR 351.401(f) (producers with production facilities for similar or identical products), the evidence on the record indicates that Guven, Onur, Ozborsan, and Ozdemir produce subject merchandise. Ozborsan stated that it produces subject merchandise at the same production facility as Onur. Production by Ozborsan and Onur is fully integrated; workers from both companies work on the same shifts to fulfill the same production orders—whether for the home market or for export. See Collapsing Memorandum at

5. On this basis, we find that Onur and Ozborsan satisfy the first criterion.

Guven and Ozborsan/Onur reported in their respective responses to section D of the questionnaire the use of an identical manufacturing process to produce subject merchandise. Both companies purchase hot-rolled and cold-rolled steel in coils; the coils are first slit, then formed, welded, and cut to length. *Id.* Furthermore, Guven and Ozborsan/Onur both produce subject merchandise in a wide variety of sizes and reported sales during the POI of nearly all of the same type of products (CONNUMs) in their U.S. and comparison-market databases.

Ozdemir, in its incomplete response to section A of the questionnaire, stated that it manufactures pipes and tubes using coils of hot-rolled and cold-rolled steel. Ozdemir also indicated that it produces both square and rectangular pipe and tube, with outside perimeters and wall thicknesses covering the full range of products included in the scope of this investigation. Since all four companies manufacture a wide variety of sizes of subject merchandise utilizing a similar production process, we conclude that Guven, Onur, Ozborsan, and Ozdemir would not require substantial retooling of their facilities in order to restructure manufacturing priorities.

In analyzing the second criterion, whether there exists significant potential for manipulation of price or production, we first consider the level of ownership. We note that the three brothers own the largest percentage of shares in Guven, Ozborsan, and Ozdemir, respectively, and one of the three brothers is a significant shareholder in Ozborsan's sister company, Onur. Based upon this family ownership, we find that there is common ownership of Guven, Ozborsan/Onur, and Ozdemir and that such ownership is one factor indicating a significant potential for the manipulation of price or production. See Collapsing Memorandum at 6.

Second, in addition to being the shareholders owning the largest percentage of shares, as indicated above, members of this family hold senior management positions within each company. One brother, who owns the largest percentage of shares in Ozborsan, is a member of Ozborsan's Board of Directors and is also the "Head of Company" for both Ozborsan and Onur. Another brother is the President of Guven and his son is the General Manager of Guven, whose responsibilities include "strategic/economic planning" and "procurement/sourcing." See Guven's response to the

Department's section A of the questionnaire, dated January 12, 2004, at page 5. Lastly, the third brother is the founder and Managing Director of Ozdemir. This brother has "full authorization \* \* \* to establish prices, selling and general expenses and production costs." See Ozdemir's response to the Department's section A of the questionnaire, dated March 22, 2004, at page 2. In addition, this person has "full control and is the decision-maker" at Ozdemir. See Collapsing Memorandum at 6. Due to the fact that key senior management positions in Guven, Ozborsan/Onur, and Ozdemir are held by members of this family, we conclude that these close management relationships are another factor indicating a significant potential for the manipulation of price or production between these companies.

Third, regarding the intertwining of operations, we have already indicated that Ozborsan and Onur share the same production facilities and management executives. Even though domestic sales are credited to Onur, and export sales are credited to Ozborsan, Onur's employees do not strictly work on products sold in Turkey, and Ozborsan's employees do not strictly work on products sold in export markets.

Furthermore, Ozborsan/Onur stated that, on occasion, it and one of the other companies have swapped hot-rolled and cold-rolled coils when size availability was an issue. *Id.* at 7. Additionally, Ozborsan/Onur stated that all three of the companies occasionally use each other's trucks for shipments to the port and for transporting raw materials from the port to the factory. According to Ozborsan/Onur, because these swaps were even exchanges (*i.e.*, the quantity swapped by each company was the same), there was no financial transaction to record, and Ozborsan/Onur kept no file documenting such exchanges.

The fact that Ozborsan/Onur does not record such transactions in its inventory records and freight ledger suggests that Ozborsan/Onur and the other company with which it exchanged coils consider each other's inventory and assets as a pool from which both can freely draw. In addition, although Ozborsan/Onur characterizes such swaps as occurring "in a few instances" and "occasionally," the fact that it did not quantify the volume of such transactions leaves open the question of how often such swaps occurred. Lastly, since Ozborsan/Onur and the other company own their own trucks, the fact that they shared these trucks with each other during the POI is evidence of shared facilities.

In addition, Guven reported that during the POI it had several transactions with one of the other two companies owned by the family. Specifically, Guven stated that it sold a significant quantity of subject and non-subject tubes, in addition to a significant quantity of hot-rolled coil, to this other company. Guven also purchased a significant quantity of tubes from this company during the POI. Lastly, Guven reported that it purchased a small amount of galvanized pipes from one of the other companies owned by the family. *Id.* at 8.

Based upon the intertwined operations described above, the Department concludes that these interactions indicate that there is a significant potential for the manipulation of price or production between these companies.

Based on these reasons, we find that Guven, Ozborsan/Onur, and Ozdemir are affiliated producers with similar or identical production facilities that would not require substantial retooling in order to restructure manufacturing priorities. We also find that there exists a significant potential for the manipulation of price or production. See Collapsing Memorandum. Therefore, we have collapsed Guven, Ozborsan/Onur, and Ozdemir, and are treating them as a single entity for purposes of the preliminary determination in this antidumping investigation.

#### Facts Available

For the reasons discussed below, we determine that the use of adverse facts available is appropriate for the preliminary determination with respect to Guven, Ozborsan/Onur, and Ozdemir.

##### A. Use of Facts Available

Section 776(a)(2) of the Act provides that, if an interested party withholds information requested by the Department, fails to provide such information by the deadline or in the form or manner requested, significantly impedes a proceeding, or provides information which cannot be verified, the Department shall use, subject to section 782(d) and (e) of the Act, facts otherwise available in reaching the applicable determination. Section 782(d) of the Act provides that if the Department determines that a response to a request for information does not comply with the Department's request, the Department shall promptly inform the responding party and provide an opportunity to remedy the deficient submission. Section 782(e) of the Act further states that 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.

In this case, Guven, Ozborsan/Onur, and Ozdemir have failed to provide pertinent information requested by the Department that is necessary to properly calculate antidumping margins for its preliminary determination. Specifically, Ozborsan/Onur failed to provide the following requested information, all of which is necessary to complete the Department's calculations: (1) Product-specific costs by CONNUM; (2) an explanation why the company was unable to determine the cost differences between products, or an explanation of why the company believes that the differences are insignificant enough that there is no cost difference between products; (3) a reconciliation of the total costs in the financial statements to the total costs reported to the Department; (4) separate cost files for Ozborsan and Onur which reconcile to each company's financial accounting system; (5) a reconciliation of the production quantities to the sales quantities; (6) depreciation expense based on the revaluated fixed asset values; and (7) calculation of general and administrative and financial expense ratios based on the fiscal year that most closely coincides with the period of investigation. In addition, Ozborsan/Onur stated that it "swapped" hot-rolled coils with one of the other companies. Ozborsan/Onur claims that no records are kept of such swaps, and Ozborsan/Onur was unable to quantify these transactions. As a result of Ozborsan/Onur's failure to provide the above requested information, the Department is unable to use the reported cost of manufacturing data to test home market sales to determine whether the sales prices can form the basis for the calculation of normal value (NV). Additionally, because of the noted omissions, the cost data cannot be used for difference in merchandise purposes or for calculating constructed value (CV).

With respect to Guven, the company failed to provide: (1) Any cost reconciliations; (2) product-specific costs and worksheets; (3) an explanation of its cost accounting system and how costs were allocated between subject and non-subject merchandise; (4) a

description of its production process; (5) detailed cost build-ups for the requested models sold in the third country and home markets; (6) an explanation of its cost response methodology; (7) an explanation as to whether the reported costs were based on world-wide production quantities and not on any specific market; (8) a reconciliation of the production quantities to the sales quantities; and (9) the requested general and administrative (G&A) and financial expense ratios based on the indexed monthly historical G&A and financial expenses and cost of goods sold for the fiscal year 2003. In addition, Guven did not report significant expense items for months for which production was reported. As a result of Guven's failure to provide the above requested information, the Department is unable to use the reported cost of manufacturing data to test home market sales to determine whether the sales prices can form the basis for NV. Additionally, because of the noted omissions, the cost data cannot be used for difference in merchandise purposes or for calculating CV. Additionally, we note that Guven did not respond to the Department's supplemental section D questionnaire by the established deadline.

With respect to Ozdemir, the company provided an incomplete section A response, and failed to provide a response to sections B, C, and D of the Department's questionnaire. Because Ozdemir withheld information requested by the Department, the Department will rely on the facts otherwise available in order to determine a margin for Ozdemir.

Thus, in reaching our preliminary determination, pursuant to sections 776(a)(2)(A), (B), and (C) of the Act, we have based Guven, Ozborsan/Onur, and Ozdemir's dumping margin on facts available.

##### B. Application of Adverse Inferences for Facts Available

In applying facts otherwise available, section 776(b) of the Act provides that the Department may use an inference adverse to the interests of a party that has failed to cooperate by not acting to the best of its ability to comply with the Department's requests for information. See, e.g., *Notice of Final Determination of Sales at Less Than Fair Value and Final Negative Critical Circumstances: Carbon and Certain Alloy Steel Wire Rod from Brazil*, 67 FR 55792, 55794-96 (August 30, 2002). Adverse inferences are appropriate "to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully." See

*Statement of Administrative Action accompanying the Uruguay Round Agreements Act*, H.R. Rep. No. 103-316, at 870 (1994) (SAA). Furthermore, "affirmative evidence of bad faith on the part of a respondent is not required before the Department may make an adverse inference." See *Antidumping Duties; Countervailing Duties*, 62 FR 27355 (May 19, 1997). Although the Department provided respondents with notice of the consequences of failure to adequately respond to the questions, in this case, Guven, Ozborsan/Onur, and Ozdemir have failed to timely provide complete and useable responses to the Department's section D questionnaires. See the Department's letters to Ozborsan/Onur, Guven, and Ozdemir on February 27, 2004, March 12, 2004, and March 17, 2004, respectively. The original questionnaire was issued on November 21, 2003, to which Ozborsan/Onur submitted its section D response on January 12, 2004 and Guven submitted its response on February 19, 2004. In order to address the deficiencies in Ozborsan/Onur's response, the Department issued a supplemental section D questionnaire on February 27, 2004. Ozborsan/Onur's response was received on March 16, 2004. On March 12, 2004, the Department issued the supplemental section D questionnaire to Guven. Guven failed to respond to the supplemental section D questionnaire by the established deadline of March 25, 2004. In these supplemental questionnaires we noted that in the previous submissions, Guven and Ozborsan/Onur failed to provide requested detailed cost of manufacturing information necessary for the Department to adequately analyze the response. Guven and Ozborsan/Onur's failure to provide this critical information in a timely manner has rendered their entire submissions inadequate and unusable for the preliminary determination. In addition, as discussed above, Ozdemir did not provide a response to sections B, C, and D of the questionnaire, which was due on March 26, 2004. This constitutes a failure on the part of these companies to cooperate to the best of their abilities to comply with a request for information by the Department within the meaning of section 776 of the Act. Therefore, the Department has preliminarily determined that in selecting from among the facts otherwise available, an adverse inference is warranted. See, e.g., *Notice of Final Determination of Sales at Less than Fair Value: Circular Seamless Stainless Steel Hollow Products from Japan*, 65 FR 42985, 42986 (July 12, ...)

2000) (the Department applied total adverse facts available (AFA) where respondent failed to respond to the antidumping questionnaires).

#### *C. Selection and Corroboration of Information Used as Facts Available*

Where the Department applies AFA because a respondent failed to cooperate by not acting to the best of its ability to comply with a request for information, section 776(b) of the Act authorizes the Department to rely on information derived from the petition, a final determination, a previous administrative review, or other information placed on the record. See also 19 CFR 351.308(c); SAA at 829-831. In this case, because we are unable to calculate margins based on Guven's, Ozborsan/Onur's, and Ozdemir's own data and because an adverse inference is warranted, we have assigned to all three companies the highest margin from the proceeding, which is the highest margin alleged for Turkey in the petition, as recalculated in the initiation and described in detail below. See *Initiation Notice*.

As noted in the *Corroboration of Normal Value* section below, the calculation of CV in the petition contains an amount of zero for profit because the Turkish producer relied upon for the calculation of the financial ratios reported a loss in its financial statements. Although a publicly available amount for profit is not currently on the record of this investigation, we will consider adding profit to CV for the final determination in the event we are able to identify a publicly available amount for profit that is usable given the facts of this proceeding.

When using facts otherwise available, section 776(c) of the Act provides that, when the Department relies on secondary information (such as the petition), it must, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal.

The SAA clarifies that "corroborate" means that the Department will satisfy itself that the secondary information to be used has probative value. See SAA at 870. The Department's regulations state that independent sources used to corroborate such evidence may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation. See 19 CFR 351.308(d); see also SAA at 870.

To assess the reliability of the petition margin for the purposes of this investigation, to the extent appropriate

information was available, we reviewed the adequacy and accuracy of the information in the petition and during our pre-initiation analysis for both this preliminary determination. See Office of AD/CVD Enforcement Initiation Checklist, at 11 (September 29, 2003) (Initiation Checklist). Also, as discussed below, we examined evidence supporting the calculations in the petition to determine the probative value of the margins in the petition for use as AFA for this preliminary determination. In accordance with section 776(c) of the Act, to the extent practicable, we examined the key elements of the export price (EP) and NV calculations on which the margins in the petition were based. See Memorandum from Paige Rivas, International Trade Analyst, to Tom Futtner, Acting Director, Office 4, Re: Corroboration of Data Contained in the Petition for Assigning Facts Available Rates, dated April 6, 2004 (Corroboration Memo).

#### 1. Corroboration of Export Price

The petitioners based EP on prices of LWRPT obtained from U.S. distributors of products that are identical in size to products manufactured and sold in Turkey. The petitioners calculated net U.S. price by deducting international freight and U.S. import duties for the U.S. price quotes. We compared the U.S. market price quotes with official U.S. import statistics and found the prices used by the petitioners to be reliable.

#### 2. Corroboration of Normal Value

With respect to the NV, the petitioners obtained, through foreign market research, two price quotes from resellers in Turkey for products manufactured by a major Turkish producer named in the Petition. The petitioners calculated net Turkish prices by deducting the average discount offered by the Turkish resellers from the price quotes.

The petitioners also provided information demonstrating reasonable grounds to believe or suspect that sales of LWRPT in the home market were made at prices below the fully absorbed cost of production (COP), within the meaning of section 773(b) of the Act.

Pursuant to section 773(b)(3) of the Act, COP consists of the cost of manufacturing (COM), selling, general, and administrative (SG&A) expenses, financial expenses, and packing expenses. The petitioners calculated COP based on the experience of a U.S. LWRPT producer, adjusted for known differences between costs incurred to produce LWRPT products in the United States and Turkey using publicly



available data. To calculate SG&A and financial expenses, the petitioners relied upon amounts reported in the 2002 financial statements of Borusan Holding A.S., which is the parent company of Mannesman Boru, a major producer of the subject merchandise in Turkey.

Based upon a comparison of the price of the foreign like product to the calculated COP, we found 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 initiated a country-wide cost investigation. For initiation purposes and for the purposes of this preliminary determination, we corrected the petitioners' conversion from dollars per metric ton to dollars per hundred feet for the 55mm x 50mm x 3mm product. See Initiation Checklist at 11 and Attachment III.

Pursuant to sections 773(a)(4), 773(b) and 773(e) of the Act, the petitioners based NV on CV. The petitioners calculated CV using the same COM, SG&A and financial expense figures used to compute the COP. Consistent with section 773(e)(2) of the Act, the petitioners included in CV an amount for profit. For profit, the petitioners relied upon amounts reported in Borusan Holding A.S.'s 2002 financial statements. However, the profit amounted to zero because Borusan reported a loss in its financial statements.

For purposes of corroborating CV, we compared the cost data submitted in the petition to information submitted by MMZ. Specifically, we compared net CV for one CONNUM for MMZ to the CV used to calculate the highest margin in the petition. This CONNUM is identified in Exhibit C2 of MMZ's March 24, 2004, submission as containing production quantities that are comparable to the product with the highest margin in the petition. We found the CV used by the petitioners to be reliable.

Therefore, based on our efforts, described above, to corroborate information contained in the petition, and in accordance with section 776(c) of the Act, we consider the highest margin in the petition to be corroborated to the extent practicable for purposes of this preliminary determination.

Accordingly, in selecting AFA with respect to Guven, Ozborsan/Onur, and Ozdemir, we have applied the margin rate of 34.89 percent, which is the highest estimated dumping margin set forth in the notice of initiation. See *Initiation Notice*, 68 FR 57667.

### Product Comparisons

In accordance with section 771(16) of the Act, all products manufactured by the respondents in the home market and covered by the description contained in the *Scope of Investigation* section, above, and sold in the home market during the POI are considered to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We have relied upon seven criteria to match U.S. sales of subject merchandise to comparison-market sales of the foreign like product: steel type, galvanized coating, whether the merchandise was painted or primed, outside perimeter, wall thickness, shape, and finish. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we compared U.S. sales to the next most similar foreign like product on the basis of the characteristics listed above.

### Fair Value Comparisons

To determine whether sales of LWRPT from Turkey were made in the United States at LTFV, we compared the EP to the NV, as described in the *Export Price* and *Normal Value* sections of this notice. In accordance with section 777A(d)(1)(A)(i) of the Act, we calculated weighted-average EPs. We compared these to weighted-average home market prices in Turkey.

Based on our examination of Turkey's inflation indices, we determined that the Turkish economy was experiencing high inflation during the POI. "High inflation" is a term used to refer to a high rate of increase in price levels. Investigations covering exports from countries with highly inflationary economies require the use of special methodologies in comparing prices and calculating CV and COP. See Policy Bulletin No. 94.5, "Differences in Merchandise Calculations in Hyperinflationary Economies," dated March 25, 1994. Generally, the Department considers the annual inflation rate to be high if it is in excess of 25 percent. Based upon our examination of the consumer price and wholesale price indices, which indicate that Turkey experienced an inflation rate over 25 percent during the POI, we find Turkey's economy experienced high inflation. See 2002 and 2003 issues of the International Monetary Fund's *International Financial Statistics*.

Because Turkey's economy experienced high inflation during the POI, as is Department practice, we limited our comparisons to home market sales made during the same month in which the U.S. sale occurred.

This methodology minimizes the extent to which calculated dumping margins are overstated or understated due solely to price inflation that occurred in the intervening period between the U.S. and home market sales. See *Notice of Preliminary Determination of Sales at Less Than Fair Value; Certain Cold-Rolled Carbon Steel Flat Products From Turkey*, 67 FR 31264 (May 9, 2002); see also *Notice of Final Determination of Sales at Less Than Fair Value; Certain Cold-Rolled Carbon Steel Flat Products From Turkey*, 67 FR 62126 (October 3, 2002).

### Export Price

In calculating U.S. price, the Department used EP, as defined in section 772(a) of the Act, because the merchandise was sold, prior to importation, by MMZ to unaffiliated purchasers in the United States. Section 772(a) of the Act defines EP as the price at which the subject merchandise is first sold (or agreed to be sold) before the date of importation by the exporter or producer outside the United States to an unaffiliated purchaser for exportation to the United States, as adjusted under subsection 772(c) of the Act. We calculated EP based on the packed prices charged to unaffiliated customers in the United States. In accordance with section 772(c)(2)(A) of the Act, we made deductions from the starting price, where applicable, for foreign movement expenses, including brokerage and handling and inland freight.

The Department interprets section 772(c)(1)(B) as requiring that any duty drawback be added to EP if two criteria are met: (1) import duties and rebates are directly linked to, and dependent upon, one another, and; (2) raw materials were imported in sufficient quantities to account for the duty drawback received on exports of the manufactured product. Since the normal criteria appear to have been met in this case, we made additions to the starting price for duty drawback in accordance with section 772(c)(1)(B) of the Act. However, we intend to further scrutinize the appropriateness of granting MMZ's requested duty drawback adjustment in light of the facts of this case in making our final determination in this investigation.

### Normal Value

#### A. Selection of Comparison Market

Section 773(a)(1) of the Act directs that NV be 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 has sufficient aggregate



value, if quantity is inappropriate) and that there is no particular market situation in the home market that prevents a proper comparison with the EP transaction. The statute contemplates that quantities (or value) will normally be considered insufficient if they are less than five percent of the aggregate quantity (or value) of sales of the subject merchandise to the United States. Based on a comparison of aggregate quantity of home market sales and U.S. sales by MMZ, we determined that the quantity of foreign like product sold in Turkey permitted a proper comparison with the sales of subject merchandise because the quantity of sales in the home market was more than five percent of the quantity of sales to the U.S. market. Accordingly, for MMZ, we based NV on home market sales. In deriving NV, we made adjustments as detailed in the *Calculation of Normal Value Based on Constructed Value* section below.

#### B. Affiliated-Party Transactions and Arm's-Length Test

MMZ reported that it sold LWRPT in the comparison market only to unaffiliated customers. Therefore, application of the arm's-length test is unnecessary.

#### C. Cost of Production Analysis

In the original petition, the petitioners alleged that sales of LWRPT in the home market were made at prices below the fully absorbed COP, and accordingly, requested that the Department conduct a country-wide sales-below-cost investigation. Based upon the comparison of the petition's adjusted prices and COP for the foreign like product, and in accordance with section 773(b)(2)(A)(i) of the Act, we found reasonable grounds to believe or suspect that sales of LWRPT in Turkey were made at prices below the COP. See *Initiation Notice*. As a result, the Department has conducted an investigation to determine whether MMZ made sales in the home market at prices below its COP during the POI within the meaning of section 773(b) of the Act. Our COP analysis is described below.

##### 1. Calculation of Cost of Production

We determined that the Turkish economy experienced significant inflation during the POI. Therefore, in order to avoid the distortive effect of inflation on our comparison of costs and prices, we requested that each respondent submit the product-specific COM incurred during each month of the reporting period. We calculated a period-average COM for each product after indexing the reported monthly

costs during to an equivalent currency level using the Wholesale Price Index for Turkey from the *International Financial Statistics* published by the International Monetary Fund. We then restated the period-average COMs in the currency values of each respective month.

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP for MMZ based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for the home market G&A expenses and interest expenses. We relied on the submitted COP data except in the specific instances noted below, where the submitted costs were not appropriately quantified or valued.

We made the following adjustments to MMZ's submitted COP data: (1) Increased the reported raw material cost to disallow the claimed offset for the sales of second quality merchandise; (2) increased the reported raw material costs to include the duty cost which was claimed as a duty drawback adjustment to U.S. price but which was not included in COM; (3) increased the reported raw material cost to reflect the higher of transfer price or market price as required by section 773(f)(2) of the Act; (4) increased fixed overhead to include the full depreciation expense on assets purchased in 2002; (5) increased G&A expenses to include accrual adjustments; and (6) revised the reported financial expense ratio to include total net foreign exchange gains and losses.

##### 2. Test of Home Market Sales Prices

As required by section 773(b) of the Act, we compared MMZ's adjusted weighted-average COP to the comparison-market sales prices of the foreign like product, in order to determine whether these sales had been made at prices below the COP within an extended period of time in substantial quantities, and whether such prices were sufficient to permit the recovery of all costs within a reasonable period of time. On a product-specific basis, we compared the revised COP to the comparison-market prices, less any applicable movement charges, taxes, rebates, commissions, and other direct and indirect selling expenses.

##### 3. Results of the COP Test

We disregarded below-cost sales where (1) 20 percent or more of a 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 for certain products, MMZ made home market sales at prices below the COP within an extended period of time in substantial quantities. Further, we found that these sales prices did not permit the recovery of costs within a reasonable period of time.

Therefore, we excluded these sales from our analysis in accordance with section 773(b)(1) of the Act.

#### D. Calculation of Normal Value Based on Comparison-Market Prices

We determined price-based NVs for MMZ as follows. Where applicable, we made adjustments for differences in cost attributable to differences in physical characteristics of the merchandise pursuant to section 773(a)(6)(C)(ii) of the Act, as well as for differences in circumstances of sale (COS) attributed to billing adjustments and imputed credit expenses in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We also made adjustments, pursuant to 19 CFR 351.410(e), for indirect selling expenses incurred on comparison-market or U.S. sales where commissions were granted on sales in one market but not in the other (the commission offset). Finally, we deducted home market packing costs and added U.S. packing costs in accordance with sections 773(a)(6)(A) and (B) of the Act.

#### 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 CV. Accordingly, for those models of LWRPT for which we could not determine the NV based on comparison-market sales, either because there were no sales of a comparable product or all sales of the comparison products failed the COP test, we based NV on CV.

In accordance with sections 773(e)(1) and (e)(2)(A) of the Act, we calculated CV based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for selling expenses, G&A, interest, profit and U.S. packing costs. We calculated the cost of materials and fabrication based on the methodology described in the "Calculation of Cost of Production" section of this notice. In accordance with section 773(e)(2)(A) of the Act, we

based selling expenses, G&A, and profit on the amounts incurred and realized by MMZ, in connection with the production and sale of the foreign like product in the ordinary course of trade for consumption in the foreign country.

#### F. Level of Trade/Constructed Export Price Offset

In accordance with section 773(a)(1)(B) of the Act, to the extent practical, the Department determined NV based on sales in the home market at the same level of trade (LOT) as the EP sales. The NV LOT is that of the starting-price sales in the home market. For EP sales, the U.S. LOT is also the level of the starting-price sale.

To determine whether NV sales are at a different LOT than the EP sales, we examined stages in the marketing process and selling activities along the chain of distribution between the producer and the unaffiliated customer. If the home market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the home market sales on which NV is based and the home market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act.

In determining whether separate LOTs exist, we obtained information from MMZ about the marketing stages for the reported U.S. and home market sales, including a description of the selling activities performed by MMZ for each channel of distribution. In identifying LOTs for EP and home market sales, we considered the selling functions reflected in the starting price before any adjustments. See 19 CFR 351.412(c)(1)(i) and (iii). We expect that, if claimed LOTs are the same, the selling functions and activities of the seller at each level should be similar. Conversely, if a party claims that LOTs are different for different groups of sales, the selling functions and activities of the seller for each group should be dissimilar.

In its questionnaire responses, MMZ reported that during the POI, it sold the foreign like product in the home market through one channel of distribution and in the United States through two channels of distribution. We found that MMZ engaged in similar selling activities for all home market sales. However, we found that there are also no differences in the selling functions performed in the U.S. channels of distribution. Based on the similarity of the selling functions, we have determined that MMZ sold LWRPT at one LOT in the home market and one LOT in the U.S. market. We also found

that the selling activities performed by MMZ in the home market are similar to those performed in the U.S. market, with the exception that MMZ provided freight and delivery in the U.S. market but did not provide this service in the home market. Specifically, MMZ engaged in sales forecasting, strategic/economic planning, packing, order/input processing, and use of direct sales personnel in both markets. Therefore, we have preliminarily determined that the LOTs in the home and U.S. markets are the same LOT. Thus, a LOT adjustment is not required for comparison of U.S. sales to home market sales.

#### G. Currency Conversions

The Department's preferred source for daily exchange rates is the Federal Reserve Bank. However, the Federal Reserve Bank does not track or publish exchange rates for Turkish Lira. Therefore, we made currency conversions based on exchange rates from the Dow Jones News/Retrieval Service.

#### Verification

In accordance with section 782(i) of the Act, we intend to verify all information relied upon in making our final determination.

#### All Others Rate

Section 735(c)(5)(A) of the Act provides for the use of an "all others" rate, which is applied to non-investigated firms. See SAA at 873. This section states that the all others rate shall generally be an amount equal to the weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins based entirely upon the facts available. Therefore, we have preliminarily assigned to all other exporters of LWRPT from Turkey a margin that is based on the margin calculated for the mandatory respondent.

#### Suspension of Liquidation

In accordance with section 733(d) of the Act, we are directing CBP to suspend liquidation of all entries of LWRPT from Turkey that are 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 NV exceeds the U.S. price, as indicated in the chart below. These suspension-of-liquidation instructions will remain in effect until

further notice. The weighted-average dumping margins are as follows:

Manufacturer/exporter	Margin (percent)
Güven .....	34.89
MMZ .....	4.75
Ozborsan/Onur .....	34.89
Ozdemir .....	34.89
All Others .....	4.75

#### Disclosure

The Department will disclose calculations performed within five days of the date of publication of this notice to the parties to the proceeding in accordance with 19 CFR 351.224(b).

#### International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our preliminary sales at LTFV determination. If our final antidumping determination is affirmative, the ITC will determine whether the imports covered by that determination are materially injuring, or threatening material injury to, the U.S. industry. The deadline for that ITC determination would be the later of 120 days after the date of this preliminary determination or 45 days after the date of our final determination.

#### Public Comment

Case briefs for this investigation must be submitted no later than one week after the issuance of the last verification report. Rebuttal briefs must be filed within five days after the deadline for submission of case briefs. 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. Further, the Department respectfully requests that all parties submitting written comments also provide the Department with an additional copy of the public version of any such comments on diskette.

Section 774 of the Act provides that the Department will hold a hearing to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs, provided that such a hearing is requested by an interested party. If a request for a hearing is made in an investigation, the hearing normally will be held two days after the deadline for submission of the rebuttal briefs, at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the

time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request within 30 days of the publication of this notice. Requests should specify the number of participants and provide a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.

As noted above, the Department will make its final determination within 135 days after the date of the publication of the preliminary determination.

This determination is issued and published pursuant to sections 733(f) and 777(i)(1) of the Act.

Dated: April 6, 2004.

**James J. Jochum,**

*Assistant Secretary for Import Administration.*

[FR Doc. 04-8377 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-580-844]

#### Steel Concrete Reinforcing Bar From The Republic of Korea: Final Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of final results of antidumping duty administrative review.

**SUMMARY:** On October 7, 2003, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on steel concrete reinforcing bar (rebar) from the Republic of Korea (Korea). The review covers rebar exported to the United States by Dongkuk Steel Mill Co., Ltd. (DSM) and Korea Iron and Steel Co., Ltd. (KISCO), which have been collapsed into a single entity for purposes of this administrative review, during the period from January 30, 2001, through August 31, 2002. After analyzing the comments received, we have made certain changes in the margin calculation. The final weighted-average dumping margin for the reviewed entity is listed below in the section entitled "Final Results of Review."

**EFFECTIVE DATE:** April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Richard Johns or Mark Manning, AD/CVD Enforcement, Office IV, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482-2305 or (202) 482-5253, respectively.

#### SUPPLEMENTARY INFORMATION:

##### Background

On October 7, 2003, the Department published in the *Federal Register* the preliminary results of the administrative review of the antidumping duty order on rebar from Korea. See *Steel Concrete Reinforcing Bar from The Republic of Korea: Notice of Preliminary Results of Antidumping Duty Administrative Review*, 68 FR 57883 (October 7, 2003) (*Preliminary Results*). During the period October through December 2003, the Department received KISCO's responses to sections A-D of the Department's questionnaire, which was issued on September 15, 2003, as a result of the Department's decision to collapse DSM and KISCO. See Memorandum from Thomas F. Futtner, Acting Office Director, to Holly A. Kuga, Acting Deputy Assistant Secretary, "Decision Memorandum: Whether to Collapse Dongkuk Steel Mill Co., Ltd., and Korea Iron and Steel Co., Ltd. Into a Single Entity," dated September 12, 2003. In January 2004, the Department conducted verification of the sales and cost of production (COP) information reported by the collapsed entity, DSM/KISCO.

In response to the Department's invitation to comment on the *Preliminary Results* of this review, DSM/KISCO filed a case brief on March 3, 2004. The petitioner<sup>1</sup> also filed a case brief on March 3, 2004. On March 10, 2004, DSM/KISCO and the petitioner filed rebuttal briefs.

The Department has conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

##### Scope of the Review

The products covered by the antidumping duty order are all rebar sold in straight lengths, currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 7214.20.00 or any other tariff item number. Specifically excluded are plain rounds (*i.e.*, non-deformed or smooth bars) and rebar that has been further processed through

<sup>1</sup> The petitioner in this proceeding is the Rebar Trade Action Coalition and its individual members (collectively, the petitioner).

bending or coating. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the order is dispositive.

##### Period of Review

The period of review (POR) is from January 30, 2001 through August 31, 2002.

##### Verification

As provided in section 782(l) of the Act, we verified the information submitted by the respondent for use in our final results. We used standard verification procedures including examination of relevant accounting and production records, and original source documents provided by the DSM/KISCO.

##### Analysis of Comments Received

All issues raised in the case brief submitted by DSM/KISCO and the petitioner are contained in the "Issues and Decision Memorandum" from Holly A. Kuga, Acting Deputy Assistant Secretary, to James J. Jochum, Assistant Secretary for Import Administration (*Issues and Decision Memorandum*). The *Issues and Decision Memorandum* is dated concurrently with this notice and hereby adopted by this notice. A list of the issues which the parties have raised is attached to this notice as an appendix. Parties can find a complete discussion of all issues raised in this administrative review in the *Issues and Decision Memorandum* which is on file in the Central Records Unit, room B-099 of the main Department of Commerce building. In addition, a complete version of the *Issues and Decision Memorandum* can be accessed directly on the Web at "<http://ia.ita.doc.gov>". The paper copy and electronic version of the *Issues and Decision Memorandum* are identical in content.

##### Changes Since the Preliminary Results

Based on our analysis of comments received, we have made certain changes in the margin calculation. These changes are discussed in the relevant sections of the *Issues and Decision Memorandum*. The Department issued the antidumping questionnaire to KISCO approximately two weeks before the fully extended deadline for the preliminary results. Therefore, KISCO's sales and costs of production data were not available for inclusion in the preliminary results. KISCO submitted its sales and COP data after the preliminary results, and we have included this information in our final results of review. Furthermore, we have corrected a programming error

contained in our preliminary results regarding the calculation of the constructed export price (CEP) offset. See *Issues and Decision Memorandum*. Lastly, we have made corrections to the reported information pursuant to minor errors found during verification. See *Issues and Decision Memorandum*.

#### Final Results of Review

We determine that the following weighted-average percentage margin exists for DSM/KISCO for the period January 30, 2001, through August 31, 2002.

Exporter/manufacturer	Margin (percent)
Dongkuk Steel Mill Co., Ltd./ .... Korea Iron and Steel Co., Ltd.	11.74

#### Assessment

The Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR § 351.212(b)(1), we have calculated importer-specific assessment rates for merchandise subject to this review. Since DSM/KISCO reported the entered values and importer for its sales, we have calculated an importer-specific *ad valorem* duty assessment rate based on the ratio of the total amount of dumping margins calculated for the examined sales to the entered value of sales used to calculate those duties. If the importer-specific assessment rate is above *de minimis* (i.e., greater than 0.50 percent *ad valorem*), we will instruct CBP to assess the importer-specific rate uniformly on all entries made during the POR. The Department will issue appropriate assessment instructions directly to the CBP within 15 days of publication of the final results of review.

#### Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of rebar from Korea entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for DSM and KISCO will be the rate shown above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the

manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered by any segment of this proceeding, the cash deposit rate will continue to be 22.89 percent, which is the "all others" rate established in the LTFV investigation. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

#### Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR § 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

#### Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective orders (APOs) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR § 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 5, 2004.

Joseph A. Spetrini,  
Acting Assistant Secretary for Import Administration.

#### Appendix 1—Issues in Decision Memorandum

##### Comments and Responses

- Whether Dongkuk Steel Mill Co., Ltd. (DSM), Korea Iron and Steel Co., Ltd. (KISCO), and Dongkuk Industries Co., Ltd. (DKI) are affiliated.
- Whether the Department should "collapse" DSM and KISCO.
- Whether the Department should classify DSM's U.S. sales as weldable rebar.
- Whether the Department should correct a clerical error in the preliminary margin program to allow for the calculation of the CEP offset.

5. Whether the Department should reverse its decision and reject DSM's sales, which are a major and significant correction to the sales listing.

6. Whether DSM/KISCO's August 11, 2003 letter supports the acceptance of new factual information.

7. Whether the Department can retroactively confer timely status.

[FR Doc. 04-8375 Filed 4-12-04; 8:45 am]  
BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-201-832]

#### Light-Walled Rectangular Pipe and Tube from Mexico: Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of preliminary determination of sales at less than fair value and postponement of final determination.

**EFFECTIVE DATE:** April 13, 2004.

**FOR FURTHER INFORMATION CONTACT:** Maisha Cryor (Prolamsa) at (202) 482-5831, Richard Johns (Galvak/Hylsa) at (202) 482-2305, Magd Zalok (LM) at (202) 482-4162, or Crystal Crittenden (Regiomontana) at (202) 482-0989; AD/CVD Enforcement, Office IV, Group II, Import Administration, Room 1870, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

#### Preliminary Determination

We preliminarily determine that light-walled rectangular pipe and tube (LWRPT) from Mexico is being sold, 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.

#### SUPPLEMENTARY INFORMATION:

##### Case History

On September 9, 2003, the Department of Commerce (the Department) received a petition for the imposition of antidumping duties on LWRPT from Mexico, filed in proper form, by California Steel and Tube, Hannibal Industries, Inc., Leavitt Tube Company, LLC, Maruichi American Corporation, Northwest Pipe Company,



Searing Industries, Inc., Vest Inc., and Western Tube and Conduit Corporation (collectively, petitioners). See Letter from petitioners to Secretary Evans of the Department and Secretary Abbott of the U.S. International Trade Commission (ITC), "Petition for the Imposition of Antidumping Duties: Light-Walled Rectangular Pipe and Tube from Mexico and Turkey," dated September 9, 2003 (Petition). The Department initiated this antidumping investigation of LWRPT from Mexico on September 29, 2003. See *Notice of Initiation of Antidumping Investigations: Light-Walled Rectangular Pipe and Tube from Mexico and Turkey*, 68 FR 57668 (October 6, 2003) (*Initiation Notice*). Since the initiation of the investigation, the following events have occurred.

The Department set aside a period for all interested parties to raise issues regarding product coverage of the scope of the investigation. See *Initiation Notice*, at 68 FR 57668. On October 27, 2003, Productos Laminados de Monterrey, S.A. de C.V. (Prolamsa) and IMSA-MEX, S.A. de C.V. and IMSA, Inc. (collectively, IMSA) submitted comments on product coverage. Petitioners and Prolamsa submitted rebuttal comments in November 2003, January 2004, and March 2004. See *Scope Comments* section below.

On October 23, 2003, the Department selected Prolamsa, Galvak, S.A. de C.V. (Galvak), Perfiles y Herrajes LM, S.A. de C.V. (LM), and Regiomontana De Perfiles Y Tubos (Regiomontana) (collectively, respondents), as mandatory respondents in this investigation. See Memorandum from Maisha Cryor, Analyst, to Thomas F. Futtner, Acting Office Director, Re: Selection of Respondents for the Antidumping Duty Investigation of Light-Walled Rectangular Pipe and Tube from Mexico, dated October 23, 2003 (Respondent Selection Memo), on file in the Central Records Unit (CRU), Room B-099 of the Main Commerce Building.

On October 24, 2003, the ITC preliminarily determined that there is a reasonable indication that an industry in the United States is materially injured by reason of LWRPT imported from Mexico that is alleged to be sold in the United States at LTFV. See *Light-Walled Rectangular Pipe and Tube from Mexico and Turkey*, 68 FR 61829 (October 30, 2003).

On October 28, 2003, the Department issued to respondents sections A-E of its antidumping questionnaire, which included proposed product characteristics that the Department intends to use to make its fair value

comparisons.<sup>1</sup> After setting aside a period of time for all interested parties to provide comments on the proposed product characteristics, the Department received comments from Galvak and petitioners on November 4, 2003, and from Prolamsa on November 5, 2003. On November 10, 2003, Galvak and petitioners submitted rebuttal comments.

After reviewing interested parties' comments, the Department revised the proposed product characteristics and instructed Prolamsa, Galvak, LM, and Regiomontana, to report their product characteristics according to the revised requirements for sections B and C of the Department's questionnaire. See Memorandum from Maisha Cryor, Analyst, to the File, RE: Revision to Product Characteristics, dated November 21, 2003.

In December 2003, we received responses to sections A-C of the antidumping questionnaire from all of the respondents. We issued supplemental questionnaires, pertaining to sections A, B, and C of the questionnaire, in December 2003, January 2004 and February 2004. Respondents replied to these supplemental questionnaires in January, February, and March of 2004. On January 9, 2004, in accordance with 19 CFR 351.301(d)(2)(i)(B), petitioners submitted allegations that home market sales were made at prices below the cost of production (COP) by each respondent in this investigation. After reviewing petitioners' allegations, the Department, in accordance with section 773(b)(2)(A)(i) of the Act, concluded that there was a reasonable basis to suspect that each respondent is selling LWRPT in Mexico at prices below the COP and initiated cost investigations on February 2, 2004, (Prolamsa)<sup>2</sup>, February

3, 2004 (Regiomontana)<sup>3</sup>, and February 4, 2004, (Galvak/Hylsa<sup>4</sup> and LM<sup>5</sup>).

On January 28, 2004, petitioners submitted a letter in support of the postponement of the preliminary determination. On February 5, 2004, pursuant to section 733(c)(1)(B) of the Act, the Department postponed the preliminary determination of this investigation by 50 days, from February 16, 2004, until April 6, 2004. See *Light-Walled Rectangular Pipe and Tube from Mexico and Turkey: Notice of Postponement of Preliminary Antidumping Duty Determinations*, 69 FR 5487 (February 5, 2004).

On February 23, 2004, all of the respondents submitted responses to section D of the Department's antidumping questionnaire. The Department issued supplemental section D questionnaires to respondents, and received timely responses in March of 2004.

#### Postponement of the Final Determination

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, 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 March 15, 2004, Galvak/Hylsa requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until

<sup>1</sup> Section A of the questionnaire requests general information concerning a company's corporate structure and business practices, the merchandise under investigation, and the manner in which the company sells that merchandise in all markets. Section B requests a complete listing of all of the company's home market sales on the foreign like product or, if the home market is not viable, sales of the foreign like product in the most appropriate third-country market (this section is not applicable to respondents in non-market economy cases). Section C requests a complete listing of the company's U.S. sales of subject merchandise. Section D requests information on the cost of production of the foreign like product and the constructed value of the merchandise under investigation. Section E requests information on further manufacturing.

<sup>2</sup> See Memo to Howard Smith from Maisha Cryor, James Balog and Gina Lee regarding Light-walled Rectangular Pipe and Tube from Mexico, RE: Petitioners' Allegation of Sales Below the Cost of Production for Productos Laminados de Monterrey, S.A. de C.V. (Prolamsa Cost Memo).

<sup>3</sup> See Memo to Thomas Futtner from Crystal Crittenden, Trinette Ruffin, and Gina Lee regarding Light-walled Rectangular Pipe and Tube from Mexico, RE: Petitioners' Allegation of Sales Below the Cost of Production for Regiomontana de Perfiles y Tubos, S.A. de C.V. (Regiomontana Cost Memo).

<sup>4</sup> See Memo to Thomas Futtner from magd Zalok, Richard Johns, Gina Lee, and James Balog regarding Light-walled Rectangular Pipe and Tube from Mexico, RE: Petitioners' Allegation of Sales Below the Cost of Production for Galvak, S.A. de C.V. and Hylsa, S.A. de C.V. (Galvak/Hylsa Cost Memo).

<sup>5</sup> See Memo to Thomas Futtner from Magd Zalok, Trinette Ruffin, and Gina Lee regarding Light-walled Rectangular Pipe and Tube from Mexico, RE: Petitioners' Allegation of Sales Below the Cost of Production for Perfiles y Herrajes L.M., S.A. de C.V. (LM Cost Memo).



135 days after the publication of the preliminary determination. Galvak/Hylsa also included a request to extend the provisional measures to not more than 135 days after the publication of the preliminary determination. Accordingly, because we have made an affirmative preliminary determination, and the requesting party accounts for a significant proportion of exports of the subject merchandise, we have postponed the final determination until not later than 135 days after the date of the publication of the preliminary determination.

#### Period of Investigation

The period of investigation (POI) is July 1, 2002, through June 30, 2003. See 19 CFR 351.204(b)(1).

#### Scope Comments

In accordance with the preamble to the Department's regulations (*see Antidumping Duties; Countervailing Duties*, 62 FR 27296, 27323 (May 19, 1997) (*Preamble*)), in the *Initiation Notice*, we set aside a period of time for parties to raise issues regarding the product coverage of the scope of the investigation and encouraged parties to submit comments on product coverage within 20 calendar days of publication of the *Initiation Notice*. See *Initiation Notice*, 68 FR at 57668. On October 27, 2003, Prolamsa requested that the Department exclude pre-primed products from the scope of the investigation because it claims that petitioners do not produce pre-primed products and, therefore, they do not have a legitimate interest in including such items in the scope of this investigation. Further, Prolamsa argued that pre-primed LWRPT should be excluded from the scope because the unique properties of the production process ensure that it is only purchased by a particular customer type. In addition, Prolamsa requested that the Department expressly state whether the subject merchandise includes all specifications and product categories of LWRPT (*i.e.*, mechanical, ornamental, etc.).

On October 27, 2003, IMSA requested that the Department exclude galvanized LWRPT from the scope of the investigation because it claims that petitioners do not produce such products and that the unique properties of galvanized LWRPT limit its interchangeability with respect to other products.

On November 3, 2003, petitioners requested that the scope of the investigation not exclude those products specified by Prolamsa and IMSA. Specifically, petitioners contend that

domestic petitioning firms produce both pre-primed and galvanized LWRPT and, therefore, they have a legitimate interest in including such products within the scope of this investigation. Petitioners also argue that exclusion of pre-primed LWRPT would enable respondents to circumvent any antidumping order on LWRPT simply by applying a primer coat to un-coated LWRPT.

Prolamsa rebutted petitioners' comments in a January 23, 2004, submission, by stating that one of the petitioning domestic producers, identified in petitioners' rebuttal comments as a producer of pre-primed LWRPT (Searing Industries), did not, in fact, produce pre-primed LWRPT during the POI. In addition, Prolamsa included an affidavit from a non-petitioning domestic producer, who opposes the inclusion of pre-primed LWRPT in this investigation. See Prolamsa's January 23, 2004, rebuttal comments at Exhibit 1. On March 4, 2004, petitioners submitted an affidavit from petitioning producer Searing Industries, stating that Searing Industries does, in fact, produce and sell pre-primed LWRPT in the normal course of business.

On March 24, 2004, Prolamsa rebutted petitioners' comments and argued that the affidavit submitted by petitioners fails to establish that Searing Industries has or is currently producing pre-primed LWRPT in the United States. In addition, Prolamsa countered petitioners' argument that exclusion of pre-primed LWRPT from the scope of the investigation would result in circumvention of any antidumping order.

We have not adopted the change to the scope of the investigation proposed by Prolamsa. Prolamsa argues that pre-primed LWRPT should be excluded from the scope of the investigation because petitioners do not manufacture the product and because the unique properties of the pre-priming production process dictate that only particular customers will purchase it. However, petitioners submitted an affidavit by a petitioning domestic producer which states that it does produce pre-primed LWRPT. In addition, the statute does not require that petitioners produce every type of product covered by the scope of the investigation. See *Notice of Final Determination of Sales at Less Than Fair Value: Circular Seamless Stainless Steel Hollow Products From Japan*, 65 FR 42985 (July 12, 2000) and accompanying *Issues and Decision Memorandum*, at Comments 1 and 2 (*Hollow Products*). Moreover, Prolamsa

has not provided any basis to distinguish pre-primed LWRPT from the class or kind of merchandise subject to this investigation. For these reasons, we find no reason to exclude pre-primed LWRPT from the scope of this investigation. See Memorandum from Maisha Cryor, Analyst, to Thomas F. Futtner, Acting Office Director Re: Consideration of Scope Exclusion Request, dated April 6, 2004 (Scope Exclusion Request Memo).

Similarly, we have not adopted the change to the scope of the investigation proposed by IMSA. IMSA also argues that galvanized LWRPT should be excluded from the scope of this investigation because petitioners do not manufacture the product and because the unique properties of LWRPT restricts its ability to be interchangeable with other products. However, also in this case, petitioners submitted evidence demonstrating that a petitioning domestic producer does, in fact, produce galvanized LWRPT. In addition, as indicated above, the statute does not require that petitioners produce every type of product covered by the scope of the investigation. See *Hollow Products* 65 FR 42985 (July 12, 2000) and accompanying *Issues and Decision Memorandum*, at Comments 1 and 2. Moreover, IMSA has not provided any basis to distinguish galvanized LWRPT from the class or kind of merchandise subject to this investigation. For these reasons, we find no reason to exclude galvanized LWRPT from the scope of this investigation. See Scope Exclusion Request Memo.

With respect to Prolamsa's request that the Department expressly state whether the subject merchandise includes all specifications and product categories of LWRPT, we note that the scope of this investigation reads, in relevant part, "[t]hese LWRPT have rectangular cross sections ranging from 0.375 x 0.625 inches to 2 x 6 inches, or square cross sections ranging from 0.375 to 4 inches, *regardless of specification.*" (emphasis added). Thus, the scope language explicitly states that LWRPT of a certain size is covered by this investigation, regardless of specification. Moreover, the phrase "regardless of specification" means that the scope covers any product meeting the physical characteristics described therein, regardless of product category. Therefore, there is no need to modify the scope language as suggested by Prolamsa. See Scope Exclusion Request Memo.

#### Scope of Investigation

The merchandise covered by this investigation is LWRPT from Mexico,

which is welded carbon-quality pipe and tube of rectangular (including square) cross-section, having a wall thickness of less than 0.156 inch. These LWRPT have rectangular cross sections ranging from 0.375 x 0.625 inches to 2 x 6 inches, or square cross sections ranging from 0.375 to 4 inches, regardless of specification. LWRPT are currently classifiable under item number 7306.60.5000 of the Harmonized Tariff System of the United States (HTSUS). The HTSUS item number is provided for convenience and customs purposes only. The written product description of the scope is dispositive.

The term "carbon-quality" applies to products in which (i) Iron predominates, by weight, over each of the other contained elements, (ii) the carbon content is 2 percent or less, by weight, and (iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated: 1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium (also called columbium), or 0.15 percent of vanadium, or 0.15 percent of zirconium.

#### Selection of Respondents

Section 777A(c)(1) of the Act directs the Department to calculate individual weighted-average dumping margins for each known exporter and producer of the subject merchandise. Where it is not practicable to examine all of the 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 from the exporting country that can reasonably be examined. The petitioners identified nine Mexican exporters/producers of subject merchandise. See Petition at Exhibit 7A. U.S. Customs and Border Protection (CBP) import statistics for the POI identified twenty-four exporters/producers of subject merchandise during the POI. Due to limited resources, we determined that we could investigate only the four Mexican producers/exporters that accounted for the largest volume of exports of subject merchandise during the POI. See Respondent Selection

Memo. Therefore, we selected Prolamsa, Galvak, LM, and Regiomontana as mandatory respondents in this investigation.

#### Collapsing Affiliated Parties

Section 771(33) of the Act defines affiliated persons. Moreover, 19 CFR 351.401(f) identifies the criteria that must be met in order to treat two or more affiliated producers as a single entity (i.e., "collapse" the firms) for purposes of calculating a dumping margin.

Specifically, 19 CFR 351.401(f)(1) provides that affiliated producers of subject merchandise will be treated as a single entity (i.e., collapsed), where (1) Those producers have production facilities for similar or identical products that would not require substantial retooling in order to restructure manufacturing priorities, and (2) the Department concludes that there is a significant potential for manipulation of price or production. 19 CFR 351.401(f)(2) of the Department's regulations provides factors the Department may consider in determining whether there is significant potential for manipulation of price or production, namely (i) The level of common ownership; (ii) the extent to which managerial employees or board members of one firm sit on the board of directors of an affiliated firm; and (iii) whether operations are intertwined, such as through the sharing of sales information, involvement in production and pricing decisions, the sharing of facilities or employees, or significant transactions between the affiliated producers.

Galvak and Hylsa are wholly-owned subsidiaries of Hylsamex, a Mexican holding company, which is 90-percent owned by Alfa, S.A. de C.V. Galvak and Hylsa requested that they be treated as affiliated parties. See Galvak/Hylsa's section A questionnaire response at 15. Pursuant to section 771(33)(F) of the Act, the Department has preliminarily determined that Galvak and Hylsa are affiliated because Galvak and Hylsa are both wholly-owned subsidiaries of Hylsamex, and thus, are "two persons controlled by {a} person."<sup>6</sup>

Galvak and Hylsa also satisfy the first requirement of the collapsing test, as they both possess production facilities of identical or similar types of merchandise, and these facilities would not require substantial retooling to restructure manufacturing priorities. In addition, they also satisfy the second requirement of the collapsing test,

<sup>6</sup> See Galvak's January 5, 2004 supplemental section A response at 2 (supplemental response).

because there is a significant potential for manipulation of price or production given that Galvak and Hylsa are owned by the same company, have a significant overlap of management positions and have intertwined operations. Therefore, we are treating Galvak and Hylsa as a single entity for purposes of our antidumping analysis. For a more detailed analysis, see Memorandum from Maisha Cryor and Richard Johns, Analysts, to Thomas F. Futtner, Acting Office Director, Regarding "Whether to Collapse Galvak, S.A. de C.V. and Hylsa, S.A. de C.V.," dated February 13, 2004 (Collapsing Memo). This single entity is hereafter referred to as Galvak/Hylsa.

#### Product Comparisons

In accordance with section 771(16) of the Act, we considered all products sold in the home market as described in the "Scope of Investigation" section of this notice, above, that were sold in the ordinary course of trade for purposes of determining appropriate product comparisons to U.S. sales. We have relied upon seven criteria to match U.S. sales of subject merchandise to comparison-market sales of the foreign like product. These criteria, in order of importance are: (1) Steel type, (2) galvanized coating, (3) whether the merchandise was painted or primed, (4) outside perimeter, (5) wall thickness, (6) shape, and (7) finish. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade, based on the characteristics listed above. Where we were unable to match U.S. sales to home market sales of the foreign like product, we based normal value (NV) on constructed value (CV).

#### Fair Value Comparisons

To determine whether sales of LWRPT from Mexico were made in the United States at LTFV, we compared the export price (EP) or constructed export price (CEP) to the NV, as described in the *Export Price and Constructed Export Price* and *Normal Value* sections of this notice. In accordance with section 777A(d)(1)(A)(i) of the Act, we calculated weighted-average EPs and CEPs. We compared these to weighted-average NVs in Mexico.

#### Export Price and Constructed Export Price

For the price to the United States, we used, as appropriate, EP or CEP as defined in sections 772(a) and (b) of the Act, respectively. Section 772(a) of the Act defines EP as the price at which the subject merchandise is first sold (or

agreed to be sold) before the date of importation by the exporter or producer outside the United States to an unaffiliated purchaser for exportation to the United States. We based EP on packed and delivered prices to unaffiliated purchasers in the United States. In accordance with section 772(c)(2) of the Act, we reduced the starting price by movement expenses and export taxes and duties, if appropriate. These deductions included, where appropriate, foreign inland freight, foreign brokerage and handling, international freight, marine insurance and U.S. customs duties.

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 the merchandise, or by a seller affiliated with the producer or exporter, to an unaffiliated purchaser, as adjusted under sections 772(c) and (d) of the Act. We based CEP on packed prices to unaffiliated purchasers in the United States. In accordance with section 772(c)(2) of the Act, we reduced the starting price by movement expenses U.S. duties, if appropriate. Movement expenses include, where applicable, expenses incurred for foreign inland freight, international freight, marine insurance, foreign and U.S. brokerage and handling, U.S. customs duties (including harbor maintenance fees and merchandise processing fees), U.S. inland insurance, U.S. inland freight, and warehousing. In accordance with section 772(d)(1) of the Act we made additional adjustments to the starting price in order to calculate CEP, by deducting direct and indirect selling expenses related to commercial activity in the United States. Pursuant to section 772(d)(3) of the Act, where applicable, we made an adjustment to the starting price for CEP profit.

We determined the EP or CEP for each company as follows:

#### *Prolamsa*

We calculated a CEP for all of Prolamsa's U.S. sales because the subject merchandise was sold directly to Prolamsa Inc., Prolamsa's U.S. affiliate, prior to being sold to the first unaffiliated purchaser in the United States. We made deductions from the starting price for movement expenses in accordance with section 772(c)(2)(A) of the Act. These items include expenses incurred for inland freight, domestic brokerage and handling, U.S. brokerage and handling and U.S. customs duties. In addition, we made deductions from the U.S. starting price for discounts and

rebates. Additionally, we made adjustments to the U.S. starting price for billing adjustments.

#### *LM*

We calculated an EP for all of LM's sales because the merchandise was sold directly by LM to the first unaffiliated purchaser in the United States prior to importation. We made deductions from the FOB, duty paid, starting price for movement expenses in accordance with section 772(c)(2)(A) of the Act. These items include expenses incurred for inland freight, domestic brokerage and U.S. customs duties, when applicable. In addition, we made deductions from the starting price for discounts, where appropriate.

#### *Regiomontana*

We calculated an EP for all of Regiomontana's sales because the merchandise was sold directly by Regiomontana to the first unaffiliated purchaser in the United States prior to importation.<sup>7</sup> We made deductions from the FOB starting price for movement expenses in accordance with section 772(c)(2)(A) of the Act. These items include inland freight, international freight, and U.S. and domestic brokerage and handling. Additionally, we adjusted for billing adjustments in accordance with 19 CFR 351.401(c).

#### *Galvak/Hylsa*

On December 2, 2003, in accordance with the instructions provided in the Department's questionnaire regarding reporting requirements for affiliated companies, Galvak and Hylsa submitted a single response to section A of the Department's questionnaire. Galvak and Hylsa, collectively, continued to submit responses to the Department's questionnaire and supplemental questionnaires. Due to the Department's decision to collapse the two companies, we accepted and conducted an analysis of the collapsed data. See Collapsing Memo.

We calculated an EP for all of Galvak/Hylsa's sales because the merchandise was sold directly by Galvak/Hylsa to the first unaffiliated purchaser in the United States prior to importation.<sup>8</sup> We note

<sup>7</sup> Petitioners requested that the Department treat Regiomontana's sales made through unaffiliated U.S. commissioned selling agents as CEP sales, and deduct the commission expense from the CEP. See Petitioners March 25, 2004, letter at 8-9. However, because all of Regiomontana's U.S. sales were made by Regiomontana to the first unaffiliated purchaser in the United States prior to importation, in accordance with section 772(a) of the Act we have treated all U.S. sales as EP sales.

<sup>8</sup> Petitioners requested that the Department treat Galvak/Hylsa's U.S. sales as CEP transactions, because Galvak/Hylsa was the importer of record

that Galvak/Hylsa's affiliated reseller in the United States provided certain administrative services pertaining to a small percentage of U.S. sales.

#### **See Galvak/Hylsa's December 31, 2003, questionnaire response at 8.**

However, the sales documents provided in the questionnaire response indicate that these services were minor and that the invoicing was done by Galvak/Hylsa. Further, the merchandise was shipped directly from Galvak/Hylsa's production facility in Mexico to the unaffiliated U.S. customer. *Id.* Therefore, we have preliminarily concluded that the sales were, in fact, EP sales. We made deductions from the FOB starting price for movement expenses in accordance with section 772(c)(2)(A) of the Act. These items include inland freight, domestic brokerage, U.S. brokerage, and warehousing. In accordance with 19 CFR 351.401(c), we increased the starting price for freight fees, brokerage and handling fees, insurance fees, and duty fees, charged to the customer, and adjusted for billing adjustments. In addition, we made deductions from the starting price for discounts, where appropriate.

#### **Normal Value**

##### *A. Selection of Comparison Market*

Section 773(a)(1) of the Act directs the Department to base NV on the price at which the foreign like product is sold in the home market, provided that, among other things, the merchandise is sold in sufficient quantities in the home market (or has sufficient aggregate value, if quantity is inappropriate). The statute provides that the total quantity of home market sales of foreign like product (or value) will normally be considered sufficient if it is five percent or more of the aggregate quantity (or value) of sales of the subject merchandise. Based on a comparison of the aggregate quantity of home market sales of foreign like product and U.S. sales of subject merchandise by Prolamsa, LM, Galvak/Hylsa, and Regiomontana, we determined that the quantity of foreign like product sold in Mexico is more than five percent of the quantity of U.S. sales of subject merchandise for each

for its own sales of subject merchandise during the POI. See Petitioners March 25, 2004, letter at 9-10. However, where the same party is both the foreign producer/exporter, as well as the importer of record, the Department's practice is to treat such sales as EP transactions. See *Certain Preserved Mushrooms from India: Preliminary Results of Antidumping Duty Administrative Review*, 69 FR 10659, 10661-10662 (March 8, 2004). Therefore, consistent with the Department's practice, we have continued to treat Galvak/Hylsa's U.S. sales as EP transactions.

respondent. Accordingly, for each of the respondents, we based NV on home market sales.

In deriving NV, we made adjustments as detailed in the *Calculation of Normal Value Based on Comparison-Market Prices and Calculation of Normal Value Based on Constructed Value* sections below.

#### B. Affiliated-Party Transactions and Arm's-Length Test

During the POI, Prolamsa, Regiomontana, LM, and Galvak/Hylsa sold foreign like product to affiliated customers.

To test whether these sales were made at arm's-length prices, we compared, on a model-specific basis, the starting prices of sales to affiliated and unaffiliated customers, net of all discounts and rebates, movement charges, direct selling expenses, commissions, and home market packing. Where the price to the affiliated party was, on average, within a range of 98 to 102 percent of the price of the same or comparable merchandise sold to unaffiliated parties, we determined that sales made to the affiliated party were at arm's-length. See 19 CFR 351.403(c); see also, *Preamble*, 69 FR at 69186. Sales to affiliated customers in the home market that were not made at arm's-length prices were excluded from our analysis because we considered them to be outside the ordinary course of trade. See 19 CFR 351.102(b).

#### C. Cost of Production Analysis

Based on timely allegations filed by the petitioners, and in accordance with section 773(b)(2)(A)(i) of the Act, we found reasonable grounds to believe or suspect that LWRPT sales were made at prices below the COP. As a result, we initiated sales below cost investigations on February 2, 2004 (Prolamsa),<sup>9</sup> on February 4, 2004 (LM<sup>10</sup> and Galvak/Hylsa),<sup>11</sup> and on February 3, 2004 (Regiomontana)<sup>12</sup> to determine whether sales were made at prices below the COP.

We conducted the COP analysis as described below.

##### 1. Calculation of Cost of Production

In accordance with section 773(b)(3) of the Act, we calculated a weighted-average COP for each respondent based on the sum of the cost of materials and fabrication of the foreign like product, plus amounts for the home market

general and administrative (G&A) expenses and interest expenses. We relied on the submitted COP data, except as noted below:

##### Galvak/Hylsa

We revised the financial expense ratio by including the full amount of net exchange losses and net gain on monetary positions instead of the selected portions of the net exchange losses and net gains that were reported. In addition, we added back certain interest income items. We also recalculated the rate based on the figures from the parent company's 2002 consolidated income statement instead of using the average of the parent company's 2002 and 2003 income statements.

For both Galvak and Hylsa, we revised their G&A ratios by using the administrative expenses, including charges from their parent companies and debt restructuring expenses, and COGS figures from Hylsa and Galvak's respective 2002 unconsolidated income statements instead of an average of their respective 2002 and 2003 income statements. See Galvak/Hylsa's Analysis Memorandum, dated April 6, 2004.

##### Prolamsa

We adjusted the reported total cost of manufacturing to include the depreciation expense related to the revaluation of fixed assets recorded in Prolamsa's audited financial statements in accordance with Mexican generally accepted accounting principles. See Prolamsa's Analysis Memorandum, dated April 6, 2004.

We adjusted the G&A ratio to reflect the 2002 profit sharing costs included in Prolamsa's 2002 audited financial statements. *Id.*

##### LM

We adjusted the reported total cost of manufacturing to include the depreciation expense related to the revaluation of fixed assets recorded in LM's audited financial statements in accordance with Mexican generally accepted accounting principles. We adjusted the G&A ratio to reflect the 2002 profit sharing costs included in LM's 2002 audited financial statements. In addition, we adjusted the reported interest expenses for exchange gains and losses, interest paid to affiliates and the gain on monetary position. See LM's Analysis Memorandum, dated April 6, 2004.

##### Regiomontana

We adjusted the G&A ratio to reflect the 2002 profit sharing costs included in Regiomontana's 2002 audited financial

statements. We adjusted the reported interest expense for the gain on monetary position. See Regiomontana's Cost Analysis Memorandum, dated April 6, 2004.

##### 2. Test of Home Market and Third-Country Market Sales Prices

As required by section 773(b)(1) of the Act, for each respondent subject to a cost investigation, we compared, on a product-specific basis, the adjusted weighted average COP to the comparison-market prices, less any applicable movement charges, taxes, rebates, commissions, and other direct and indirect selling expenses to determine whether these sales had been made at prices below the COP. For those sales that we determined were made below COP, we examined whether they had been made within an extended period of time in substantial quantities, and whether such prices were sufficient to permit the recovery of all costs within a reasonable period of time. See sections 773(b)(1)(A) and (B) of the Act.

##### 3. Results of the COP Test

Pursuant to section 773(b)(2)(C) of the Act, when less than 20 percent of the respondent's sales of a given product were at prices less than the COP, we did not disregard any below-cost sales of that product because the below-cost sales were not made in substantial quantities within an extended period of time. When 20 percent or more of the respondent's sales of a given product during the POI were at prices less than the COP, we disregarded the below-cost sales because they were made in substantial quantities within an extended period of time pursuant to sections 773(b)(2)(B) and (C) of the Act and because, based on comparisons of prices to weighted-average COPs for the POI, we determined that these sales were at prices which would not permit recovery of all costs within a reasonable period of time in accordance with section 773(b)(2)(D) of the Act. Based on this test, we disregarded below-cost sales with respect to Galvak/Hylsa. See Analysis Memorandum to the file dated April 6, 2004, for additional information. For the remaining respondents, less than 20 percent of sales of a given product were at prices less than COP. Therefore, we did not disregard any below-cost sales for these respondents.

##### D. Calculation of Normal Value Based on Comparison-Market Prices

We determined price-based NVs for respondent companies as follows. For all respondents, we made adjustments to the starting price for any differences

<sup>9</sup> See Prolamsa Cost Memo.

<sup>10</sup> See LM Cost Memo.

<sup>11</sup> See Galvak/Hylsa Cost Memo.

<sup>12</sup> See Regiomontana Cost Memo.



in packing costs, in accordance with section 773(a)(6) of the Act, and we deducted from starting prices movement expenses pursuant to section 773(a)(6)(B)(ii) of the Act. In addition, where applicable, we made adjustments to starting prices to account for differences in cost attributable to differences in the physical characteristics of the merchandise sold in the U.S. and home markets pursuant to section 773(a)(6)(C)(ii) of the Act, as well as for differences in circumstances of sale (COS) in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We also made adjustments, pursuant to 19 CFR 351.410(e), for indirect selling expenses incurred on comparison-market or U.S. sales where commissions were granted on sales in one market but not in the other market, where applicable.

Company-specific adjustments are described below.

#### *Prolamsa*

We based NV for Prolamsa on prices to unaffiliated customers or, as indicated above, affiliated customers, if affiliated party home market sales satisfied the arm's-length test. We reduced the home market starting price for rebates in accordance with 19 CFR 351.401(c). In addition, we reduced the starting price for inland freight pursuant to section 773(a)(6)(B) of the Act. In accordance with 19 CFR 351.401(c), we increased the starting price for interest revenue and adjusted for billing adjustments and discounts. We also made COS adjustments to the starting price for imputed credit expenses in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. Finally, we deducted home market packing costs from, and added U.S. packing costs to the starting price in accordance with sections 773(a)(6)(A) and (B) of the Act.

#### *LM*

We based NV for LM on prices to unaffiliated customers or, as indicated above, affiliated customers, if affiliated party home market sales satisfied the arm's-length test. We reduced the home market starting price for rebates in accordance with 19 CFR 351.401(c). We reduced the home market starting price for discounts and inland freight pursuant to section 773(a)(6)(B) of the Act. We also made COS adjustments to the starting price for imputed credit expenses in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. Finally, we deducted home market packing costs from, and added U.S. packing costs to the starting price in accordance with sections 773(a)(6)(A) and (B) of the Act.

#### *Galvak/Hylsa*

We based NV for Galvak/Hylsa on prices to unaffiliated customers or, as indicated above, affiliated customers, if affiliated party home market sales satisfied the arm's-length test. In accordance with 19 CFR 351.401(c), we increased the starting price for freight fees charged to the customer and interest revenue, and adjusted for billing adjustments. We reduced the home market starting price for movement expenses such as inland freight and warehousing pursuant to section 773(a)(6)(B) of the Act. We also made COS adjustments to the starting price for imputed credit expenses and warranty expenses in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We deducted home market packing costs from, and added U.S. packing costs to, the starting price in accordance with sections 773(a)(6)(A) and (B) of the Act.

#### *Regiomontana*

We based NV for Regiomontana on prices to unaffiliated customers or, as indicated above, affiliated customers, if affiliated party home market sales satisfied the arm's-length test. Where applicable, we made an adjustment for inland freight pursuant to section 773(a)(6)(B) of the Act. In accordance with 19 CFR 351.401(c), we increased the starting price for handling fees charged to the customer and interest revenue and adjusted for billing adjustments and discounts. We also made COS adjustments to the starting price for imputed credit expenses in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. Finally, we deducted home market packing costs from, and added U.S. packing costs to, the starting price in accordance with sections 773(a)(6)(A) and (B) of the Act.

#### *E. Calculation of Normal Value Based on Constructed Value*

Section 773(b)(1) of the Act provides that if, after disregarding all sales made at prices below the COP, there are no comparison market sales made in the ordinary course of trade, NV shall be based on constructed value (CV). We calculated CV in accordance with section 773(e) of the Act. Specifically, section 773(e) of the Act provides that CV shall be based on the sum of the cost of materials and fabrication for the foreign like product, plus amounts for selling, general and administrative expenses (SG&A), profit, and U.S. packing.

In accordance with section 773(e)(2)(A) of the Act, we used the actual amounts incurred and realized by

each respondent in connection with the production and sale of the foreign like product, in the ordinary course of trade, for consumption in the comparison market to calculate SG&A expenses and profit. For price-to-CV comparisons, we made adjustments to CV for COS differences, pursuant to section 773(a)(8) of the Act.

#### *F. Level of Trade/Constructed Export Price Offset*

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we determined NV based on sales in the comparison market at the same level of trade (LOT) as the U.S. sales (either EP or CEP transactions). The NV LOT is that of the starting-price sale in the comparison market or, when the NV is based on CV, that of the sales from which we derive SG&A expenses and profit. For EP sales, the U.S. LOT is also the level of the starting-price sale, which is usually the price of the sale from the exporter to the importer. For CEP sales, it is the level of the constructed sale from the exporter to the importer.

To determine whether comparison market sales are at a different LOT than EP or CEP transactions, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison-market sales are at a different LOT, and the difference affects price comparability with U.S. sales, 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 a LOT adjustment pursuant to section 773(a)(7)(A) of the Act. For CEP sales, if the LOT of the home market sale is more remote from the factory than the CEP level and there is no basis for determining whether the difference between the LOT of the home market sale and the CEP transaction affects price comparability, we adjust NV pursuant to section 773(a)(7)(B) of the Act (the CEP offset provision). See *Final Determination of Sales at Less Than Fair Value: Greenhouse Tomatoes From Canada*, 67 FR 8781 (February 26, 2002).

To determine whether a LOT adjustment is warranted, we obtained information from each respondent about the marketing stages at which its reported U.S. and comparison-market sales were made, including a description of the selling activities performed by the respondent for each of its channels of distribution. In identifying LOTs for EP and comparison market sales, we considered the selling



functions reflected in the starting price before any adjustments. For CEP sales, we considered only the selling activities reflected in the price after the deduction of expenses and profit pursuant to section 772(d) of the Act. Generally, if the claimed LOTs are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that LOTs are different for different groups of sales, the functions and activities of the seller should be dissimilar.

In conducting our LOT analysis for each respondent, we took into account the specific customer types, channels of distribution, and selling functions of each respondent. For Galvak/Hylsa, Regiomontana, Prolamsa and LM, we found that there was a single LOT in the United States and a single, identical, LOT in the comparison market.

Therefore, it was not necessary to make a LOT or CEP offset adjustment. For a further discussion of our LOT analysis for each respondent, see their respective Level of Trade Memorandums, dated April 6, 2004.

#### G. Currency Conversions

We made currency conversions to 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 intend to verify all information relied upon in making our final determination.

#### All Others Rate

Section 735(c)(5)(A) of the Act provides for the use of an "all others" rate, which is applied to non-investigated firms. See *Statement of Administrative Action*, H.R. Doc. No. 103-316, Vol. I (1994). This section states that the all others rate shall generally be an amount equal to the weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins based entirely upon the facts available. Therefore, we have preliminarily assigned to all other exporters of LWRPT from Mexico a margin that is based on the weighted-average margins calculated for all mandatory respondents.

#### Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing CBP to suspend liquidation of all shipments of

LWRPT from Mexico that are 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 NV exceeds the U.S. price, as indicated below. These suspension-of-liquidation instructions will remain in effect until further notice. The weighted-average dumping margins are as follows:

Manufacturer/exporter	Margin (percent)
Prolamsa .....	5.56
LM .....	13.61
Galvak/Hylsa .....	19.89
Regiomontana .....	4.45
All Others .....	11.59

#### Disclosure

The Department will disclose to the parties to the proceeding the calculations performed in the preliminary determination within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

#### International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our preliminary sales at LTFV determination. If our final antidumping determination is affirmative, the ITC will determine whether the imports covered by that determination are materially injuring or threatening material injury to the U.S. industry. The deadline for the final ITC determination would be the later of 120 days after the date of this preliminary determination or 45 days after the date of our final determination.

#### Public Comment

Case briefs for this investigation must be submitted no later than one week after the issuance of the last verification report. Rebuttal briefs must be filed within five days after the deadline for submission of case briefs. 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. Further, the Department respectfully requests that all parties submitting written comments also provide the Department with an additional copy of the public version of any such comments on diskette.

Section 774 of the Act provides that the Department will hold a hearing to

afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs, provided that such a hearing is requested by an interested party. If a request for a hearing is made in an investigation, the hearing normally will be held two days after the deadline for submission of the rebuttal briefs, at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate in a hearing if one is requested, must submit a written request within 30 days of the publication of this notice. Requests should specify the number of participants and provide a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.

As noted above, the Department will make its final determination within 135 days after the date of the publication of the preliminary determination.

This determination is issued and published pursuant to sections 733(f) and 777(i)(1) of the Act.

Dated: April 6, 2004.

**James J. Jochum,**

*Assistant Secretary for Import Administration.*

[FR Doc. 04-8376 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-DS-P

#### DEPARTMENT OF COMMERCE

#### National Oceanic and Atmospheric Administration

[I.D. 040804A]

#### Proposed Information Collection; Comment Request; Coast Pilot Report

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA).  
**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

**DATES:** Written comments must be submitted on or before June 14, 2004.

**ADDRESSES:** Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer,

Department of Commerce, Room 6625, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at [dHynek@doc.gov](mailto:dHynek@doc.gov)).

**FOR FURTHER INFORMATION CONTACT:**

Requests for additional information or copies of the information collection instrument and instructions should be directed to Oren Stembel at 301-713-2750, ext. 165, or at [Oren.Stembel@noaa.gov](mailto:Oren.Stembel@noaa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

NOAA produces the U.S. Nautical Coast Pilot, a series of nine books that supplement marine nautical charts. The Coast Pilot contains information essential to navigators in U.S. coastal and intra-coastal waters but that cannot be shown graphically on charts. The Coast Pilot Report is offered to the public as a means for recommending changes to the publication.

**II. Method of Collection**

A paper form is used.

**III. Data**

*OMB Number:* 0648-0007.

*Form Number:* NOAA Form 77-6.

*Type of Review:* Regular submission.

*Affected Public:* Individuals or households.

*Estimated Number of Respondents:* 100.

*Estimated Time Per Response:* 30 minutes.

*Estimated Total Annual Burden Hours:* 50.

*Estimated Total Annual Cost to Public:* \$0.

**IV. Request for Comments**

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 7, 2004.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 04-8385 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-JE-S

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

[I.D. 112803C]

RIN 0648-AR74

**Fisheries of the Exclusive Economic Zone Off Alaska; Rebuilding Overfished Fisheries; Correction**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Correction to a notice.

**SUMMARY:** This document corrects a notice published in the *Federal Register* on April 5, 2004, announcing the approval of Amendment 17 to the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs. This action is necessary to correct an error made regarding the approval date of the amendment. All other information remains unchanged.

**FOR FURTHER INFORMATION CONTACT:** Gretchen Harrington, 907-586-7228 or [gretchen.harrington@noaa.gov](mailto:gretchen.harrington@noaa.gov).

**SUPPLEMENTARY INFORMATION:** NMFS published a notice announcing the approval of Amendment 17 to the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crabs on April 5, 2004 (69 FR 17651, FR Doc. 04-7509). While the amendment was approved on March 11, 2004, the notice announced an approval date of March 18, 2004. This action corrects this error.

**Correction**

In the *Federal Register* of April 5, 2004, in FR Doc. 04-7509, on page 17651, in the first column, correct the "Dates" caption to read:

DATES: The amendment was approved on March 11, 2004.

Also, on page 17652, in the first column, under the heading Response to Comments, in response 5, lines 9 and 10, "March 18, 2004." is corrected to read "March 11, 2004."

Dated: April 7, 2004.

**Alan D. Risenhoover,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 04-8384 Filed 4-12-04; 8:45 am]

BILLING CODE 3510-22-S

**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**Proposed Collection; Comment Request**

**AGENCY:** Office of the Assistant Secretary of Defense (Health Affairs) DoD.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary of Defense (Health Affairs) announces a proposed information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written comments and recommendations on the continuing information collection should be sent to Lt Col Michael Hartzell, 5111 Leesburg Pike, Suite 810, Falls Church, VA, 22041-3206.

**FOR FURTHER INFORMATION CONTACT:** To request more information on this information collection, please write to the above address or contact LTC Michael Hartzell, by calling 703 681-3636 or e-mail at [michael.hartzell@tma.osd.mil](mailto:michael.hartzell@tma.osd.mil).

*Title Associated Form and OMB Number:* Viability of TRICARE Standard Survey; OMB Number 0720—[to Be Determined].

*Needs and Uses:* Data will be collected from civilian providers to determine how many are/not accepting TRICARE Standard patients and to ascertain the reasons.

Information will be used to assess the scope and nature of any problems related to beneficiary access to care.

*Affected Public:* Individuals.  
*Annual Burden Hours:* 2340.

*Number of Respondents:* 9,360.

*Responses per Respondent:* 1.  
*Average Burden per Response:* 15 minutes.

*Frequency:* Annual.

**SUPPLEMENTARY INFORMATION:** The Health Program Analysis and Evaluation Directorate (HPAE) under authority of

the Office of the Assistant Secretary of defense (Health Affairs)/TRICARE Management Activity will undertake an evaluation of the Department of Defense's TRICARE Standard healthcare option. HPAE will collect and analyze data that are necessary to meet the requirements outlined in section 723 of the National Defense Authorization Act for Fiscal Year 2004. Activities include the collection and analysis of data obtained from civilian physicians (M.D.s & D.O.s) within U.S. TRICARE market areas. Specifically, telephone surveys of civilian providers will be conducted in the TRICARE market areas to determine how many healthcare providers are accepting new patients under TRICARE Standard in each market area. The telephone surveys will be conducted in at least 20 TRICARE market areas in the United States each fiscal year until all market areas in the United States have been surveyed. In prioritizing the order in which these market areas will be surveyed, representatives of TRICARE beneficiaries will be consulted in identifying locations with historical evidence of access-to-care problems under TRICARE Standard. These areas will receive priority in surveying. Information will be collected telephonically to determine the number of healthcare providers that currently accept TRICARE Standard beneficiaries as patients under TRICARE Standard in each market area. Providers will also be asked if they would accept TRICARE Standard beneficiaries as new patients under TRICARE Standard. Analyses and reports will include all legislative requirements.

Dated: April 7, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04-8256 Filed 4-12-04; 8:45 am]

BILLING CODE 5001-06-M

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Submission for OMB Review; Comment Request

#### ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

**DATES:** Consideration will be given to all comments received by May 13, 2004.

**Title, Form, and OMB Number:** Intercontinental Ballistic Missile Hardened Intersite Cable Right-of-Way Landowner/Tenant Questionnaire; AF Form 3951; OMB Number 0701-0141.

**Type of Request:** Extension.  
**Number of Respondents:** 4,000.  
**Responses per Respondent:** 1.  
**Annual Responses:** 4,000.  
**Average Burden per Response:** 15 minutes.

**Annual Burden Hours:** 1,000.  
**Needs and Uses:** The information collection requirement is used to report changes in ownership/lease information, conditions of missile cable route and associated appurtenances, and projected building/excavation projects. The information collected is used to ensure the integrity of the Hardened Intersite Cable System (HICS) and to maintain a close contact public relations program with involved personnel and agencies. This information also aids in notifying landowners and tenants when HICS preventative or corrective maintenance becomes necessary to ensure uninterrupted Intercontinental Ballistic Missile command and control capability.

**Affected Public:** Individuals or households; farms; State, local or tribal government.

**Frequency:** Biennially.  
**Respondent's Obligation:** Voluntary.  
**OMB Desk Officer:** Ms. Jacqueline Zeiher. Written comments and recommendations on the proposed information collection should be sent to Ms. Zeiher at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

**DOD Clearance Officer:** Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/ESCD/Information Management Division, 1225 Jefferson Davis Highway, Suite 504, Arlington, VA 22202-4326.

Dated: April 7, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04-8257 Filed 4-12-04; 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 Meeting date change.

**SUMMARY:** On Tuesday, December 30, 2003 (68 FR 75219) the Department of

Defense announced closed meetings of the Defense Science Board (DSB) Task Force on Critical Homeland Infrastructure Protection. The meeting originally announced for June 17-18, 2004, has been rescheduled to June 23-24, 2004. It will be held at SAIC, 4001 N. Fairfax Drive, Suite 500, Arlington, VA.

Dated: April 7, 2004.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04-8258 Filed 4-12-04; 8:45 am]

BILLING CODE 5001-06-M

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before June 14, 2004.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection

necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 7, 2004.

**Angela C. Arrington,**  
Leader, Regulatory Information Management Group, Office of the Chief Information Officer.

#### Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Annual Progress Reporting Form for Special Demonstration Programs.

*Frequency:* Annually.

*Affected Public:* Not-for-profit institutions; businesses or other for-profit, State, local, or tribal gov't, SEAs or LEAs.

*Reporting and Recordkeeping Hour Burden:*

Responses: 41.

Burden Hours: 1,148.

*Abstract:* This data collection will be conducted annually to obtain program and performance information from Rehabilitation Services Administration (RSA) grantees on their project activities. The data will be collected in accordance with the Government Performance and Results Act. Grantees will submit data via an internet form.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2499. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address [vivian\\_reese@ed.gov](mailto:vivian_reese@ed.gov). Requests may also be electronically mailed to the Internet address [OCIO\\_RIMG@ed.gov](mailto:OCIO_RIMG@ed.gov) or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address [SheilaCarey@ed.gov](mailto:SheilaCarey@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information

Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 04-8343 Filed 4-12-04; 8:45 am]

BILLING CODE 4000-01-P

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before June 14, 2004.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 7, 2004.

**Angela C. Arrington,**  
Leader, Regulatory Information Management Group, Office of the Chief Information Officer.

#### Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Report of Early Intervention Services on IFSPs Provided to Infants, Toddlers and Their Families in Accordance with Part C and Report of Number and Type of Personnel Employed and Contracted to Provide Early Intervention Services.

*Frequency:* Annually.

*Affected Public:* State, local, or tribal gov't, SEAs or LEAs (primary).

*Reporting and Recordkeeping Hour Burden:*

Responses: 56.

Burden Hours: 4,760.

*Abstract:* This package provides instructions and forms necessary for States to report, by race and ethnicity, the number of infants and toddlers with disabilities and their families receiving different types of Part C services, and the number of personnel employed and contracted to provide services for infants and toddlers with disabilities and their families. Data are obtained from state and local service agencies and are used to assess and monitor the implementation of IDEA and for Congressional reporting.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2496. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address [vivian\\_reese@ed.gov](mailto:vivian_reese@ed.gov). Requests may also be electronically mailed to the Internet address [OCIO\\_RIMG@ed.gov](mailto:OCIO_RIMG@ed.gov) or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address [SheilaCarey@ed.gov](mailto:SheilaCarey@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 04-8344 Filed 4-12-04; 8:45 am]

BILLING CODE 4000-01-P



**DEPARTMENT OF EDUCATION****Notice of Proposed Information Collection Requests**

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before June 14, 2004.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 7, 2004.

**Angela C. Arrington,**

*Leader, Regulatory Information Management Group, Office of the Chief Information Officer.*

**Office of Special Education and Rehabilitative Services**

*Type of Review:* Reinstatement.

*Title:* Report of Children with Disabilities Exiting Special Education During the School Year.

*Frequency:* Annually.

*Affected Public:* State, local, or tribal gov't, SEAs or LEAs (primary).

*Reporting and Recordkeeping Hour Burden:*

Responses: 60.

Burden Hours: 39,420.

*Abstract:* This package provides instructions and a form necessary for States to report the number of students aged 14 and older served under IDEA-B exiting special education. This form satisfies reporting requirements and is used by OSEP to monitor SEAs, and for Congressional reporting.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2495. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address [vivian\\_reese@ed.gov](mailto:vivian_reese@ed.gov). Requests may also be electronically mailed to the Internet address [OCIO\\_RIMG@ed.gov](mailto:OCIO_RIMG@ed.gov) or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address [Sheila\\_Carey@ed.gov](mailto:Sheila_Carey@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 04-8345 Filed 4-12-04; 8:45 am]

BILLING CODE 4000-01-P

**DEPARTMENT OF EDUCATION****Notice of Proposed Information Collection Requests**

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information

collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before June 14, 2004.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 7, 2004.

**Angela C. Arrington,**

*Leader, Regulatory Information Management Group, Office of the Chief Information Officer.*

**Office of Special Education and Rehabilitative Services**

*Type of Review:* Reinstatement.

*Title:* Report of Children with Disabilities Exiting Special Education During the School Year.

*Frequency:* Annually.

*Affected Public:* State, local, or tribal gov't, SEAs or LEAs (primary).

*Reporting and Recordkeeping Hour Burden:*



Responses: 60.  
Burden Hours: 7,950.

**Abstract:** This package provides instructions and a form necessary for States to report Personnel serving children with disabilities served under IDEA-B. This form satisfies reporting requirements and is used by OSEP for monitoring, implementing IDEA, and Congressional reporting.

Requests for copies of the proposed information collection request may be accessed from <http://edicsweb.ed.gov>, by selecting the "Browse Pending Collections" link and by clicking on link number 2494. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202-4651 or to the e-mail address [vivian\\_reese@ed.gov](mailto:vivian_reese@ed.gov). Requests may also be electronically mailed to the Internet address [OCIO\\_RIMG@ed.gov](mailto:OCIO_RIMG@ed.gov) or faxed to 202-708-9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address [Sheila\\_Carey@ed.gov](mailto:Sheila_Carey@ed.gov). Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339.

[FR Doc. 04-8346 Filed 4-12-04; 8:45 am]

BILLING CODE 4000-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. QF83-168-009 and EL04-86-000]

#### Wilbur Power LLC; Notice of Filing

April 6, 2004.

Take notice that on March 31, 2004, Gaylord Container Corporation (Gaylord), a corporation with its principal place of business at Austin, Texas, tendered for filing an amended request for Limited Waiver of Qualifying Cogeneration Operating and Efficiency Standards pursuant to section 292.205(c) of the Commission's regulations. Gaylord requests expedited consideration.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party

must file a motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may be viewed on the Commission's Web site at <http://www.ferc.gov>, using the eLibrary (FERRIS) link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659. Protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: April 20, 2004.

Linda Mitry,  
Acting Secretary.

[FR Doc. E4-804 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket Nos. RP04-155-000 and RP03-398-000]

#### Northern Natural Gas Company; Notice of Technical Conference

April 6, 2004.

Take notice that a technical conference will be held on Tuesday, April 20, 2004, from 10 a.m. to 5 p.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The purpose of the conference is to address Northern Natural Gas Company's (Northern) proposal to lower the acceptable levels of oxygen and carbon dioxide in gas received on its system. The technical conference was ordered in a February 27, 2004, order<sup>1</sup> accepting and suspending a filing by Northern to increase its rates and make various changes to its tariff.

All interested persons are permitted to attend. To assist Staff, attendees are requested to e-mail [Eric.Winterbauer@ferc.gov](mailto:Eric.Winterbauer@ferc.gov) stating your name, the name of the entity you represent, the names of the persons who

will be accompanying you, and a telephone number where you can be reached. Northern should be prepared to discuss its proposal, including the rationale for its proposal and any possible ramifications. Persons protesting aspects of Northern's proposal should be prepared to answer questions and discuss alternatives.

The issues to be discussed will include, but are not limited to:

A. Why does Northern need the more stringent gas quality standards it has proposed in this case?

1. What is the current status of Northern with regard to problems caused by the quality of gas, e.g. have there been ruptures due to corrosion? If so, when did they occur? Has Northern had to issue any OFOs due to corrosive conditions on the pipeline? Are there other Federal regulations affecting its decision to seek more stringent standards?

2. What are the corresponding carbon dioxide and oxygen standards on interconnecting pipelines?

3. Why is Northern proposing the changes at this specific time?

B. How did Northern decide upon the specifics of its gas quality proposal?

1. Why change the currently effective carbon dioxide level from 2 percent to less than or equal to 1 percent, as opposed to some other level? Why change the oxygen tolerance level from .2 percent to less than or equal to .02 percent, as opposed to some other level?

2. What reports or studies were used in making these determinations? (Please provide any such reports.)

3. What alternatives to these levels did Northern consider?

C. What effects will Northern's proposal have on entities upstream or downstream of Northern, including interconnecting pipelines or local distribution companies (financial, operational, or otherwise)?

D. What alternatives are there to Northern's proposal (operational or otherwise)?

Linda Mitry,  
Acting Secretary.

[FR Doc. E4-805 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

<sup>1</sup> Northern Natural Gas Co., 106 FERC ¶ 61,195 (2004).

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP04-249-000]

**AES Ocean Express, LLC, Complainant v. Florida Gas Transmission Company, Respondent; Notice of Complaint and Request for Fast Track Processing**

April 6, 2004.

Take notice that on April 5, 2004, AES Ocean Express, LLC (Complainant) submitted a complaint against the Florida Gas Transmission Company (Respondent). The Complainant asserts that for over two years it has attempted to establish an agreement that would allow it to interconnect its pipeline facilities with those of the Respondent in Broward County, Florida. The Complainant alleges that the Respondent has violated Commission policy by conditioning any interconnection agreement with the Complainant on unjust and unreasonable terms and conditions. The Complainant requests that the Commission direct the Respondent to establish an interconnection that will enable the Complainant to make deliveries at Broward County, Florida, on terms that are consistent with the Commission's interconnection policy.

Any person desiring to be heard or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's rules of practice and procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. The answer to the complaint and all comments, interventions or protests must be filed on or before the comment date. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or for TTY, contact (202) 502-8659. The answer to the complaint, comments, protests and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: April 15, 2004.

Linda Mitry,

Acting Secretary.

[FR Doc. E4-803 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP04-238-000]

**El Paso Natural Gas Company; Notice of Revenue Crediting Report**

April 6, 2004.

Take notice that on March 31, 2004, El Paso Natural Gas Company (El Paso) tendered for filing its revenue crediting report for the calendar year 2003.

El Paso states that the report details its crediting of risk sharing revenues for the calendar year 2003 in accordance with section 25.3 of the General Terms and Conditions of its Volume No. 1-A Tariff. El Paso states that this is its final revenue crediting report since the risk sharing revenue crediting provisions terminated on December 31, 2003.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed on or before the date as indicated below. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the eLibrary. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link.

Intervention and Protest Date: April 13, 2004.

Linda Mitry,

Acting Secretary.

[FR Doc. E4-806 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

**DEPARTMENT OF ENERGY****Federal Energy Regulatory Commission**

[Docket No. RP04-239-000]

**Texas Eastern Transmission, LP; Notice of Tariff Filing**

April 6, 2004.

Take notice that on March 31, 2004, Texas Eastern Transmission, LP (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Seventh Revised Volume No. 1, First Revised Sheet No. 525, to be effective May 1, 2004.

Texas Eastern states that the purpose of this filing is to modify section 3.13(A) of the General Terms and Conditions of its Tariff to reflect the assignment of North Jersey Energy Associates' Rate Schedule FTS-5 Service Agreement to Public Service Electric & Gas Company effective May 1, 2004.

Texas Eastern states that copies of its filing have been served upon to all affected customers and interested State commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the eLibrary. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll-free at (866) 208-3676, or TTY, contact (202) 502-8659. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's Web site under the e-Filing link.

Linda Mitry,

Acting Secretary.

[FR Doc. E4-807 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Notice of Application for Transfer of License and Soliciting Comments, Motions To Intervene, and Protests

April 1, 2004.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type*: Partial transfer of license.

b. *Project No.*: 3021-086.

c. *Date Filed*: March 17, 2004.

d. *Applicants*: Allegheny Hydro No. 8, L.P., Allegheny Hydro No. 9, L.P.

(Allegheny Hydro 8 and 9), and, each solely in its capacity as the owner trustee for the project, Fleet National Bank (formerly the Connecticut National Bank) (Fleet), State Street Bank and Trust Company (State Street) and U.S. Bank National Association (U.S. Bank).

e. *Name and Location of Project*: The Allegheny River Lock and Dam Nos. 8 and 9 Hydroelectric Project is located at the U.S. Army Corps of Engineers' Allegheny River Lock and Dam No. 8 and Allegheny River Lock and Dam No. 9 on the Allegheny River in Armstrong County, Pennsylvania.

f. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791a-825r.

g. *Applicant Contacts*: For Allegheny Hydro 8 and 9: David L. Schwartz, Latham & Watkins LLP, Suite 1000, 555 Eleventh Street, NW., Washington, DC 20004-1304. (202) 637-2125. For Fleet, State Street, and U.S. Bank: Thomas F. Steichen, U.S. Bank National Association, West Side Flats Center, EP-MN-WS4L, 60 Livingston Avenue, St. Paul, MN 55107.

h. *FERC Contact*: James Hunter, (202) 502-6086.

i. *Deadline for Filing Comments, Protests, and Motions to Intervene*: May 3, 2004.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings. Please include the project number (P-3021-086) on any comments or motions filed.

The Commission's rules of practice and procedure require all interveners filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the documents on that resource agency.

j. *Description of Application*:

Applicants state that, in June 1997, State Street purchased Fleet's interest in the project as owner-trustee and, in January 2003, U.S. Bank purchased State Street's interest. Applicants now seek after-the-fact approval of the two purchases and the substitution of State Street for Fleet and U.S. Bank for State Street as co-licensee, each solely in its capacity as owner trustee.

k. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "FERRIS" link. Enter the docket number (P-3021) in the docket number field to access the document. For assistance, call toll-free 1-866-208-3676 or e-mail [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov). For TTY, call (202) 502-8659. A copy is also available for inspection and reproduction at the addresses in item g. above.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

m. *Comments, Protests, or Motions to Intervene* — Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

n. *Filing and Service of Responsive Documents* — Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", OR "MOTION TO INTERVENE", as

applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and eight copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

o. *Agency Comments*—Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E4-802 Filed 4-12-04; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Sunshine Act Meeting

April 7, 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.

**DATE AND TIME**: April 14, 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.

**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# MO04-3, 000, REGIONAL MARKET MONITOR STATE OF MARKET PRESENTATIONS
- Markets, Tariffs and Rates—Electric**
- E-1. DOCKET# ER96-2495, 016, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
OTHER#S ER96-2495, 017, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER97-1238, 011, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER97-1238, 012, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER97-4143, 004, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER97-4143, 005, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER98-542, 006, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER98-542, 007, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER98-2075, 010, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER98-2075, 011, AEP POWER MARKETING, INC., AEP SERVICE CORPORATION, CSW POWER MARKETING, INC., CSW ENERGY SERVICES, INC., AND CENTRAL AND SOUTH WEST SERVICES, INC.  
ER91-569, 018, ENTERGY SERVICES, INC.  
ER91-569, 019, ENTERGY SERVICES, INC.  
ER97-4166, 010, SOUTHERN COMPANY ENERGY MARKETING L.P.  
ER97-4166, 011, SOUTHERN COMPANY ENERGY MARKETING L.P.
- PL02-8, 000, CONFERENCE ON SUPPLY MARGIN ASSESSMENT
- E-2. DOCKET# RM04-7, 000, MARKET-BASED RATES FOR PUBLIC UTILITIES
- E-3. OMITTED
- E-4. OMITTED
- E-5. DOCKET# ER02-2189, 001, SOUTHERN CALIFORNIA EDISON COMPANY
- E-6. DOCKET# PL04-5, 000, POLICY STATEMENT ON MATTERS RELATED TO BULK POWER SYSTEM RELIABILITY
- E-7. DOCKET# EL04-52, 000, REPORTING BY TRANSMISSION PROVIDERS ON VEGETATION MANAGEMENT PRACTICES RELATED TO DESIGNATED TRANSMISSION FACILITIES
- E-8. DOCKET# PL03-1, 000, PRICING POLICY FOR EFFICIENT OPERATION AND EXPANSION OF TRANSMISSION GRID
- E-9. DOCKET# EL00-95, 045, SAN DIEGO GAS & ELECTRIC COMPANY V. SELLERS OF ENERGY AND ANCILLARY SERVICES INTO MARKETS OPERATED BY THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
OTHER#S EL00-95, 083, SAN DIEGO GAS & ELECTRIC COMPANY V. SELLERS OF ENERGY AND ANCILLARY SERVICES INTO MARKETS OPERATED BY THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
EL00-95, 087, SAN DIEGO GAS & ELECTRIC COMPANY V. SELLERS OF ENERGY AND ANCILLARY SERVICES INTO MARKETS OPERATED BY THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
EL00-98, 042, INVESTIGATION OF PRACTICES OF THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
EL00-98, 071, INVESTIGATION OF PRACTICES OF THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
EL00-98, 074, INVESTIGATION OF PRACTICES OF THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE
- E-10. DOCKET# ER04-564, 000, WAYNE-WHITE COUNTIES ELECTRIC COOPERATIVE
- E-11. DOCKET# ER04-517, 000, CALPEAK POWER, LLC  
OTHER#S ER04-517, 001 CALPEAK POWER, LLC
- E-12. DOCKET# ER04-215, 000 PACIFIC GAS AND ELECTRIC COMPANY
- E-13. DOCKET# ER04-337, 000, PACIFIC GAS AND ELECTRIC COMPANY  
OTHER#S ER04-337, 001, PACIFIC GAS AND ELECTRIC COMPANY  
ER04-337, 002, PACIFIC GAS AND ELECTRIC COMPANY  
ER04-337, 003, PACIFIC GAS AND ELECTRIC COMPANY
- E-14. OMITTED
- E-15. DOCKET# ER03-708, 000, PACIFIC GAS AND ELECTRIC COMPANY
- E-16. DOCKET# ER03-901, 000, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
- E-17. OMITTED
- E-18. DOCKET# ER04-142, 000, PACIFIC GAS AND ELECTRIC COMPANY  
OTHER#S ER04-143, 000, PACIFIC GAS AND ELECTRIC COMPANY  
ER04-295, 000, PACIFIC GAS AND ELECTRIC COMPANY
- E-19. OMITTED
- E-20. DOCKET# ER03-683, 002, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION  
OTHER#S ER03-683, 003, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
- E-21. DOCKET# ER01-2201, 004, ENTERGY SERVICES, INC.  
OTHER#S ER01-2201, 005, ENTERGY SERVICES, INC.  
EL02-46, 003, ENTERGY SERVICES, INC.  
EL02-46, 004, ENTERGY SERVICES, INC.
- E-22. DOCKET# QF86-681, 005, ORMESA LLC
- E-23. DOCKET# ES03-43, 000, AQUILA, INC.  
OTHER#S ES03-43, 001, AQUILA, INC.  
ES03-43, 002, AQUILA, INC.  
ES03-43, 003, AQUILA, INC.  
ES03-43, 004, AQUILA, INC.  
ES04-13, 000, AQUILA, INC.
- E-24. DOCKET# EL00-95, 087, SAN DIEGO GAS & ELECTRIC COMPANY V. SELLERS OF ENERGY AND ANCILLARY SERVICES INTO MARKETS OPERATED BY THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE  
OTHER#S EL00-98, 074, INVESTIGATION OF PRACTICES OF THE CALIFORNIA INDEPENDENT SYSTEM OPERATOR AND THE CALIFORNIA POWER EXCHANGE
- E-25. DOCKET# EL01-93, 007, MIRANT AMERICAS ENERGY MARKETING, L.P., MIRANT NEW ENGLAND, LLC, MIRANT KENDALL, LLC, AND MIRANT, LLC V. ISO NEW ENGLAND INC.
- E-26. DOCKET# ER03-683, 001, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION

- E-27.  
OMITTED
- E-28.  
DOCKET# EL03-133, 001, AMERICAN REF-FUEL COMPANY, COVANTA ENERGY GROUP, MONTENAY POWER CORPORATION, AND WHEELABRATOR TECHNOLOGIES, INC.
- E-29.  
OMITTED
- E-30.  
OMITTED
- E-31.  
OMITTED
- E-32.  
DOCKET# ER04-115, 001, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION  
OTHER#S EL04-47, 001, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION  
EL04-50, 000, PACIFIC GAS & ELECTRIC COMPANY  
ER04-242, 000, PACIFIC GAS AND ELECTRIC COMPANY
- E-33.  
OMITTED
- E-34.  
OMITTED
- E-35.  
OMITTED
- E-36.  
DOCKET# ER04-190, 002, MIDWEST GENERATION EME, LLC  
OTHER#S EL04-22, 001, MIDWEST GENERATION EME, LLC V. COMMONWEALTH EDISON COMPANY AND EXELON GENERATION COMPANY, LLC
- E-37.  
OMITTED
- E-38.  
DOCKET# ER03-836, 001, NEW YORK INDEPENDENT SYSTEM OPERATOR, INC.
- E-39.  
DOCKET# EL04-81, 000, ALLETE, INC.
- E-40.  
DOCKET# EL04-83, 000, MORGAN ENERGY CENTER, LLC  
OTHER#S QF01-84, 001, MORGAN ENERGY CENTER, LLC
- E-41.  
DOCKET# EL03-221, 000, BOROUGH OF ZELIENOPLE, PENNSYLVANIA V. AMERICAN TRANSMISSION SYSTEMS, INC.
- E-42.  
DOCKET# EL04-54, 000, HAVILAND HOLDINGS, INC. V. SOUTHWEST POWER POOL, INC.
- E-43.  
DOCKET# EL04-55, 000, HAVILAND HOLDINGS, INC. V. PUBLIC SERVICE COMPANY OF NEW MEXICO
- E-44.  
DOCKET# EL04-57, 000, FPL ENERGY MARCUS HOOK, L.P. V. PJM INTERCONNECTION, L.L.C.
- E-45.  
DOCKET# EC99-81, 006, DOMINION RESOURCES, INC. AND CONSOLIDATED NATURAL GAS COMPANY  
OTHER#S MG00-6, 009, DOMINION TRANSMISSION, INC.
- E-46.  
DOCKET# EL04-78, 000, MIDWEST ISO TRANSMISSION OWNERS  
OTHER#S EL04-79, 000, MIDWEST STAND-ALONE TRANSMISSION COMPANIES
- E-47.  
DOCKET# EL03-54, 000, CITIES OF ANAHEIM, AZUSA, BANNING, COLTON, AND RIVERSIDE CALIFORNIA AND CITY OF VERNON, CALIFORNIA V. CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
- E-48.  
DOCKET# EL04-62, 000, INLAND POWER & LIGHT COMPANY  
OTHER#S EL04-63, 000, EAST TEXAS ELECTRIC COOPERATIVE, INC.  
EL04-64, 000, NORTH WEST RURAL ELECTRIC COOPERATIVE  
EL04-67, 000, OREGON TRAIL ELECTRIC CONSUMERS COOPERATIVE, INC.  
EL04-68, 000, BRIDGER VALLEY ELECTRIC ASSOCIATION, INC.  
EL04-69, 000, WAYNE-WHITE COUNTIES ELECTRIC COOPERATIVE
- E-49.  
DOCKET# EL02-115, 000, AVISTA CORPORATION, AVISTA ENERGY, INC., ENRON POWER MARKETING, INC. AND PORTLAND GENERAL ELECTRIC COMPANY
- E-50.  
DOCKET# EL04-76, 000, BIG RIVERS ELECTRIC CORPORATION
- E-51.  
OMITTED
- E-52.  
DOCKET# ER03-689, 000, WPS CANADA GENERATION, INC., MAINE PUBLIC SERVICE COMPANY, AND THE NORTHERN MAINE INDEPENDENT SYSTEM ADMINISTRATOR, INC.  
ER03-689, 001, WPS CANADA GENERATION, INC., MAINE PUBLIC SERVICE COMPANY, AND THE NORTHERN MAINE INDEPENDENT SYSTEM ADMINISTRATOR, INC.  
ER03-689, 002, WPS CANADA GENERATION, INC., MAINE PUBLIC SERVICE COMPANY, AND THE NORTHERN MAINE INDEPENDENT SYSTEM ADMINISTRATOR, INC.  
ER04-210, 000, WPS CANADA GENERATION, INC., MAINE PUBLIC SERVICE COMPANY, AND THE NORTHERN MAINE INDEPENDENT SYSTEM ADMINISTRATOR, INC.
- E-53.  
DOCKET# ID-3966, 001, MICHAEL J. CHESSER
- E-54.  
DOCKET# ER03-343, 004, ITC HOLDINGS CORPORATION, ITC HOLDINGS LIMITED PARTNERSHIP, INTERNATIONAL TRANSMISSION COMPANY, DTE ENERGY AND DETROIT EDISON COMPANY  
OTHER#S ER03-576, 002, DETROIT EDISON COMPANY
- E-55.  
DOCKET# ER00-3109, 001, ADIRONDACK HYDRO DEVELOPMENT CORPORATION  
OTHER#S ER96-1635, 008, BLACK HILLS PEPPERELL POWER ASSOCIATES, INC.
- ER99-1248, 003, HARBOR COGENERATION COMPANY  
ER99-2287, 001, BLACK HILLS POWER, INC.  
ER00-1952, 001, BLACK HILLS COLORADO, LLC  
ER01-1784, 004, FOUNTAIN VALLEY POWER, L.L.C.  
ER01-1844, 001, BLACK HILLS GENERATION, INC.
- Miscellaneous Agenda**
- M-1.  
DOCKET# RM01-10, 001, STANDARDS OF CONDUCT FOR TRANSMISSION PROVIDERS
- Markets, Tariffs and Rates—Gas**
- G-1.  
DOCKET# RP04-92, 000, GEORGIA PUBLIC SERVICE COMMISSION
- G-2.  
DOCKET# RP03-563, 002, NORTHERN BORDER PIPELINE COMPANY
- G-3.  
DOCKET# RP04-12, 000, FLORIDA GAS TRANSMISSION COMPANY  
OTHER#S RP04-12, 001, FLORIDA GAS TRANSMISSION COMPANY  
RP04-12, 002, FLORIDA GAS TRANSMISSION COMPANY
- G-4.  
DOCKET# RP04-156, 000, NORTHWEST PIPELINE CORPORATION
- G-5.  
DOCKET# RP04-47, 000, HIGH ISLAND OFFSHORE SYSTEM, L.L.C.
- G-6.  
DOCKET# RP03-625, 000, CHANDELEUR PIPE LINE COMPANY
- G-7.  
DOCKET# RP03-460, 000, NORTHERN NATURAL GAS COMPANY
- G-8.  
DOCKET# RP04-87, 000, SOUTHERN STAR CENTRAL GAS PIPELINE INC.
- G-9.  
DOCKET# RP04-136, 002, IROQUOIS GAS TRANSMISSION SYSTEM, L.P.
- G-10.  
OMITTED
- G-11.  
DOCKET# RP96-389, 083, COLUMBIA GULF TRANSMISSION COMPANY
- G-12.  
DOCKET# RP03-280, 001, COLUMBIA GAS TRANSMISSION CORPORATION
- G-13.  
OMITTED
- G-14.  
DOCKET# RP03-64, 001, GULF SOUTH PIPELINE COMPANY, LP  
OTHER#S RP03-64, 002, GULF SOUTH PIPELINE COMPANY, LP
- G-15.  
OMITTED
- G-16.  
DOCKET# RP03-612, 001, QUESTAR SOUTHERN TRAILS PIPELINE COMPANY
- G-17.  
DOCKET# RP03-343, 002, NORTHERN NATURAL GAS COMPANY  
OTHER#S RP03-343, 001, NORTHERN NATURAL GAS COMPANY
- G-18.



DOCKET# RP97-71, 021,  
TRANSCONTINENTAL GAS PIPE LINE  
CORPORATION

G-19.  
OMITTED

G-20.  
DOCKET# PR97-1, 002, CONSUMERS  
POWER COMPANY

G-21.  
OMITTED

G-22.  
DOCKET# OR04-1, 000, AMERICAS  
PROPANE, LP, CHS INC.,  
CONOCOPHILLIPS COMPANY,  
DYNEGY LIQUIDS MARKETING AND  
TRADE, FERRELLGAS, L.P., AND  
NATIONAL PROPANE GAS  
ASSOCIATION V. MID-AMERICA  
PIPELINE COMPANY, LLC  
OTHER#S IS04-154, 001, MID-AMERICA  
PIPELINE COMPANY, LLC

G-23.  
DOCKET# RP00-336, 018, EL PASO  
NATURAL GAS COMPANY  
OTHER#S RP00-336, 025, EL PASO  
NATURAL GAS COMPANY

G-24.  
DOCKET# RP04-61, 001, EL PASO  
NATURAL GAS COMPANY

G-25.  
OMITTED

G-26.  
DOCKET# RP04-218, 000, TRUNKLINE  
GAS COMPANY, LLC

#### Energy Projects—Hydro

H-1.  
DOCKET# P-2017, 020, SOUTHERN  
CALIFORNIA EDISON COMPANY

H-2.  
DOCKET# P-12020, 002, MARSEILLES  
HYDRO POWER, LLC  
OTHER#S P-11863, 001, MARSEILLES  
LAND AND WATER COMPANY

#### Energy Projects—Certificates

C-1.  
DOCKET# CP03-350, 000, GEORGIA  
STRAIT CROSSING PIPELINE LP

C-2.  
DOCKET# CP93-117, 003, SAN DIEGO  
GAS & ELECTRIC COMPANY

C-3.  
DOCKET# CP04-10, 000, ENCANA  
BORDER PIPELINES LIMITED AND  
OMIMEX CANADA, LTD.  
OTHER#S CP04-11, 000, CHINOOK  
PIPELINE COMPANY AND OMIMEX  
CANADA, LTD.

C-4.  
DOCKET# CP04-36, 000, WEAVER'S  
COVE ENERGY, LLC  
OTHER#S CP04-41, 000, MILL RIVER  
PIPELINE, LLC  
CP04-42, 000, MILL RIVER PIPELINE, LLC  
CP04-43, 000, MILL RIVER PIPELINE, LLC

**Magalie R. Salas,**  
Secretary.

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 Web site at <http://www.capitolconnection.gmu.edu> and click on "FERC".

[FR Doc. 04-8428 Filed 4-9-04; 11:18 am]

BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[FAL-7647-1]

### Riverhills Battery Superfund Site; Notice of Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of settlement.

**SUMMARY:** Under Section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Environmental Protection Agency (EPA) has entered into an Agreement for proposed settlement of past and future response cost at the Riverhills Battery Superfund Site (Site) located in Tampa, Hillsborough County, Florida, with Gulf Coast Lead, and Gulf Coast Recycling, Inc. EPA will consider public comments on paragraphs Thirty-Six (36) and Thirty-Seven (37) of the Agreement until May 13, 2004. EPA may withdraw from or modify the Agreement should such comments disclose facts or considerations which indicate the Agreement is inappropriate, improper, or inadequate. Copies of the Agreement are available from: Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region 4, Superfund Enforcement & Information Management Branch, Waste Management Division, 61 Forsyth Avenue, SW., Atlanta, Georgia 30303, [Batchelor.Paula@EPA.Gov](mailto:Batchelor.Paula@EPA.Gov), (404) 562-8887.

Written comments may be submitted to Ms. Batchelor at the above address within 30 days of the date of publication.

Dated: March 25, 2004.

**Rosalind H. Brown,**  
Chief, Superfund Enforcement & Information Management Branch, Waste Management Division.

[FR Doc. 04-8313 Filed 4-12-04; 8:45 am]

BILLING CODE 6560-50-M

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7646-8]

### Final Modified NPDES Permits for Log Transfer Facilities Operating in Alaska Prior to October 22, 1985, and Possessing a Section 404 Permit But Not a Section 402 permit (AK-G70-0000), and All Other Log Transfer Facilities Operating in Alaska (AK-G70-1000)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Final Modified NPDES General Permits.

**SUMMARY:** The Director of the Office of Water, EPA Region 10, is publishing notice of the availability of two modified National Pollutant Discharge Elimination System (NPDES) general permits (numbers AK-G70-0000 and AK-G70-1000) for coverage of log transfer facilities (LTFs) operating in Alaska, pursuant to the provisions of the Clean Water Act, 33 U.S.C. 1251 *et seq.* General permit AK-G70-0000 ("pre-1985 permit") includes section 402 modifications to section 404 permits issued to LTFs prior to October 22, 1985, in accordance with section 407 of the Water Quality Act of 1987 (Public Law 100-4). All other LTFs can apply to be authorized to discharge under general permit number AK-G70-1000 ("post-1985 permit").

Because general permit AK-G70-0000 contains modifications of the existing permits originally issued under section 404 of the Clean Water Act for LTFs operating prior to October 22, 1985, the modified permit conditions apply to discharges of bark and wood debris from those LTFs upon the effective date of the permit. Under modified AK-G70-0000, to be authorized to discharge bark or wood debris in a project area zone of deposit, a pre-1985 LTF must: Submit a Notification form to EPA and the Alaska Department of Environmental Conservation (ADEC); and, receive a final decision document and authorization of a project area zone of deposit from ADEC. General permit AK-G70-1000 authorizes discharges to marine waters of Alaska (extending from the Alexander Archipelago west through central Gulf of Alaska and Prince William Sound to Kodiak Island) from LTFs, not possessing pre-1985, section 404 permits, or from LTFs which have received a previous individual permit. In order to be authorized to discharge bark or wood debris under AK-G70-1000, a LTF must: Submit a Notice Of Intent application for permit coverage to EPA and the Alaska Department of

Environmental Conservation (ADEC); receive a final decision document and authorization of a project area zone of deposit from ADEC; and, receive written authorization to discharge from EPA. For LTFs that received written authorization to discharge under AK-G70-1000 prior to these modifications, the modified permit conditions will apply to discharges of bark and wood debris from those LTFs upon the effective date of the permit.

Except for those LTFs operating in areas excluded from general permit coverage under the post-1985 permit, the modified general permits authorize the discharge of bark and wood debris, under the specified terms of the general permits, into both near-shore and offshore marine waters in Alaska. Two modifications were made to both of the general permits. One of the modifications provides that ADEC must issue a final decision document authorizing a project area zone of deposit (ZOD) to each LTF prior to that LTF discharging bark and wood debris under the permits. The second modification requires that when conducting the annual bark monitoring, if continuous coverage of bark and wood debris is found at minus 60 feet, the bark monitoring survey must continue deeper until the continuous coverage ends, or at minus 100 feet in depth, whichever occurs first.

**DATES:** The modified general NPDES permits shall become effective on April 27, 2004. The post-1985 general permit and the authorization to discharge shall expire at midnight on March 21, 2005.

**ADDRESSES:** The complete administrative record for the modified general NPDES permits are available for public review by contacting EPA Region 10, 1200 Sixth Avenue, Seattle, Washington 98101, Telephone: (206) 553-0523 or (206) 553-1643, or via EMAIL to the following address: [washington.audrey@epa.gov](mailto:washington.audrey@epa.gov). For those with impaired hearing or speech, please contact EPA's telecommunication device for the deaf (TDD) at 206/553-1698. Copies of the modified general NPDES permits, supporting statement of basis for the draft general NPDES permits, response to public comments, and today's publication are available from the EPA Alaska Operations Office at 222 West 7th Avenue, #19, Anchorage, Alaska 99513-7588, 907/271-6561 or the Alaska Department of Environmental Conservation at 410 Willoughby Avenue, Suite 105, Juneau, Alaska 99801. These documents can also be found by visiting the Region 10 Web site at <http://www.epa.gov/r10earth/water/htm>.

**FOR FURTHER INFORMATION CONTACT:** Audrey Washington at (206) 553-0523.

**SUPPLEMENTARY INFORMATION:**

**Public Comment**

Pursuant to section 402 of the Clean Water Act, 33 U.S.C. 1342, EPA originally proposed and solicited comments on the draft general permits in the *Federal Register* at 65 FR 11999 (March 7, 2000). In response to petitions to review the permits brought by the Natural Resources Defense Council and nine other petitioners, the United States Court of Appeals for the Ninth Circuit, on February 13, 2002, ruled that the EPA did not provide adequate notice of and opportunity to comment on the general NPDES permits, and remanded the permits to EPA to take further comment on the project area ZOD. On October 22, 2002, EPA proposed modifications to, and requested additional public comments on, general NPDES permits AK-G70-0000 and AK-G70-1000 (67 FR 64885). The public comment period was twice extended (67 FR 68869 and 68 FR 2540), and closed on January 27, 2003. Notice for public comment was also published in the *Anchorage Daily News*, *Ketchikan Daily News*, *The Seward Phoenix Log*, *The Valdez Vanguard*, and *The Cordova Times*. Additionally, copies of the draft modifications to the permits were sent to all known log transfer facilities operating under a section 404 permit issued prior to October 22, 1985.

Public comment was solicited on five proposed modifications to the general permits related to: (1) The timing of final zone of deposit authorization by the State of Alaska; (2) exclusion of permit coverage in impaired waterbodies; (3) a limit on continuous bark or wood debris coverage of one acre and 10 centimeters at any point within a project area ZOD; (4) a lower threshold amount for continuous coverage to invoke amendments to a facility's Pollution Prevention Plan; and, (5) increasing the depth of bark surveys of continuous coverage on the ocean bottom to—100 feet.

In response to numerous comments received from facility representatives, tribal representatives, concerned citizens, environmental groups, the U.S. Forest Service, U.S. Fish and Wildlife Service, the National Marine Fisheries Service, local municipalities, and the State of Alaska, the Director has decided to make two out of the five proposed modifications; e.g., numbers 1 and 5 above. All comments, along with EPA's responses, are summarized in the Response to Comments document, which may be obtained at the above

addresses, or viewed on the Region 10 Web site listed above.

**Legal Requirements**

*Coastal Zone Management Act*

The State of Alaska, Office of Management and Budget, Division of Governmental Coordination, found the original general permits to be consistent with the approved Alaska Coastal Zone Management Program. The successor agency for the coastal zone consistency review, the Alaska Department of Natural Resources, Office of Project Management and Permitting, concurred that the modified general permits were not "major amendments" and did not require a new consistency determination.

*Endangered Species Act and Essential Fish Habitat*

Consultation under the Endangered Species Act was conducted with the U.S. Fish and Wildlife Service and National Marine Fisheries Service. The EPA determined that the actions are not likely to adversely affect any threatened or listed species. EPA has also made a determination that the actions have no adverse effects on Essential Fish Habitat.

*State Water Quality Standards and State Certification*

The State of Alaska, Department of Environmental Conservation certified under section 401 of the Clean Water Act, that the subject discharges under both of the original general-permits comply with the Alaska State Water Quality Standards and sections 208(e), 301, 302, 303, 306 and 307 of the Clean Water Act. The Department determined that the general permit modifications were of a minor nature and that a new certification was not necessary.

*Executive Order 12866*

EPA has determined that this general permit is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

*Paperwork Reduction Act*

The information collection requirements of this permit were previously approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and assigned OMB control numbers 2040-0086 (NPDES permit application) and 2040-0004 (discharge monitoring reports).

**Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires that EPA prepare a regulatory flexibility analysis for rules subject to the requirements of 5 U.S.C. 553(b) that have a significant impact on a substantial number of small entities. The permit issued today, however, is not a "rule" subject to the requirements of 5 U.S.C. 553(b) and is therefore not subject to the RFA.

**Unfunded Mandates Reform Act**

Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104-4, generally requires Federal agencies to assess the effects of their "regulatory actions" (defined to be the same as "rules" subject to the RFA) on tribal, state, and local governments and the private sector. The permit issued today, however, is not a "rule" subject to the RFA and is therefore not subject to the requirements of UMRA.

**Appeal of Permit**

Any interested person may appeal the modifications of the Log Transfer Facility General NPDES permits in the Federal Court of Appeals in accordance with section 509(b)(1) of the Clean Water Act. This appeal must be filed within 120 days of the permit effective date. The permit effective date is defined at 40 CFR 23.2 to be at 1 p.m. eastern time, two weeks after the date of publication in the **Federal Register**. Persons affected by a general NPDES permit may not challenge the conditions of the permit as a right of further EPA proceedings. Instead, they may either challenge the permit in court or apply for an individual NPDES permit and then request a formal hearing on the issuance or denial of an individual NPDES permit.

Dated: April 5, 2004.

**Robert R. Robichaud,**

*Associate Director, Office of Water, Region 10.*

[FR Doc. 04-8314 Filed 4-12-04; 8:45 am]

BILLING CODE 6560-50-P

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**FEDERAL COMMUNICATIONS COMMISSION**
**Federal Advisory Committee Act  
Notice of Public Meeting**

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, this notice advises interested persons that the

Advisory Committee on Diversity for Communications in the Digital Age has been established and is holding its third meeting, which will be held at the Federal Communications Commission in Washington, DC. The Diversity Committee was established by the Federal Communications Commission to examine current opportunities and develop recommendations for policies and practices that will further enhance the ability of minorities and women to participate in telecommunications and related industries.

**DATES:** May 10, 2004, 2 p.m. to 5 p.m.

**ADDRESSES:** Federal Communications Commission, Commission Meeting Room, Room TW-C305, 445 12th St. SW, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Jane E. Mago, Designated Federal Officer of the Committee on Diversity, or Maureen C. McLaughlin, Alternate Designated Federal Officer of the Committee on Diversity, 202-418-2030, e-mail [Jane.Mago@fcc.gov](mailto:Jane.Mago@fcc.gov), [Maureen.McLaughlin@fcc.gov](mailto:Maureen.McLaughlin@fcc.gov). Press Contact, Audrey Spivak, Office of Media Relations, 202-418-0512, [aspivak@fcc.gov](mailto:aspivak@fcc.gov).

**SUPPLEMENTARY INFORMATION:** The Diversity Committee was established by the Federal Communications Commission to examine current opportunities and develop recommendations for policies and practices that will further enhance the ability of minorities and women to participate in telecommunications and related industries. The Diversity Committee will prepare periodic and final reports to aid the FCC in its oversight responsibilities and its regulatory reviews in this area. In conjunction with such reports and analyses, the Diversity Committee will make recommendations to the FCC concerning the need for any guidelines, incentives, regulations or other policy approaches to promote diversity of participation in the communications sector. The Diversity Committee will also develop a description of best practices within the communications sector for promoting diversity of participation.

**Agenda**

The May 10, 2004 meeting will include reports from the Diversity Committee's four subcommittees regarding progress towards the final report to the Commission. The four subcommittees are: Career Advancement, which aims to (a) assess current executive training programs and other career development programs that target minorities and women in the

telecom industries; (b) identify recommendations and "best practices" that would facilitate opportunities in upper level management and ownership; and (c) focus both on industry-specific measures, as well as recommendations extending across the telecom sectors; Financial Issues, which aims to (a) identify the obstacles to capital access faced by minorities and women in the telecommunications industries; (b) assess current practices regarding the access to capital; (c) develop recommendations and identify "best practices" to address these obstacles; and (d) focus both on industry-specific measures, as well as issues that extend across the telecommunications sectors; New Technologies, which aims to (a) assess what ownership and career advancement opportunities are available in new and emerging technologies (e.g., broadband, digital television, cable, satellite, low power FM) and the convergence of these technologies; and (b) develop recommendations for facilitating opportunities for minorities and women in new industries as they form; and Transactional Transparency, which aims to (a) identify what enhancements or additions are needed, and develop suggested "best practices" in order to increase the participation of minorities and women; (b) assess current practices of how potential investment opportunities in telecom industries are identified and how that information is disseminated; and (c) focus both on industry-specific measures, as well as recommendations extending across the telecom sectors.

Information concerning the activities of the Diversity Committee can be reviewed at the Committee's Web site <http://www.fcc.gov/DiversityFAC>. Material relevant to the May 10th meeting will be posted there. Members of the general public may attend the meeting. The Federal Communications Commission will attempt to accommodate as many people as possible. However, admittance will be limited to the seating available. A live RealAudio feed will be available over the Internet; information on how to tune in can be found at the Commission's Web site <http://www.fcc.gov>.

*The public may submit written comments to the Committee's Designated Federal Officer before the meeting.*

Federal Communications Commission.

**William F. Caton,**

*Deputy Secretary.*

[FR Doc. 04-8333 Filed 4-12-04; 8:45 am]

BILLING CODE 6712-01-P

**FEDERAL COMMUNICATIONS COMMISSION****Sunshine Act Meeting**

April 8, 2004.

The Federal Communications Commission will hold an open meeting on the subjects listed below on Thursday, April 15, 2004, which is scheduled to commence at 9:30 a.m. in Room TW-C305, at 445 12th Street, SW., Washington, DC.

*Item No.:* 1.

*Bureau:* Office of Engineering and Technology.

*Title:* Review of Part 15 and other Parts of the Commission's Rules (ET Docket No. 01-278; RM-9375, and RM-10051).

*Summary:* The Commission will consider a Third Report and Order concerning rule changes for radio frequency identification systems operating at 433 MHz.

*Item No.:* 2.

*Bureau:* Media

*Title:* Digital Audio Broadcasting Systems and Their Impact on the Terrestrial Radio Broadcast Service (MM Docket No. 99-325).

*Summary:* The Commission will consider a Further Notice of Proposed Rulemaking concerning rule changes for radio stations that broadcast digital audio using In-Band On-Channel ("IBOC") technology.

*Item No.:* 3.

*Bureau:* Office of Engineering and Technology.

*Title:* Unlicensed Operation in the Band 3650-3700 MHz; Additional Spectrum for Unlicensed Devices Below 900 MHz and in the 3 GHz Band (ET Docket No. 02-380); and Amendment of the Commission's Rules with Regard to the 3650-3700 MHz Government Transfer Band (ET Docket No. 98-237).

*Summary:* The Commission will consider a Notice of Proposed Rulemaking concerning use of the 3650-3700 MHz band.

*Note:* The summaries listed in this notice are intended for the use of the public attending open Commission meetings. Information not summarized may also be considered at such meetings. Consequently these summaries should not be interpreted to limit the Commission's authority to consider any relevant information.

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418-0500; TTY 1-888-835-5322.

Audio/Video coverage of the meeting will be broadcast live over the Internet from the FCC's Audio/Video Events Web page at [www.fcc.gov/realaudio](http://www.fcc.gov/realaudio).

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993-3100 or go to [www.capitolconnection.gmu.edu](http://www.capitolconnection.gmu.edu). Audio and video tapes of this meeting can be purchased from CACI Productions, 341 Victory Drive, Herndon, VA 20170, (703) 834-1470, Ext. 19; Fax (703) 834-0111.

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Qualex International (202) 863-2893; Fax (202) 863-2898; TTY (202) 863-2897. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio tape. Qualex International may be reached by e-mail at [Qualexint@aol.com](mailto:Qualexint@aol.com).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04-8482 Filed 4-9-04; 1:58 pm]

BILLING CODE 6712-01-U

**FEDERAL ELECTION COMMISSION****Sunshine Act Meeting****PUBLIC HEARING ON POLITICAL COMMITTEE STATUS.**

**PLACE:** 999 E Street, NW., Washington, DC (ninth floor).

**PREVIOUSLY ANNOUNCED DATES AND TIMES:** Wednesday, April 14 and Thursday, April 15, 2004, 10 a.m. The starting time has been changed to 9 a.m. on Wednesday April 14, 2004. The starting time has been changed to 9:30 a.m. on Thursday, April 15, 2004.

**PERSON TO CONTACT FOR INFORMATION:** Mr. Robert Biersack, Acting Press Officer, Telephone: (202) 694-1220.

Darlene Harris,

Deputy Secretary of the Commission.

[FR Doc. 04-8429 Filed 4-9-04; 8:45 am]

BILLING CODE 6715-01-M

**FEDERAL HOUSING FINANCE BOARD**

[No. 2004-N-07]

**Submission for OMB Review; Comment Request**

**AGENCY:** Federal Housing Finance Board.

**ACTION:** Notice.

**SUMMARY:** In accordance with the requirements of the Paperwork Reduction Act of 1995, the Federal Housing Finance Board (Finance Board)

has submitted the information collection entitled "Members of the Banks" to the Office of Management and Budget (OMB) for review and approval of a three-year extension of the OMB control number, which is due to expire on May 31, 2004.

**DATES:** Interested persons may submit comments on or before May 13, 2004.

**ADDRESSES:** Send comments to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for the Federal Housing Finance Board, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Jonathon F. Curtis, Senior Financial Analyst, Regulations & Research Division, Office of Supervision, by e-mail at [curtisj@fhfb.gov](mailto:curtisj@fhfb.gov), by telephone at 202/408-2866, or by regular mail at the Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

**SUPPLEMENTARY INFORMATION:****A. Need For and Use of the Information Collection**

Section 4 of the Federal Home Loan Bank Act (Bank Act) establishes the eligibility requirements an institution must meet in order to become a member of a Federal Home Loan Bank (Bank). See 12 U.S.C. 1424. Part 925 of the Finance Board regulations—the membership rule—implements section 4 of the Bank Act. See 12 CFR part 925. The membership rule provides uniform requirements an applicant for Bank membership must meet and review criteria a Bank must apply to determine if an applicant satisfies the statutory and regulatory membership eligibility requirements.

More specifically, the membership rule implements the statutory eligibility requirements and provides guidance to an applicant on how it may satisfy such requirements. The rule authorizes a Bank to approve or deny each membership application subject to the statutory and regulatory requirements and permits an applicant to appeal to the Finance Board a Bank's decision to deny certification as a Bank member. The rule also imposes a continuing obligation on a current Bank member to provide information necessary to determine if it remains in compliance with applicable statutory and regulatory eligibility requirements.

The information collection, which is contained in §§ 925.2 through 925.31 of the membership rule, 12 CFR 925.2-925.31, is necessary to enable a Bank to determine if a respondent satisfies the statutory and regulatory requirements to be certified initially and maintain its status as a member eligible to obtain



Bank advances. The Finance Board requires and uses the information collection to determine whether to uphold or overrule a Bank's decision to deny member certification to an applicant.

The OMB number for the information collection is 3069-0004. The OMB clearance for the information collection expires on May 31, 2004.

The likely respondents are institutions that are or want to become members of a Bank.

#### B. Burden Estimate

The Finance Board has analyzed the cost and hour burden for the four facets of the information collection—membership application process, minimum capital stock calculation, membership withdrawals and transfer of membership to another Bank district. The first notice inadvertently omitted the burden estimates for two of the four facets of the information collection. As explained in more detail below, the estimate for the total annual hour burden is 12,346 hours.

##### 1. Membership Application Process

The Finance Board estimates the total annual average number of applicants for Bank membership at 300, with 1 response per applicant. The estimate for the average hours per application is 24.5 hours. The Finance Board estimates the total annual average number of applications appealed to the Finance Board at one. The estimate for the average hours per appellate application is 10 hours. The estimate for the total annual hour burden for the membership application process is 7450 hours (300 applicants × 1 application × 24.5 hours + 1 appellant × 1 appeal × 10 hours).

##### 2. Minimum Capital Stock Calculation

The Finance Board estimates the total annual average number of Bank members that must calculate the minimum capital stock requirement at 8,100, with 1 response per member. The estimate for the average hours per maintenance response is 0.6 hours. The estimate for the total annual hour burden for the minimum capital stock calculation is 4860 hours (8100 members × 1 response × 0.6 hours).

##### 3. Membership Withdrawals

The Finance Board estimates the total annual average number of members that will file to withdraw from Bank membership at 30, with 1 filing per member. The estimate for the average hours per filing is 0.6 hours. The estimate for the total annual hour burden for membership withdrawals is

18 hours (30 members × 1 filing × 0.6 hours).

##### 4. Transfer of Membership to Another Bank District

The Finance Board estimates the total annual average number of members that will file to transfer membership to another Bank district at 5, with 1 filing per member. The estimate for the average hours per filing is 3.5 hours. The estimate for the total annual hour burden for membership transfers is 18 hours (5 members × 1 filing × 3.5 hours).

#### C. Comment Request

In accordance with the requirements of 5 CFR 1320.8(d), the Finance Board published a request for public comments regarding this information collection in the *Federal Register* on February 5, 2004. See 69 FR 5546 (Feb. 5, 2004). The 60-day comment period closed on April 5, 2004. The Finance Board received one comment urging increased use of electronic information. The Finance Board encourages the use of information technology to reduce the information collection burden. However, the extent of use is determined by each Bank. The comment is available on the Finance Board Web site at [http://www.fhfb.gov/pressroom/pressroom\\_regs.htm](http://www.fhfb.gov/pressroom/pressroom_regs.htm).

Written comments are requested on: (1) Whether the collection of information is necessary for the proper performance of Finance Board functions, including whether the information has practical utility; (2) the accuracy of the Finance Board's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments may be submitted to OMB in writing at the address listed above.

Dated: April 5, 2004.

By the Federal Housing Finance Board.

**Donald Demitros,**

*Chief Information Officer.*

[FR Doc. 04-8254 Filed 4-12-04; 8:45 am]

BILLING CODE 6725-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Improving the Quality of Genetic Testing and Assuring Its Appropriate Integration Into Clinical and Public Health Practice

*Announcement Type:* New.

*Funding Opportunity Number:* 04137.

*Catalog of Federal Domestic*

*Assistance Number:* 93.064.

*Application Deadline:* June 14, 2004.

*Executive Summary:* The number of genetic tests available to the clinical and public health communities is increasing, as is the number of tests being ordered. For many genetic tests, significant concerns exist related to test ordering, analytical and clinical validation, quality control, result reporting, and use of test results in medical decision making. Surveys carried out previously have indicated variability and gaps in each of these areas with potentially significant implications for the delivery of genetic testing services to the public. Initially, to address these issues, the scope of work for this project will include a technology and practice assessment linked to development of a program to improve one, or more aspects of the genetic testing process.

The goals of this program are (1) to conduct a technology and practice assessment within the scope of genetic testing laboratory services in the United States that will evaluate elements important for assuring the quality, appropriate use, and to what extent an understanding of benefits and limitations are applied; (2) to conduct a pilot study to test concepts potentially useful for improving the quality of the genetic testing process; and (3) to compare relevant international activities (those occurring outside the United States) to efforts undertaken in this project. The focus will be on one, or more health conditions and/or group of technologies that can provide insights into a broader spectrum of genetic testing issues. The target audiences for the assessment are laboratories performing genetic tests and users of genetic laboratory services (i.e. clinical and public health practitioners who order and use genetic tests and results). Important factors to consider include technologies employed, methods used for test validation and quality control, and pre- and post-analytic factors pertinent to the collection and use of patient/population-based information and the use of test results for health-care



decision-making. This program is also expected to recognize international efforts that address similar issues and their potential impact on practices within the U.S. As such, a review of relevant international efforts will be undertaken as part of this project proposed.

### I. Funding Opportunity Description

**Authority:** This program is authorized under section 317(k)(2) of the Public Health Service Act, 42 U.S.C. section 247b(k)(2), as amended.

**Purpose:** The purpose of the program is to improve the quality of laboratory genetic testing practices relevant to clinical and public health settings.

This program will assess current practices and the impact of technology on the provision of genetic testing services within the U.S. The project will take a quality systems approach in which technical and management aspects of each component of the system is recognized as contributing to the overall quality of testing and its potential impact on clinical and public health decision making. The initial part of this project must include a U.S. technology and practice assessment. The proposed assessment can be undertaken in several formats. It may be general in nature with the intent to capture data covering a broad spectrum of topics or focused on a subset of health conditions and/or technologies that can serve as models reflective of broader genetic testing issues. The assessment will be used to document variability in practices and expected to be helpful in identifying opportunities to address shortcomings and improve the quality of genetic testing and laboratory practices. This assessment should not be duplicative of past efforts but build upon them, or be novel in the areas explored and approaches taken.

Conclusions made from the assessment should be relevant to the broader community that performs genetic testing or uses genetic test results. Relevant issues can include test validation, quality assurance, quality control, proficiency testing, and the methods by which laboratories communicate with clinical and public health care providers, payers, policy makers, and others toward assuring appropriate use of their services. As such, it is also important to consider both the laboratories and users of their services (*i.e.* clinical/public health professionals) as target populations for the assessment and follow up efforts. The latter part of this program requires that the applicant propose a study or pilot program to test concepts that can

potentially improve the quality of laboratory practice related to one or more of the issues documented during the assessment. Efforts can include developing and evaluating novel quality assurance practices, developing educational/training programs to improve the knowledge and competencies among laboratory and health care professionals (*i.e.*, in the use and communication of genetic tests and results), or undertaking studies useful for informing professional groups and regulatory bodies toward the development, implementation, and evaluation of guidelines, standards, and/or regulatory requirements. As a final component to this program, a review of international efforts relevant to the work undertaken will be performed. The intent for this final requirement is to take a broader look at what is happening in other parts of the world relevant to the work undertaken in this program and comment upon opportunities that may benefit both U.S. practices as well as those in other countries. Less guidance is provided in addressing this part of the program since the nature of the work will depend on the direction the applicant proposes for earlier aims and their connectivity with the international community. This program addresses the "Healthy People 2010" focus area(s) of "Access to Quality Health Services" and "Public Health Infrastructure."

Measurable outcomes of the program will be in alignment with the following performance goals for the Public Health Practice Program Office: Increase the number of frontline public health workers at the state and local level that are competent and prepared to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies and prepare frontline state and local health departments and laboratories to respond to current and emergency health threats.

**Activities:** This project requires several activities be undertaken and as such it is vital that the applicant clearly state what is intended to be accomplished each year, or part thereof, of the three-year proposal. Funding for years two and three are dependent on the availability of funds and progress made.

Awardee activities for this program are as follows:

a. Develop and conduct assessments of laboratory practices which gather specific information related to technology assessment, test validation, quality assurance practices, personnel competencies, and ways in which tests are ordered and results are reported and used for medical and public health

decision making. The recipient is expected to provide an analysis of the data that is potentially broadly applicable to genetic testing in clinical and/or public health practice settings.

b. Conduct a pilot project to test and evaluate a process for improving the quality of laboratory testing that is based upon findings from the assessment described above.

c. Where appropriate, educational efforts should be conducted for laboratory staff and/or health care professionals as a component of the research or pilot project proposed. An evaluation of the educational activity should be undertaken to assess its usefulness and broader applicability. Particular emphasis should be placed upon the clinical/laboratory interface and/or public health laboratory setting.

d. Develop and implement a comparative analysis between U.S. and non-U.S. practices and policies relevant to the project proposed.

e. Convene advisory group(s) (comprised of knowledgeable and experienced persons), as appropriate, to develop recommendations useful for carrying out the work proposed.

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. Serve in an advisory capacity to the awardee in the development of data collection instruments and not otherwise be involved in the collection, use, or ownership of the data.

b. Assist in collaborating with other organizations, government entities, CDC staff, and others in carrying out program activities.

c. Assist in preparing training and education programs.

d. Assist forming expert focus groups, which may be composed of national and international experts, to develop strategies and recommendations.

### II. Award Information

**Type of Award:** Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

**Fiscal Year Funds:** 2004.

**Approximate Total Funding:** \$225,000.

**Approximate Number of Awards:** One.

**Approximate Average Award:** \$225,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

**Floor of Award Range:** None.

**Ceiling of Award Range:** \$225,000 (This ceiling is for the first 12-month budget period.)

*Anticipated Award Date:* September 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Three 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 be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Colleges.
- Research institutions.
- Hospitals.
- Community-based organizations.
- State and local governments or their

Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

#### 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.

**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

**Application:** You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25.
- If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point unredacted.
- 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.
- Single spaced.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

The narrative should consist of goals and objectives, methods and technical approach, project management and staffing, evaluation plan, and proposed budget for carrying out the recipient activities consistent with the evaluation criteria listed section "H". The budget justification will be counted in the stated page limit. 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 Vitae
- Letters of Support

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/pubcomm.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

**Application Deadline Date:** June 14, 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 carrier's 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 apply to this program.

#### IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- None.

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/pgofunding/budgetguide.htm>.

#### IV.6. Other Submission Requirements

**Application Submission Address:** Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04137, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

#### V. Application Review Information

##### V.1. Criteria

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:

##### 1. Methods and Technical Approach (30 points)

a. Does applicant clearly and succinctly describe the steps to be taken in the planning and implementation of the proposed cooperative agreement?

b. Are the methods used to carry out the responsibilities of the proposed cooperative agreement must be feasible and explained in sufficient detail?

##### 2. Project Management and Staffing (30 points)

a. Does the applicant describe a project management and staffing plan, and must demonstrate sufficient knowledge, expertise, and other resources required to perform the responsibilities in this project?

b. Does the applicant describe the staff qualifications and time allocations of key personnel to be assigned to this project, facilities and equipment, and other resources available for performance of this project?

##### 3. Goals and Objectives (20 points)

a. Does the applicant clearly describe an understanding of the objectives of this project and the relevance of the proposal to the stated objectives?

b. Are the goals and objectives measurable, specific, and achievable?

##### 4. Evaluation Plan (20 points)

Does the applicant describe the schedule for accomplishing the activities to be carried out in this project and methods for evaluating the accomplishments?

##### 5. Budget (Reviewed, but not Scored)

The proposed budget must be reasonable, clearly justified, and consistent with the intended use of funds.

##### 6. Performance Measures (Reviewed, but not Scored)

The application should be consistent with the Government Performance and Results Act of 1993.

##### 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 PHPPPO. 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 may be given to organizations that routinely provide and/or utilize clinical or public health genetic testing laboratory services. Preference may also be given to organizations that have contributed to the development, or use of quality assurance programs for genetic testing, have engaged in research or assessment of new technologies and their implications for clinical and public health practice, have participated in activities relevant to the translation of research findings to clinical and public health applications, and/or participated in efforts to develop domestic and international genetic testing policies.

Preferences may be given to organizations that have expertise in heritable human conditions of public health significance that can be applied to the efforts described in this program announcement in such a way that results will be broadly applicable to other areas of genetic testing. Lastly, preferences will be given to applications demonstrating collaboration among clinical and public health entities in developing and carrying out the work proposed. Entities can include clinical and public health academic departments, state and local public health organizations, professional organizations that focus on clinical and/or public health issues, and other such groups.

#### 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 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://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgofunding/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 less than 90 days before the end of the budget period. 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, 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 or Contract 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: Ira Lubin, Ph.D., Centers for Disease Control and Prevention, PHPPPO, DLS, 4770 Buford HWY, MSG23, Telephone: 770-488-8070, Fax: 770-488-8278, E-mail: [ilubin@cdc.gov](mailto:ilubin@cdc.gov).

For financial, grants management, or budget assistance, contact: Sharon Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2748, E-mail: [sqr2@cdc.gov](mailto:sqr2@cdc.gov).

#### VIII. Other Information

For information about the Centers for Disease Control and Prevention see <http://www.cdc.gov>.

For information about the genetic activities within the Division sponsoring this cooperative agreement, see <http://www.phppo.cdc.gov/dls/genetics/default.asp>.

Dated: April 7, 2004.

**William P. Nichols,**  
Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-8291 Filed 4-12-04; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Trauma Information and Exchange Program

Announcement Type: Competing Continuation Funding.

Opportunity Number: 04075.  
Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates:  
Letter of Intent Deadline: May 13, 2004.  
Application Deadline: July 12, 2004.

#### I. Funding Opportunity Description

**Authority:** This program is authorized under sections 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a) and 247b(k)(2)] as amended.

**Purpose:** The purpose of the Trauma Information and Exchange Program (TIEP) is to make data and information on trauma care in the United States more accessible to a broad spectrum of individuals and organizations, including trauma care professionals and professional associations, trauma centers and other acute care hospitals, trauma care systems, emergency medical services (EMS) systems, injury researchers and research organizations, public health agencies, health care payers, and the general public. TIEP will also foster the exchange and use of information to improve trauma care. This program addresses the "Healthy People 2010" focus area of Injury and Violence Prevention.

Measurable outcomes of the program will be in alignment with the National Center for Injury Prevention and Control (NCIPC): Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence.

**Activities:** Awardee activities for this program are as follows:

1. Provide a full-time director/coordinator with authority and responsibility to fulfill the requirements of the program.
2. Provide qualified staff, other resources, and knowledge to implement the components of the program.
3. Develop and implement a comprehensive plan to periodically update a detailed description of trauma centers in the United States, including key personnel, as well as their capabilities.
4. Develop and implement a plan that enables an exchange of information among trauma centers and trauma organizations nationwide.
5. Develop and implement a plan for a uniform surveillance system for trauma centers that will enable researchers and research organizations to conduct research on quality of trauma care and trauma center and trauma system effectiveness.
6. Develop and implement a plan for the dissemination of available information on trauma, trauma centers,

and trauma care systems to the public, researchers and healthcare practitioners.

#### II. Award Information

Type of Award: Grant.  
Fiscal Year Funds: 2004.  
Approximate Total Funding: \$495,000.  
Approximate Number of Awards: One.

Approximate Average Award: \$495,000.

Floor of Award Range: None.  
Ceiling of Award Range: \$495,000.

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.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.  
Project Period Length: One year.

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

**1. Eligible applicants:** Applications may be submitted by public and private organizations, community-based organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
  - Private nonprofit organizations.
  - Small, minority, women-owned businesses.
  - Universities.
  - Colleges.
  - Research institutions.
  - Hospitals.
  - Community-based organizations.
  - Faith-based organizations.
  - Federally recognized Indian tribal governments.
  - Indian tribes.
  - Indian tribal organizations.
  - State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
  - Political subdivisions of States (in consultation with States).
- A Bona Fide Agent is an agency/organization identified by the State as

eligible to submit an application under the State eligibility in lieu of a State application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

### III.2. Cost Sharing or Matching

Matching funds are not required for this program.

### III.3. Other Eligibility Requirements

If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

- If you request a funding amount greater than the ceiling of award range.

**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):** 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. Your LOI must be written in the following format:

- Maximum number of pages: Two.
- Font size: 12-point un-reduced.
- 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.

**Application:** You must submit a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 20.
- If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point un-reduced.
- 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:

- Background and Need.
- Methods.
- Evaluation.
- Staff and Resources.
- Budget and justification.

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/pubcomm.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.

### IV.3. Submission Dates and Times

**LOI Deadline Date:** May 13, 2004.

**Application Deadline Date:** July 12, 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:

- None

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 must be less than 12 months of age. 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:** Phyllis C. McGuire, Project Officer, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway NE., Mailstop F-41, Atlanta, GA 30341-3724, Telephone: 770-488-1275, E-mail address: [PMcGuire@cdc.gov](mailto:PMcGuire@cdc.gov).

**Application Submission Address:** Submit the original and two copies of your application by mail or express delivery service to: Technical Information Management—PA 04075, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

## V. Application Review Criteria

### V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate



the accomplishment of the various identified objectives of the grant. 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.

#### 1. Background and Need (40 Percent)

Applicant should describe the background and need for a comprehensive trauma information program including; development, current challenges in organizing and delivering trauma care, challenges of developing and maintaining trauma systems, implementation and evaluation of a plan to periodically update a detailed description of trauma centers in the United States, development of a plan to exchange information and link resources of trauma centers and a plan for a uniform surveillance program.

#### 2. Methods (30 Percent)

Applicant should provide a detailed description of all proposed activities required to implement a comprehensive trauma information and exchange program including letters of support and collaboration needed to achieve each objective and the overall program goal(s). Applicants should provide a reasonable, logically sequenced and complete schedule for implementing all activities. Applicant should include position descriptions, lines of command, and collaborations as appropriate to accomplishing the program goal(s) and objectives. Applicant should describe a plan and implementation dissemination of available trauma information.

#### 3. Staff and Resources (20 Percent)

Can applicant provide adequate facilities, staff and/or collaborators, including a full-time coordinator and resources to accomplish the proposed goal(s) and objectives during the project period? Applicant should demonstrate staff and/or collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

#### 4. Evaluation (10 Percent)

The proposed evaluation plan should be detailed and capable of documenting program process and outcome measures. Applicant should demonstrate staff and/or collaborator availability, expertise, and capacity to perform the evaluation.

#### 5. Budget and Justification (Not Scored)

Itemized budget and justification for the estimated costs of the contract; specify the period of performance, and method of selection.

A detailed budget and narrative justification consistent with the stated objectives and planned program activities should be included. CDC may not approve or fund all proposed activities. The applicant should be precise about the program purpose of each budget item. Proposed contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance, and method of selection.

##### V.2. Review and Selection Process

Application will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the NCIPC. 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 "Review Criteria" section above.

##### V.3. Anticipated Announcement and Award Dates

Anticipated award date: September 1, 2004.

#### 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 fiscal officer identified in the application.

##### 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://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-8: Public Health System Reporting Requirements
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2010
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-15: Proof of Non-Profit Status
- AR-21: Small, Minority, and Women-Owned Business
- AR-22: Research Integrity
- AR-23: States and Faith-Based Organizations

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.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 less than 90 days before the end of the budget period. 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 or Contract Specialist listed in the "Agency Contacts" section of this announcement.

#### VII. Agency Contacts

For program technical assistance, contact: Phyllis C. McGuire, Project Officer, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway NE., Mailstop F41, Atlanta, GA 30341-3724, Telephone: 770-488-1275, E-mail address: [PMcGuire@cdc.gov](mailto:PMcGuire@cdc.gov).

For budget assistance, contact: Angie Tuttle, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770.488.2719, E-mail: [AEN4@cdc.gov](mailto:AEN4@cdc.gov).

Dated: April 7, 2004.

William P. Nichols,

Acting Director, Procurement and Grants  
Office, Centers for Disease Control and  
Prevention.

[FR Doc. 04-8293 Filed 4-12-04; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine

*Announcement Type:* New.

*Funding Opportunity Number:* 04140.

*Catalog of Federal Domestic*

*Assistance Number:* 93.064.

*Key Dates:*

*Letter of Intent Deadline:* May 13,  
2004.

*Application Deadline:* June 14, 2004.

*Executive Summary:* This program will evaluate the effectiveness of standardized approaches to quality assurance in pathology and laboratory medicine, in order to determine approaches that produce measurable and sustainable improvements against established benchmarks. Areas of primary interest are: pre-analytic process, including the test requisition; post-analytic processes, including the test report; implementation of CLIA-waived tests in point of service environments; error identification and reduction; and quality assurance activities in anatomic pathology (autopsies, surgical pathology, cytopathology and/or genetic testing).

#### I. Funding Opportunity Description

**Authority:** This program is authorized under section 317 (k) (2) of the Public Health Service Act, 42 U.S.C. 247b (k)(2), as amended.

**Purpose:** The purpose of the program is to determine standardized approaches to quality assurance in pathology and laboratory medicine that can be applied in multiple, diverse settings (e.g. community hospitals, academic medical centers, and independent laboratories) that demonstrate measurable and sustainable improvements over time. The program focuses on specific opportunities for error reduction, or process improvement in: pre-analytic processes, including test requisitions; post-analytic processes, including test reports; implementation of CLIA-waived tests in point of service environments, and; anatomic pathology (autopsies, surgical pathology, and cytology and/or

genetic testing). This program addresses the "Healthy People 2010" focus area(s) of "Access to Quality Health Services" and "Public Health Infrastructure".

Measurable outcomes of the program will be in alignment with the following performance goal for the Public Health Practice Program Office (PHPPO): To assure that public health infrastructure at the Federal, state, and local levels has the capacity to provide essential public health services to the citizens of the nation to respond to bioterrorism, other infectious disease outbreaks, other public health threats, emergencies and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats."

#### Activities

Awardee activities for this program are as follows:

- Evaluate quality assurance methods that have been standardized and implemented in multiple, diverse laboratory settings for common laboratory practices.
  - Determine best practices in quality assurance methods for addressing pre-analytic components of laboratory testing, including the test requisition.
  - Determine best practices in quality assurance methods for addressing post-analytic components of laboratory testing, including the test report.
  - Determine best practices in quality assurance methods for addressing implementation of CLIA-waived tests in the point of service test environment.
  - Determine best practices in quality assurance methods in anatomic pathology (autopsy, surgical pathology and/or cytopathology).
  - Provide leadership in assessing the impact of reporting surgical pathology results in a template format.
  - Provide leadership in developing strategies that lead to wider use of proven methods of quality assurance and error reduction.
  - Provide leadership in developing strategies that lead to improved use of CLIA-waived tests.
  - Provide leadership in developing programs that evaluate and improve laboratory practice over a specified time period.
- 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:
- Provide consultation and technical assistance in the planning, implementation, and evaluation of program activities.

- Provide information on numbers and types of laboratories and numbers and types of waived tests.

- Provide consultation and technical assistance related to scientific information on errors in laboratory medicine.

- Provide information on CLIA regulations and their impact on laboratory testing.

- Provide information from the CDC-sponsored Institute for Quality in Laboratory Medicine.

#### II. Award Information

*Type of Award:* Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2004.

*Approximate Total Funding:*  
\$100,000.

*Approximate Number of Awards:*  
One.

*Approximate Average Award:*  
\$100,000.

*Floor of Award Range:* None.

*Ceiling of Award Range:* \$100,000  
(This ceiling is for the first 12-month budget period.).

*Anticipated Award Date:* September 1, 2004.

*Budget Period Length:* 12 months.

*Project Period Length:* Three 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 be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations.
- Private nonprofit organizations.
- Universities.
- Research institutions.
- Community-based organizations.
- Faith-based organizations.
- State and local governments or their

Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

A Bona Fide Agent is an agency/organization identified by the state as

eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

### III.2. Cost Sharing or Matching

Matching funds are not required for this program.

### III.3. Other

CDC will accept and review applications with budgets greater than the ceiling of the award range.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process.

You will be notified that your application did not meet submission requirements.

Applicants must have experience in the administration and evaluation of standardized quality assurance programs in multiple, diverse laboratory sites (including community hospitals and academic medical centers). This experience is required for an applicant to be able to assess the effectiveness of these quality assurance programs and to determine best practices.

**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: [www.cdc.gov/od/pgo/forminfo.htm](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: two.
- Font size: 12-point un-reduced.
- Single 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:

- Description of organization.
- Goals and objectives.
- Methods and Technical Approach.
- Project Management and Staffing (Expertise in standardized processes for quality assurance in laboratory medicine and pathology).

- Budget—total funds to be requested.

**Application:** You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point un-reduced.
- 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.
- Double spaced.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Applicant's knowledge of and experience with standardized approaches to quality assurance in laboratory medicine and pathology.
- Applicant's knowledge of and experience with quality assurance activities addressing pre-analytic processes (including test requisition), post-analytic processes (including test report), implementation of CLIA-waived tests in point of service environments, error identification and reduction; anatomic pathology and/or genetic testing.

- Applicant's proposal (including plan, methods, objectives, timeline, and staff) to evaluate the effectiveness of standardized approaches to quality assurance activities in pre-analytic processes (including test requisition), post-analytic processes (including test report), implementation of CLIA-waived tests in point of service environments, error identification and reduction; anatomic pathology and/or genetic testing.

- Applicant's proposed performance measures.
- Applicant's proposed budget and budget justification (which will not be counted toward the page limit for the narrative).

Additional information may be included in the application appendices. The appendices will not be counted

toward the narrative page limit. This additional information includes:

- Examples of past work on standardized quality assurance measures in pathology and laboratory medicine.
- Publications in standardized approaches to quality assurance in pathology and laboratory medicine.
- Organizational charts.
- Letters of support.

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 [www.dunandbradstreet.com](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/pubcomm.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:** May 13, 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:** June 14, 2004.

#### **Explanation of Deadlines:**

Applications must be received in the CDC Procurement and Grants Office by 4:00 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 apply to this program.

#### IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- None.

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: Tracy L. Carter, M.P.H., Centers for Disease Control and Prevention, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Highway NE, MS-G25, Atlanta, GA 30341, Telephone: 770 488-2523, Fax: 770-488-8282, E-mail: [tsc1@cdc.gov](mailto:tsc1@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—PA# 04140, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

### V. Application Review Information

#### V.1. Criteria

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:

#### 1. Methods and Technical Approach (30 Points)

- a. Are the proposed methods feasible?
- b. Will the proposed methods achieve the program goals and objectives?
- c. Do the proposed methods address pre-analytic processes?
- d. Do the proposed methods address post-analytic processes?
- e. Do the proposed methods address implementation of waived tests in the point of service environment?
- f. Do the proposed methods address anatomic pathology?

#### 2. Project Management and Staffing (30 Points)

- a. Does the applicant have the staff, knowledge, and expertise required to perform the responsibilities associated with the project?
- b. Are adequate qualified personnel committed to the project?

#### 3. Program Goals and Objectives (20 Points)

Does the proposal address the program goals and objectives?

#### 4. Evaluation Plan (20 Points)

Does the applicant describe a feasible schedule for accomplishing the activities related to this project and a plan for evaluating their progress?

#### V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by PHPO. 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.

### 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 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://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-10 Smoke-Free Workplace Requirements.
- AR-11 Healthy People 2010.
- AR-12 Lobbying Restrictions.
- AR-15 Proof of Non-Profit Status.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.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 less than 90 days before the end of the budget period. 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, 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 or Contract

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: Toby L. Merlin, MD, Project Officer, Centers for Disease Control and Prevention, Division of Laboratory Systems, Public Health Practice Program Office, 4770 Buford Highway NE, MS-G25, Telephone: 770-488-8256, E-mail: [tmerlin@cdc.gov](mailto:tmerlin@cdc.gov).

For financial, grants management, or budget assistance, contact: Sharon Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2748, E-mail: [sqr2@cdc.gov](mailto:sqr2@cdc.gov).

Dated: April 7, 2004.  
**William P. Nichols,**  
*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*  
 [FR Doc. 04-8292 Filed 4-12-04; 8:45 am]  
**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:* Reporting and Recordkeeping.  
*Title:* Case Plan Requirement, Section 422, 471(a)(16) and 475(5)(A)(B) of the Social Security Act.  
*OMB No.* 0980-0140.  
*Description:* Under section 471(a) of Title IV-E of the Social Security Act

(the Act), to be eligible to receive Title IV-E Federal financial assistance payments, states must develop a case plan (as defined in section 475(11) for each child receiving foster care maintenance payments. Section 471(a)(16) states that in order for a state to be eligible for payments under this part, there must be a state plan, approved by the Secretary of the U.S. Department of Health and Human Services, which provides for the development of a case plan for each child receiving foster care assistance under the state plan and provides for a case review system which meets the requirements described in section 475(5)(B) with respect to each child. Through these requirements, states also comply, in part, with Title IV-B, section 422(b)(10) of the Act, which assures certain protections for children in foster care.

*Respondents:* State Title IV-B and Title IV-E Agencies  
*Annual Burden Estimates*

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Plan .....	701,461	1	2.60	1,823,799

*Estimated Total Annual Burden Hours:* 1,823,799.  
 In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [grjohnson@acf.hhs.gov](mailto:grjohnson@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 7, 2004.  
**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 04-8338 Filed 4-12-04; 8:45 am]  
**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Statement of Organization, Functions and Delegations of Authority**

Notice is hereby given that I delegate to the Commissioner, Administration on Developmental Disabilities, with authority to further redelegate, the following authority vested in the Assistant Secretary for Children and Families by the Secretary under Title II, Subtitle D, Parts 2 and 5 of the Help America Vote Act of 2002, Pub. L. 107-252, 116 Stat 1666, 1698-1699, 1702-1703 (2002), 42 U.S.C. 15421-15425, 15461-15462.

(A) Authority to administer the Title II, Subtitle D, Parts 2 and 5 of the Help America Vote Act of 2002, Pub. L. 107-252, 116 Stat 1666, 1698-1699, 1702-

1703 (2002), 42 U.S.C. 15421-15425, 15461-15462, and as amended, hereafter.

(B) Effect on Existing Delegations.

None

(A) Limitations.

1. This delegation shall be exercised under the Department's existing delegation and policy on regulations.

2. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

3. I hereby affirm and ratify any actions taken by the Commissioner, Administration on Developmental Disabilities, or any other Administration on Developmental Disabilities officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

4. Any redelegation shall be in writing and prompt notifications must be provided to all affected managers, supervisors, and other personnel.

(D) Effective Date.

This delegation is effective immediately.

Dated: April 2, 2004.

**Wade F. Horn,**  
*Assistant Secretary for Children and Families.*  
 [FR Doc. 04-8335 Filed 4-12-04; 8:45 am]  
**BILLING CODE 4184-01-P**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Administration for Children and Families Statement of Organization, Functions and Delegations of Authority**

Notice is hereby given that I delegate to the Commissioner, Administration on Developmental Disabilities, with authority to further redelegate, the following authority vested in the Assistant Secretary for Children and Families by the Secretary under the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Pub.L. 106-402, 114 Stat. 1677 (2000), 42 U.S.C. 15001 *et seq.*

**(a) Authority Delegated**

Authority to administer the Developmental Disabilities Assistance and Bill of Rights Act of 2000, (The Act), Pub. L. 106-402, 114 Stat. 1677 (2000), 42 U.S.C. 15001 *et seq.*, and as amended, hereafter, including authority to make the initial decision regarding withholding of funds from States pursuant to section 127 of the Act (42 U.S.C. 15027).

**(b) Effect on Existing Delegations**

Replaces.

**(c) Limitations**

1. This delegation shall be exercised under the Department's existing delegation and policy on regulations.

2. This delegation does not include authority to hear appeals under 45 CFR 1386, subpart D, 45 CFR 1386.20(e), or 45 CFR 1386.34(d).

3. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

4. I hereby affirm and ratify any actions taken by the Commissioner, Administration on Developmental Disabilities, or any other Administration on Developmental Disabilities officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

5. Any redelegation shall be in writing and prompt notifications must be provided to all affected managers, supervisors, and other personnel.

**(d) Effective Date**

This delegation is effective immediately.

Dated: April 2, 2004.

Wade F. Horn,  
Assistant Secretary for Children and Families.  
[FR Doc. 04-8336 Filed 4-12-04; 8:45 am]

BILLING CODE 4184-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2003N-0482]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Mammography Facilities, Standards, and Lay Summaries for Patients**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Mammography Facilities, Standards, and Lay Summaries for Patients" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of February 9, 2004 (69 FR 5991), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910-0309. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8250 Filed 4-12-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2003N-0424]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substantial Evidence of Effectiveness of New Animal Drugs**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substantial Evidence of Effectiveness of New Animal Drugs", has been approved by the Office of Management and Budget (OMB) under provisions of the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of January 7, 2004 (69 FR 923), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). 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. OMB has now approved the information collection and has assigned OMB control number 0910-0356. The approval expires on March 31, 2007.

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8252 Filed 4-12-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 2003N-0397]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Threshold of Regulation for Substances Used in Food-Contact Articles**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Threshold of Regulation for Substances Used in Food-Contact Articles" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of January 23, 2004 (69 FR 3372), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910-0298. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8305 Filed 4-12-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0154]

#### Medical Devices; Semicritical Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of semicritical reprocessed single-use devices (SUDs) whose exemption from premarket submission is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a premarket notification (510(k)). FDA is requiring submission of these data to ensure that these reprocessed SUDs are substantially equivalent to predicate devices in accordance with MDUFMA. **DATES:** These actions are effective April 13, 2004. Manufacturers of reprocessed SUDs identified in the list whose exemptions are being terminated must submit 510(k)s for these devices by July 13, 2005, or these devices may no longer be legally marketed.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

[www.fda.gov/dockets/ecomments](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:

Barbara A. Zimmerman, 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

On October 26, 2002, MDUFMA (Public Law 107-250) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data to ensure that the reprocessed SUDs are substantially equivalent to predicate devices. The required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before the enactment of the new law, the agency required a manufacturer of a reprocessed SUD to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt critical and semicritical reprocessed SUDs will no longer be exempt from premarket notification requirements. Manufacturers of these identified devices will need to submit 510(k)s that include validation data as specified by FDA.

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an "original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition."

Reprocessed SUDs are divided into the following three categories: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions contained in MDUFMA, and all three reflect a classification scheme recognized in the

industry.<sup>1</sup> These categories of devices are defined as follows:

1. A *critical reprocessed SUD* is intended to contact normally sterile tissue or body spaces during use.
2. A *semicritical reprocessed SUD* is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.
3. A *noncritical reprocessed SUD* is intended to make topical contact and not penetrate intact skin.

In the *Federal Register* of April 30, 2003 (68 FR 23139), FDA explained its methodology and criteria for determining which device types should no longer be exempt from premarket submission requirements in accordance with MDUFMA. As described in the April 2003 *Federal Register* notice, in the first step of this process, the agency categorized all known types of SUDs that were being reprocessed as critical, semicritical, or noncritical using the previously listed definitions. Next, FDA evaluated the overall risk (high, moderate, or low) associated with the reprocessed SUDs using the review prioritization scheme (RPS) that had been previously described in a draft guidance document.<sup>2</sup> In the RPS guidance, FDA set forth factors that could be used to evaluate the risk associated with reprocessed SUDs and assign an overall risk to each SUD based on the risk of the following: (1) Infection and (2) inadequate performance following reprocessing. The designation of "high risk" was assigned to those devices that posed the greatest risk of infection and inadequate performance after reprocessing.

In addition to the previously listed steps, FDA also identified all reprocessed SUDs intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD). As stated in the April 2003 *Federal Register* notice, these are generally devices intended for use in neurosurgery and ophthalmology. This criterion was used in FDA's evaluation because insufficient scientific information exists at this time to establish standard methods to eliminate CJD infectious agents.

<sup>1</sup> Spaulding, E. H., "The Role of Chemical Disinfection in the Prevention of Nosocomial Infections," P. S. Brachman and T. C. Eickoff (ed), Proceedings of International Conference on Nosocomial Infections, 1970, American Hospital Association, Chicago, 1971:254-274.

<sup>2</sup> The draft guidance entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (appendix 2 superseded) is available on the Center for Devices and Radiological Health's (CDRH) Web site at <http://www.fda.gov/cdrh/reuse/1156.pdf>.

Using this process and criteria, FDA developed a reference list (attachment 1 of the April 2003 **Federal Register** notice). This list identifies the entire group of reprocessed SUDs, and the levels of risk associated with the devices, that FDA considered when implementing the new statutory requirements in section 510(o) of the act. (For more detailed information on the process FDA used to identify these SUDs and assign risk categorizations, see 68 FR 23139.)

## II. Requirements for 510(k) Exempt Critical Reprocessed SUDs

In the April 2003 **Federal Register** notice, as required by MDUFMA, FDA published a list of critical reprocessed SUDs whose exemptions from premarket submission were being terminated and for which validation data in 510(k) submissions would be necessary. In the notice, FDA identified those critical reprocessed SUDs that were either "high" risk, as described

previously, or intended to come in contact with tissue at high risk of being infected with the causative agents of CJD (see list I of the April 2003 **Federal Register** notice). FDA also published a revised version of this list in the **Federal Register** of June 26, 2003 (68 FR 38071).

## III. Requirements for 510(k) Exempt Semicritical Reprocessed SUDs

As discussed previously, MDUFMA also requires FDA to review the semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices will require 510(k)s with validation data in order to ensure their substantial equivalence to predicate devices. FDA is required to identify these devices in a notice published in the **Federal Register** by April 26, 2004. The attached list of semicritical reprocessed SUDs implements this MDUFMA requirement. Using the methodology and criteria described in this document for

developing the list of critical reprocessed SUDs, the agency determined which semicritical reprocessed SUDs should be subject to premarket submission requirements. All devices identified in the attached list have been determined to be high risk semicritical reprocessed SUDs. It should be noted that not all exempt semicritical devices have been listed. Semicritical reprocessed SUDs that are not listed at this time may be added to future updates of the list.

As required by MDUFMA, manufacturers of the devices identified in the attached list must submit 510(k)s that include validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of 510(k)s identified in 21 CFR 807.87, within 15 months of publication of this notice or they may no longer legally market these devices after that date.

LIST 1.—SEMICRITICAL REPROCESSED SINGLE-USE DEVICES PREVIOUSLY EXEMPT FROM PREMARKET NOTIFICATION REQUIREMENTS THAT WILL NOW REQUIRE 510(K)S WITH VALIDATION DATA

21 CFR Section	Classification Name	Product Code for Non-reprocessed Device	Product Code for Reprocessed Device	Product Code Name for Reprocessed Device
872.5410	Orthodontic appliance and accessories	EJF	NQS	Orthodontic metal bracket
876.4680	Ureteral stone dislodger	FGO, FFL	NQT, NQU	Flexible and basket stone dislodger
868.6810	Tracheobronchial suction catheter	BSY	NQV	Tracheobronchial suction catheter

## IV. Requirements for 510(k) Exempt Noncritical Reprocessed SUDs

MDUFMA does not require FDA to take any action under section 510(o) of the act for noncritical reprocessed SUDs that are exempt from premarket submission requirements.

## V. Stakeholder Input

In the **Federal Register** of February 4, 2003 (68 FR 5643), FDA invited interested persons to provide information and share views on the implementation of MDUFMA. Since that time, the agency has received comments on various MDUFMA provisions, including several on its implementation of section 510(o) of the act. One comment expressed concern about the agency's reliance on the Review Prioritization Scheme (RPS). According to the comment, the RPS is a subjective and incomplete method for accurately assessing the risk associated with reprocessing. The comment further stated that Congress's intent was for the Spaulding criteria to be the primary mechanism used to determine whether

the exempt status of reprocessed SUDs remains appropriate.

As stated in the April 30, 2003 **Federal Register** notice, the agency continues to believe that the RPS is an appropriate risk-based tool for identifying those devices that are likely to raise concerns about both infection transmission and inadequate performance following reprocessing. FDA believes that the flowchart that is part of the RPS provides an objective, science-based assessment of these risks for each type of reprocessed device. In addition, while MDUFMA defines the terms "critical reprocessed single-use device" and "semi-critical reprocessed single-use device" in new section 201(mm)(1) and (mm)(2) of the act, new section 510(o)(2)(A) states that "[t]he Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices." Given this statutory language, FDA believes that while Congress used the Spaulding definitions to initially

categorize reprocessed SUDs, Congress also authorized the agency to apply additional criteria in determining the devices for which 510(k) exemptions should be terminated.

The agency also received a comment that identified specific reprocessed SUDs whose exemption from the 510(k) requirements should be terminated. The agency considered these recommendations while finalizing this document. Although this list of semicritical reprocessed SUDs does not include all of those devices that were recommended in the comment, the agency believes that 510(k)s with validation data should be required in accordance with MDUFMA for the devices identified on the list due to concerns about infection transmission and performance. As stated in the April 2003 **Federal Register** notice, the agency recognizes that the lists of critical and semicritical devices may need to be reevaluated and updated over time. Therefore, FDA will consider comments from the public on additional devices

that should be included on the lists at any time.

Finally, FDA would like to take this opportunity to remind entities that reprocess SUDs of the guidance document entitled "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices." FDA announced the availability of this guidance in the **Federal Register** of July 8, 2003 (68 FR 40679). This guidance document provides FDA's recommendations for manufacturers of reprocessed SUDs to assist them in complying with MDUFMA's validation data submission requirement and should be helpful to manufacturers of those semicritical reprocessed SUDs listed below in preparing their 510(k)s. This guidance may be found on CDRH's Web site at <http://www.fda.gov/cdrh/guidance/html>.

#### VI. Paperwork Reduction Act of 1995

This document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information described in this document were approved under OMB control number 0910-0514.

#### VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-8307 Filed 4-12-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Fifth Joint Project Management Workshop on Improving Agency/Industry Communication Throughout the Drug Development Process; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) in cosponsorship with the Drug Information Association (DIA) is announcing a public workshop entitled "The Fifth Joint Project Management Workshop: Improve Agency/Industry Communication Throughout the Drug Development Process." The workshop will focus on facilitating the drug development and drug review processes through interactions between industry and FDA to effectively manage risk to expedite products of public benefit to market.

**Date and Time:** The public workshop will be held on May 11, 2004, from 8:30 a.m. to 5 p.m., May 12, 2004, from 8:30 a.m. to 5 p.m., and May 13, 2004, from 8:30 a.m. to 12:30 p.m.

**Location:** The public workshop will be at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD.

**Contact Person:** Julieann Dubeau, Center for Drug Evaluation and Research (HFD-180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301-827-7310, FAX: 301-827-1305, e-mail:

[Dubeau@cder.fda.gov](mailto:Dubeau@cder.fda.gov), or Gail Sherman, Center for Biologics Evaluation and Research (HFM-42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, FAX: 301-827-3079, e-mail: [Sherman@cber.fda.gov](mailto:Sherman@cber.fda.gov), or Camela Pastorius, Drug Information Association, 800 Enterprise Rd., suite 200, Horsham, PA 19044, 215-442-6196, FAX: 215-442-6103, e-mail: [Camela.Pastorius@diahome.org](mailto:Camela.Pastorius@diahome.org).

**Registration:** Mail or fax your registration information and registration fee to Drug Information Association (DIA), P.O. Box 827192, Philadelphia, PA 19182-7192. You may obtain registration forms from DIA (see *Contact Person*) or from FDA at <http://www.fda.gov/cber/meetings.htm>. Additional information regarding registration fees and online registration can be found at [http://www.diahome.org/docs/events/events\\_search\\_detail.cfm](http://www.diahome.org/docs/events/events_search_detail.cfm). (FDA has verified the Web site, but we are not

responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Camela Pastorius (see *Contact Person*) by May 4, 2004.

**SUPPLEMENTARY INFORMATION:** FDA (the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research) and DIA are cosponsoring a public workshop as part of a continuing effort to develop higher levels of teamwork, communication, and procedural knowledge to facilitate drug development and review in the United States. The workshop's target audience is project directors, leaders, managers, and regulatory affairs representatives from industry; and FDA reviewers, regulatory project managers, and consumer safety officers. At the conclusion of the workshop, the participants should be able to do the following: (1) Identify FDA/industry cultural differences that influence interactions between the two groups, (2) effectively manage constructive interactions in a changing environment, and (3) manage communication strategies for facilitating drug approvals.

Dated: April 6, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-8251 Filed 4-12-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999D-2335]

#### Guidance for Industry and Food and Drug Administration Staff; Premarket Approval Applications for Absorbable Powder for Lubricating a Surgeon's Glove; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove." This guidance describes the information FDA recommends that you provide in a PMA for absorbable powder for lubricating a surgeon's glove.

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the



guidance document entitled "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" 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:** Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the *Federal Register* of July 30, 1999 (64 FR 41744), FDA announced the availability of a draft guidance for comment entitled "Medical Glove Guidance Manual." (See <http://www.fda.gov/cdrh/dsma/135.html> for the draft guidance.) Elsewhere in the same issue of the *Federal Register* (64 FR 41710), FDA proposed that the 1999 draft guidance serve as a special control for class II gloves. However, chapter 4 of the 1999 draft guidance contained a section that discussed PMAs for absorbable powder for lubricating surgeon's gloves. Because the section discussing PMAs for absorbable powder is not relevant to class II gloves, FDA is removing this section and issuing it as a separate guidance document. FDA did not receive any comments on this section of the 1999 draft guidance. Because the recommendations in this section were available in draft form for comment, FDA is issuing this guidance as a final document. As with any guidance, however, you may submit comments at any time.

##### **II. Significance of Guidance**

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 PMAs for

absorbable powder for lubricating a surgeon's glove. 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 statute and regulations.

##### **III. Electronic Access**

To receive "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" by 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 (1230) 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>.

##### **IV. 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 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910-0231). The labeling provisions addressed in the guidance have been approved by OMB under the PRA, OMB control number 0910-0485.

##### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. 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: March 30, 2004.

**Beverly Chernaik Rothstein,**

*Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.*

[FR Doc. 04-8306 Filed 4-12-04; 8:45 am]

BILLING CODE 4160-01-5

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **Proposed Data Collection; Comment Request Health Information National Trends Survey (HINTS) II**

**SUMMARY:** In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Health Information National Trends Survey (HINTS) II. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Health Information National Trends Survey (HINTS) is a biennial survey designed to provide nationally representative, population-based data on health information for the United States. The NCI funded HINTS to assist in its effort to (1) encourage programmatic and interdisciplinary approaches to cancer communication research, and (2) accelerate development of innovative health communication models, theories, and research strategies in cancer prevention, control, and care. HINTS II, scheduled to commence in early 2005, will preserve the methodological integrity of the first cycle of HINTS by using the telephone as the primary mode of data collection as well as



retaining approximately 50% of the questionnaire content. In addition, HINTS II will experiment with alternative modes of data collection (i.e., the Internet). Data will be used (1) to understand individuals' sources of and access to cancer-related information; (2) to measure progress in improving cancer knowledge and communication to the general public; (3) to develop appropriate messages for the public

about cancer prevention, detection, diagnosis, treatment, and survivorship; and (4) to identify research gaps and guide decisions about NCI's research efforts in health promotion and health communication. *Frequency of response:* One-time. *Affected public:* Individuals. *Type of Respondents:* U.S. Adults, Pilot Survey, Screeners and Interview. The annual reporting burden is as follows: *Estimated Number of Respondents:*

10,389; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .37; and *Estimated Total Annual Burden Hours Requested:* 3,836. The annualized cost to respondents is estimated at \$38,360. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Frequency of response	Average hours per response	Annual hour burden
Pilot Survey .....	150	1	.4167	63
HINTS II Screener .....	10,239	1	.0833	854
HINTS II Interview* .....	7,004	1	.4167	2,919
<b>Totals .....</b>				<b>3,836</b>

\*HINTS II interview respondents are a subset of the screener respondents (N = 10,389).

**Request For Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. **FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Bradford W. Hesse, Ph.D., Project Officer, National Cancer Institute, NIH, EPN 4068, 6130 Executive Boulevard MSC 7365, Bethesda, Maryland 20892-7365, or call non-toll-free number (301) 594-9904, or FAX your request to (301) 480-2198, or E-mail your request, including your address, to [hesseb@mail.nih.gov](mailto:hesseb@mail.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of this notice.

Dated: April 1, 2004.

**Rachelle Ragland-Greene,**

*OMB Clearance Liaison, National Cancer Institute, National Institutes of Health.*

[FR Doc. 04-8270 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**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.

#### Query Tool for Accurate Protein Identification

Rodney L. Levine (NHLBI)  
U.S. Patent Application No. 10/446,865  
filed 29 May 2003 (DHHS Reference  
No. E-306-2002/0-US-01)

*Licensing Contact:* Michael Shmilovich; 301/435-5019;  
[shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

PHS seeks a commercial developer for the following software database query tool: A data-mining tool (software based query generator) that provides a script that identifies an isolated protein by using physical properties of the protein and submitting the query into a protein database (e.g., SWISS-PROT). The inventors identified that by combining an accurate determination of the ratio of at least one amino acid per molecule and at least one physical parameter of the protein; an accurate and unique match can be made by the query results. Parameters include the ratios of amino acids to others (e.g., C/F, W/C, C/Y etc.), the molecular weight, the ratio of positively to negatively charged moieties, and/or the isoelectric point.

#### Bromotyrosine-Derived Inhibitors of Mycothiol-S-Conjugate Amidase

Carole A. Bewley *et al.* (NIDDK)

U.S. Provisional Application No. 60/395,219 filed 10 Jul 2002 (DHHS Reference No. E-196-2002/0-US-01); PCT Application No. PCT/US03/21456 filed 09 Jul 2003, which published as WO 04/004659 on 15 Jan 2004 (DHHS Reference No. E-196-2002/0-PCT-02)

*Licensing Contact:* Michael Ambrose; 301/594-6565; [ambrosem@mail.nih.gov](mailto:ambrosem@mail.nih.gov).

Mycobacterium tuberculosis has reemerged as a leading cause of death by an infectious agent, especially among populations that are immunocompromised. With this increase in the rate of infection there has also been an increase in the number of drug resistant strains, making treatment of such infections more difficult. As such, the development of new antituberculars with novel modes

of action is paramount in the fight against such infections.

The current invention uses the finding of two mycothiol-related amidases that are unique to actinomycetes and thus share no homology to eukaryotic enzymes thus reducing potential side effects for new therapeutics. These amidases are novel targets for new therapeutics and classes of antimycobacterials. This invention describes a series of synthetic bromotyrosine-containing analogs that exhibit amidase inhibition and thus have potential for therapeutic development.

*This research has been described, in part, in: GM Nicholas et al., Bioorg. Med. Chem. Lett. (2002) 12:2487-2490; B Fetterolf and CA Bewley, Bioorg. Med. Chem. Lett. (Submitted, March 26, 2004).*

#### Radio Frequency Cauterization Biopsy

Bradford J. Wood and Christian Pavlovich (CC)

U.S. Patent Application No. 10/274,074 filed 17 Oct 2002 (DHHS Reference No. E-207-2001/1-US-02)

*Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

The invention is a method and apparatus for using radio frequency (RF) energy to cauterize the needle track after percutaneous image-guided needle biopsy. The invention is designed to limit the risks of bleeding and needle track seeding that are inherent risks of any needle biopsy. The device uses a coaxial biopsy arrangement with the outer needle coated with a non-conducting polymer that insulates the needle shaft and the tissue immediately in contact with the shaft. As the needle is pulled back from the organ or tumor target, RF energy is applied to an exposed end portion of the probe, causing cauterization and coagulation of the tissue immediately adjacent to the needle track. Modular insertions could plug the needle into any cauterization or radiofrequency generator. A variation on the device could be used to limit bleeding after catheter placement into organs, such as for nephrostomy, biliary drainage, or transhepatic islet cell transplantation.

#### Endoluminal Radiofrequency Cauterization System

Bradford J. Wood (CC)

U.S. Patent 6,676,657 issued 13 Jan 2004 (DHHS Reference No. E-244-2000/1-US-01)

*Licensing Contact:* Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

The invention is a device for occluding the lumen of a hollow organ, vessel or aneurysm by delivering radio frequency energy to its inner wall. The apparatus uses specialized electrodes that contact the walls of the organ to substantially conform to the inner surface. RF energy is then applied to the electrode at any of a broad range of desired frequencies for selected times at power levels of from 20 to 200 watts. Delivery of RF energy may be regulated by monitoring temperature, tissue impedance or other parameters at or near the site of the electrode. A temperature sensor located near the electrode allows microprocessor-based control of the power delivered to the electrode site as a function of tissue temperature. The device has applications in therapeutic thrombosis of an aneurysm, stopping blood flow to a tumor or bleeding vessel, or reducing stricture or stenosis in, for example, a bronchus, esophagus, intestine segment or a blood vessel. The invention also may be useful in reducing stenosis in a coronary artery or to reduce a restenotic lesion from intimal hyperplasia that may occur after angioplasty.

Dated: April 4, 2004.

**Steven M. Ferguson,**  
*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 04-8268 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, NIH.

*Date:* May 6, 2004.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* Topics proposed for discussion include Office of the Director updates, Institute and Center Director presentations, and an Advisory Committee to the Director

(ACD) working group report from the Blue Ribbon Panel on Conflict of Interest.

*Place:* National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Shelly Pollard, ACD Coordinator, National Institutes of Health, 9000 Rockville Pike, Building, 2 Room BE15, Bethesda, MD 20892, (301) 496-0959.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed in this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: <http://www.nih.gov/about/director/acd.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS.)

Dated: April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8276 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Director's Council of Public Representatives.

*Date:* April 29, 2004.

*Time:* 8:30 a.m. to adjournment.

*Agenda:* Among the topics proposed for discussion are: (1) The role of public trust in building communities of research; (2) COPR public trust efforts; (3) NIH public trust initiative; (4) Presentation of COPR Report on Enhancing Public Input and Transparency in the Research Priority Setting Process at the NIH; and (5) Public comment.

*Place:* National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20852.

*Contact Person:* Jennifer E. Gorman Vetter, NIH Public Liaison/COPR Coordinator, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892. (301) 435-4448; [gorman@od.nih.gov](mailto:gorman@od.nih.gov).

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested persons.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: [www.nih.gov/about/publicliaison/index.html](http://www.nih.gov/about/publicliaison/index.html), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS.)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**  
*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8281 Filed 4-12-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, Novel Technologies for in Vivo Imaging (SBIR/STTR).

*Date:* April 29-30, 2004.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Joyce C. Pegues, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892. 301/594-1286; [peguesj@mail.nih.gov](mailto:peguesj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**  
*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8280 Filed 4-12-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel Clinical Research.

*Date:* May 3, 2004.

*Time:* 8 a.m. to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Office of Review, One Democracy Plaza, 6701 Democracy Blvd., Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mohan Viswanathan, PhD, Deputy Director, Office of Review, NCCR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892-4874, (301) 435-0829, [mv10f@nih.gov](mailto:mv10f@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**  
*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8274 Filed 4-12-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* AIDS Research Advisory Committee, NIAID.

*Date:* May 24, 2004.

*Time:* 1 p.m. to 8 p.m.

*Agenda:* Director's Report and Restructuring of the DAIDS Clinical Research Networks.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

*Contact Person:* Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, Room 4139, 6700-B Rockledge Drive, MSC 7610, Bethesda, MD 20892-7601, 301-435-3732.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8271 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Allergy and Infectious Diseases Council Acquired Immunodeficiency Syndrome Subcommittee.

*Date:* May 24, 2004.

*Closed:* 8:30 a.m. to 10:15 a.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room A, Bethesda, MD 20892.

*Open:* 1 p.m. to Adjournment.

*Agenda:* Program advisory discussions and presentations.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room E1/E2, Bethesda, MD 20892.

*Contact Person:* John J McGowan, PhD, Director, Division of Extramural Activities, NIAID, Room 2142, 6700-B Rockledge Drive, MSC 7610, Rockville, MD 20892-7610, 301-496-7291.

*Name of Committee:* National Advisory Allergy and Infectious Diseases Council Microbiology and Infectious Diseases Subcommittee.

*Date:* May 24, 2004.

*Closed:* 8:30 a.m. to 10:15 a.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room F1/F2, Bethesda, MD 20892.

*Open:* 1 p.m. to adjournment.

*Agenda:* Program advisory discussions and presentations.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room F1/F2, Bethesda, MD 20892.

*Contact Person:* John J McGowan, PhD, Director, Division of Extramural Activities, NIAID, Room 2142, 6700-B Rockledge Drive, MSC 7610, Rockville, MD 20892-7610, 301-496-7291.

*Name of Committee:* National Advisory Allergy and Infectious Diseases Council Allergy, Immunology and Transplantation Subcommittee.

*Date:* May 24, 2004.

*Closed:* 8:30 a.m. to 10:15 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

*Open:* 1 p.m. to adjournment.

*Agenda:* Program advisory discussion and presentations.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Conference Room D, Bethesda, MD 20892.

*Contact Person:* John J McGowan, PhD, Director, Division of Extramural Activities, NIAID, Room 2142, 6700-B

Rockledge Drive, MSC 7610, Rockville, MD 20892-7610, 301-496-7291.

*Name of Committee:* National Advisory Allergy and Infectious Diseases Council.

*Date:* May 24, 2004.

*Open:* 10:30 a.m. to 11:40 a.m.

*Agenda:* A report from the Institute Director and the Director of the Vaccine Research Center.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, E1/E2, Bethesda, MD 20892.

*Closed:* 11:40 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, E1/E2, Bethesda, MD 20892.

*Contact Person:* John J McGowan, PhD, Director, Division of Extramural Activities, NIAID, Room 2142, 6700-B Rockledge Drive, MSC 7610, Rockville, MD 20892-7610, 301-496-7291.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by nongovernmental employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building. Information is also available on the Institute's/Center's home page: <http://www.niaid.nih.gov/facts.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8272 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Clinical Products Distribution Center.

*Date:* May 4, 2004.

*Time:* 8:30 a.m. to 11:30 a.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Terrace Room, Bethesda, MD 20815.

*Contact Person:* Tracy A. Shahan, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-451-2606, [tshahan@niaid.nih.gov](mailto:tshahan@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Immune Tolerance Network-Clinical Site Monitoring Group.

*Date:* May 4, 2004.

*Time:* 11:30 a.m. to 4 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Terrace Room, Bethesda, MD 20815.

*Contact Person:* Tracy A. Shahan, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-451-2606, [tshahan@niaid.nih.gov](mailto:tshahan@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8273 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Deafness and Other Communication Disorders Advisory Council.

*Date:* May 21, 2004.

*Open:* 8:30 a.m. to 11:30 a.m.

*Agenda:* Staff reports on divisional, programmatic and special activities.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Closed:* 11:30 a.m. to adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Craig A. Jordan, PhD, Director, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892-7180, 301-496-8693, [jordanc@nidcd.nih.gov](mailto:jordanc@nidcd.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without

a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page; [www.nidcd.nih.gov/about/councils/ndcdac/ndcdac.htm](http://www.nidcd.nih.gov/about/councils/ndcdac/ndcdac.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS.)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8277 Filed 4-12-04; 8:45 am]

BILLING CODE 4146-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Deafness and Other Communications Disorders Special Emphasis Panel, Health Communication.

*Date:* May 19, 2004.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone conference call.)

*Contact Person:* Sheo Singh, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892, 301-496-8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS.)



Dated: April 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 04-8279 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institutes of Neurological Disorders and Stroke; Notice of Closed Meeting.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, SNRP Review.

*Date:* April 12-16, 2004.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Kaimana Beach Hotel, 2863 Kalakaua Avenue, Honolulu, HI 96815.

*Contact Person:* Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard, MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892-9529. (301) 496-5388; [wiehorn@ninds.nih.gov](mailto:wiehorn@ninds.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: April 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 04-8282 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel, Resequencing the Genome Mouse Strains.

*Date:* May 20, 2004.

*Time:* 9:30 a.m. to 3 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, 3446, Research Triangle Park, NC 27709 (Telephone Conference Call).

*Contact Person:* RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nat. Inst. of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, 919/541-0752.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 04-8284 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Center for Scientific Review Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Center for Scientific Review Advisory Committee Workgroup.

*Date:* May 17, 2004.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* Discussion of activities to evaluate organization and function of the Center for Scientific Review Process.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Mark Malik, PhD, Executive Secretary, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7776, Bethesda, MD 20892, (301) 594-6806, [malikk@csr.nih.gov](mailto:malikk@csr.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.csr.nih.gov/drgac.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory  
Committee Policy.

[FR Doc. 04-8275 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Visual Systems SBIR.

*Date:* April 6, 2004.

*Time:* 4 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone conference call.)

*Contact Person:* Jerome R. Wujek, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892. (301) 435-2507; wujekjer@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Cognitive Neuroscience in Clinical Populations.

*Date:* April 7, 2004.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone conference call.)

*Contact Person:* Michael A. Steinmetz, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5172, MSC 7844, Bethesda, MD 20892. 301-435-1247; steinmem@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, T Cell Biology.

*Date:* April 14, 2004.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone conference call.)

*Contact Person:* Cathleen L. Cooper, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, Department of Health and Human Services, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892. 301-435-3566; coopercl@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Fluorescent Molecular Rotor for Blood Plasma Viscometry.

*Date:* April 23, 2004.

*Time:* 10 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone conference call.)

*Contact Person:* Robert T. Su, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892. 301 435-1195.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS.)

*Dated:* April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8278 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Cardiovascular Signaling and Transportation.

*Date:* April 8, 2004.

*Time:* 1:30 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, pinkus@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG 1 BBHP-H (28) Minority/Disability Predoctoral Fellowship Reviews.

*Date:* April 9, 2004.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Mary Sue Krause, MED, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 435-0902, krausem@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Neurogenetics Special Emphasis Panel.

*Date:* April 20, 2004.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Carole L. Jelsema, PhD, Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892, (301) 435-1248, jelsemac@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, High Resolution Electron Microscopy.

*Date:* April 21-23, 2004.

*Time:* 8 p.m. to 10 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Swissotel Washington, The Watergate, 2650 Virginia Avenue, NW, Washington, DC 20037.

*Contact Person:* Richard D. Rodewald, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, (301) 435-1024, [rodewalr@csr.nih.gov](mailto:rodewalr@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Leukemia.

**Date:** April 22 2004.

**Time:** 1 p.m. to 2:30 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

**Contact Person:** Marcia Litwack, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6206, MSC 7840, Bethesda, MD 20892, (301) 435-1719, [litwackm@csr.nih.gov](mailto:litwackm@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 6, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-8283 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### National Toxicology Program

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) announces plans for future evaluations of Methylphenidate and Adderall®, Magnesium Sulfate, and Genistein and Soy Formula; Requests public comments on these substances; and solicits the nominations of scientists qualified to serve on expert panels evaluating these compounds.

#### Summary

The CERHR plans to convene 3 expert panels to evaluate potential reproductive and developmental toxicities of (1) methylphenidate (Ritalin®) and Adderall®, (2) magnesium sulfate, and (3) genistein and soy formula. For each evaluation, the expert panel will consist of approximately 12 scientists, selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other

relevant areas of science. The CERHR invites the submission of public comments on any of these substances and the nomination of scientists to serve on the expert panels for their evaluation (see below). These meetings are tentatively scheduled for 2004 and 2005 although the exact dates and locations are not yet established. As plans are finalized, they will be announced in the **Federal Register** and posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>). These expert panel meetings will be open to the public with time scheduled for oral public comment.

#### Evaluation of Methylphenidate and Adderall®

Methylphenidate (Ritalin®, CAS RN: 113-45-1) and Adderall® (amphetamine, CASRN: 300-62-9 and dextraamphetamine, CASRN: 51-64-9) are stimulants used to treat attention deficit disorder with hyperactivity and narcolepsy in children and adults. Methylphenidate is also used off-label to treat depression. CERHR selected these chemicals for expert panel evaluation because of: (1) The increasing use of these drugs in children, (2) public concern for long-term effects of these drugs on child development and behavior, (3) the availability of human exposure data, and (4) findings from developmental studies in humans and experimental animals.

#### Evaluation of Magnesium Sulfate

Magnesium sulfate (CASRN: 7487-88-9) is the most common magnesium salt used for seizure prophylaxis in preeclampsia or seizure control in eclampsia, and for inhibition of uterine contractions during preterm labor. CERHR selected this chemical for expert panel evaluation because of: (1) The existence of an adequate exposure database, (2) concern for the survival and development of the infant after maternal treatment, and (3) the availability of developmental toxicity data.

#### Evaluation of Genistein and Soy Formula

Genistein (CASRN: 446-72-0) is found in some legumes, such as soybeans and clover, or in products obtained from animals ingesting genistein-containing feed. Genistein is a phytoestrogen, defined as a non-steroidal, estrogenic, naturally occurring plant product. It is found in food, in over-the-counter dietary supplements, and is the primary phytoestrogen in soy formula. Soy formula is administered to infants as a supplement or replacement

for maternal breast milk or cow's milk. CERHR selected these substances for expert panel evaluation because of: (1) The availability of numerous reproductive and developmental studies in laboratory animals and humans, (2) exposure information in infants and women of reproductive age, and (3) public concern for effects on infant or child development.

#### Request for Public Comment on Substances To Be Evaluated

The CERHR invites input from the public and other interested parties on these substances, including toxicology information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence. Information and comments should be forwarded to the CERHR at P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709 (mail), (919) 541-3455 (phone), (919) 316-4511 (fax), or [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov) (e-mail). Information and comments received by 60 days from the publication date of this notice will be made available to the CERHR staff and the appropriate expert panel for consideration in the evaluation and posted on the CERHR Web site.

#### Request for the Nomination of Scientists for the Expert Panels

The CERHR invites nominations of qualified scientists to serve on the individual expert panels for: (1) Methylphenidate and Adderall®, (2) magnesium sulfate, and (3) genistein and soy formula. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry that include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, certification by an appropriate scientific board or other entities, and participation in similar committee activities.

All panel members serve as individual experts in their specific areas of expertise and not as representatives of their employers or other organizations. Scientists on the expert panel will be selected to represent a wide range of expertise, including, but not limited to, developmental toxicology, reproductive toxicology, neonatology and child development, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations received by 60 days from the publication date of

this notice will be considered for these panels and for inclusion in the CERHR Expert Registry. Nominations, including contact information and a current curriculum vitae (if possible) should be forwarded to the CERHR at the address given above.

#### Background Information About the CERHR

The NTP established the CERHR in June 1998 [Federal Register, December 14, 1998: Volume 63, Number 239, page 68782]. The CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

Information about CERHR and its process for nominating agents for review or scientists for its expert registry can be obtained from its homepage (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (contact information provided above). The CERHR selects chemicals for evaluation based upon several factors, including production volume, extent of human exposure, public concern, and published evidence of reproductive or developmental toxicity.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the Federal Register (July 16, 2001: Volume 66, Number 136, pages 37047-37048) and is available on the CERHR Web site under "About CERHR" or in printed copy from the CERHR.

Dated: April 1, 2004.

**Kenneth Olden,**

*Director, National Institute of Environmental Health Sciences.*

[FR Doc. 04-8269 Filed 4-12-04; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed

projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

*Proposed Project: National Outcomes Performance Assessment of the Collaborative Initiative to Help End Chronic Homelessness*—(OMB No. 0930-0247; Extension, no change)—This Initiative is coordinated by the U.S. Interagency Council on the Homeless and involves the participation of three Council members: the Department of Housing and Urban Development (HUD), the Department of Health and Human Services (HHS), and the Department of Veterans Affairs (VA). Within HHS, SAMHSA's Center for Mental Health Services is the lead agency.

This project will monitor the implementation and effectiveness of the Initiative. A national assessment of client outcomes is needed to assure a high level of accountability and to identify which models work best for which people, using the same methods for all sites. To this end, this project will provide a site-by-site description of program implementation, as well as descriptive information on clients served; services received; housing quality, stability, and satisfaction; and, client outcomes in health and functional domains. The VA Northeast Program Evaluation Center (NEPEC), based at the VA Connecticut Healthcare System in West Haven, Connecticut, is responsible for conducting this project.

Data collection will be conducted over a 36-month period. At each site, a series of measures will be used to assess (1) program implementation (e.g., number and types of housing units produced and intensity and types of treatment and supportive services provided), (2) client descriptive information (e.g., demographic and clinical characteristics, and housing and treatment services received) and, (3) client outcomes.

Client outcomes will be measured using a series of structured instruments administered by evaluation personnel employed and funded by the local VA medical center or outpatient clinic involved at each Initiative site who will work closely with central NEPEC staff. Assessments will be conducted through face-to-face interviews and, when needed, telephone interviews. Interviews (approximately one hour in length) will be conducted at baseline, defined as the date of entry into the clinical treatment program leading to placement into permanent housing, and quarterly (every 3 months) thereafter for up to three years. Discharge data will be collected from program staff at the time of official discharge from the program, or when the client has not had any clinical contact from members of the program staff for at least 6 months. In addition to client interviews, key informant interviews with program managers at each site will be conducted annually.

At most Initiative sites, it is expected that more people will be screened and or evaluated for participation in the program than receive the full range of core housing and treatment services. Entry into the Initiative is conceptualized as a two-phase process involving an Outreach/Screening/Assessment Phase (Phase I), and an Active Housing Placement/Treatment Phase (Phase II) that is expected to lead to exit from homelessness; in some programs these two phases may be described as the Outreach and Case Management Phases. It will be important to have at least some minimal information on all clients so as to be able to compare those who enter Housing/Treatment with those who do not.

Client-level data at the time of first contact with the program (i.e., before the client receives more intensive treatment or housing services) will be collected using a screener form. The screener form will be completed by a member of the clinical staff when prospective clients are first told about the program, and express interest in participating in the program (i.e. when they enter Phase I). The purpose of this form is to identify the sampling frame of the evaluation at each site, or the pool of potential clients from which clients are then selected. Program implementation will be measured using a series of progress summaries.

Initiative sites will be responsible for screening potential participants, assessing homeless and disabling condition eligibility criteria for the program, and documenting eligibility as part of the national performance

assessment. Each site will identify a limited number of portals of entry into the program in a relatively small geographic area, so that the evaluator can practically and systematically contact clients about participating in the

evaluation. VA evaluation staff, clinical program staff, and NEPEC will work together to establish systematic procedures for assessing eligibility, enrolling clients into the Housing/Treatment Activity of the Initiative,

obtaining written informed consent to participate in the national performance assessment, and other evaluation activities.

The estimated response burden to collect this information is as follows:

Respondents form name	No. of respondents	Responses per respondent	Hours per response	Total hour burden
<b>Clients:</b>				
Baseline assessment .....	1,500	1	1.50	2,250
Follow-up assessment .....	1,500	8 <sup>1</sup>	1.25	15,000
Sub-total .....				17,250
<b>Clinicians:</b>				
Screening .....	30 <sup>2</sup>	100	0.25	750
Discharge .....	30 <sup>3</sup>	13	0.40	156
Sub-total .....				906
<b>Administrators:</b>				
Network definition .....	60	1	0.25	15
Network participation .....	105	4	0.75	315
Sub-total .....				330
<b>Total</b> .....				18,486.
<b>3-yr. Annual Avg.</b> .....				6,162.

<sup>1</sup> Assumes average follow-up period of 2 yrs. due to delayed recruitment at some sites & 20% attrition overall.  
<sup>2</sup> Assumes an average of 2 screening clinicians per site, and twice the number of persons screened as enrolled.  
<sup>3</sup> Assumes an average of 2 discharge clinicians per site, and discharge rate of 25%.

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received by June 14, 2004.

Dated: April 6, 2004.

**Anna Marsh,**  
 Executive Officer, SAMHSA.  
 [FR Doc. 04-8294 Filed 4-12-04; 8:45 am]  
 BILLING CODE 4162-20-P

Local Law Enforcement Training, Federal Law Enforcement Training Center, Glynco, GA 31524, 912-267-2343.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, as amended), and with the approval of the Secretary of the Department of Homeland Security and the concurrence of the Office of Management and Budget, the Federal Law Enforcement Training Center announces the renewal of the Advisory Committee to the National Center for State and Local Law Enforcement Training (the Federal Law Enforcement Training Center was transferred from the Department of the Treasury to the Department of Homeland Security pursuant to section 403 of Public Law 107-296). The primary purpose of the Advisory Committee is to provide a forum for discussion and interchange between a broad cross-section of representatives for the law enforcement community and related training institutions on training issues and needs. Although FLETC representatives participate in the training committee activities of the major police membership associations, no forum exists which provides the broad representation required to meet the needs of the National Center. The uniqueness of the program requires an appropriately selected and specifically

dedicated group. The Committee does not duplicate functions being performed within Department of Homeland Security or elsewhere in the Federal Government.

Dated: March 29, 2004.

**Stanley Moran,**  
 Director, National Center for State and Local Law Enforcement Training.  
 [FR Doc. 04-8043 Filed 4-12-04; 8:45 am]  
 BILLING CODE 4810-32-P

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Law Enforcement Training Center**

**Charter Renewal, Notice**

**AGENCY:** Federal Law Enforcement Training Center, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** The Charter for the Advisory Committee to the National Center for State and Local Law Enforcement Training at the Federal Law Enforcement Training Center was renewed for a 2-year period beginning January 14, 2004.

**FOR FURTHER INFORMATION CONTACT:** Reba Fischer, Designated Federal Officer, National Center for State and

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG-2004-17511]

**Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers: 1625-0025 [Formerly 2115-0100], 1625-0030 [Formerly 2115-0120], 1625-0072 [Formerly 2115-0613], 1625-0078 [Formerly 2115-0623] and 1625-0082 [Formerly 2115-0628].**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of five Information Collection Requests (ICRs).



The ICRs comprise (1) 1625-0025, Carriage of Bulk Solids Requiring Special Handling—46 CFR Part 148; (2) 1625-0030, Oil and Hazardous Materials Transfer Procedures; (3) 1625-0072, Waste Management Plans, Refuse Discharge Logs, and Letters of Instruction for Certain Persons-in-Charge (PIC); (4) 1625-0078, Licensing and Manning Requirements for Officers of Towing Vessels; and (5) 1625-0082, Navigation Safety Equipment and Emergency Instructions for Certain Towing Vessels. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

**DATES:** Comments must reach the Coast Guard on or before June 14, 2004.

**ADDRESSES:** To make sure that your comments and related material do not enter the docket [USCG-2004-17511] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2) By delivery to 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. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at 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 may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICR are available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (CG-611), U.S. Coast Guard Headquarters, room 6106 (Attn: Mr. Arthur Requina), 2100 Second Street SW., Washington, DC 20593-0001. The telephone number is 202-267-2326.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, 202-267-2326, for questions on these documents; or Ms. Andrea M. Jenkins, Program Manager, U.S. DOT, 202-366-0271, for questions on the docket.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

We encourage you to participate in this request for comment by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>, and they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act" below.

**Submitting comments:** If you submit a comment, please include your name and address, identify the docket number for this request for comment [USCG-2004-17511], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

**Viewing comments and documents:** To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in 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.

**Privacy Act:** Anyone can search the electronic form of all comments received in 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 the

Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 [65 FR 19477], or you may visit <http://dms.dot.gov>.

**Information Collection Requests**

1. **Title:** Carriage of Bulk Solids Requiring Special Handling—46 CFR Part 148.

**OMB Control Number:** 1625-0025 [Formerly 2115-0100].

**Summary:** The information in the application for a special permit allows the Coast Guard to: (1) Determine the severity of the hazard posed by the material; (2) set specific guidelines for safe carriage; or, (3) if the material presents too great a hazard, deny permission for shipping the material.

**Need:** The Coast Guard administers and enforces statutes and rules for the safe transport and stowage of hazardous materials, including bulk solids. Under 46 CFR part 148, the Coast Guard may issue special permits for the carriage of bulk solids requiring special handling.

**Respondents:** Owners and operators of vessels that carry certain bulk solids.

**Frequency:** On occasion.

**Burden Estimates:** The estimated burden is 1,130 hours a year.

2. **Title:** Oil and Hazardous Materials Transfer Procedures.

**OMB Control Number:** 1625-0030 [Formerly 2115-0120].

**Summary:** The collection of information requires vessels with a cargo capacity of 250 barrels or more of oil or hazardous materials to develop and maintain transfer procedures. Transfer procedures provide basic safety information for operating transfer systems with the goal of pollution prevention.

**Need:** Title 33 U.S.C. 1231 authorizes the Coast Guard to prescribe regulations related to the prevention of pollution.

Title 33 CFR part 155 prescribe pollution prevention regulations including those related to transfer procedures.

**Respondents:** Owners and operators of vessels.

**Frequency:** On occasion.

**Burden Estimate:** The estimated burden is 89 hours a year.

3. **Title:** Waste Management Plans, Refuse Discharge Logs, and Letters of Instruction for Certain Persons-in-Charge (PIC).

**OMB Control Number:** 1625-0072 [Formerly 2115-0613].

**Summary:** This information is needed to ensure that: (1) certain U.S. oceangoing vessels develop and maintain a waste management plan; (2) certain U.S. oceangoing vessels maintain refuse discharge records; and (3) certain individuals that act as

person-in-charge of the transfer of fuel receive a letter of instruction, for prevention of pollution.

*Need:* This collection of information is needed as part of the Coast Guard's pollution prevention compliance program.

*Respondents:* Owners, operators, masters, and persons-in-charge of vessels.

*Frequency:* On occasion.

*Burden Estimate:* The estimated burden is 55,484 hours a year.

4. *Title:* Licensing and Manning Requirements for Officers of Towing Vessels.

*OMB Control Number:* 1625-0078 [Formerly 2115-0623].

*Summary:* Licensing and manning requirements ensure that towing vessels operating on the navigable waters of the U.S. are under the control of licensed officers who meet certain qualification and training standards.

*Need:* Title 46 CFR part 10 prescribe regulations for the licensing of maritime personnel. This information collection is necessary to ensure that a mariner's training information is available to assist in determining his or her overall qualifications to hold certain licenses.

*Respondents:* Owners and operators towing vessels.

*Frequency:* On occasion.

*Burden Estimates:* The estimated burden is 17,159 hours a year.

5. *Title:* Navigation Safety Equipment and Emergency Instructions for Certain Towing Vessels.

*OMB Control Number:* 1625-0082 [Formerly 2115-0628].

*Summary:* Navigation safety regulations help assure that the mariner piloting a towing vessel has adequate equipment, charts, maps, and other publications. For inspected towing vessels, a muster list and emergency instructions provide effective plans and references for crew to follow in an emergency situation.

*Need:* The purpose of the regulations is to improve the safety of towing vessels and the crews that operate them.

*Respondents:* Owners, operators and masters of vessels.

*Frequency:* On occasion

*Burden Estimates:* The estimated burden is 367,701 hours a year.

Dated: April 8 2004.

**Nathaniel S. Heiner,**  
*Acting, Assistant Commandant for C4 and Information Technology.*

[FR Doc. 04-8351 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-15-P

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4903-N-29]

**Notice of Submission of Proposed Information Collection to OMB; Description of Materials**

**AGENCY:** Office of the Chief Information Officer.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

HUD is requesting renewal of the approval to collect this information. This collection provides information on the materials used and assembly required for new single-family home construction and improvements. HUD/FHA uses this information to estimate the value of the homes and compute the maximum mortgage amount for FHA insurance.

**DATES:** Comments Due Date: May 13, 2004.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502-0192) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail [Wayne\\_Eddins@HUD.gov](mailto:Wayne_Eddins@HUD.gov);

telephone (202) 708-2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, a survey instrument to obtain information from faith based and community organizations on their likelihood and success at applying for various funding programs. This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

*Title of Proposal:* Description of Materials.

*OMB Approval Number:* 2502-0192.

*Form Numbers:* HUD-92005.

*Description of the Need for the Information and its Proposed Use:* This collection provides information on the materials used and assembly required for new single family home construction and improvements. HUD/FHA uses this information to estimate the value of the homes and compute the maximum mortgage amount for FHA insurance.

*Respondents:* Business or other for-profit.

*Frequency of Submission:* On occasion.

	Number of respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting burden: .....	2,500	0.5		2		25,000

**Total Estimated Burden Hours:** 25,000.

**Status:** Extension of a currently approved collection.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: April 7, 2004.

**Wayne Eddins,**

Departmental PRA Compliance Officer, Office of the Chief Information Officer.

[FR Doc. 04-8342 Filed 4-12-04; 8:45 am]

BILLING CODE 4210-72-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Endangered and Threatened Wildlife and Plants; 5-Year Review of the Bull Trout

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of review.

**SUMMARY:** The U.S. Fish and Wildlife Service (Service), announces a 5-year review of the bull trout (*Salvelinus confluentus*) under section 4(c)(2)(A) of the Endangered Species Act of 1973 (Act) (16 U.S.C. 1531 *et seq.*). The purpose of reviews conducted under this section of the Act is to ensure that the classification of species as threatened or endangered on the List of Endangered and Threatened Wildlife and Plants (List) is accurate.

The 5-year review is an assessment of the best scientific and commercial data available at the time of the review. Therefore, we are requesting submission of any new information (best scientific and commercial data) on the bull trout since its original listing as a threatened species conterminously in the lower 48

states in 1999 (64 FR 58932). If the present classification of this species is not consistent with the best scientific and commercial information available, the Service will recommend whether or not a change is warranted in the Federal classification of bull trout. Any change in Federal classification would require a separate final rule-making process.

**DATES:** Information submitted for our consideration must be received on or before July 1, 2004.

**ADDRESSES:** Information submitted should be sent to the U.S. Fish and Wildlife Service, Bull Trout Coordinator, Attention: Bull Trout 5-year Review, 911 NE. 11th Avenue, Portland, Oregon, 97232. Information received in response to this notice and review will be available for public inspection by appointment, during normal business hours, at the above address. New information regarding the bull trout may also be sent electronically to [R1BullTrout5Y@r1.fws.gov](mailto:R1BullTrout5Y@r1.fws.gov).

**FOR FURTHER INFORMATION CONTACT:** John Young at the above address, or at 503/231-2767.

#### SUPPLEMENTARY INFORMATION:

##### Why Is a 5-Year Review Conducted?

Section 4(c)(2)(A) of the Act requires that we conduct a review of listed species at least once every 5 years. We are then, under section 4(c)(2)(B) and the provisions of subsections (a) and (b), to determine, on the basis of such a review, whether or not any species should be removed from the List (delisted), or reclassified from endangered to threatened, or threatened to endangered. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing those species currently

under active review. This notice announces our active review of the bull trout.

#### What Information Is Considered in the Review?

The 5-year review considers all new information available at the time of the review. This review will consider the best scientific and commercial data that has become available since the current listing determination or most recent status review, such as:

- A. Species biology including, but not limited to, population trends, distribution, abundance, demographics, and genetics;
- B. Habitat conditions including, but not limited to, amount, distribution, and suitability;
- C. Conservation measures that have been implemented that benefit the species;
- D. Threat status and trends (see five factors under heading "How do we determine whether a species is endangered or threatened?"); and
- E. Other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

#### How Is the Bull Trout Currently Listed?

The List is found in 50 CFR 17.11 (wildlife) and 17.12 (plants). Amendments to the List through final rules are published in the **Federal Register**. The List is also available on our Internet site at <http://endangered.fws.gov/wildlife.html#Species>. In Table 1 below, we provide a summary of the listing information for the bull trout.

TABLE 1.—SUMMARY OF THE LISTING INFORMATION FOR THE BULL TROUT

Common name	Scientific name	Status	Where listed	Final listing rule
bull trout .....	<i>Salvelinus confluentus</i> .....	Threatened .....	U.S.A., conterminous (lower 48 states).	64 FR 58932(01-NOV-99).

#### Definitions Related to This Notice

The following definitions are provided to assist those persons who contemplate submitting information regarding the species being reviewed:

A. *Species* includes any species or subspecies of fish, wildlife, or plant, and any distinct population segment of any species of vertebrate, which interbreeds when mature.

B. *Endangered* means any species that is in danger of extinction throughout all or a significant portion of its range.

C. *Threatened* means any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

#### How Do We Determine Whether a Species is Endangered or Threatened?

Section 4(a)(1) of the Act establishes that we determine whether a species is endangered or threatened based on one or more of the five following factors:

- A. The present or threatened destruction, modification, or curtailment of its habitat or range;
- B. Overutilization for commercial, recreational, scientific, or educational purposes;
- C. Disease or predation;
- D. The inadequacy of existing regulatory mechanisms; or
- E. Other natural or manmade factors affecting its continued existence.

Section 4(a)(1) of the Act requires that our determination be made on the basis

of the best scientific and commercial data available.

#### What Could Happen as a Result of This Review?

If we find that there is new information concerning the bull trout indicating a change in classification may be warranted, we may propose a new rule that could do one of the following: (a) Reclassify the species from threatened to endangered; or (b) remove the species from the List. If we determine that a change in classification is not warranted, the bull trout will remain on the List under its current status.

#### Public Solicitation of New Information

We request any new information concerning the status of the bull trout, see "What information is considered in the review?" heading for specific criteria. Information submitted should be supported by documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

#### Authority

This document is published under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: March 4, 2004.

**David J. Wesley,**  
Acting Regional Director, Region 1, Fish and Wildlife Service.

[FR Doc. 04-8295 Filed 4-12-04; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Aquatic Nuisance Species Task Force Meeting

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a meeting of the Aquatic Nuisance Species (ANS) Task Force. The meeting topics are identified in the **SUPPLEMENTARY INFORMATION** section.

**DATES:** The Aquatic Nuisance Species Task Force will meet from 8 a.m. to 5 p.m. on Wednesday, May 26, 2004, and 8 a.m. to 12 p.m. on Thursday, May 27, 2004. Minutes of the meeting will be available for public inspection during regular business hours, Monday through Friday.

**ADDRESSES:** The Aquatic Nuisance Species Task Force meeting will be held

at the Holiday Inn Select, 2200 I-70 Dr. SW, Columbia, Missouri 65203. Phone (573) 445-8531. Minutes of the meeting will be maintained in the office of Chief, Division of Environmental Quality, U.S. Fish and Wildlife Service, Suite 322, 4401 North Fairfax Drive, Arlington, Virginia 22203-1622.

**FOR FURTHER INFORMATION CONTACT:** Everett Wilson, Acting Executive Secretary, Aquatic Nuisance Species Task Force, at (703) 358-2148.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces meetings of the Aquatic Nuisance Species Task Force. The Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990.

Topics to be covered during the ANS Task Force meeting include: introduction of new members; an update of activities from each of the Task Force's regional panels; status reports from several Task Force committees and working groups, including the Prevention and Outreach Committees, the New Zealand mudsnail working group, and the Caulerpa working group; presentations by the Mississippi River Basin Panel; an update on ballast water management activities; an update on the activities of the National Invasive Species Council; and other topics.

Dated: March 16, 2004.

**Mamie A. Parker,**  
Co-Chair, Aquatic Nuisance Species Task Force, Assistant Director—Fisheries & Habitat Conservation.

[FR Doc. 04-8309 Filed 4-12-04; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[MT030-1020-04-PH]

#### North Dakota: Dakotas Advisory Council Meeting

**AGENCY:** Bureau of Land Management, North Dakota Field Office, Interior.

**ACTION:** Announcement of meeting for Dakotas Resource Advisory Council.

**SUMMARY:** The Dakotas Advisory Council will meet in Dickinson, ND to discuss Paleontological and coal resources and review the sage grouse program. The agenda includes a day trip to the Gascoyne mine area. The meeting will be open to the public.

**DATES:** The meeting dates are:

1. May 26, 2004, 1 p.m. to 5 p.m., Dickinson, ND.

2. May 27, 2004, 8 a.m. to 5 p.m., Rhame, ND.

3. May 28, 2004, 8 a.m. to noon, Dickinson, ND.

**ADDRESSES:** The meeting will be held at Badlands Best Western Inn, 71 Museum Drive, Dickinson, ND 58601.

**FOR FURTHER INFORMATION CONTACT:** Douglas Burger, Field Office Manager, North Dakota Field Office, 2933 3rd Ave. W, Dickinson, North Dakota. Telephone 701.227.7700.

**Public Comment Procedures:** The meeting is open to the public and a public comment period is set for 8 a.m. on May 28, 2004. The public may make oral statements before the Council or file written statements for the Council to consider. Depending on the number of persons wishing to make an oral statement, a per-person time limit may be established.

**SUPPLEMENTARY INFORMATION:** The 15-member Council advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in the Dakotas. Summary minutes of the meeting will be available for public inspection and copying. Participants will go on a field tour Thursday, May 27 to tour the Gascoyne Mine which is a contender for becoming a new mine/powerplant operation in ND, from there we will proceed to Muddy Buttes south of Rhame to see Paleontological resources and discuss the significance of that site.

Dated: April 6, 2004.

**Michael A. Nash,**  
Assistant Field Manager, Minerals.  
[FR Doc. 04-8327 Filed 4-12-04; 8:45 am]  
BILLING CODE 4310-55-P

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Proposed Information Collection Request Submitted for Public Comment and Recommendations; Workforce Investment Act (WIA) Financial Reporting Requirements for Formula Funded Grants

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of

information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

**DATES:** Submit comments on or before June 14, 2004.

**ADDRESSES:** Send comments to Isabel Danley, Office of Grants and Contract Management, Employment and Training Administration, United States Department of Labor, 200 Constitution Avenue, NW., Room N-4720, Washington, DC 20210, 202-693-3047 (this is not a toll-free number), *danley.isabel@dol.gov*, and/or fax 202-693-3362.

**FOR FURTHER INFORMATION CONTACT:** Isabel Danley, Office of Grants and Contract Management, Employment and Training Administration, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, 202-693-3047 (this is not a toll-free number), *danley.isabel@dol.gov*, and/or fax 202-693-3362.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This proposed information collection notice is requesting an extension of authority to collect WIA financial data contained on formats provided to the

States in ETA Training and Employment Guidance Letter No. 16-99, dated June 23, 2000. This data collection was granted an extension by OMB in Notice of Action Number 1205-0408, dated February 12, 2001. The collection of information pursuant to that notice expired on February 29, 2004; however, OMB granted an extension through May 2004. The financial reporting requirements for the WIA formula funded grants are set forth in Public Law 105-220, dated August 7, 1998, and WIA Final Rule, 20 CFR part 652, *et al.*, dated August 11, 2000. Data collected are utilized by the Department to evaluate the performance and expenditure levels of the States and local areas in carrying out the statutory intent of the WIA appropriated funds. This is the Department's exclusive collection of financial data for WIA formula funded grants, all of which is collected electronically.

**II. Desired Focus of Comments**

Currently, the Department is soliciting comments concerning the proposed extension/reinstatement of the WIA Financial Reporting Requirements for Formula Funded Grants to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

A copy of the proposed ICR can be obtained by contacting the office listed above in the **ADDRESSES** section of this notice.

**III. Current Actions**

*Type of Review:* Extension/ Reinstatement (without change).  
*Agency:* Employment and Training Administration.

*Title:* WIA Financial Reporting Requirements for Formula Funded Grants.

*OMB Number:* 1205-0408.

*Agency Number:* ETA 9076 A-F.

*Affected Public:* States, local governments, Private Industry Councils and/or other for profit and non-profit organizations.

*Total Respondents:* 56.

*Frequency:* Quarterly.

*Total Responses:* 12 per respondent per year (3 each quarter, one for each year of appropriated funds available for expenditure).

*Average Time per Response:* 1 hour.

PY 2003 yr. of responses	Total respondents	Frequency	Total responses	Average Time per response	Annual burden hours
PY 2001 .....	56	Quarterly .....	224	1 hour .....	224
PY 2002 .....	56	Quarterly .....	224	1 hour .....	224
PY 2003 .....	56	Quarterly .....	224	1 hour .....	224
Totals .....	.....	.....	672	.....	672

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: April 6, 2004.

Emily Stover DeRocco,

*Assistant Secretary for Employment and Training.*

[FR Doc. 04-8302 Filed 4-12-04; 8:45 am]

BILLING CODE 4510-30-P

**DEPARTMENT OF LABOR**

**Employment and Training Administration**

[SGA/DFA 04-103]

**Solicitation for Grant Applications (SGA); Grants for Workforce Investment Boards; Correction**

**AGENCY:** Employment and Training Administration (ETA), Labor.

**ACTION:** Notice; correction.

**SUMMARY:** The Employment and Training Administration published a document in the **Federal Register** of April 6, 2004, at 69 FR 18126, Doc. 04-

7658 concerning the availability up to \$5.5 million for grants to eligible Workforce Investment Boards (WIBs) that have demonstrated successfully the ability to form working partnerships with grassroots faith-based and community organizations (FBCOs). The document contained incorrect page limitation.

**FOR FURTHER INFORMATION CONTACT:** James W. Stockton, Grants Officer, Division of Federal Assistance, Fax (202) 693-2879.

*Corrections*

In the **Federal Register** of April 6, 2004, in FR Doc. 04-7658, on page



18128, in the first column, is corrected to read:

*Submission of Applications:* The Statement of Work must be limited to 10 pages.

Signed at Washington, DC, this 8th day of April, 2004.

James W. Stockton,  
Grant Officer.

[FR Doc. 04-8322 Filed 4-12-04; 8:45 am]

BILLING CODE 4510-30-M

## DEPARTMENT OF LABOR

### Bureau of Labor Statistics

#### Proposed Collection; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the Annual Refiling Survey (ARS) forms and a change in its publication practices in the Quarterly Census of Employment and Wages (QCEW) program.

A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

**DATES:** Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before June 14, 2004.

**ADDRESSES:** Send comments to Amy A. Hobby, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 3255, 2 Massachusetts Avenue, NE., Washington, DC 20212, telephone number 202-691-7628 (this is not a toll free number).

**FOR FURTHER INFORMATION CONTACT:** Amy A. Hobby, BLS Clearance Officer, telephone number 202-691-7628. (See **ADDRESSES** section).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The ARS forms are used to verify and update existing 2002 North American Industry Classification System (NAICS) codes. They also are used to update employers' business names and addresses and other geographical information. In addition, the forms provide a source of multiple worksite information, which is critical to the development of the BLS Business Establishment List (BEL). The BEL serves as a sampling frame and a benchmark for many BLS surveys.

##### II. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected;
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
- Evaluate the change in the agency's publication practices in the QCEW program.

##### III. Current Action

The QCEW program publishes employment and wage data for groupings defined by industry and geography. The ARS is used to verify the industry code and location of businesses. For each grouping, there are three data items produced and published: the number of establishments, employment, and wages. The proposed publication

change only applies to the number of establishments data item.

The BLS proposes to publish the number of establishments for every industry by geography grouping, regardless of the size of the grouping. Currently, the number, or frequency, of establishments may be suppressed from publication when a grouping is very small—usually one, two, or three establishments. This prevents the possible indirect disclosure of respondent identifying information through the use of information from another source. However, Statistical Policy Working Paper 22 from the Office of Management and Budget (OMB), states, "Frequency data for establishments are generally not considered sensitive because so much information about an establishment is publicly available." Further, because the QCEW is constructed to cover virtually all non-agricultural employers and employment, the BLS cannot protect that an establishment exists and is included in the QCEW file. Therefore, the BLS does not consider publishing the number of establishments in an industry-by-geography grouping, even if one, to be a disclosure of confidential information even though it may be possible to infer the identity of a business establishment in that grouping. All other information on establishments maintained by the BLS in its QCEW file is confidential and will be used by the BLS for exclusively statistical purposes. The BLS believes that by following allowable OMB disclosure policies, the usefulness of one of the nation's most comprehensive economic statistical data sources will be vastly improved.

The BLS uses the Annual Refiling Survey (ARS) forms to gather industrial and geographical data on business establishments. The revised ARS forms are designed to verify and update NAICS codes, geographical information, and multiple worksite information.

*Type of Review:* Revision of a currently approved collection.

*Agency:* Bureau of Labor Statistics.

*Title:* Annual Refiling Survey.

*OMB Number:* 1220-0032.

*Affected Public:* Individuals or households; business or other for-profit; not-for-profit institutions; farms; Federal government; State, local, or tribal government.

*Frequency:* Annually.

Form	Total respondents	Frequency	Total responses	Average time per response (hours)	Estimated total burden hours
3023-NVS .....	2,286,757	Once .....	2,286,757	.083	189,800
3023-NVM .....	35,951	Once .....	35,951	.25	8,988
3023-NCA .....	165,397	Once .....	165,397	.167	27,621
Totals .....	2,488,105	.....	2,488,105	.....	226,409

Total Burden Cost (Capital/Startup): \$0.

Total Burden Cost (Operating/Maintenance): \$0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed in Washington, DC, this 5th day of April, 2004.

Cathy Kazanowski,

Chief, Division of Management Systems,  
Bureau of Labor Statistics.

[FR Doc. 04-8303 Filed 4-12-04; 8:45 am]

BILLING CODE 4510-24-P

## DEPARTMENT OF LABOR

### Veterans' Employment and Training Service

#### Homeless Veterans' Reintegration Program (HVRP) Grants to Intermediaries for Program Year 2004

*Federal Agency:* U.S. Department of Labor, Veterans' Employment and Training Service.

*Funding Opportunity:* Homeless Veterans' Reintegration Program (HVRP) Grants to Intermediaries for Program Year 2004.

*Announcement Type:* Initial Solicitation for Grant Applications (SGA).

*Funding Opportunity Number:* SGA 04-05.

*Catalogue of Federal Domestic Assistance #:* 17-805.

*Dates:* Applications are due on May 13, 2004.

Period of Performance is Program Year (PY) 2004, July 1, 2004, through June 30, 2005.

*Executive Summary* (Applicants For Grant Funds Should Read This Notice In Its Entirety): The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with the requirements of 38 U.S.C. 2021, as added by section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the

Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to expedite the reintegration of homeless veterans into the labor force.

The Homeless Veterans' Reintegration Program (HVRP) is making grants in three (3) categories: urban, non-urban, and a new category being introduced this year—"intermediaries." Separate Solicitations for Grant Applications (SGAs) are being issued for each grant category. This is the solicitation for HVRP grants for "Intermediaries." The results of these three (3) separately competed grant categories will provide valuable information on approaches and techniques that work in the different environments.

Grants to Intermediaries are intended to address two overall objectives: (1) To coordinate efforts in order to collectively provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (2) to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans. In achieving the HVRP grant objectives, the intermediary is expected to sub-award a substantial portion of its grant award to eligible local grass-roots organizations. Applicants and their sub-awardees/contractors will coordinate efforts in order to design programs that assist homeless veterans by collectively ensuring that they receive job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. It is anticipated that "intermediaries" with established connections and working relationships to grassroots faith-based and community organizations will connect those smaller organizations and the people they serve to the local employment service delivery system for some of these services. These programs are to be designed to be flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce.

Under this solicitation covering Fiscal Year (FY) 2004, VETS anticipates that up to \$1,500,000 will be available for grant awards up to a maximum of \$250,000 each. This notice contains all of the necessary information and forms to apply for grant funding. The period of performance for these Program Year 2004 grants will be July 1, 2004 through June 30, 2005. Two (2) optional years of funding may be available, depending upon Congressional funding appropriations, the agency's decision to exercise the optional year(s) of funding, and satisfactory grantee performance.

#### I. Funding Opportunity Description

The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with the requirements of 38 U.S.C. 2021, as added by section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to expedite the reintegration of homeless veterans into the labor force.

##### 1. Program Concept and Emphasis

This Solicitation for Grant Applications (SGA) seeks to make grants to "intermediary" organizations with established connections to and working relationships with grassroots faith-based and community organizations and that have the ability to connect those smaller organizations and the people they serve to the local employment service delivery system. HVRP grants to intermediaries are intended to address two overall objectives: (a) To coordinate efforts in order to collectively provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (b) to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

In achieving the HVRP grant overall objectives, the intermediary is expected to provide a substantial portion of its award to eligible local grass-roots

organizations through sub-awards/contracts. In their collaboration, the intermediaries will achieve the following objectives:

- Organize collaboration between local grass-roots organizations and the local employment service delivery system to assist homeless veterans in reentering the workforce by leveraging the resources of both faith-based and community organizations and the local employment service delivery system.
- Expand the access of faith-based and community organization clients and customers to the training, employment opportunities, and employment services offered by the local employment service delivery system.
- Thoroughly document the impact and outcomes of these grant investments through quarterly, annual, and follow-up reporting.

Under this Program Year 2004 HVRP competition, eligible "intermediaries" are defined as State and Local Workforce Investment Boards, local public agencies, for-profit/commercial entities, and non-profit organizations including faith-based and community organizations. For the purposes of this announcement, the eligible local grassroots organizations to which sub-awards/contracts must be made must be non-profit organizations that:

- Have social services as a major part of their mission; and
- Are headquartered in the local community to which they provide these services; and
- Have a total annual operating budget of \$300,000 or less or have seven (7) or fewer full-time equivalent employees.

The intermediary will assist the sub-awardees/contractors, as appropriate, in administrative tasks so that maximum efforts can be focused on providing supportive services and employment assistance to homeless veterans. VETS' encourages and expects the intermediary's staff to provide mentoring and technical assistance to build the smaller organizations' capacity to be a permanent contributor to the local employment service delivery system.

For this Fiscal Year (FY) 2004 grant solicitation, VETS seeks applicants that will collectively provide direct services through a case management approach that networks with Federal, State, and local resources for veteran support programs. Successful applicants will have clear strategies for employment and retention of employment for homeless veterans. Successful applicants' and their grass-roots organization sub-awardees/contractors will collaborate efforts in order to

design programs that assist homeless veterans by collectively ensuring the provision of job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. Successful applicants will also design programs that are flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce. The HVRP in FY 2004 will seek to continue to strengthen development of effective delivery systems, to provide comprehensive services through a case management approach that addresses complex problems facing homeless veterans trying to transition into gainful employment, and to improve strategies for employment and retention in employment.

## 2. Community Awareness Activities

In order to promote networking between the HVRP funded program and local service providers (and thereby eliminate gaps or duplication in services and enhance the provision of assistance to participants), the grantee and/or sub-awardees/contractors collectively must provide project orientation workshops and program awareness activities that it determines are the most feasible for the types of providers listed below. Grantees are encouraged to demonstrate strategies for incorporating small faith-based and community organizations (defined as organizations with social services budgets of approximately \$300,000 or seven (7) or fewer full-time employees) into their outreach plans. Project orientation workshops conducted by grantees have been an effective means of sharing information and informing the community of the availability of other services; they are encouraged but not mandatory. Rather, grantees and/or sub-awardees/contractors will have the flexibility to attend service provider meetings, seminars, and conferences, to outstation staff, and to develop individual service contracts as well as to involve other agencies in program planning.

*The grantee and/or sub-awardees/contractors collectively will be responsible for providing project awareness, program information, and orientation activities to the following:*

A. Direct providers of services to homeless veterans including shelter and soup kitchen operators: to make them aware of the services available to homeless veterans to make them job-ready and to aid their placement into jobs.

B. Federal, State, and local entitlement and social service agencies such as the Social Security Administration (SSA), Department of Veterans Affairs (DVA), State Workforce Agencies (SWAs) and their local One-Stop Centers (which integrate Workforce Investment Act (WIA), labor exchange, and other employment and social services), mental health services, and healthcare detoxification facilities: to familiarize them with the nature and needs of homeless veterans.

C. Civic and private sector groups, in particular Veterans' Service Organizations, support groups, job training and employment services, and community-based organizations including faith-based organizations: to provide information on homeless veterans and their needs.

The grantee and/or sub-awardees/contractors collectively will also be responsible for participating in "Stand Down" events. A "Stand Down" is an event held in a locality, usually for three (3) days, where services are provided to homeless veterans along with shelter, meals, clothing, employment services, and medical attention. This type of event is mostly a volunteer effort, which is organized within a community and brings service providers together such as the Department of Veterans Affairs (DVA), Disabled Veterans' Outreach Program Specialists (DVOPs) and Local Veterans' Employment Representatives (LVERs) from the State Workforce Agencies, Veteran Service Organizations, military personnel, civic leaders, and a variety of other interested persons, groups, and organizations. Many services are provided on-site with referrals also made for continued assistance after the Stand Down event. These events can often be the catalyst that enables homeless veterans to get back into mainstream society. The Department of Labor has supported replication of these events and many have been held throughout the nation.

*In areas where an HVRP is operating, grantees and/or sub-awardees/contractors collectively are encouraged and expected to participate fully and offer their services for all locally planned Stand Down event(s). Toward this end, up to \$5,000 of the currently requested HVRP grant funds may be used to supplement the Stand Down efforts, where funds are not otherwise available, and may be requested in the budget and explained in the budget narrative.*

## 3. Scope of Program Design

*The overall project design must include the following services:*

A. Outreach, intake, assessment, peer counseling to the degree practical, employment services, and follow-up support services to enhance retention in employment. Program staff providing outreach services should have experience in dealing with, and an understanding of the needs of homeless veterans.

B. Provision of or referral to employment services such as: job search workshops, job counseling, assessment of skills, resume writing techniques, interviewing skills, subsidized trial employment (work experience), job development services, job placement into unsubsidized employment, job placement follow-up services to enhance retention in employment.

C. Provision of or referral to training services such as: basic skills instruction, remedial education activities, life skills and money management training, on-the-job training, classroom training, vocational training, specialized and/or licensing training programs, and other formal training programs as deemed appropriate to benefit the participant. At least 80% of the enrolled HVRP participants must participate in training activities.

D. Grantees and/or sub-awardees/contractors will perform a preliminary assessment of each participant's eligibility for Department of Veterans Affairs (DVA) service-connected disability, compensation, and/or pension benefits. As appropriate, grantees and/or sub-awardees/contractors will work with the Veterans Service Organizations (VSOs) or refer the participants to DVA in order to file a claim for compensation or pension. Grantees and/or sub-awardees/contractors will track progress of claims and report outcomes in case management records.

E. Coordination with veterans' services programs, including: Disabled Veterans' Outreach Program Specialists (DVOPs) and Local Veterans' Employment Representatives (LVERs) in the local employment service delivery system, as well as Veterans' Workforce Investment Programs (VWIPs), DVA services, including its Health Care for Homeless Veterans, Domiciliary Care, Regional Benefits Assistance Program, and Transitional Housing under Homeless Provider Grant and per diem programs.

F. Networking with Veterans' Service Organizations such as: The American Legion, Disabled American Veterans, Veterans of Foreign Wars, Vietnam Veterans of America, the American Veterans (AMVETS).

G. Referral as necessary to health care, counseling, and rehabilitative services

including, but not limited to: alcohol and drug rehabilitation, therapeutic services, Post Traumatic Stress Disorder (PTSD) services, mental health services as well as coordination with McKinney Homeless Assistance Act (MHAA) Title VI programs for health care for the homeless, and health care programs under the Homeless Veterans Comprehensive Assistance Act of 2001.

H. Referral to housing assistance, as appropriate, provided by: local shelters, Federal Emergency Management Administration (FEMA) food and shelter programs, transitional housing programs and single room occupancy housing programs funded under MHAA Title IV (and under HVCAA), and permanent housing programs for disabled homeless persons funded under MHAA Title IV (and under HVCAA).

#### 4. Results-Oriented Model

No specific model is mandatory, but the applicant and/or sub-awardees/contractors must collectively design a program that is responsive to the needs of the local community and achieves the overall objectives of the HVRP program. The HVRP objectives are to successfully reintegrate homeless veterans into the workforce and to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

Under the Government Performance and Results Act (GPRA), Congress and the public are looking for program results rather than program processes. The outcome measurement established for HVRP grants is for grantees and/or sub-awardees/contractors to collectively meet a minimum entered employment rate of 58%, determined by dividing the number of entered employments by the number of HVRP enrollments. (Actual performance outcomes will be reported quarterly in spreadsheet format to be provided to grantees at the post award conference.) While the percentage of HVRP enrollments that entered employment is an important outcome, it is also necessary to evaluate and measure the program's long-term results, through the 90-day and 180-day follow-up period, to determine the quality and success of the program.

The applicants and/or sub-awardees/contractors program should be based on a results-oriented model. The first phase of activity should consist of the level of outreach necessary to introduce the program to eligible homeless veterans. Outreach also includes establishing contact with other agencies that encounter homeless veterans. Once the eligible homeless veterans have been identified, an assessment must be made

of each individual's abilities, interests, needs, and barriers to employment. In some cases, participants may require referrals to services such as rehabilitation, drug or alcohol treatment, or a temporary shelter before they can be enrolled into HVRP. Once the eligible homeless veteran is "stabilized," the assessment must concentrate on the employability of the individual and whether the individual is to be enrolled into the HVRP program. A determination should be made as to whether the individual would benefit from pre-employment preparation such as resume writing, job search workshops, employment related counseling, and case management, or possibly an initial entry into the job market through temporary jobs. Additionally, sheltered work environments, classroom training, and/or on-the-job training must be evaluated. Such services should be noted in an Employability Development Plan to facilitate the staff's successful monitoring of the plan. Entry into full-time employment or a specific job-training program should follow, in keeping with the ultimate objective of HVRP, to bring the participant closer to self-sufficiency. Supportive services may assist the HVRP enrolled participant at this point or even sooner.

Job development, a crucial part of the employability process, is usually when there are no competitive job openings that the HVRP enrolled participant is qualified to apply for, therefore, a job opportunity is created or developed specifically for that HVRP enrolled participant with an employer. HVRP enrolled participants who are ready to enter employment and/or who are in need of intensive case management services are to be referred to the DVOP and LVER staff at a local One-Stop Office. DVOP and LVER staff are able to provide HVRP enrolled participants the following services: job development, employment services, case management and career counseling. Most DVOP and LVER staff received training in case management at the National Veterans' Training Institute. All DVOP and LVER staff provide employment related services to veterans who are most at a disadvantage in the labor market. VETS' urges working hand-in-hand with DVOP/LVER staff to achieve economies of resources.

The applicant and/or sub-awardees/contractors program must include tracking of program participants. Tracking should begin with the referral to employment and continue through the 90-day and 180-day follow-up periods after entering employment to determine whether the veteran is in the



same or similar job. It is important that the grantee and/or sub-awardees/contractors maintain contact with veterans after placement to ensure that employment-related problems that may arise are addressed. The 90-day and 180-day follow-ups are fundamental to assessing the results of the program success. Grantee and/or sub-awardees/contractors need to budget for 90-day and 180-day follow-up activity so that it can be performed for those enrolled participants placed at or near the end of the grant performance period. All grantees and/or sub-awardees/contractors, prior to the end of the grant performance period, must obligate sufficient funds to ensure that follow-up activities are completed. Such results will be reported in the final technical performance report.

## II. Award Information

1. *Type of Funding Instrument:* One (1) year grant.

2. *Funding Levels:* The total funding available for this Intermediaries HVRP solicitation is up to \$1,500,000. Awards are expected to range from \$100,000 to a maximum of \$250,000. The Department of Labor reserves the right to negotiate the amounts to be awarded under this competition. Please be advised that requests exceeding \$250,000 will be considered non-responsive.

3. *Period of Performance:* The period of performance will be for twelve (12) months from date of award unless modified by the Grant Officer. It is expected that successful applicants and/or sub-awardees/contractors will begin program operations under this solicitation on July 1, 2004. All program funds must be obligated by June 30, 2005; a limited amount of funds may be obligated and reserved for follow-up activities and closeout.

4. *Optional Year(s) Funding:* Should Congress appropriate additional funds for this purpose, VETS may consider two (2) optional years of funding. The Government does *not*, however, guarantee optional year(s) funding for any grantee (or sub-awardees/contractors). In deciding whether to exercise any optional year funding, VETS will consider grantee (including sub-awardees/contractors) overall performance during the previous period of operations as follows:

A. The grantee and/or sub-awardees/contractors collectively must meet, at minimum, 85% of the planned goals for Federal expenditures, enrollments, and placements in each quarter and/or at least 85% of planned cumulative goals by the end of the third quarter; and

B. The grantee and sub-awardees/contractors must be in compliance with all terms identified in the Solicitation for Grant Application (SGA) and grant award document; and

C. All program and fiscal reports must have been submitted by the established due date and must be verifiable for accuracy.

## III. Eligibility Information

1. *Eligible Applicants:* Applications for funds will be accepted from State and local Workforce Investment Boards, local public agencies, for-profit/commercial entities, and nonprofit organizations, including faith-based and community organizations. Applicants and their sub-awardees/contractors must have a familiarity with the area and population to be served and the ability to administer an effective and timely program. Applicants must also have established connections to and working relationships with grassroots faith-based and community organizations, and have the ability to connect those smaller organizations and the people they serve to the local employment service delivery system.

Eligible applicants will generally fall into one of the following categories:

- State and local Workforce Investment Boards (WIBs), established under sections 111 and 117 of the Workforce Investment Act.
- Public agencies, meaning any public agency of a State or of a general purpose political subdivision of a State that has the power to levy taxes and spend funds, as well as general corporate and police powers. (This typically refers to cities and counties.) A State agency may propose in its application to serve one or more of the potential jurisdictions located in its State. This does not preclude a city or county agency from submitting an application to serve its own jurisdiction.
- For-profit/commercial entities.
- Nonprofit organizations. If claiming 501(c)(3) status, the Internal Revenue Service statement indicating 501(c)(3) status approval must be submitted.

To be eligible for a sub-award/contract from an Intermediary Grantee, an organization must be a local, grassroots non-profit entity that:

- Have social services as a major part of their mission; and
- Are headquartered in the local community to which they provide these services; and
- Have a total annual operating budget of \$300,000 or less or have seven (7) or fewer full-time equivalent employees.

**Note:** Qualifying applications from grantees in the below listed States that are

not currently receiving HVRP funds may receive priority funding over applicants in those States that are currently receiving HVRP funds: Alaska, Arkansas, Delaware, Georgia, Idaho, Kansas, Mississippi, Montana, Nebraska, New Hampshire, North Dakota, Rhode Island, South Dakota, Utah, Vermont, Virginia, West Virginia, and Wyoming.

2. *Cost Sharing:* Cost sharing and/or matching funds are *not* required. However, we do encourage the use of leveraging and/or matching funds.

### 3. *Other Eligibility Criteria:*

A. This SGA is for Intermediaries HVRP grants. Separate SGAs for urban and non-urban HVRP grants have been simultaneously issued.

B. The proposal must include an outreach component that uses either DVOP/LVER staff or a trained outreach cadre. Programs must be "employment focused." The services provided must be directed toward: (1) Increasing the employability of homeless veterans through training or arranging for the provision of services that will enable them to work; and (2) matching homeless veterans with potential employers.

C. Applicants are encouraged to utilize, through partnerships or sub-awards/contracts, experienced public agencies, private nonprofit organizations, private businesses, faith-based and community organizations, and colleges and universities (especially those with traditionally high enrollments of minorities) that have an understanding of unemployment and the barriers to employment unique to homeless veterans, a familiarity with the area to be served, and the capability to effectively provide the necessary services.

D. To be eligible for enrollment under this grant an individual must be homeless *and* a veteran defined as follows:

- The term "*homeless or homeless individual*" includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either a supervised public or private shelter designed to provide temporary living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. [42 U.S.C. 11302(a)].

- The term "*veteran*" means a person who served in the active military, naval, or air service, and who was discharged or released under conditions other than dishonorable. [38 U.S.C. 101(2)]



#### IV. Application and Submission Information

1. *Address To Request an Application and Amendments:* Application announcements or forms will not be mailed. The **Federal Register** may be obtained from your nearest government office or library. Additional application packages may be obtained from the VETS Web site at <http://www.dol.gov/vets> and at <http://www.fedgrants.gov/>. The application forms and their instructions, and other pertinent materials are included in the Appendices. If copies of the standard forms are needed, they can also be downloaded from: [http://www.whitehouse.gov/omb/grants/grants\\_forms.html](http://www.whitehouse.gov/omb/grants/grants_forms.html).

To receive amendments to this Solicitation, all applicants must register their name and address in writing with the Grant Officer at the following address: U.S. Department of Labor, Procurement Services Center, Attn: Cassandra Mitchell, Reference SGA 04-05, 200 Constitution Avenue, NW., Room N-5416, Washington, DC 20210, Phone Number: (202) 693-4570 (not a toll free number).

2. *Content and Form of Application:* The grant application must consist of three (3) separate and distinct sections: the Executive Summary, the Technical Proposal, and the Cost Proposal. The information provided in these three (3) sections is essential to gain an understanding of the programmatic and fiscal contents of the grant proposal.

A complete grant application package must include:

- An original blue ink-signed and two (2) copies of the cover letter.
- An original and two (2) copies of the Executive Summary (see below).
- An original and two (2) copies of the Technical Proposal (see below) that includes a completed Technical Performance Goals Form (Appendix D).
- An original and two (2) copies of the Cost Proposal (see below) that includes an original blue ink-signed Application for Federal Assistance, SF-424 (Appendix A), a Budget Narrative, Budget Information Sheet SF-424A (Appendix B), an original blue ink-signed and Assurances and Certifications Signature Page (Appendix C), and Direct Cost Description for Applicants and Sub-applicants (Appendix E), and a completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F).

A. *Section 1—Executive Summary:* A one to two page "Executive Summary" reflecting the grantees overall strategy, timeline, and outcomes to be achieved in their grant proposal is required. This

executive summary does not count against the 15-page limit. The executive summary should include:

- The proposed area to be served through the activities of this grant.
- Years of grantee's service to the residents in the proposed area to be served.
- Projects and activities that will expedite the reintegration of homeless veterans into the workforce.
- Summary of outcomes, benefits, and value added by the project.

B. *Section 2—Technical Proposal* consists of a narrative proposal that demonstrates the need for this particular grant program, the services and activities proposed to obtain successful outcomes for the homeless veterans to be served; and the applicants' and/or sub-awardees'/contractors' ability to collectively accomplish the expected outcomes of the proposed project design.

*The technical proposal narrative must not exceed fifteen (15) pages double-spaced, font size no less than 11 pt., and typewritten on one (1) side of the paper only. Note:* Resumes, charts, standard forms, transmittal letters, Memorandums of Understanding, agreements, lists of contracts and grants, letters of support are not included in the page count. If provided, include these documents as attachments to the technical proposal.

*Required Content:* There are program activities that all applications must contain to be found technically acceptable under this SGA. Programs must be "employment focused" and must be responsive to the rating criteria in Section V(1). *The required activities are:* outreach, pre-enrollment assessments, employment development plans for all clients, case management, job placement and job retention follow-up (at 90 and 180 days) after individual enters employment, utilization/coordination of services with DVOP and LVER staff, and community linkages with other programs and services that provide support to homeless veterans.

*The following format for the technical proposal is recommended:*

*Need for the program:* The applicant must identify the geographical area to be served and provide an estimate of the number of homeless veterans in the designated geographical area. Include poverty and unemployment rates in the area and identify the disparities in the local community infrastructure that exacerbate the employment barriers faced by the targeted veterans. Include labor market information and job opportunities in the employment fields and industries that are in demand in the geographical area to be served.

*Approach or strategy to increase employment and job retention:*

Applicants must be responsive to the Rating Criteria contained in Section V(1) and address all of the rating factors as thoroughly as possible in the narrative.

*The applicant must:*

- Describe the specific supportive employment and training services to be provided under this grant and the sequence or flow of such services;

- Indicate the type(s) of training that will be provided and how it relates to the jobs that are in demand, length of training, training curriculum, and how the training will improve the eligible veterans' employment opportunities within that geographical area;

- Provide a follow-up plan that addresses retention after 90 and 180 days with participants who have entered employment;

- Include the completed Planned Quarterly Technical Performance Goals (and planned expenditures) form listed in Appendix D.

*Linkages with facilities that serve homeless veterans:* Describe program and resource linkages with other facilities that will be involved in identifying potential clients for this program. Describe any networks with other related resources and/or other programs that serve homeless veterans. Indicate how the program will be coordinated with any efforts that are conducted by public and private agencies in the community. If a Memorandum of Understanding (MOU) or other service agreement with service providers exists, copies should be provided.

*Linkages with other providers of employment and training services to homeless veterans:* Describe the networks the program will have with other providers of services to homeless veterans; include a description of the relationship with other employment and training programs such as Disabled Veterans' Outreach Program (DVOP), the Local Veterans' Employment Representative (LVER) program, and programs under the Workforce Investment Act such as the Veterans' Workforce Investment Program (VWIP); and list the type of services that will be provided by each. Note the type of agreement in place, if applicable. Linkages with the workforce development system must be delineated. Describe any networks with any other resources and/or other programs for homeless veterans. Indicate how the program will be coordinated with any efforts for the homeless that are conducted by agencies in the community. Indicate how the applicant and/or sub-awardees/

contractors will coordinate with any "continuum of care" efforts for the homeless among agencies in the community. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Linkages with other Federal agencies:** Describe program and resource linkages with the Department of Housing and Urban Development (HUD), Department of Health and Human Services (HHS), and Department of Veterans Affairs (DVA) including the Compensated Work Therapy (CWT) and per diem programs. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Proposed supportive service strategy for veterans:** Describe how supportive service resources for veterans will be obtained and used. If resources are provided by other sources or linkages, such as Federal, State, local, faith-based and community organization programs or colleges and universities, including those with traditionally high enrollments of minorities, the applicant must fully explain the use of these resources and how they will be applied. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Organizational capability to provide required program activities:** The applicant's relevant current or prior experience in operating employment and training programs should be clearly described. A summary narrative of program experience and employment and training performance outcomes is required. *The applicant should provide information showing outcomes of all past employment and training programs in terms of enrollments and placements.* An applicant that had operated a HVRP, other Homeless Employment and Training program, or VWIP program must include the final or most recent technical performance reports. The applicant must also provide evidence of key staff capability. It is preferred that grantee be well established and not in the start-up phase or process.

**Proposed housing strategy for homeless veterans:** Describe how housing resources for eligible homeless veterans will be obtained or accessed. These resources must be from linkages or sources other than the HVRP grant such as HUD, HHS, community housing resources, DVA leasing, or other programs.

**C. Section 3—The Cost Proposal must contain the following:** (1) Standard Form SF-424, "Application for Federal Assistance," (with the original signed in

blue-ink) (Appendix A) must be completed;

The Catalog of Federal Domestic Assistance number for this program is 17.805 and it must be entered on the SF-424, in Block 10.

The organizational unit section of Block 5 of the SF-424 must contain the Dun and Bradstreet Number (DUNS) of the applicant. Beginning October 1, 2003, all applicants for Federal grant funding opportunities are required to include a DUNS number with their application. See OMB Notice of Final Policy Issuance, 68 Federal Register 38402 (June 27, 2003). Applicants' DUNS number should be entered into Block 5 of SF-424. The DUNS number is a nine-digit identification number that uniquely identifies business entities. There is no charge for obtaining a DUNS number. To obtain a DUNS number call 1-866-705-5711 or access the following Web site: <http://www.dunandbradstreet.com/>. Requests for exemption from the DUNS number requirement must be made to the Office of Management and Budget.

(2) A completed Standard Form SF-424A "Budget Information Sheet" (Appendix B) must be included;

(3) As an attachment to SF-424A, the applicant must provide a detailed cost breakout of each line item on the Budget Information Sheet. Please label this page or pages the "Budget Narrative" and ensure that costs reported on the SF-424A correspond accurately with the Budget Narrative;

*The Budget Narrative must include, at a minimum:*

- Breakout of all personnel costs by position, title, salary rates, and percent of time of each position to be devoted to the proposed project (including sub-awardees/contractors) by completing the "Direct Cost Descriptions for Applicants and Sub-Applicants" form (Appendix E);

- Explanation and breakout of extraordinary fringe benefit rates and associated charges (*i.e.*, rates exceeding 35% of salaries and wages);

- Explanation of the purpose and composition of, and method used to derive the costs of, each of the following: travel, equipment, supplies, sub-awards/contracts, and any other costs. The applicant must include costs of any required travel described in this Solicitation. Mileage charges may not exceed 37.5 cents per mile or the current Federal rate;

- All associated costs for retaining participant information pertinent to the follow-up survey, 180 days after the program performance period ends;

- Description/specification of, and justification for, equipment purchases, if

any. Tangible, non-expendable, personal property having a useful life of more than one year and a unit acquisition cost of \$5,000 or more per unit must be specifically identified; and

- Identification of all sources of leveraged or matching funds and an explanation of the derivation of the value of matching/in-kind services. If resources/matching funds and/or the value of in-kind contributions are made available, please show in Section B of the Budget Information Sheet.

(4) A completed Assurance and Certification signature page (Appendix C) must be submitted;

(5) All applicants must submit evidence of satisfactory financial management capability, which must include recent (within the last 18 months) financial and/or audit statements. Grantees and sub-awardees/contractors are required to utilize Generally Accepted Accounting Practices (GAAP), maintain a separate accounting for these grant funds, and have a checking account;

(6) All applicants must include, as a separate appendix, a list of all employment and training government grants and contracts that it has had in the past three (3) years, including grant/contract officer contact information. VETS reserves the right to have a DOL representative review and verify this data;

(7) A completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F) must be provided.

**3. Submission Dates and Times (Acceptable Methods of Submission):** The grant application package must be received at the designated place by the date and time specified or it will not be considered. Any application received at the Office of Procurement Services after 4:45 p.m. e.t., May 13, 2004, will not be considered unless it is received before the award is made and:

- It is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the U.S. Department of Labor at the address indicated; or

- It was sent by registered or certified mail not later than the fifth calendar day before May 13, 2004; or

- It was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5:00 p.m. at the place of mailing two (2) working days, excluding weekends and Federal holidays, prior to May 13, 2004.

**4. Intergovernmental Review:** Not Applicable.

**5. Funding Restrictions:**

A. Proposals exceeding \$250,000 will be considered non-responsive, if

B. There is a limit of one (1) application per submitting organization and location. If two (2) applications from the same organization for the same location are submitted, the application with the later date will be considered non-responsive.

C. Due to the limited availability of funding, if an organization was awarded Fiscal Year 2003 HVRP funds for a specific location and will be receiving second and possible third year funding, that organization at that specific location will be considered ineligible to compete for FY 2004 HVRP funds.

D. There will not be reimbursement of pre-award costs unless specifically agreed upon in writing by the Department of Labor.

E. Entities described in section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities are not eligible to receive funds under this announcement because section 18 of the Lobbying Disclosure Act of 1995, Public Law 104-65, 109 Stat. 691, prohibits the award of Federal funds to these entities.

F. The government is prohibited from directly funding religious activity.\* HVRP grants may not be used for religious instruction, worship, prayer, proselytizing or other inherently religious practices. Neutral, secular criteria that neither favor nor disfavor religion must be employed in the selection of grant and sub-awardees/contractors grant recipients. In addition, under the Workforce Investment Act (WIA) and Department of Labor regulations implementing the WIA, a recipient may not train a participant in religious activities, or permit participants to construct, operate, or maintain any part of a facility that is primarily used or devoted to religious instruction or worship. Under WIA, "no individual shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with, any such program or activity because of race, color, religion, sex (except as otherwise permitted under Title IX of the Education Amendments of 1972), national origin, age, disability, or political affiliation or belief."

\* The term "direct" funding is used to describe funds that are provided "directly" by a governmental entity or an intermediate organization with the same duties as the government entity, as opposed to funds that an organization receives as the result of the genuine and independent private choice of a beneficiary. In other contexts, the term "direct" funding may be used to refer to those funds that an organization receives directly from the Federal

government (also known as "discretionary" funding), as opposed to funding that it receives from a State or local government (also known as "indirect" or "block grant" funding). In this SGA, the term "direct" has the former meaning.

#### G. Limitations on Administrative and Indirect Costs:

- Administrative costs, which consist of all direct and indirect costs associated with the supervision and management of the program, are limited to and will not exceed 20% of the total grant award.

- Indirect costs claimed by the applicant must be based on a Federally approved rate. A copy of the negotiated approved and signed indirect cost negotiation agreement must be submitted with the application. Furthermore, indirect costs are considered a part of administrative costs for HVRP purposes and, therefore, may not exceed 20% of the total grant award.

- If the applicant does not presently have an approved indirect cost rate, a proposed rate with justification may be submitted. Successful applicants will be required to negotiate an acceptable and allowable rate within 90 days of grant award with the appropriate DOL Regional Office of Cost Determination or with the applicant's cognizant agency for indirect cost rates (See Office of Management and Budget Web site at <http://www.whitehouse.gov/omb/grants/attach.html>).

- Indirect cost rates traceable and trackable through the State Workforce Agency's Cost Accounting System represent an acceptable means of allocating costs to DOL and, therefore, can be approved for use in grants to State Workforce Agencies.

#### 6. Other Submission Requirements:

The only acceptable evidence to establish the date of mailing of a late application sent by registered or certified mail is the U.S. Postal Service postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. If the postmark is not legible, an application received after the above closing time and date shall be processed as if mailed late. "Postmark" means a printed, stamped or otherwise placed impression (not a postage meter machine impression) that is readily identifiable without further action as having been applied and affixed by an employee of the U.S. Postal Service on the date of mailing. Therefore applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the date of mailing of a late

application sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee is the date entered by the Post Office clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the same meaning as defined above. Therefore, applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the time of receipt at the U.S. Department of Labor is the date/time stamp of the Procurement Services Center on the application wrapper or other documentary evidence or receipt maintained by that office. Applications sent by other delivery services, such as Federal Express, UPS, etc., will also be accepted.

*All applicants are advised that U.S. mail delivery in the Washington, DC, area has been erratic due to security and anthrax concerns. All applicants must take this into consideration when preparing to meet the application deadline, as you assume the risk for ensuring a timely submission, that is, if, because of these mail problems, the Department does not receive an application or receives it too late to give proper consideration, even if it was timely mailed, the Department is not required to consider the application.*

#### V. Application Review Information

##### 1. Application Evaluation Criteria

Applications will receive up to 100 total points based on the following criteria:

##### A. Need for the Project: 10 Points

The applicant will document the need for this project, as demonstrated by: (i) The potential number or concentration of homeless individuals and homeless veterans in the proposed project area relative to other similar areas of jurisdiction, (ii) the rates of poverty and/or unemployment in the proposed project area as determined by the census or other surveys; and (iii) the extent of the gaps in the local infrastructure to effectively address the employment barriers that characterize the target population.

##### B. Overall Strategy To Increase Employment and Retention in Employment: 35 Points

The application must include a description of the approach to providing comprehensive employment and training services, including job training,

job development, obtaining employer commitments to hire, placement and post-placement follow-up services. Applications must address how they will target occupations in emerging industries. Supportive services provided as part of the strategy of promoting job readiness and job retention must be indicated. The applicant must identify the local services and sources of training to be used for participants. At least 80% of enrolled participants must participate in training services. A description of the relationship, if any, with other employment and training programs such as State Workforce Agencies (including DVOP and LVER Programs), One-Stops, VWIP, other WIA programs, and Workforce Investment or Development Boards or entities where in place, must be specified. Applications must indicate how the activities will be tailored or responsive to the needs of homeless veterans. A participant flow chart may be used to show the sequence and mix of services.

**Note:** The applicant must complete Appendix D, the Technical Performance Goals Form, with proposed programmatic outcomes, including participants served, placement/entered employments and job retention. Of the 35 points possible in the strategy to increase employment and retention, 5 points will be awarded to grant proposals that demonstrate the ability to maintain a six-month employment retention rate of 50 percent or greater. Applicants whose applications persuasively propose to use peer counselors who are themselves veterans will be awarded five (5) of the available points in the scoring criteria.

**C. Quality and Extent of Linkages With Other Providers of Services to the Homeless and to Veterans: 20 Points**

The application must provide information on the quality and extent of the linkages this program will have with other providers of services to homeless veterans in the local community including faith-based and community organizations. For each service, the applicant must specify who the provider is, the source of funding (if known), and the type of linkages/referral system established or proposed. Describe, to the extent possible, how the project would be incorporated into the community's continuum of care approach to respond to homelessness and show any linkages to HUD, HHS or DVA programs that will be advantageous to the proposed program.

**D. Demonstrated Capability in Providing Required Program Services, Including Programmatic Reporting and Participant Tracking: 25 Points**

The applicant must describe its relevant prior experience in operating

employment and training programs and providing services to participants similar to those that are proposed under this solicitation. Specific outcomes previously achieved by the applicant and/or sub-awardees/contractors must be described, such as job placements, benefits secured, network coalitions, *etc.* The applicant and/or sub-awardees/contractors must also address its capacity for timely startup of the program, programmatic reporting, and participant tracking. The applicant and/or sub-awardees/contractors should describe its staff experience and ability to manage the administrative, programmatic and financial aspects of a grant program. Include a recent (within the last 18 months) financial statement or audit. Final or most recent technical reports for other relevant employment and training programs must be submitted, if applicable. Because prior HVRP grant experience is not a requirement for this grant, some applicants may not have any technical performance reports to submit.

**E. Quality of Overall Housing Strategy: 10 Points**

The application must demonstrate how the applicant and/or sub-awardees/contractors propose to obtain or access housing resources for veterans in the program and entering the labor force. This discussion should specify the provisions made to access temporary, transitional, and permanent housing for participants through community resources, HUD, DVA lease, or other means. *HVRP funds may not be used for housing or vehicles.*

**2. Review and Selection Process**

Applications will initially be screened to ensure timeliness, completeness, and responsiveness to the SGA requirements. Applications that satisfy this initial screening will receive further review as explained below.

Technical proposals will be reviewed by a Department of Labor review panel using the point scoring system specified above in Section V(1). The review panel will assign scores after careful evaluation by each panel member and rank applications based on this score. The ranking will be the primary basis to identify applicants as potential grantees. The review panel may establish a competitive range and/or a minimum qualifying score, based upon the proposal evaluation, for the purpose of selecting qualified applicants. The review panel's conclusions are advisory in nature and not binding on the Grant Officer.

Cost proposals will be considered in two (2) ways. The Department of Labor

review panel will screen all applicant cost proposals to ensure expenses are allocable, allowable, and reasonable. If the review panel concludes that the cost proposal contains an expense(s) that is not allocable, allowable, and/or reasonable, the application may be considered ineligible for funding. Further, VETS and the Grant Officer will consider applicant information concerning the proposed cost per placement, percentage of participants placed into unsubsidized employment, average wage at placement, and 180-day retention in employment percentage. The national average cost per placement for HVRP for last year was \$2,100.

The Government reserves the right to ask for clarification on any aspect of a grant application. The Government also reserves the right to discuss any potential grantee concerns amongst Department of Labor staff. The Government further reserves the right to select applicants out of rank order if such a selection would, in its opinion, result in the most effective and appropriate combination of funding, program, and administrative costs, *e.g.*, cost per enrollment and placement, demonstration models, and geographic service areas. The Grant Officer's determination for award under SGA 04-05 is the final agency action. The submission of the same proposal from any prior year HVRP competition does not guarantee an award under this Solicitation.

**VI. Award Administration Information**

**1. Award Notices**

A. The Notice of Award signed by the Grant Officer is the authorizing document and will be provided through postal mail and/or by electronic means to the authorized representative as listed on the SF-424 Grant Application. Notice that an organization has been selected as a grant recipient does not constitute approval of the grant application as submitted. Before the actual grant award, the Grant Officer may enter into negotiations concerning such items as program components, funding levels, and administrative systems. If the negotiations do not result in an acceptable submittal, the Grant Officer reserves the right to terminate the negotiation and decline to fund the proposal.

B. A post-award conference will be held for those grantees awarded FY 2004 HVRP funds through this competition. The post-award conference is expected to be held in July or August 2004. Up to two (2) representatives must be present; a financial and a program representative are recommended. The



site of the post-award conference has not yet been determined, however, for planning and budgeting purposes, please allot five (5) days and use Washington, DC, as the conference site. The post-award conference will focus on providing information and assistance on reporting, record keeping, grant requirements, and also include best practices from past projects. Costs associated with attending this conference for up to two grantee representatives will be allowed as long as they were incurred in accordance with Federal travel regulations. Such costs must be charged as administrative costs and reflected in the proposed budget.

## 2. Administrative and National Policy Requirements

Unless specifically provided in the grant agreement, DOL's acceptance of a proposal and an award of Federal funds to sponsor any program(s) does not provide a waiver of any grant requirements and/or procedures. For example, the OMB circulars require that an entity's procurement procedures must provide all procurement transactions will be conducted, as practical, to provide open and free competition. If a proposal identifies a specific entity to provide the services, the DOL award does not provide the justification or basis to sole-source the procurement, *i.e.*, avoid competition. All grants will be subject to the following administrative standards and provisions, as applicable to the particular grantee and/or sub-awardees/contractors:

- 29 CFR part 93—Lobbying.
- 29 CFR part 95—Uniform

Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations, and with Commercial Organizations.

- 29 CFR part 96—Federal Standards for Audit of Federally Funded Grants, Contracts and Agreements.

- 29 CFR part 97—Uniform

Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

- 29 CFR part 98—Federal Standards for Government-wide Debarment and Suspension (Non procurement) and Government-wide Requirements for Drug-Free Workplace (Grants).

- 29 CFR part 99—Audit of States, Local Governments, and Nonprofit Organization.

- 29 CFR parts 30, 31, 32, 33 and 36—

Equal Employment Opportunity in Apprenticeship and Training; Nondiscrimination in Federally Assisted Programs of the Department of

Labor, Effectuation of Title VI of the Civil Rights Act of 1964; Nondiscrimination on the Basis of Handicap in Programs and Activities; and Nondiscrimination on the Basis of Sex in Education Programs Receiving or Benefiting from Federal Financial Assistance.

## 3. Reporting

The grantee will submit the reports and documents listed below:

### A. Quarterly Financial Reports

No later than 30 days after the end of each Federal fiscal quarter, the grantee must report outlays, program income, and other financial information (including sub-awardees/contractors information) on a federal fiscal quarterly basis using SF-269A, Financial Status Report, Short Form and submit a copy of the HHS/PMS 272 drawdown report. These reports must cite the assigned grant number and be submitted to the appropriate State Director for Veterans' Employment and Training (DVET).

### B. Quarterly Program Reports

No later than 30 days after the end of the Federal fiscal quarter, grantees also must submit a Quarterly Technical Performance Report (including sub-awardees/contractors information) to the DVET that contains the following:

(1) A comparison of actual accomplishments to planned goals for the reporting period in spreadsheet format (to be provided after grant award) and any findings related to monitoring efforts;

(2) An explanation for variances of plus or minus 15% of planned program and/or expenditure goals, to include: Identification of a corrective action that will be taken to meet the planned goals, if required; and a timetable for accomplishment of the corrective action.

### C. 90-Day Follow-Up Report

No later than 120 days after the grant performance period expiration date, the grantee must submit a follow-up report (including sub-awardees/contractors information) showing results and performance as of the 90th day after the grant period, and containing the following:

(1) Final Financial Status Report SF-269A Short Form (that zeros out all unliquidated obligations); and

(2) Technical Performance Report including updated goals chart.

### D. 180-Day Follow-Up Report

No later than 210 days after the grant performance expiration date, the grantee must submit a follow-up report

(including sub-awardees/contractors information) showing the results and performance as of the 180th day after the grant period, and containing the following:

(1) Final Financial Status Report SF-269A Short Form (if not previously submitted); and

(2) Final Narrative Report identifying: (a) The total combined (directed/assisted) number of veterans placed into employment during the entire grant period;

(b) The number of veterans still employed after the 180 day follow-up period;

(c) If the veterans are still employed at the same or similar job, if not, what are the reason(s);

(d) Whether training received was applicable to jobs held;

(e) Wages at placement and during follow-up period;

(f) An explanation regarding why those veterans placed during the grant, but not employed at the end of the follow-up period, are not so employed; and

(g) Any recommendations to improve the program.

## VII. Agency Contact

Questions and applications are to be forwarded to: U.S. Department of Labor, Procurement Services Center, Attn: Cassandra Mitchell, Reference SGA 04-05, 200 Constitution Avenue, NW., Room N-5416, Washington, DC 20210, Phone Number: (202) 693-4570 (this is not a toll free number).

**Resources for the Applicant:** Applicants may review "VETS' Guide to Competitive and Discretionary Grants" located at [http://www.dol.gov/vets/grants/Final\\_VETS\\_Guide-linked.pdf](http://www.dol.gov/vets/grants/Final_VETS_Guide-linked.pdf). Applicants may also find these resources useful: America's Service Locator <http://www.servicelocator.org/> provides a directory of our nation's One-Stop Career Centers; the National Association of Workforce Boards maintains an Internet site (<http://www.nawb.org/asp/wibdir.asp>) that contains contact information for the State and local Workforce Investment Boards; and the homepage for the Department of Labor, Center for Faith-Based & Community Initiatives (<http://www.dol.gov/cfbci>).

**Comments:** Comments are to be submitted to the Veterans' Employment and Training Service (VETS), U.S. Department of Labor, Room S-1312, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-4701 (this is not a toll free number). Written comments are limited to ten (10) pages or fewer and may be transmitted by facsimile to (202) 693-4755. Receipt of



submissions, whether by U.S. mail, e-mail, or facsimile transmittal, will not be automatically acknowledged; however, the sender may request confirmation that a submission has been received, by telephoning VETS at (202) 693-4701 or (202) 693-4753 (TTY/TDD).

Signed at Washington, DC, this 6th day of April, 2004.

**Lisa Harvey,**

*Acting Grant Officer.*

**Appendices**

Appendix A: Application for Federal Assistance SF-424

Appendix B: Budget Information Sheet SF-424A

Appendix C: Assurances and Certifications

**Signature Page**

Appendix D: Quarterly Technical Performance Goals Form

Appendix E: Direct Cost Descriptions for Applicants and Sub-Applicants

Appendix F: Survey on Ensuring Equal Opportunity for Applicants

Appendix G: The Glossary of Terms

Appendix H: List of Common Acronyms

**BILLING CODE 4510-79-P**

APPLICATION FOR  
FEDERAL ASSISTANCE

Version 7/03

<b>1. TYPE OF SUBMISSION:</b> Application		<b>2. DATE SUBMITTED</b>	Applicant Identifier
<input type="checkbox"/> Construction	Pre-application	<b>3. DATE RECEIVED BY STATE</b>	State Application Identifier
<input type="checkbox"/> Non-Construction	<input type="checkbox"/> Construction	<b>4. DATE RECEIVED BY FEDERAL AGENCY</b>	Federal Identifier
<input type="checkbox"/> Non-Construction			
<b>5. APPLICANT INFORMATION</b>			
Legal Name:		Organizational Unit:	
		Department:	
Organizational DUNS:		Division:	
<b>Address:</b>		<b>Name and telephone number of person to be contacted on matters involving this application (give area code)</b>	
Street:		Prefix:	First Name:
City:		Middle Name	
County:		Last Name	
State:	Zip Code	Suffix:	
Country:		Email:	
<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</b>		Phone Number (give area code)	Fax Number (give area code)
□□-□□□□□□□□			
<b>8. TYPE OF APPLICATION:</b>		<b>7. TYPE OF APPLICANT:</b> (See back of form for Application Types)	
<input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		Other (specify)	
If Revision, enter appropriate letter(s) in box(es) (See back of form for description of letters.)			
Other (specify)		<b>9. NAME OF FEDERAL AGENCY:</b>	
<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b>		<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b>	
TITLE (Name of Program):		□□-□□□□	
<b>12. AREAS AFFECTED BY PROJECT (Cities, Counties, States, etc.):</b>			
<b>13. PROPOSED PROJECT</b>		<b>14. CONGRESSIONAL DISTRICTS OF:</b>	
Start Date:	Ending Date:	a. Applicant	b. Project
<b>15. ESTIMATED FUNDING:</b>		<b>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b>	
a. Federal	\$ .00	a. Yes. <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON	
b. Applicant	\$ .00	DATE:	
c. State	\$ .00	b. No. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E. O. 12372	
d. Local	\$ .00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
e. Other	\$ .00	<b>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</b>	
f. Program Income	\$ .00	<input type="checkbox"/> Yes if "Yes" attach an explanation. <input type="checkbox"/> No	
g. TOTAL	\$ .00		
<b>18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.</b>			
a. Authorized Representative			
Prefix	First Name	Middle Name	
Last Name			Suffix
b. Title			c. Telephone Number (give area code)
d. Signature of Authorized Representative			e. Date Signed

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## INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

This is a standard form used by applicants as a required face sheet for pre-applications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:	Item:	Entry:																
1.	Select Type of Submission.	11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.																
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).	12.	List only the largest political entities affected (e.g., State, counties, cities).																
3.	State use only (if applicable).	13.	Enter the proposed start date and end date of the project.																
4.	Enter Date Received by Federal Agency Federal Identifier number: If this application is a continuation or revision to an existing award, enter the present Federal Identifier number. If for a new project, leave blank.	14.	List the applicant's Congressional District and any District(s) affected by the program or project																
5.	Enter legal name of applicant, name of primary organizational unit (including division, if applicable), which will undertake the assistance activity, enter the organization's DUNS number (received from Dun and Bradstreet), enter the complete address of the applicant (including country), and name, telephone number, e-mail and fax of the person to contact on matters related to this application.	15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.																
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.	16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.																
7.	Select the appropriate letter in the space provided. <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">A. State</td> <td style="width: 50%;">I. State Controlled Institution of Higher Learning</td> </tr> <tr> <td>B. County</td> <td>J. Private University</td> </tr> <tr> <td>C. Municipal</td> <td>K. Indian Tribe</td> </tr> <tr> <td>D. Township</td> <td>L. Individual</td> </tr> <tr> <td>E. Interstate</td> <td>M. Profit Organization</td> </tr> <tr> <td>F. Intermunicipal</td> <td>N. Other (Specify)</td> </tr> <tr> <td>G. Special District</td> <td>O. Not for Profit Organization</td> </tr> <tr> <td>H. Independent School District</td> <td></td> </tr> </table>	A. State	I. State Controlled Institution of Higher Learning	B. County	J. Private University	C. Municipal	K. Indian Tribe	D. Township	L. Individual	E. Interstate	M. Profit Organization	F. Intermunicipal	N. Other (Specify)	G. Special District	O. Not for Profit Organization	H. Independent School District		17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
A. State	I. State Controlled Institution of Higher Learning																		
B. County	J. Private University																		
C. Municipal	K. Indian Tribe																		
D. Township	L. Individual																		
E. Interstate	M. Profit Organization																		
F. Intermunicipal	N. Other (Specify)																		
G. Special District	O. Not for Profit Organization																		
H. Independent School District																			
8.	Select the type from the following list: <ul style="list-style-type: none"> <li>• "New" means a new assistance award.</li> <li>• "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.</li> <li>• "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. If a revision enter the appropriate letter:  <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">A. Increase Award</td> <td style="width: 50%;">B. Decrease Award</td> </tr> <tr> <td>C. Increase Duration</td> <td>D. Decrease Duration</td> </tr> </table> </li> </ul>	A. Increase Award	B. Decrease Award	C. Increase Duration	D. Decrease Duration	18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)												
A. Increase Award	B. Decrease Award																		
C. Increase Duration	D. Decrease Duration																		
9.	Name of Federal agency from which assistance is being requested with this application.																		
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.																		

OMB Approval No. 0348-0044

**BUDGET INFORMATION - Non-Construction Programs**  
**SECTION A - BUDGET SUMMARY**

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		Total (g)
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	
1.		\$	\$	\$	\$	0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	0.00

**SECTION B - BUDGET CATEGORIES**

Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (9)
	(1)	(2)	(3)	(4)	
a. Personnel	\$	\$	\$	\$	0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges (sum of 6a-6h)	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS (sum of 6i and 6j)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	0.00
7. Program Income	\$	\$	\$	\$	0.00

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SECTION C - NON-FEDERAL RESOURCES						
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources		(e) TOTALS	
8.	\$	\$	\$	\$	\$	0.00
9.						0.00
10.						0.00
11.						0.00
12. TOTAL (sum of lines 8-11)	\$	0.00 \$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION D - FORECASTED CASH NEEDS						
Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter		
13. Federal	\$ 0.00 \$	\$	\$	\$		
14. Non-Federal	0.00					
15. TOTAL (sum of lines 13 and 14)	\$ 0.00 \$	0.00 \$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT						
(a) Grant Program	FUTURE FUNDING PERIODS (Years)					
	(b) First	(c) Second	(d) Third	(e) Fourth		
16.	\$	\$	\$	\$	\$	\$
17.						
18.						
19.						
20. TOTAL (sum of lines 16-19)	\$	0.00 \$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION F - OTHER BUDGET INFORMATION						
21. Direct Charges:						
22. Indirect Charges:						
23. Remarks:						



## INSTRUCTIONS FOR THE SF-424A

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**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

## General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

## Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in Column (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

## Lines 1-4, Columns (c) through (g)

For *new applications*, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For *continuing grant program applications*, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For *supplemental grants and changes* to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

## Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-l - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program

**INSTRUCTIONS FOR THE SF-424A (continued)**

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

**Section C. Non-Federal Resources**

**Lines 8-11** Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

**Column (a)** - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

**Column (b)** - Enter the contribution to be made by the applicant.

**Column (c)** - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

**Column (d)** - Enter the amount of cash and in-kind contributions to be made from all other sources.

**Column (e)** - Enter totals of Columns (b), (c), and (d).

**Line 12** - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

**Section D. Forecasted Cash Needs**

**Line 13** - Enter the amount of cash needed by quarter from the grantor agency during the first year.

**Line 14** - Enter the amount of cash from all other sources needed by quarter during the first year.

**Line 15** - Enter the totals of amounts on Lines 13 and 14.

**Section E. Budget Estimates of Federal Funds Needed for Balance of the Project**

**Lines 16-19** - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

**Line 20** - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

**Section F. Other Budget Information**

**Line 21** - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

**Line 22** - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

**Line 23** - Provide any other explanations or comments deemed necessary.

**CERTIFICATIONS AND ASSURANCES****ASSURANCES AND CERTIFICATIONS SIGNATURE PAGE**

The Department of Labor will not award a grant or agreement where the grantee/recipient has failed to accept the ASSURANCES AND CERTIFICATIONS contained in this section. By signing and returning this signature page, the grantee/recipient is providing the certifications set forth below:

- A. Certification Regarding Lobbying, Debarment, Suspension, Other Responsibility Matters - Primary Covered Transactions and Certifications Regarding Drug-Free/Tobacco-Free Workplace,
- B. Certification of Release of Information
- C. Assurances - Non-Construction Programs
- D. Applicant is not a 501(c)(4) organization

APPLICANT NAME and LEGAL ADDRESS:

If there is any reason why one of the assurances or certifications listed cannot be signed, please explain. Applicant need only submit and return this signature page with the grant application. All other instruction shall be kept on file by the applicant.

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SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL

TITLE

---

APPLICANT ORGANIZATION

DATE SUBMITTED

**Please Note:** This signature page and any pertinent attachments which may be required by these assurances and certifications shall be attached to the applicant's Cost Proposal.

**RECOMMENDED FORMAT FOR PLANNED  
QUARTERLY TECHNICAL PERFORMANCE GOALS**  
(data entered cumulatively)

**Performance Goals**

	1ST QTR	2ND QTR	3RD QTR	4TH QTR
<b>Assessments</b>				
<b>Participants Enrolled</b>				
<b>Placed Into Transitional Or Permanent Housing</b>				
<b>Direct Placements Into Unsubsidized Employment</b>				
<b>Assisted Placements Into Unsubsidized Employment</b>				
<b>Combined Placements Into Unsubsidized Employment (Direct &amp; Assisted)</b>				

<b>Cost Per Placement</b>				
<b>Number Retaining Jobs For 90 Days</b>				
<b>Number Retaining Jobs For 180 Days</b>				
<b>Rate of Placement Into Unsubsidized Employment</b>				
<b>Average Hourly Wage At Placement</b>				

**Employability Development Services - (As Applicable)**

<b>Classroom Training</b>				
<b>On-The-Job Training</b>				
<b>Remedial Education</b>				
<b>Vocational Counseling</b>				
<b>Pre-employment Services</b>				
<b>Occupational Skills Training</b>				
_____				
_____				
_____				
_____				

**Planned Expenditures**

	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
<b>Total Expenditures</b>	\$ _____	\$ _____	\$ _____	\$ _____
<b>Administrative Costs</b>	\$ _____	\$ _____	\$ _____	\$ _____
<b>Participant Services*</b>	\$ _____	\$ _____	\$ _____	\$ _____

\*Services may include training and/or supportive.

Direct Cost Descriptions For Applicants and Sub-Applicants\*

Position Title(s)	Annual Salary/Wage Rate	% of Time Charged to Grant	Proposed Administration Costs **	Proposed Program Costs

Sub-Total

Administration

Program

Fringe Benefits For All Positions

Contractual

Travel

Indirect Costs

Equipment

Supplies

Total Costs -----

Administration

Program

\*\* Administrative costs are associated with the supervision and management of the program and do not directly or immediately affect participants.

\* Direct costs for all funded positions for both applicant and sub-applicant(s) must be provided.





## SURVEY ON ENSURING EQUAL OPPORTUNITY

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

**NOTE:** Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

**Purpose:** This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?

Yes  No

2. How many full-time equivalent employees does the applicant have? (Check only one box).

3 or Fewer  15-50  
 4-5  51-100  
 6-14  over 100

3. What is the size of the applicant's annual budget? (Check only one box.)

Less Than \$150,000  
 \$150,000 - \$299,999  
 \$300,000 - \$499,999  
 \$500,000 - \$999,999  
 \$1,000,000 - \$4,999,999  
 \$5,000,000 or more

4. Is the applicant a faith-based/religious organization?

Yes  No

5. Is the applicant a non-religious community-based organization?

Yes  No

6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?

Yes  No

7. Has the applicant ever received a government grant or contract (Federal, State, or local)?

Yes  No

8. Is the applicant a local affiliate of a national organization?

Yes  No

### Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.
2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.
3. Annual budget means the amount of money your organization spends each year on all of its activities.
4. Self-identify.
5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.
6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.
7. Self-explanatory.
8. Self-explanatory

#### **Paperwork Burden Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1225-0083**. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.**

**U.S. Department of Labor**  
**Veterans' Employment and Training Service**

**GLOSSARY OF TERMS**

**Adequate Employment** – See Unsubsidized Employment.

**Administrative Costs** - Administrative costs shall consist of all direct and indirect costs associated with the supervision and management of the program. These costs shall include the administrative costs, both direct and indirect, of sub-recipients and contractors.

**Adult Basic Education** - Education for adults whose inability to speak, read, or write the English language or to effectively reason mathematically, constitutes a substantial impairment of their ability to get or retain employment commensurate with their real ability, which is designed to help eliminate such inability and raise the level, of education of such individuals with a view to making them less likely to become dependent on others, to improve their ability to benefit from occupational training and otherwise increase their opportunities for more productive and profitable employment, and to make them better able to meet their adult responsibilities.

**Ancillary Services** – Employment and training related activities other than core training that may enhance a participant's employability.

**Apprenticeship Training** – A formal occupational training program that combines on-the-job training and related instruction and in which workers learn the practical and conceptual skills required for a skilled occupation, craft, or trade. It may be registered or unregistered.

**Assessment/Intake** - A process for screening individual applicants for program eligibility making the level of need determinations; making an initial determination what services or programs can best benefit the applicants; providing information about services, program eligibility, and the availability of those services, and the routing or selecting individual applicants for particular service delivery or program participation.

**Assisted Placements Into Unsubsidized Employment** - Assisted placements into unsubsidized employment should be recorded where the definition for placement with unsubsidized employment above is met, but the placement was arranged by an agency to which the homeless veteran was referred to.

**Average Hourly Wage At Placement** - The average hourly wage at placement is the average hourly wage rates at placement of all assisted placements plus direct placements.

**Assurance and Certifications** - The act of signifying intent to comply with applicable federal and State laws and regulations as a condition for receiving and expanding USDOL grant funds.

**Barriers to Employment** - Characteristics that may hinder an individual's hiring promotion or participation in the labor force. Identification of these barriers will vary by location and labor market. Some examples of individuals who may face barriers to employment include: single parents, women, displaced homemakers, youth, public assistance recipients, older workers, substance abusers, teenage parents, certain veterans, ethnic minorities, and those with limited English speaking ability or a criminal record or with a lack of education, work experience, credential, child care arrangements, transportation or alternative working parents.

**Campaign Badge veteran** - A veteran who served on active duty during the war (e.g., WWII), action (e.g., Korea, Vietnam), in a campaign, or an expedition for which a campaign badge of an expeditionary medal has been authorized (e.g. Bosnia, Grenada, Haiti, Panama, Southeast Asia, and Somalia).

**Case Management** - A client centered approach in the delivery of intensive services, designed to prepare and coordinate comprehensive employment plans for participants, to assure access to the necessary training and supportive services, and to provide support during program participation and after job placement.

**Case Manager** - One who coordinates, facilitates or provides direct services to a client or trainee from application through placement, post placement follow-up, or other case closing, exclusively, through periodic contact and the provision of appropriate assistance.

**Classroom Training** - Any training of the type normally conducted in an institutional setting, including vocational education, which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs. It may also include training designed to enhance the employability of individuals by upgrading basic skills, throughout the provision of courses such as remedial education, training in the primary language of persons with limited English language proficiency, or English as a second language training.

**Close Out** - Grant close out is the process by which the Federal grantor agency (in the case of VETS grants, Department of Labor) determines that all applicable administrative actions and all required work of the grant have been completed by the grantee and the grantor.

**Cognizant Federal Agency** - The federal agency that is assigned audit or indirect cost rate approval responsibility for a particular recipient organization by the Office of Management and Budget (OMB Circular A-87 and A-102 [20 CFR, Part 97]).

**Community Based Organization** - means a private non-profit organization that is representative of a community or a significant segment of a community and that has demonstrated expertise and effectiveness in the field of workforce investment. Faith-Based organizations are considered a subset.

**Cost Per Placement** - The cost per placement into unsubsidized employment is obtained by dividing the total funds expended by the total of direct placements plus assisted placements.

**Counseling** - A form of assistance which provides guidance in the development of a participant's vocational goals and the means to achieve those goals; and/or assist a participant with the solution to one or more individual problems which may pose a barrier (s) to sustained employment.

**Counselor** - (Employment/Vocational): A trained and qualified professional authorized to provide direct assistance (beyond advising and informing) through planning, testing, training and otherwise readying an individual for sustained employment.

**Customized Training** - A training program designed to meet the special requirements of an employer who has entered into an agreement with a Service Delivery Area to hire individuals who are trained to the employer's specifications. The training may occur at the employer's site or may be provided by a training vendor able to meet the employer's requirements. Such training usually requires a commitment from the employer to hire a specified number of trainees who satisfactorily complete the training.

**Direct Placements Into Unsubsidized Employment** - A direct placement into unsubsidized employment must be a placement made directly by staff with an established employer who covers all employment costs for 20 or more hours per week at or above the minimum wage. Day labor and other very short-term placements should not be recorded as placements into unsubsidized employment.

**Disabled Veteran** - A veteran who is entitled to compensation under laws administered by the Veterans Administration; or an individual who was medically discharged or otherwise released from active duty, due to service-connected disability.

**Disallowed Costs** - Disallowed costs are those charges to a grant that the grantor agency (or its representative) determines to be unallowable in accordance with the applicable Federal Cost Principles or other conditions in the grant.

**Disabled Veterans' Outreach Program** (DVOP) - A program of Federal assistance through grants to States to staff and support in accordance with 38 U.S.C. 4103A, appointed to perform a number of duties chief among which are direct employer contact, particularly with Federal contractors, Federal employers using individualized job development techniques, and with veterans (particularly with disabled veterans) using a case management approach to client-centered services.

**Economically Disadvantaged** - An individual who (a) receives, or is a member of a family which receives, cash welfare payments under a Federal, state, or local welfare program; (b) has, or is a member of a family which has, received a total family income for the six-month period prior to application for the program involved (exclusive of unemployment compensation, child support payments, and welfare payments) which, in relation to family size, was not in excess of the higher of (i) the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673 (2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 9902(2)), or (ii) 70 percent of the lower living standard income level; (c) is receiving (or has been determined within the 6-month period prior to the application for



program involved to be eligible to receive) food stamps pursuant to the Food Stamp Act of 1977; (d) qualifies as a homeless individual under section 103 of the Stewart B. McKinney Homeless Assistance Act; (e) is a foster child on behalf of whom state or local government payments are made or (f) in cases permitted by regulations of the Secretary, is an individual with a disability whose income meets the requirements of clause (a) or (b), but who is a member of a family whose income does not meet such requirements.

**Eligible** - Meeting the minimum requisite qualifications to be considered for the provision of services or entry into a position under a funded program or as required by law.

**Employability Development Services (EDS)** - This includes services and activities that will develop or increase the employability of the participant. Generally, this includes vocational counseling, classroom and on-the-job training, pre-employment services (such as job seeking skills and job search workshops), temporary or trial employment, sheltered work environments and other related services and activities. Planned services should assist the participant in addressing specific barriers to employment and finding a job. These activities may be provided by the applicant or by a Sub-grantee, contractor or another source such as the local Workforce Investment Act program or the DVOP personnel or LVERs. Such services are not mandatory but entries should reflect the services described in the application and the expected number of participants receiving or enrolled in such services during each quarter. Participants may be recorded more than once if they receive more than one service.

**Employment Development Plan (EDP)** - An individualized written plan or intervention strategy for serving an individual which, as a result of an assessment of the veteran's economic needs, vocational interests, aptitudes, work history, etc., defines a reasonable vocational or employment goal and the developmental services or steps required to reach the goal and which documents the accomplishments made by the individual.

**Employment Service** - the state level organization or public labor exchange system affiliated with the Department of Labor's United States Employment Service.

**Enlistments** - Individuals who have expressed an interest, signed up for a workshop or enrollment in the program.

**Entered Employment** - Applicants for service who were placed in jobs or otherwise obtained employment as a result of services used or received.

**Entered Employment Rate** - This is a method used to determine the percentage of participants who become employed. The percentage is calculated by dividing the number of total participants who were enrolled in the program by the number of participants who were placed or entered employment through the program.

**Enrolled Veteran** - Shall be synonymous with the term participant. A veteran who has been determined eligible for services at intake and who is receiving or scheduled to receive core training.

**Faith-Based Organization** – see “community-based organization”.

**Follow-up** - The tracking of clients for a period of time up to 180 days after initial placement, last referral date for services or completion of training programs to determine current status, outcome or whether to offer additional services (such as additional referral, job retention advisement, etc.).

**Full-Time Equivalent (FTE)** – a personnel charge to the grant equal to 2,080 hours per year.

**FY** - Fiscal Year. For federal government purposes, any twelve month period beginning on October 1 and ending on September 30.

**General Equivalency Diploma (GED)** – A high school equivalency diploma that is obtained by passing the General Educational Diploma Equivalency Test that measures the application of skills and knowledge generally associated with four (4) years of traditional high school instruction.

**Grant Officer's Technical Representative (GOTR)** - An individual (usually the DVET) serving on behalf of the Grant Officer who maintains and ensures the integrity of the approved grant agreement by reviewing and making recommendations regarding technical matters not involving a change in scope, cost, or conditions.

**Homeless or homeless individual** – includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either supervised public or private shelter designed to provide temporary living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. [Reference 42 U.S.C., Section 11302 (a)].

**Indirect cost** - A cost that is incurred for a common or joint purpose benefiting more than one cost objective and that is not readily assignable to the cost objective specifically benefited.

**In-kind Services** – Property or services which benefit federally assisted project or program and which are contributed without charge to the grantee.

**Institutional Skills Training** – training conducted in an institutional setting and designed to ensure that individuals acquire the skills, knowledge, and abilities necessary to perform a job or group of jobs in an occupation for which there is a demand.

**Intake** – A process for screening individual applicants for eligibility; making an initial determination whether the program can benefit the applicants; providing information about the program, its services and the availability of those services; and selecting individual applicants for participation in the program.

**Intensive Services** - The provision of concentrated staff services to clients who indicate the need for facilitation or interventions to secure lasting employment. The case management approach to service delivery is a viable model for successfully providing such services and obtaining the clients goals.

**Job Club Activities** - A form of job search assistance provided in a group setting. Usually job clubs provide instruction and assistance in completing job applications and developing resumes and focus on maximizing employment opportunities in the labor market and developing job leads. Many job clubs use telephone banks and provide group support to participants before and after they interview for job openings.

**Job Development** - The process of marketing a program participant to employers, including informing employers about what the participant can do and soliciting a job interview for that individual with the employer (targeted job development); and the development of one or more job openings or training opportunities with one or more employers using a variety of techniques and means of contact.

**Job Placement Services** - Job placement services are geared towards placing participants in jobs and may involve activities such as job search assistance, training, or job development. These services are initiated to enhance and expedite participants' transition from training to employment.

**Job Search Assistance** - An activity, which focuses on building practical skills and knowledge to identify and initiate employer contact and conduct successful interview with employers. Various approaches may be used to include participation in a job club, receive instruction in identifying personal strengths and goals, resume application preparation, learn interview techniques, and receive labor market information. Job search assistance is often self-service activity in which individuals obtain information about specific job openings or general jobs or occupational information.

**Labor Exchange** - Refers to the services provided to job seekers and employers by the State Employment Services Agencies, or other designated entities. Preparatory services to job seekers may include assessment, testing, counseling, provision of labor market information, targeted job development, resulting in job referral and follow-up with former applicants and prospective employers. Employer-oriented services may include accepting job orders, screening applicants, referring qualified applicants and providing follow-up to foster job retention and develop additional job openings or training opportunities.

**Labor Exchange Delivery System (LEDS)** - Describes the system of matching jobs and training opportunities with applicants operating with Federal employment and job training funds.

**Labor Force** - The sum of all civilians classified as employed and unemployed and members of the Armed Forces stationed in the United States. [Bureau of Labor Statistics Bulletin 2175].

**Labor Market Area** – an economically integrated geographic area within which individuals can reside and find employment within a reasonable distance or can readily change employment without changing their place of residence.

**Literacy and Bilingual Training** – See Adult Basic Education.

**Local Veterans' Employment Representative** (LVER) Program - A program of Federal assistance through grants to States to staff in accordance with 38 U.S.C.4104 to perform a number of duties, chief among which are the provision of intensive (case management) services to targeted eligible veterans with emphasis on VA, VR&E, and to functionally supervise without necessarily exercising line supervisor authority over the provision of services to veterans by SDP staff.

**Minimum Economic Need** – the level of wages paid to a program participant that will enable that participant to become economically self-sufficient.

**Minority Veterans** – for the purposes of the HVRP and VWIP programs, veterans who are Workforce Investment Act (WIA) eligible and are members of the following ethnic categories: African American, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander.

**National Veterans' Training Institute** (NVTI) - An agency contracted with USDOL/VETS to develop and provide skills development and enhancement training to individuals who are determined by the Assistant Secretary for Veterans' Employment and Training and who deliver or monitor the provision of employment and training services to veterans (38 U.S.C. 4109).

**Number Retaining Job for 90 Days** -To be counted as retaining a job for 90 days, continuous employment with one or more employers for at least 90 days must be verified and the definition for either direct placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 90 days as long as the client has been steadily employed for that length of time.

**Number Retaining Job For 180 Days** - To be counted as retaining a job for 180 days, continuous employment with one or more employers for at least 180 days must be verified, and the definition for either placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 180 days as long as the client has been steadily employed for that length of time.

**Occupational Skills Training** – Includes both (1) vocational education which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs, and (2) on-the-job training.

**Offender** – Any adult or juvenile who has been subject to any stage of the criminal justice process for whom services under this program may be beneficial or who requires assistance in overcoming artificial barriers to employment resulting from a record of arrest or conviction.

**On-the-Job Training (OJT)** – means training by an employer that is provided to a paid participant while engaged in productive work in a job that: (a) provides knowledge or skill essential to the full and adequate performance of the job; (b) provides reimbursement to the employer of up to 50 percent of the wage rate of the participant, for the extraordinary costs of providing the training and additional supervision related to the participant is being trained, taking into account the content of the training, the prior work experience of the participant, and the service strategy of the participant, as appropriate. Usually in the OJT agreement, there is a promise on the part of the employer to hire the trainee upon successful completion of the training.

**On-Site Industry-Specific Training** – This is training which is specifically tailored to the needs of a particular employer and/or industry. Participants may be trained according to specifications developed by an employer for an occupation or group of occupations at a job site. Such training is usually presented to a group of participants in an environment or job site representative of the actual job/occupation, and there is often an obligation on the part of the employer to hire a certain number of participants who successfully complete the training.

**Outreach** - An active effort by program staff to encourage individuals in the designated service delivery area to avail themselves of program services.

**Outside Funds** – Resources pledged to the grant program that have a quantified dollar value. Such resources may include training funds from programs such as WIA Title I that are put aside for the exclusive use by participants enrolled in a program. Outside funds do not include in-kind services.

**Participant** – means an individual who has been determined to be eligible to participate in and who is receiving services (except follow-up services) under the program. Participation shall be deemed to commence on the first day, following determination of eligibility, on which the individual began receiving subsidized employment, training, or other services provided under the program. An individual who receives only outreach and/or intake assessment services does not meet this definition.

**Participants Enrolled** - A client should be recorded as having been enrolled when an intake form has been completed, and services, referral, and/or employment has been received through the program. This should be an unduplicated count over the year, i.e., each participant is recorded only once, regardless of the number of times she or he receives assistance.

**Participants Services** - This cost includes supportive, training, or social rehabilitation services, which will assist in stabilizing the participant. This category should reflect all costs other than administrative.



**Placed Into Transitional Or Permanent Housing** - A placement into transitional or permanent housing should be recorded when a veteran served by the program upgrades his/her housing situation during the reporting period from shelter/streets to transitional housing or permanent housing or from transitional housing to permanent housing. Placements resulting from referrals by staff shall be counted. This item is however an unduplicated count over the year, except that a participant may be counted once upon entering transitional housing and again upon obtaining permanent housing.

**Placement** - the act of securing unsubsidized employment for or by a participant.

**Placement Rate** - This is a method used to determine the percentage of participants who become employed. The figure is calculated by dividing the number of total participants who were registered for services or enrolled in the program by the number of applicants or program participants who were placed or otherwise entered employment.

**Pre-apprenticeship Training** - Any training designed to increase or upgrade specific academic, or cognitive, or physical skills required as a prerequisite for entry into a specific trade or occupation.

**Pre-enrollment Assessment** - The process of determining the employability and training needs of individuals before enrolling them into the program. Individual factors usually addressed during pre-enrollment assessment include: an evaluation and/or measurement of vocational interests and aptitudes, present abilities, previous education and work experience, income requirements, and personal circumstances.

**Preference** - The application of priorities in the consideration and selection through appointment or assignment of staff to funded positions, or in the provision of direct services and order of referral to listed openings in the order designated by statute regulation, and grant agreement.

**Program Resources** - Includes the total of both program or grant and outside funds.

**Program Year (PY)** - The 12-month period beginning July 1 in the fiscal year for which the appropriation is made, and ending on the following June 30.

**Qualified** - An individual who has been determined to possess the requisite knowledge, skills, and abilities for positions within the context of the selection process used to identify and rank persons possessing those attributes.

**Rate of Placement Into Unsubsidized Employment** - The rate of placement into unsubsidized employment is obtained by dividing the number placed into unsubsidized employment, plus the number of assisted placements into unsubsidized employment by the number of clients enrolled.

**Recently Separated Veteran** - Refers to an individual who applies for program participation or assistance within 48 months of separation from active U.S. military service [29 U.S.C. 1503 (27) (c)].

**Remedial Education** – Education instruction, particularly in basic skills, to raise an individual's general competency level in order to succeed in vocational education or skill training programs, or employment.

**Service Connected Disabled** - Refers to (1) a veteran who is entitled to compensation under laws administered by the Department of Veterans' Affairs, or (2) an individual who was discharged or released from active duty because of a service-connected disability (38 U.S.C. 4211 (3); 29 U.S.C., Chapter 19, section 1503 (27) (C))

**Service Delivery Point (SDP)** - Includes offices of the public employment delivery system operated directly or by contract with the State Workforce Agency as grantee within a State and may include One -Stop Career Centers, local employment service offices, and any satellite or itinerant offices at which labor exchange services are available.

**Solicitation for Grant Applications (SGA)** - A document which provides the requirements and instructions for the submission by eligible applicants identified in the document's text of requests for Federal domestic assistance (funds) for one or more programs or grants-in-aid.

**State Workforce Agency (SWA)** - The State level organization, as affiliated with the former United States Employment Service.

**Subgrant** – An award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee.

**Subgrantee** – The government or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided.

**Suitable Employment** – See "Unsubsidized Employment".

**Substance Abuser** – An individual dependent on alcohol or drugs, especially narcotics, whose dependency constitutes or results in a substantial barrier to employment.

**Supportive Services** – means services which are necessary to enable an individual eligible for training, but who cannot afford to pay for such services, to participate in a training program funded under the grant. Such supportive services may include transportation, health care, financial assistance (except as a post-termination service), drug and alcohol abuse counseling and referral, individual and family counseling, special services and materials for individuals with disabilities, job coaches, child care and dependent care, temporary shelter, financial counseling, and other reasonable expenses required for participation in the training program and may be provided in-kind or through cash assistance.

**Targeted Job Development** - The identification and marketing of a group of qualified applicants with similar occupations or employment barriers requiring personal visitation/phone contact with those employers likely to employ these individuals.

**Total Planned Expenditures** - Identified forecasted financial needs to accomplish programmatic objectives broken down into fiscal quarters.

**Unsubsidized Employment** - Employment not financed from funds provided under the grant. In the grant program the term "adequate" or "suitable" employment is also used to mean placement in unsubsidized employment which pays an income adequate to accommodate the participants' minimum economic needs.

**Upgrading or Retraining** - Training given to an individual who needs such training to advance above an entry level or dead-end position. This training shall include assisting veterans in acquiring needed state certification to be employed in the same field as they were trained in the military (i.e., Commercial Truck Driving License (CDL), Emergency Medical Technician (EMT), Airframe & Power Plant (A&P), Teaching Certificate, etc.)

**Veteran** - An individual who served in the United States active military, naval, or air service, and who was discharged or released there from under conditions other than dishonorable (29 U.S.C. Chapter 19, section 1503 (27) (A) [for WIA, Section 168 (VWIP) and WIA, Title I training/services]).

**Veterans' Workforce Investment Program (VWIP)** - Competitively awarded employment and training grants to meet the needs of veterans with significant barriers to employment; with service-connected disabilities; who served on active duty in the armed forces during a campaign or expedition for which a campaign badge has been authorized; and recently separated veterans. The U.S. Department of Labor, Veterans' Employment and Training Service awards VWIP grants as authorized under the Workforce Investment Act (WIA), Section 168.

**Vocational Exploration Training** - Through assessments such as interest inventories and/or counseling, a process of identifying occupations or occupational areas in which a person may find satisfaction and potential, and for which his or her aptitudes and other qualifications may be appropriate.

**Vocational Guidance** - The provision of information, suggestions, and advice through discussion with individuals who are considering a geographical or vocational choice or change, relating to their career decision.

**Wartime Veteran** - See "campaign veteran above."

**Welfare and/or Public Assistance recipient** - An individual who, during the course of the program year, receives or is a member of a family who receives cash welfare or public assistance payments under a Federal, state, or local welfare program.

**Workforce Investment Act** (WIA) – The purpose of this Act is to establish programs to prepare youth and unskilled adults for entry into the labor force and to afford job training to those economically disadvantaged individuals and other individuals, including veterans, who face serious barriers to employment and who are in need of such training to obtain prospective employment. The Act requires the Assistant Secretary for Veterans' Employment and Training to consult with the Secretary of the Department of Veterans Affairs to ensure that programs funded under VWIP of this Act meet the employment and training needs of service-connected disabled, Campaign, and recently separated veterans and are coordinated, to the maximum extent feasible, with related programs and activities.

**Work Experience** – A temporary activity (six months or less) which provides an individual with the opportunity to acquire the skills and knowledge necessary to perform a job, including appropriate work habits and behaviors, and which may be combined with classroom or other training. When wages are paid to a participant on work experience and when such wages are wholly paid for under WIA, the participant may not receive this training under a private, for profit employer.

**Youth** – An individual between 20 and 24 years of age.

USDOL/VETSLIST OF COMMON ACRONYMS

ADVET	Assistant Director for Veterans' Employment and Training
ASVET	Assistant Secretary (of Labor) for Veterans' Employment and Training
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CWT	Compensated Work Therapy
DOD	Department of Defense
DV	Disabled Veteran
DVA	Department of Veterans Affairs (see also VA)
DVET	Director for Veterans' Employment and Training Service
DVOP	Disabled Veterans' Outreach Program
DTAP	Disabled Veterans' Transition Assistance Program
EDP	Employment Development Plan
ES	Employment Service
ETA	Employment and Training Administration
FARS	Financial Accounting and Reporting System
FCJL	Federal Contractor Job Listing
FCP	Federal Contracting Program
FEMA	Federal Emergency Management Administration
FY	Fiscal Year
GOTR	Grant Officer's Technical Representative
GPRA	Government Performance and Results Act of 1994
HHS	Department of Health and Human Services
HHS/PMS	Health and Human Services/Payment Management System
HUD	Department of Housing and Urban Development
HVCAA	Homeless Veterans' Comprehensive Assistance Act - Title 38 USC, Section 2001
HVRP	Homeless Veterans' Reintegration Project
IEP	Individual Employment Plan
ISS	Individual Support System
IV-TP	Incarcerated Veterans' Transition Program
LEDS	Labor Exchange Delivery System
LESO	Local Employment Service Office
LMI	Labor Market Information
LVER	Local Veterans' Employment Representative
MHAA	McKinney-Vento Homeless Assistance Act - Title 42 USC, Section 11302(a)
MOU	Memorandum of Understanding
NOGA	Notice of Grant Award
NVTI	National Veterans' Training Institute
OASAM	Office of the Assistant Secretary for Administration and Management
OASVET	Office of the Assistant Secretary (of Labor) for Veterans' Employment and Training
OCD	Office of Cost Determination
OMB	Office of Management and Budget
OPM	Office of Personnel Management
OJT	On-the-Job-Training
PAC	Post Award Conference
PB	Personnel Benefits
PL	Public Law
PS	Personal Services



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PY	Program Year
RAVET	Regional Administrator for Veterans' Employment and Training
SDP	Service Delivery Point
SDV	Special Disabled Veteran
SF	Standard Form
SGA	Solicitation For Grant Applications
SSA	Social Security Administration
SWA	State Workforce Agency
TAP	Transition Assistance Program
UCX	Unemployment Compensation (Insurance) for ex-service members
UI	Unemployment Insurance
USC	United States Code
USDOL	United States Department of Labor
VA	Department of Veterans Affairs
VARO	Veterans' Administration Regional Office
VAMC	Veterans' Administration Medical Center
VETS	Veterans' Employment and Training Service
VEV	Vietnam-Era Veteran
VOE	Veterans and Other Eligible Persons
VPL	Veterans Program Letter
VR&E	Vocational Rehabilitation and Employment (formerly VR&C)
VSO	Veteran Service Organization
VWIP	Veterans' Workforce Investment Program (WIA, Section 168)
WIA	Workforce Investment Act of 1998
WIB	Workforce Investment Board

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## DEPARTMENT OF LABOR

### Veterans Employment and Training Service

#### Non-Urban Homeless Veterans' Reintegration Program (HVRP) Grants for Program Year (PY) 2004

**Funding Opportunity:** Non-Urban Homeless Veterans' Reintegration Program (HVRP) Grants for Program Year (PY) 2004.

**Announcement Type:** Initial Solicitation for Grant Applications (SGA).

**Funding Opportunity Number:** SGA 04-04.

**Catalogue of Federal Domestic Assistance #:** 17-805.

**Date(s):** Applications are due on May 13, 2004. Period of Performance is PY 2004, July 1, 2004 through June 30, 2005.

**Executive Summary (Applicants For Grant Funds Should Read This Notice In Its Entirety):** The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with the requirements of 38 U.S.C. 2021, as added by section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to expedite the reintegration of homeless veterans into the labor force.

The Homeless Veterans' Reintegration Program (HVRP) grants are designated in three (3) award categories: urban, non-urban, and intermediaries. Separate Solicitations for Grant Applications (SGAs) are being issued for each grant category. This is the solicitation for "Non-Urban HVRP grants." Previous HVRP grants have provided valuable information on approaches and techniques that work in the different environments. The only jurisdictions that are eligible to be served through this non-urban competition for HVRPs are the metropolitan areas *outside* of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico (*see* Appendix I).

HVRP grants are intended to address two objectives: (1) To provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (2) to stimulate the development of effective service delivery systems that will

address the complex problems facing homeless veterans. Successful applicants will design programs that assist eligible veterans by providing job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. Successful programs will also be designed to be flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce.

Under this solicitation covering Fiscal Year (FY) 2004, VETS anticipates that up to \$1,600,000 will be available for grant awards up to a maximum of \$200,000 for each grant award. VETS expects to award approximately eight (8) grants. This notice contains all of the necessary information and forms to apply for grant funding. The period of performance for these PY 2004 grants will be July 1, 2004 through June 30, 2005. Two (2) optional years of funding may be available, depending upon Congressional funding appropriations, the agency's decision to exercise the optional year(s) of funding, and satisfactory grantee performance.

#### I. Funding Opportunity Description

The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with the requirements of 38 U.S.C. 2021, as added by section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to provide job training, counseling, and placement services (including job readiness, literacy training, and skills training) to expedite the reintegration of homeless veterans into the labor force.

##### 1. Program Concept and Emphasis

HVRP grants are intended to address two objectives: (a) to provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (b) to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

For this Fiscal Year (FY) 2004 grant solicitation, VETS seeks applicants that will provide direct services through a case management approach that networks with Federal, State, and local resources for veteran support programs. Successful applicants will have clear

strategies for employment and retention of employment for homeless veterans. Successful applicants will design programs that assist eligible veterans by providing job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. Successful applicants will also design programs that are flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce. The HVRP in PY 2004 will seek to continue to strengthen development of effective service delivery systems, to provide comprehensive services through a case management approach that address complex problems facing eligible veterans trying to transition into gainful employment, and to improve strategies for employment and retention in employment.

The only jurisdictions eligible to be served through this Non-Urban HVRP competition in PY 2004 are the metropolitan areas *outside* of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico (*See* Appendix I).

##### 2. Community Awareness Activities

In order to promote networking between the HVRP funded program and local service providers (and thereby eliminate gaps or duplication in services and enhance the provision of assistance to participants), the grantee must provide project orientation workshops and/or program awareness activities that it determines are the most feasible for the types of providers listed below. Grantees are encouraged to demonstrate strategies for incorporating small faith-based and community organizations (defined as organizations with social services budgets of approximately \$300,000 or seven (7) or fewer full-time employees) into their outreach plans. Project orientation workshops conducted by grantees have been an effective means of sharing information and informing the community of the availability of other services; they are encouraged but not mandatory. Rather, grantees will have the flexibility to attend service provider meetings, seminars, and conferences, to outstation staff, and to develop individual service contracts as well as to involve other agencies in program planning.

*The grantee will be responsible for providing project awareness, program information, and orientation activities to the following:*

A. Direct providers of services to homeless veterans including shelter and

soup kitchen operators: to make them aware of the services available to homeless veterans to make them job-ready and to aid their placement into jobs.

B. Federal, State, and local entitlement and social service agencies such as the Social Security Administration (SSA), Department of Veterans Affairs (DVA), State Workforce Agencies (SWAs) and their local One-Stop Centers (which integrate Workforce Investment Act, labor exchange, and other employment and social services), mental health services, and healthcare detoxification facilities: to familiarize them with the nature and needs of homeless veterans.

C. Civic and private sector groups, in particular Veterans' Service Organizations, support groups, job training and employment services, and community-based organizations (including faith-based organizations): to provide information on homeless veterans and their needs.

The grantee will also be responsible for participating in "Stand Down" events. A "Stand Down" is an event held in a locality, usually for three (3) days, where services are provided to homeless veterans along with shelter, meals, clothing, employment services, and medical attention. This type of event is mostly a volunteer effort, which is organized within a community and brings service providers together such as the Department of Veterans Affairs (DVA), Disabled Veterans' Outreach Program Specialists (DVOPs) and Local Veterans' Employment Representatives (LVERs) from the State Workforce Agencies, Veteran Service Organizations, military personnel, civic leaders, and a variety of other interested persons, groups, and organizations. Many services are provided on-site with referrals also made for continued assistance after the Stand Down event. These events can often be the catalyst that enables homeless veterans to get back into mainstream society. The Department of Labor has supported replication of these events and many have been held throughout the nation.

*In areas where an HVRP is operating, grantees are expected and encouraged to participate fully and offer their services for all locally planned Stand Down event(s).* Toward this end, up to \$5,000 of the currently requested HVRP grant funds may be used to supplement the Stand Down efforts, where funds are not otherwise available, and may be requested in the budget and explained in the budget narrative.

### 3. Scope of Program Design

*The project design must include the following services:*

A. Outreach, intake, assessment, peer counseling to the degree practical, employment services, and follow-up support services to enhance retention in employment. Program staff providing outreach services should have experience in dealing with, and an understanding of the needs of, homeless veterans.

B. Provision of or referral to employment services such as: job search workshops, job counseling, assessment of skills, resume writing techniques, interviewing skills, subsidized trial employment (work experience), job development services, job placement into unsubsidized employment, job placement follow-up services to enhance retention in employment.

C. Provision of or referral to training services such as: basic skills instruction, remedial education activities, life skills and money management training, on-the-job training, classroom training, vocational training, specialized and/or licensing training programs, and other formal training programs as deemed appropriate to benefit the participant. At least 80% of the enrolled HVRP participants must participate in training activities.

D. Grantees will perform a preliminary assessment of each participant's eligibility for Department of Veterans Affairs (DVA) service-connected disability, compensation, and/or pension benefits. As appropriate, grantees will work with the Veterans Service Organizations or refer the participants to DVA in order to file a claim for compensation or pension. Grantees will track progress of claims and report outcomes in case management records.

E. Coordination with veterans' services programs, including: Disabled Veterans' Outreach Program Specialists (DVOPs), Local Veterans' Employment Representatives (LVERs) in the State Workforce Agencies (SWAs) or in the workforce development system's One-Stop Centers, as well as Veterans' Workforce Investment Programs (VWIPs), Department of Veterans Affairs (DVA) services, including its Health Care for Homeless Veterans, Domiciliary Care, Regional Benefits Assistance Program, and Transitional Housing under Homeless Provider Grant and per diem programs.

F. Networking with Veterans' Service Organizations such as: The American Legion, Disabled American Veterans, Veterans of Foreign Wars, Vietnam

Veterans of America, the American Veterans (AMVETS).

G. Referral as necessary to health care, counseling, and rehabilitative services including, but not limited to: alcohol and drug rehabilitation, therapeutic services, Post Traumatic Stress Disorder (PTSD) services, mental health services, as well as coordination with McKinney Homeless Assistance Act (MHAA) Title VI programs for health care for the homeless, and health care programs under the Homeless Veterans Comprehensive Assistance Act of 2001.

H. Referral to housing assistance, as appropriate, provided by: local shelters, Federal Emergency Management Administration (FEMA) food and shelter programs, transitional housing programs and single room occupancy housing programs funded under MHAA Title IV (and under HVCAA), and permanent housing programs for disabled homeless persons funded under MHAA Title IV (and under HVCAA).

4. *Results-Oriented Model:* No specific model is mandatory, but the applicant must design a program that is responsive to the needs of the local community and achieves the HVRP objectives. The HVRP objectives are to successfully reintegrate homeless veterans into the workforce and to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

Under the Government Performance and Results Act (GPRA), Congress and the public are looking for program results rather than program processes. The outcome measurement established for HVRP grants is for grantees to meet a minimum entered employment rate of 58%, determined by dividing the number of entered employments by the number of HVRP enrollments. (Actual performance outcomes will be reported quarterly in spreadsheet format to be provided to grantees at the post award conference.) While the percentage of HVRP enrollments that entered employment is an important outcome, it is also necessary to evaluate and measure the program long-term results, through the 90-day and 180-day follow-up period, to determine the quality and success of the program.

The applicant's program should be based on a results-oriented model. The first phase of activity should consist of the level of outreach necessary to introduce the program to eligible homeless veterans. Outreach also includes establishing contact with other agencies that encounter homeless veterans. Once the eligible homeless veterans have been identified, an assessment must be made of each

individual's abilities, interests, needs, and barriers to employment. In some cases, homeless veterans may require referrals to services such as rehabilitation, drug or alcohol treatment, or a temporary shelter before they can be enrolled into HVRP. Once the eligible homeless veteran is "stabilized," the assessment must concentrate on the employability of the individual and whether the individual is to be enrolled into the HVRP program. A determination should be made as to whether the individual would benefit from pre-employment preparation such as resume writing, job search workshops, related counseling, and case management, or possibly an initial entry into the job market through temporary jobs. Additionally, sheltered work environments, classroom training and/or on-the-job training must be evaluated. Such services should be noted in an Employability Development Plan to facilitate the staff's successful monitoring of the plan. Entry into full-time employment or a specific job-training program should follow, in keeping with the overall objective of HVRP, to bring the participant closer to self-sufficiency. Supportive services may assist the HVRP enrolled participant at this point or even earlier.

Job development, a crucial part of the employability process, is usually when there are no competitive job openings that the HVRP enrolled participant is qualified to apply for, therefore, a job opportunity is created or developed specifically for that HVRP enrolled participant with an employer. HVRP enrolled participants who are ready to enter employment and/or who are in need of intensive case management services are to be referred to the DVOP and LVER staff at a One-Stop Center. DVOP and LVER staff are able to provide HVRP enrolled participants the following services: job development, employment services, case management and career counseling. Most DVOP and LVER staff received training in case management at the National Veterans' Training Institute. All DVOP and LVER staff provide employment related services to veterans who are most at a disadvantage in the labor market. VETS' urges working hand-in-hand with DVOP/LVER staff to achieve economies of resources.

The applicant's program must include tracking of program participants. Tracking should begin with the referral to employment and continue through the 90-day and 180-day follow-up periods after entering employment to determine whether the veteran is in the same or similar job. It is important that the grantee maintain contact with

veterans after placement to ensure that employment-related problems are addressed. The 90-day and 180-day follow-ups are fundamental to assessing program results. Grantees need to budget for 90-day and 180-day follow-up activity so that it can be performed for those HVRP enrolled participants placed at or near the end of the grant performance period. All grantees, prior to the end of the grant performance period, must obligate sufficient funds to ensure that follow-up activities are completed. Such results will be reported in the final technical performance report.

## II. Award Information

1. *Type of Funding Instrument:* One (1) year grant.

2. *Funding Levels:* The total funding available for this Non-Urban HVRP solicitation is up to \$1,600,000. It is anticipated that approximately eight (8) awards will be made under this solicitation. Awards are expected to range from \$100,000 to a maximum of \$200,000. The Department of Labor reserves the right to negotiate the amounts to be awarded under this competition. Please be advised that requests exceeding \$200,000 will be considered non-responsive.

3. *Period of Performance:* The period of performance will be for twelve (12) months from date of award unless modified by the Grant Officer. It is expected that successful applicants will begin program operations under this solicitation on July 1, 2004. All program funds must be obligated by June 30, 2005; a limited amount of funds may be obligated and reserved for follow-up activities and closeout.

4. *Optional Year Funding:* Should Congress appropriate additional funds for this purpose, VETS may consider an optional two (2) years of funding. The Government does *not*, however, guarantee optional year funding for any grantee. In deciding whether to exercise any optional year(s) of funding, VETS will consider grantee performance during the previous period of operations as follows:

A. The grantee must meet, at minimum, 85% of planned goals for Federal expenditures, enrollments, and placements into employment in each quarter and/or at least 85% of planned cumulative goals by the end of the third quarter; and

B. The grantee must be in compliance with all terms identified in the Solicitation for Grant Application (SGA) and grant award document; and

C. All program and fiscal reports must have been submitted by the established

due dates and must be verifiable for accuracy.

## III. Eligibility Information

1. *Eligible Applicants:* Applications for funds will be accepted from State and local Workforce Investment Boards, local public agencies, for-profit/commercial entities, and nonprofit organizations, including faith-based and community organizations. Applicants must have a familiarity with the area and population to be served and the ability to administer an effective and timely program.

Eligible applicants will generally fall into one of the following categories:

- State and local Workforce Investment Boards (WIBs), established under sections 111 and 117 of the Workforce Investment Act.
- Public agencies, meaning any public agency of a State or of a general purpose political subdivision of a State that has the power to levy taxes and spend funds, as well as general corporate and police powers. (This typically refers to cities and counties.) A State agency may propose in its application to serve one or more of the potential jurisdictions located in its State. This does not preclude a city or county agency from submitting an application to serve its own jurisdiction.
- For-profit/commercial entities.
- Nonprofit organizations. If claiming 501(c)(3) status, the Internal Revenue Service statement indicating 501(c)(3) status approval must be submitted.

**Note:** Qualifying applications from grantees in the below listed States that are not currently receiving HVRP funds (and are *not* listed on Appendix I) may receive priority funding over applicants in those States that are currently receiving HVRP funds: Alaska, Idaho, Montana, North Dakota, South Dakota, Vermont, and Wyoming.

2. *Cost Sharing:* Cost sharing and/or matching funds are *not* required. However, we do encourage the use of sharing and/or matching funds.

3. *Other Eligibility Criteria:*

A. This SGA is for Non-Urban HVRP grants. Separate SGAs for urban and intermediaries HVRP grants have been simultaneously issued.

B. The proposal must include an outreach component that uses either DVOP/LVER staff or a trained outreach cadre. Programs must be "employment focused." The services provided must be directed toward: (1) Increasing the employability of homeless veterans through training or arranging for the provision of services that will enable them to work; and (2) matching homeless veterans with potential employers.

C. Applicants are encouraged to utilize, through partnerships or sub-awards, experienced public agencies, private nonprofit organizations, private businesses, faith-based and community organizations, and colleges and universities (especially those with traditionally high enrollments of minorities) that have an understanding of unemployment and the barriers to employment unique to homeless veterans, a familiarity with the area to be served, and the capability to effectively provide the necessary services.

D. To be eligible for participation under this grant an individual must be homeless and a veteran defined as follows:

- The term "homeless or homeless individual" includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either a supervised public or private shelter designed to provide temporary living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. (42 U.S.C. 11302 (a)).

- The term "veteran" means a person who served in the active military, naval, or air service, and who was discharged or released under conditions other than dishonorable. (38 U.S.C. 101(2))

#### IV. Application and Submission Information

1. *Address to Request an Application and Amendments:* Application announcements or forms will not be mailed. The **Federal Register** may be obtained from your nearest government office or library. Additional application packages may be obtained from the VETS Web site at <http://www.dol.gov/vets> and at <http://www.fedgrants.gov/>. The application forms and their instructions, and other pertinent materials are included in the Appendices. If copies of the standard forms are needed, they can also be downloaded from [http://www.whitehouse.gov/omb/grants/grants\\_forms.html](http://www.whitehouse.gov/omb/grants/grants_forms.html).

To receive amendments to this Solicitation, all applicants must register their name and address in writing with the Grant Officer at the following address: U.S. Department of Labor, Procurement Services Center, Attn: Cassandra Mitchell, Reference SGA 04-04, 200 Constitution Avenue, NW., Room N-5416, Washington, DC 20210,

Phone Number: (202) 693-4570 (not a toll free number).

#### 2. *Content and Form of Application:*

The grant application must consist of three (3) separate and distinct sections: The Executive Summary, the Technical Proposal, and the Cost Proposal. The information provided in these three (3) sections is essential to gain an understanding of the programmatic and fiscal contents of the grant proposal.

*A complete grant application package must include:*

- An original blue ink-signed and two (2) copies of the cover letter.
- An original and two (2) copies of the Executive Summary (see below).
- An original and two (2) copies of the Technical Proposal (see below) that includes a completed Technical Performance Goals Form (Appendix D).
- An original and two (2) copies of the Cost Proposal (see below) that includes an original blue ink-signed Application for Federal Assistance, SF-424 (Appendix A), a Budget Narrative, Budget Information Sheet SF-424A (Appendix B), an original blue ink-signed and Assurances and Certifications Signature Page (Appendix C), Direct Cost Description for Applicants and Sub-applicants (Appendix E), and a completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F).

A. *Section 1—Executive Summary:* A one to two page "Executive Summary" reflecting the grantees overall strategy, timeline, and outcomes to be achieved in their grant proposal is required. This executive summary does not count against the 15-page limit. The executive summary should include:

- The proposed area to be served through the activities of this grant.
- Years of grantee's service to the residents in the proposed area to be served.
- Projects and activities that will expedite the reintegration of homeless veterans into the workforce.
- Summary of outcomes, benefits, and value added by the project.

B. *Section 2—The Technical Proposal* consists of a narrative proposal that demonstrates the need for this particular grant program, the services and activities proposed to obtain successful outcomes for the homeless veterans to be served; and the applicant's ability to accomplish the expected outcomes of the proposed project design.

*The technical proposal narrative must not exceed fifteen (15) pages double-spaced, font size no less than 11 pt., and typewritten on one (1) side of the paper only.*

**Note:** Resumes, charts, standard forms, transmittal letters, Memorandums of

Understanding, agreements, lists of contracts and grants, and letters of support are not included in the page count. If provided, include these documents as attachments to the technical proposal.

*Required Content:* There are program activities that all applications must contain to be found technically acceptable under this SGA. Programs must be "employment focused" and must be responsive to the rating criteria in Section V(1). *The required activities are:* outreach, pre-enrollment assessments, employment development plans for all clients, case management, job placement and job retention follow-up (at 90 and 180 days) after individual enters employment, utilization/coordination of services with DVOP and LVER staff, and community linkages with other programs and services that provide support to homeless veterans.

*The following format for the technical proposal is recommended:*

*Need for the program:* The applicant must identify the geographical area to be served and provide an estimate of the number of homeless veterans in the designated geographical area. Include poverty and unemployment rates in the area and identify the disparities in the local community infrastructure that exacerbate the employment barriers faced by the targeted veterans. Include labor market information and job opportunities in the employment fields and industries that are in demand in the geographical area to be served.

*Approach or strategy to increase employment and job retention:* Applicants must be responsive to the Rating Criteria contained in Section V(1) and address all of the rating factors as thoroughly as possible in the narrative.

*The applicant must:*

- Describe the specific supportive employment and training services to be provided under this grant and the sequence or flow of such services;
- Indicate the type(s) of training that will be provided and how it relates to the jobs that are in demand, length of training, training curriculum, and how the training will improve the eligible veterans' employment opportunities within that geographical area;
- Provide a follow-up plan that addresses retention after 90 and 180 days with participants who have entered employment;
- Include the completed Planned Quarterly Technical Performance Goals (and planned expenditures) form listed in Appendix D.

*Linkages with facilities that serve homeless veterans:* Describe program and resource linkages with other facilities that will be involved in identifying potential clients for this



program. Describe any networks with other related resources and/or other programs that serve homeless veterans. Indicate how the program will be coordinated with any efforts that are conducted by public and private agencies in the community. If a Memorandum of Understanding (MOU) or other service agreement with service providers exists, copies should be provided.

**Linkages with other providers of employment and training services to homeless veterans:** Describe the networks the program will have with other providers of services to homeless veterans; include a description of the relationship with other employment and training programs such as Disabled Veterans' Outreach Program (DVOP), the Local Veterans' Employment Representative (LVER) program, and programs under the Workforce Investment Act such as the Veterans' Workforce Investment Program (VWIP); and list the type of services that will be provided by each. Note the type of agreement in place, if applicable. Linkages with the workforce development system must be delineated. Describe any networks with any other resources and/or other programs for homeless veterans. Indicate how the program will be coordinated with any efforts for the homeless that are conducted by agencies in the community. Indicate how the applicant will coordinate with any "continuum of care" efforts for the homeless among agencies in the community. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Linkages with other Federal agencies:** Describe program and resource linkages with the Department of Housing and Urban Development (HUD), Department of Health and Human Services (HHS), and Department of Veterans Affairs (DVA) including the Compensated Work Therapy (CWT) and per diem programs. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Proposed supportive service strategy for veterans:** Describe how supportive service resources for veterans will be obtained and used. If resources are provided by other sources or linkages, such as Federal, State, local, or faith-based and community programs, the applicant must fully explain the use of these resources and how they will be applied. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

**Organizational capability to provide required program activities:** The applicant's relevant current or prior experience in operating employment and training programs should be clearly described. A summary narrative of program experience and employment and training performance outcomes is required. *The applicant should provide information showing outcomes of all past employment and training programs in terms of enrollments and placements.* An applicant that has operated a HVRP, other Homeless Employment and Training program, or VWIP program must include the final or most recent technical performance reports. The applicant must also provide evidence of key staff capability. It is preferred that the grantee be well established and not in the start-up phase or process.

**Proposed housing strategy for homeless veterans:** Describe how housing resources for eligible homeless veterans will be obtained or accessed. These resources must be from linkages or sources other than the HVRP grant such as HUD, HHS, community housing resources, DVA leasing, or other programs.

**C. Section 3—The Cost Proposal must contain the following:**

(1) Standard Form SF-424, "Application for Federal Assistance" (with the original signed in blue-ink) (Appendix A) must be completed;

The Catalog of Federal Domestic Assistance number for this program is 17.805 and it must be entered on the SF-424, in Block 10.

The organizational unit section of Block 5 of the SF-424 must contain the Dun and Bradstreet Number (DUNS) of the applicant. Beginning October 1, 2003, all applicants for Federal grant funding opportunities are required to include a DUNS number with their application. See OMB Notice of Final Policy Issuance, 68 FR 38402 (June 27, 2003). Applicants' DUNS number should be entered into Block 5 of SF-424. The DUNS number is a nine-digit identification number that uniquely identifies business entities. There is no charge for obtaining a DUNS number. To obtain a DUNS number call 1-866-705-5711 or access the following Web site: <http://www.dunandbradstreet.com>.

Requests for exemption from the DUNS number requirement must be made to the Office of Management and Budget.

(2) Standard Form SF-424A "Budget Information Sheet" (Appendix B) must be included;

(3) As an attachment to SF-424A, the applicant must provide a detailed cost breakout of each line item on the Budget Information Sheet. Please label this page

or pages the "Budget Narrative" and ensure that costs reported on the SF-424A correspond accurately with the Budget Narrative;

*The Budget Narrative must include, at a minimum:*

- Breakout of all personnel costs by position, title, salary rates, and percent of time of each position to be devoted to the proposed project (including sub-awardees/contractors) by completing the "Direct Cost Descriptions for Applicants and Sub-Applicants" form (Appendix E);
  - Explanation and breakout of extraordinary fringe benefit rates and associated charges (*i.e.*, rates exceeding 35% of salaries and wages);
  - Explanation of the purpose and composition of, and method used to derive the costs of, each of the following: Travel, equipment, supplies, sub-awards/contracts, and any other costs. The applicant must include costs of any required travel described in this Solicitation. Mileage charges may not exceed 37.5 cents per mile, or the current Federal rate;
  - All associated costs for retaining participant information pertinent to the follow-up survey, 180 days after the program performance period ends;
  - Description/specification of, and justification for, equipment purchases, if any. Tangible, non-expendable, personal property having a useful life of more than one year and a unit acquisition cost of \$5,000 or more per unit must be specifically identified; and
  - Identification of all sources of leveraged or matching funds and an explanation of the derivation of the value of matching/in-kind services. If resources/matching funds and/or the value of in-kind contributions are made available, please show in Section B of the Budget Information Sheet.
- (4) A completed Assurance and Certification signature page (Appendix C) must be submitted;
- (5) All applicants must submit evidence of satisfactory financial management capability, which must include recent (within 18 months) financial and/or audit statements. Grantees are required to utilize Generally Accepted Accounting Practices (GAAP), maintain a separate accounting for these grant funds, and have a checking account;
- (6) All applicants must include, as a separate appendix, a list of all employment and training government grants and contracts that it has had in the past three (3) years, including grant/contract officer contact information. VETS reserves the right to have a DOL representative review and verify this data;

(7) A completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F) must be provided.

3. *Submission Dates and Times* (Acceptable Methods of Submission): The grant application package must be received at the designated place by the date and time specified or it will not be considered. Any application received at the Office of Procurement Services after 4:45 p.m. ET, May 13, 2004, will not be considered unless it is received before the award is made and:

- It is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the U.S. Department of Labor at the address indicated; or
- It was sent by registered or certified mail not later than the fifth calendar day before May 13, 2004; or
- It was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5:00 p.m. at the place of mailing two (2) working days, excluding weekends and Federal holidays, prior to May 13, 2004.

4. *Intergovernmental Review*: Not Applicable.

5. *Funding Restrictions*:

A. Proposals exceeding \$200,000 will be considered non-responsive.

B. There is a limit of one (1) application per submitting organization and location. If two (2) applications from the same organization for the same location are submitted, the application with the later date will be considered non-responsive.

C. Due to the limited availability of funding, if an organization was awarded Fiscal Year 2003 HVRP funds for a specific location and will be receiving second and possible third year funding, that organization at that specific location will be considered ineligible to compete for FY 2004 HVRP funds.

D. There will not be reimbursement of pre-award costs unless specifically agreed upon in writing by the Department of Labor.

E. The only potential jurisdictions that will be served through this non-urban competition for HVRPs in FY 2004 are the metropolitan areas outside of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico (see Appendix I).

F. Entities described in section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities are not eligible to receive funds under this announcement because section 18 of the Lobbying Disclosure Act of 1995, Public Law No. 104-65, 109 Stat. 691, prohibits the award of Federal funds to these entities.

G. The government is prohibited from directly funding religious activity.<sup>1</sup> These grants may not be used for religious instruction, worship, prayer, proselytizing or other inherently religious practices. Neutral, secular criteria that neither favor nor disfavor religion must be employed in the selection of grant and sub-grant recipients. In addition, under the Workforce Investment Act (WIA) and Department of Labor regulations implementing the WIA, a recipient may not train a participant in religious activities, or permit participants to construct, operate, or maintain any part of a facility that is primarily used or devoted to religious instruction or worship. Under WIA, "no individual shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with, any such program or activity because of race, color, religion, sex (except as otherwise permitted under Title IX of the Education Amendments of 1972), national origin, age, disability, or political affiliation or belief."

H. *Limitations on Administrative and Indirect Costs*:

• Administrative costs, which consist of all direct and indirect costs associated with the supervision and management of the program, are limited to and will not exceed 20% of the total grant award.

• Indirect costs claimed by the applicant must be based on a Federally approved rate. A copy of the negotiated approved and signed indirect cost negotiation agreement must be submitted with the application. Furthermore, indirect costs are considered a part of administrative costs for HVRP purposes and, therefore, may not exceed 20% of the total grant award.

• If the applicant does not presently have an approved indirect cost rate, a proposed rate with justification may be submitted. Successful applicants will be required to negotiate an acceptable and allowable rate within 90 days of grant award with the appropriate DOL Regional Office of Cost Determination or

<sup>1</sup> The term "direct" funding is used to describe funds that are provided "directly" by a governmental entity or an intermediate organization with the same duties as the government entity, as opposed to funds that an organization receives as the result of the genuine and independent private choice of a beneficiary. In other contexts, the term "direct" funding may be used to refer to those funds that an organization receives directly from the Federal government (also known as "discretionary" funding), as opposed to funding that it receives from a State or local government (also known as "indirect" or "block grant" funding). In this SGA, the term "direct" has the former meaning.

with the applicant's cognizant agency for indirect cost rates (See Office of Management and Budget Web site at <http://www.whitehouse.gov/omb/grants/attach.html>).

• Indirect cost rates traceable and trackable through the State Workforce Agency's Cost Accounting System represent an acceptable means of allocating costs to DOL and, therefore, can be approved for use in grants to State Workforce Agencies.

6. *Other Submission Requirements*:

The only acceptable evidence to establish the date of mailing of a late application sent by registered or certified mail is the U.S. Postal Service postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. If the postmark is not legible, an application received after the above closing time and date shall be processed as if mailed late. "Postmark" means a printed, stamped or otherwise placed impression (not a postage meter machine impression) that is readily identifiable without further action as having been applied and affixed by an employee of the U.S. Postal Service on the date of mailing. Therefore applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the date of mailing of a late application sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee is the date entered by the Post Office clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the same meaning as defined above. Therefore, applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the time of receipt at the U.S. Department of Labor is the date/time stamp of the Procurement Services Center on the application wrapper or other documentary evidence or receipt maintained by that office. Applications sent by other delivery services, such as Federal Express, UPS, etc., will also be accepted.

*All applicants are advised that U.S. mail delivery in the Washington, DC area has been erratic due to security and anthrax concerns. All applicants must take this into consideration when preparing to meet the application deadline, as you assume the risk for ensuring a timely submission, that is, if, because of these mail problems, the*

Department does not receive an application or receives it too late to give proper consideration, even if it was timely mailed, the Department is not required to consider the application.

## V. Application Review Information

### 1. Application Evaluation Criteria

Applications will receive up to 100 total points based on the following criteria:

#### A. Need for the Project: 10 points

The applicant will document the need for this project, as demonstrated by: (i) The potential number or concentration of homeless individuals and homeless veterans in the proposed project area relative to other similar areas; (ii) the rates of poverty and/or unemployment in the proposed project area as determined by the census or other surveys; and (iii) the extent of the gaps in the local infrastructure to effectively address the employment barriers that characterize the target population.

#### B. Overall Strategy To Increase Employment and Retention in Employment: 35 points

The application must include a description of the approach to providing comprehensive employment and training services, including job training, job development, obtaining employer commitments to hire, placement, and post-placement follow-up services. Applicants must address how they will target occupations in emerging industries. Supportive services provided as part of the strategy of promoting job readiness and job retention must be indicated. The applicant must identify the local services and sources of training to be used for participants. At least 80% of enrolled participants must participate in training services. A description of the relationship, if any, with other employment and training programs such as State Workforce Agencies (including DVOP and LVER Programs), One-Stops, VWIP, other WIA programs, and Workforce Investment or Development Boards or entities where in place, must be specified. Applicant must indicate how the activities will be tailored or responsive to the needs of homeless veterans. A participant flow chart may be used to show the sequence and mix of services.

**Note:** The applicant must complete Appendix D, the Technical Performance Goals Form, with proposed programmatic outcomes including participants served, placement/entered employments and job retention. Of the 35 points possible in the strategy to increase employment and retention, 5 points will be awarded to grant proposals that demonstrate the ability to

maintain a 180 day employment retention rate of fifty (50) percent or greater. Applicants whose applications persuasively propose to use peer counselors who are themselves veterans will be awarded five (5) of the available points in the scoring criteria.

### C. Quality and Extent of Linkages With Other Providers of Services to the Homeless and to Veterans: 20 points

The application must provide information on the quality and extent of the linkages this program will have with other providers of services to homeless veterans in the local community including faith-based and community organizations. For each service, the applicant must specify who the provider is, the source of funding (if known), and the type of linkages/referral system established or proposed. Describe, to the extent possible, how the project would be incorporated into the community's continuum of care approach to respond to homelessness and show any linkages to HUD, HHS or DVA programs that will be advantageous to the proposed program.

### D. Demonstrated Capability in Providing Required Program Services, Including Programmatic Reporting and Participant Tracking: 25 points

The applicant must describe its relevant prior experience in operating employment and training programs and providing services to participants similar to those that are proposed under this solicitation. Specific outcomes previously achieved by the applicant must be described, such as job placements, benefits secured, network coalitions, etc. The applicant must also address its capacity for timely startup of the program, programmatic reporting, and participant tracking. The applicant should describe its staff experience and ability to manage the administrative, programmatic and financial aspects of a grant program. Include a recent (within the last 18 months) financial statement or audit. Final or most recent technical reports for other relevant employment and training programs must be submitted, if applicable. Because prior HVRP grant experience is not a requirement for this grant, some applicants may not have any technical performance reports to submit.

### E. Quality of Overall Housing Strategy: 10 points

The application must demonstrate how the applicant proposes to obtain or access housing resources for veterans in the program and entering the labor force. This discussion should specify the provisions made to access temporary, transitional, and permanent

housing for participants through community resources, HUD, DVA lease, or other means. *HVRP funds may not be used for housing or vehicles.*

## 2. Review and Selection Process

Applications will initially be screened to ensure timeliness, completeness, and responsiveness to the SGA requirements. Applications that satisfy this initial screening will receive further review as explained below.

Technical proposals will be reviewed by a Department of Labor review panel using the point scoring system specified above in Section V(1). The review panel will assign scores after careful evaluation by each panel member and rank applications based on this score. The ranking will be the primary basis to identify applicants as potential grantees. The review panel may establish a competitive range and/or minimum qualifying score, based upon the proposal evaluation, for the purpose of selecting qualified applicants. The review panel's conclusions are advisory in nature and not binding to the Grant Officer.

Cost proposals will be considered in two (2) ways. The Department of Labor review panel will screen all applicant cost proposals to ensure expenses are allocable, allowable, and reasonable. If the review panel concludes that the cost proposal contains an expense(s) that is not allocable, allowable, and/or reasonable, the application may be considered ineligible for funding. Further, VETS and the Grant Officer will consider applicant information concerning the proposed cost per placement, percentage of participants placed into unsubsidized employment, average wage at placement, and 180 day retention in employment percentage. The national average cost per placement for HVRP for last year was \$2,100.

The Government reserves the right to ask for clarification on any aspect of a grant application. The Government also reserves the right to discuss any potential grantee concerns amongst Department of Labor staff. The Government further reserves the right to select applicants out of rank order if such a selection would, in its opinion, result in the most effective and appropriate combination of funding, program, and administrative costs, e.g., cost per enrollment and placement, demonstration models, and geographic service areas. The Grant Officer's determination for award under SGA 04-04 is the final agency action. The submission of the same proposal from any prior year HVRP competition does not guarantee an award under this Solicitation.

## VI. Award Administration Information

### 1. Award Notices

A. The Notice of Award signed by the Grant Officer is the authorizing document and will be provided through postal mail and/or by electronic means to the authorized representative listed on the SF-424 Grant Application. Notice that an organization has been selected as a grant recipient does not constitute approval of the grant application as submitted. Before the actual grant award, the Grant Officer may enter into negotiations concerning such items as program components, funding levels, and administrative systems. If the negotiations do not result in an acceptable submittal, the Grant Officer reserves the right to terminate the negotiation and decline to fund the proposal.

B. A post-award conference will be held for those grantees awarded FY 2004 HVRP funds through this competition. The post-award conference is expected to be held in July or August 2004. Up to two (2) representatives must be present; a financial and a program representative are recommended. The site of the post-award conference has not yet been determined, however, for planning and budgeting purposes, please allot five (5) days and use Washington, DC as the conference site. The post-award conference will focus on providing information and assistance on reporting, record keeping, grant requirements, and also include best practices from past projects. Costs associated with attending this conference for up to two grantee representatives will be allowed as long as they are incurred in accordance with Federal travel regulations. Such costs must be charged as administrative costs and reflected in the proposed budget.

### 2. Administrative and National Policy Requirements

Unless specifically provided in the grant agreement, DOL's acceptance of a proposal and an award of Federal funds to sponsor any program(s) does not provide a waiver of any grant requirements and/or procedures. For example, the OMB circulars require that an entity's procurement procedures must provide all procurement transactions will be conducted, as practical, to provide open and free competition. If a proposal identifies a specific entity to provide the services, the DOL award does not provide the justification or basis to sole-source the procurement, *i.e.*, avoid competition. All grants will be subject to the following administrative standards and

provisions, as applicable to the particular grantee:

- 29 CFR part 93—Lobbying.
- 29 CFR part 95—Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations, and with Commercial Organizations.
- 29 CFR part 96—Federal Standards for Audit of Federally Funded Grants, Contracts and Agreements.
- 29 CFR part 97—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.
- 29 CFR part 98—Federal Standards for Government-wide Debarment and Suspension (Non procurement) and Government-wide Requirements for Drug-Free Workplace (Grants).
- 29 CFR part 99—Audit of States, Local Governments, and Nonprofit Organization.
- 29 CFR parts 30, 31, 32, 33 and 36—Equal Employment Opportunity in Apprenticeship and Training; Nondiscrimination in Federally Assisted Programs of the Department of Labor, Effectuation of Title VI of the Civil Rights Act of 1964; Nondiscrimination on the Basis of Handicap in Programs and Activities; and Nondiscrimination on the Basis of Sex in Education Programs Receiving or Benefiting from Federal Financial Assistance.

### 3. Reporting

The grantee will submit the reports and documents listed below:

#### A. Quarterly Financial Reports:

No later than 30 days after the end of each Federal fiscal quarter, the grantee must report outlays, program income, and other financial information on a Federal fiscal quarterly basis using SF-269A, Financial Status Report, Short Form, and submit a copy of the HHS/PMS 272 draw down report. These reports must cite the assigned grant number and be submitted to the appropriate State Director for Veterans' Employment and Training (DVET).

#### B. Quarterly Program Reports:

No later than 30 days after the end of each Federal fiscal quarter, grantees also must submit a Quarterly Technical Performance Report to the DVET that contains the following:

- (1) A comparison of actual accomplishments to planned goals for the reporting period in spreadsheet format (to be provided after grant award) and any findings related to monitoring efforts;
- (2) An explanation for variances of plus or minus 15% of planned program and/or expenditure goals, to include:

identification of corrective action that will be taken to meet the planned goals, if required; and a timetable for accomplishment of the corrective action.

#### C. 90-Day Follow-Up Report:

No later than 120 days after the grant performance expiration date, the grantee must submit a follow-up report showing results and performance as of the 90th day after the grant period, and containing the following:

- (1) Final Financial Status Report SF-269A, Short Form (that zeros out all unliquidated obligations); and
- (2) Technical Performance Report including updated goals chart.

#### D. 180-Day Follow-Up Report:

No later than 210 days after the grant performance expiration date, the grantee must submit a follow-up report showing the results and performance as of the 180th day after the grant period, and containing the following:

- (1) Final Financial Status Report SF-269A, Short Form (if not previously submitted); and
- (2) Final Narrative Report identifying:
  - (a) The total combined (directed/assisted) number of veterans placed into employment during the entire grant period;
  - (b) The number of veterans still employed after the 180 day follow-up period;
  - (c) If the veterans are still employed at the same or similar job and, if not, what are the reason(s);
  - (d) Whether training received was applicable to jobs held;
  - (e) Wages at placement and during follow-up period;
  - (f) An explanation regarding why those veterans placed during the grant, but not employed at the end of the follow-up period, are not so employed; and
  - (g) Any recommendations to improve the program.

## VII. Agency Contact

Questions and applications are to be forwarded to: U.S. Department of Labor, Procurement Services Center, Attention: Cassandra Mitchell, Reference SGA 04-04, 200 Constitution Avenue NW., Room N-5416, Washington, DC 20210, Phone Number: (202) 693-4570 (this is not a toll free number).

#### Resources for the Applicant:

Applicants may review "VETS' Guide to Competitive and Discretionary Grants" located at [http://www.dol.gov/vets/grants/Final\\_VETS\\_Guide-linked.pdf](http://www.dol.gov/vets/grants/Final_VETS_Guide-linked.pdf). Applicants may also find these resources useful: America's Service Locator <http://www.servicelocator.org/> provides a directory of our nation's One-Stop Career Centers; the National

Association of Workforce Boards maintains an Internet site (<http://www.nawb.org/asp/wibdir.asp>) that contains contact information for the State and local Workforce Investment Boards; and the homepage for the Department of Labor, Center for Faith-Based & Community Initiatives (<http://www.dol.gov/cfbci>).

*Comments:* Comments are to be submitted to the Veterans' Employment and Training Service (VETS), U.S. Department of Labor, Room S-1312, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-4701. Written comments are limited to ten (10) pages or fewer and may be

transmitted by facsimile to (202) 693-4755. Receipt of submissions, whether by U.S. mail, e-mail, or facsimile transmittal, will not be automatically acknowledged; however, the sender may request confirmation that a submission has been received, by telephoning VETS at (202) 693-4701 or (202) 693-4753 (TTY/TDD).

Signed at Washington, DC this 6th day of April, 2004.

**Lisa Harvey,**  
*Acting Grant Officer.*

#### **Appendices**

Appendix A: Application for Federal Assistance SF-424

Appendix B: Budget Information Sheet SF-424A

Appendix C: Assurances and Certifications Signature Page

Appendix D: Quarterly Technical Performance Goals Form

Appendix E: Direct Cost Descriptions for Applicants and Sub-Applicants

Appendix F: Survey on Ensuring Equal Opportunity for Applicants

Appendix G: The Glossary of Terms

Appendix H: List of Common Acronyms

Appendix I: List of 75 Largest Cities Nationwide

**BILLING CODE 4510-79-P**



**APPLICATION FOR FEDERAL ASSISTANCE**

Version 7/03

<b>1. TYPE OF SUBMISSION:</b> Application		<b>2. DATE SUBMITTED</b>	Applicant Identifier
<input type="checkbox"/> Construction	Pre-application	<b>3. DATE RECEIVED BY STATE</b>	State Application Identifier
<input type="checkbox"/> Non-Construction	<input type="checkbox"/> Construction	<b>4. DATE RECEIVED BY FEDERAL AGENCY</b>	Federal Identifier
<input type="checkbox"/> Non-Construction	<input type="checkbox"/> Non-Construction		
<b>5. APPLICANT INFORMATION</b>			
Legal Name:		Organizational Unit:	
Organizational DUNS:		Department:	
Address:		Division:	
Street:		Name and telephone number of person to be contacted on matters involving this application (give area code)	
City:		Prefix:	First Name:
County:		Middle Name	
State:		Last Name	
Zip Code	Suffix:		
Country:		Email:	
<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</b> □□-□□□□□□□□		Phone Number (give area code)	Fax Number (give area code)
<b>8. TYPE OF APPLICATION:</b> <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es) (See back of form for description of letters.) Other (specify) <input type="checkbox"/> <input type="checkbox"/>		<b>7. TYPE OF APPLICANT:</b> (See back of form for Application Types) Other (specify)	
<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b> TITLE (Name of Program): □□-□□□□		<b>9. NAME OF FEDERAL AGENCY:</b>	
<b>12. AREAS AFFECTED BY PROJECT</b> (Cities, Counties, States, etc.):		<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b>	
<b>13. PROPOSED PROJECT</b> Start Date: Ending Date:		<b>14. CONGRESSIONAL DISTRICTS OF:</b> a. Applicant b. Project	
<b>15. ESTIMATED FUNDING:</b>		<b>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b>	
a. Federal	\$ .00	a. Yes. <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON	
b. Applicant	\$ .00	DATE:	
c. State	\$ .00	b. No. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E. O. 12372	
d. Local	\$ .00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
e. Other	\$ .00	<b>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</b>	
f. Program Income	\$ .00	<input type="checkbox"/> Yes If "Yes" attach an explanation. <input type="checkbox"/> No	
g. TOTAL	\$ .00		
<b>18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.</b>			
<b>a. Authorized Representative</b>			
Prefix	First Name	Middle Name	
Last Name	Suffix		
b. Title	c. Telephone Number (give area code)		
d. Signature of Authorized Representative	e. Date Signed		

## INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

This is a standard form used by applicants as a required face sheet for pre-applications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:	Item:	Entry:
1.	Select Type of Submission.	11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).	12.	List only the largest political entities affected (e.g., State, counties, cities).
3.	State use only (if applicable).	13.	Enter the proposed start date and end date of the project.
4.	Enter Date Received by Federal Agency Federal Identifier number: If this application is a continuation or revision to an existing award, enter the present Federal Identifier number. If for a new project, leave blank.	14.	List the applicant's Congressional District and any District(s) affected by the program or project
5.	Enter legal name of applicant, name of primary organizational unit (including division, if applicable), which will undertake the assistance activity, enter the organization's DUNS number (received from Dun and Bradstreet), enter the complete address of the applicant (including country), and name, telephone number, e-mail and fax of the person to contact on matters related to this application.	15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.	16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
7.	Select the appropriate letter in the space provided. A. State B. County C. Municipal D. Township E. Interstate F. Intermunicipal G. Special District H. Independent School District I. State Controlled Institution of Higher Learning J. Private University K. Indian Tribe L. Individual M. Profit Organization N. Other (Specify) O. Not for Profit Organization	17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
8.	Select the type from the following list: • "New" means a new assistance award. • "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date. • "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. If a revision enter the appropriate letter: A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration	18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)
9.	Name of Federal agency from which assistance is being requested with this application.		
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.		

OMB Approval No. 0348-0044

**BUDGET INFORMATION - Non-Construction Programs**  
**SECTION A - BUDGET SUMMARY**

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		Total (g)
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	
1.		\$		\$		0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	0.00

**SECTION B - BUDGET CATEGORIES**

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	\$	\$	\$	\$	0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges (sum of 6a-6h)	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS (sum of 6i and 6j)	\$	\$ 0.00	\$ 0.00	\$ 0.00	0.00
7. Program Income	\$	\$	\$	\$	0.00

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Standard Form 424A (Rev. 7-97)  
Prescribed by OMB Circular A-102

SECTION C - NON-FEDERAL RESOURCES					
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS	
8.	\$	\$	\$	\$	0.00
9.					0.00
10.					0.00
11.					0.00
12. TOTAL (sum of lines 8-11)	\$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
	\$	\$	\$	\$	\$
13. Federal	0.00				
14. Non-Federal	0.00				
15. TOTAL (sum of lines 13 and 14)	\$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT					
(a) Grant Program	FUTURE FUNDING PERIODS (Years)				
	(b) First	(c) Second	(d) Third	(e) Fourth	
16.	\$	\$	\$	\$	
17.					
18.					
19.					
20. TOTAL (sum of lines 16-19)	\$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION F - OTHER BUDGET INFORMATION					
21. Direct Charges:					
22. Indirect Charges:					
23. Remarks:					

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## INSTRUCTIONS FOR THE SF-424A

Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

**General Instructions**

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

**Section A. Budget Summary Lines 1-4 Columns (a) and (b)**

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not* requiring a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program requiring budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in Column (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

**Lines 1-4, Columns (c) through (g)**

For *new* applications, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For *continuing grant program applications*, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For *supplemental grants and changes* to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

**Section B Budget Categories**

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-1 - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program



## INSTRUCTIONS FOR THE SF-424A (continued)

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

**Section C. Non-Federal Resources**

**Lines 8-11** Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

**Column (a)** - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

**Column (b)** - Enter the contribution to be made by the applicant.

**Column (c)** - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

**Column (d)** - Enter the amount of cash and in-kind contributions to be made from all other sources.

**Column (e)** - Enter totals of Columns (b), (c), and (d).

**Line 12** - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

**Section D. Forecasted Cash Needs**

**Line 13** - Enter the amount of cash needed by quarter from the grantor agency during the first year.

**Line 14** - Enter the amount of cash from all other sources needed by quarter during the first year.

**Line 15** - Enter the totals of amounts on Lines 13 and 14.

**Section E. Budget Estimates of Federal Funds Needed for Balance of the Project**

**Lines 16-19** - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

**Line 20** - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

**Section F. Other Budget Information**

**Line 21** - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

**Line 22** - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

**Line 23** - Provide any other explanations or comments deemed necessary.

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**CERTIFICATIONS AND ASSURANCES****ASSURANCES AND CERTIFICATIONS SIGNATURE PAGE**

The Department of Labor will not award a grant or agreement where the grantee/recipient has failed to accept the ASSURANCES AND CERTIFICATIONS contained in this section. By signing and returning this signature page, the grantee/recipient is providing the certifications set forth below:

- A. Certification Regarding Lobbying, Debarment, Suspension, Other Responsibility Matters - Primary Covered Transactions and Certifications Regarding Drug-Free/Tobacco-Free Workplace,
- B. Certification of Release of Information
- C. Assurances - Non-Construction Programs
- D. Applicant is not a 501(c)(4) organization

APPLICANT NAME and LEGAL ADDRESS:

If there is any reason why one of the assurances or certifications listed cannot be signed, please explain. Applicant need only submit and return this signature page with the grant application. All other instruction shall be kept on file by the applicant.

---

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL

TITLE

---

APPLICANT ORGANIZATION

DATE SUBMITTED

**Please Note:** This signature page and any pertinent attachments which may be required by these assurances and certifications shall be attached to the applicant's Cost Proposal.

**RECOMMENDED FORMAT FOR PLANNED  
QUARTERLY TECHNICAL PERFORMANCE GOALS**  
(data entered cumulatively)

**Performance Goals**

	1ST QTR	2ND QTR	3RD QTR	4TH QTR
<b>Assessments</b>				
<b>Participants Enrolled</b>				
<b>Placed Into Transitional Or Permanent Housing</b>				
<b>Direct Placements Into Unsubsidized Employment</b>				
<b>Assisted Placements Into Unsubsidized Employment</b>				
<b>Combined Placements Into Unsubsidized Employment (Direct &amp; Assisted)</b>				

<b>Cost Per Placement</b>				
<b>Number Retaining Jobs For 90 Days</b>				
<b>Number Retaining Jobs For 180 Days</b>				
<b>Rate of Placement Into Unsubsidized Employment</b>				
<b>Average Hourly Wage At Placement</b>				

**Employability Development Services - (As Applicable)**

<b>Classroom Training</b>				
<b>On-The-Job Training</b>				
<b>Remedial Education</b>				
<b>Vocational Counseling</b>				
<b>Pre-employment Services</b>				
<b>Occupational Skills Training</b>				
_____				
_____				
_____				
_____				

**Planned Expenditures**

	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
<b>Total Expenditures</b>	\$ _____	\$ _____	\$ _____	\$ _____
<b>Administrative Costs</b>	\$ _____	\$ _____	\$ _____	\$ _____
<b>Participant Services*</b>	\$ _____	\$ _____	\$ _____	\$ _____

\*Services may include training and/or supportive.

Direct Cost Descriptions For Applicants and Sub-Applicants\*

Position Title(s)	Annual Salary/Wage Rate	% of Time Charged to Grant	Proposed Administration Costs **	Proposed Program Costs

Sub-Total

Administration      Program

Fringe Benefits For All Positions

Contractual

Travel

Indirect Costs

Equipment

Supplies

Total Costs -----

Administration      Program

\*\* Administrative costs are associated with the supervision and management of the program and do not directly or immediately affect participants.

\* Direct costs for all funded positions for both applicant and sub-applicant(s) must be provided.



## SURVEY ON ENSURING EQUAL OPPORTUNITY

Federal Agency Use Only

OMB No. 1225-0083 Exp. 02/28/2006

**NOTE:** Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

**Purpose:** This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?
  - Yes
  - No
2. How many full-time equivalent employees does the applicant have? (Check only one box.)
  - 3 or Fewer
  - 4-5
  - 6-14
  - 15-50
  - 51-100
  - over 100
3. What is the size of the applicant's annual budget? (Check only one box.)
  - Less Than \$150,000
  - \$150,000 - \$299,999
  - \$300,000 - \$499,999
  - \$500,000 - \$999,999
  - \$1,000,000 - \$4,999,999
  - \$5,000,000 or more
4. Is the applicant a faith-based/religious organization?
  - Yes
  - No
5. Is the applicant a non-religious community-based organization?
  - Yes
  - No
6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?
  - Yes
  - No
7. Has the applicant ever received a government grant or contract (Federal, State, or local)?
  - Yes
  - No
8. Is the applicant a local affiliate of a national organization?
  - Yes
  - No



## Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.
2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.
3. Annual budget means the amount of money your organization spends each year on all of its activities.
4. Self-identify.
5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.
6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.
7. Self-explanatory.
8. Self-explanatory

### **Paperwork Burden Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1225-0083**. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. If you have comments or concerns regarding the status of your individual submission of this form, write directly to: Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.**

**U.S. Department of Labor**  
**Veterans' Employment and Training Service**

**GLOSSARY OF TERMS**

**Adequate Employment** – See Unsubsidized Employment.

**Administrative Costs** - Administrative costs shall consist of all direct and indirect costs associated with the supervision and management of the program. These costs shall include the administrative costs, both direct and indirect, of sub-recipients and contractors.

**Adult Basic Education** - Education for adults whose inability to speak, read, or write the English language or to effectively reason mathematically, constitutes a substantial impairment of their ability to get or retain employment commensurate with their real ability, which is designed to help eliminate such inability and raise the level, of education of such individuals with a view to making them less likely to become dependent on others, to improve their ability to benefit from occupational training and otherwise increase their opportunities for more productive and profitable employment, and to make them better able to meet their adult responsibilities.

**Ancillary Services** – Employment and training related activities other than core training that may enhance a participant's employability.

**Apprenticeship Training** – A formal occupational training program that combines on-the-job training and related instruction and in which workers learn the practical and conceptual skills required for a skilled occupation, craft, or trade. It may be registered or unregistered.

**Assessment/Intake** - A process for screening individual applicants for program eligibility making the level of need determinations; making an initial determination what services or programs can best benefit the applicants; providing information about services, program eligibility, and the availability of those services, and the routing or selecting individual applicants for particular service delivery or program participation.

**Assisted Placements Into Unsubsidized Employment** - Assisted placements into unsubsidized employment should be recorded where the definition for placement with unsubsidized employment above is met, but the placement was arranged by an agency to which the homeless veteran was referred to.

**Average Hourly Wage At Placement** - The average hourly wage at placement is the average hourly wage rates at placement of all assisted placements plus direct placements.

**Assurance and Certifications** - The act of signifying intent to comply with applicable federal and State laws and regulations as a condition for receiving and expanding USDOL grant funds.

**Barriers to Employment** - Characteristics that may hinder an individual's hiring promotion or participation in the labor force. Identification of these barriers will vary by location and labor market. Some examples of individuals who may face barriers to employment include: single parents, women, displaced homemakers, youth, public assistance recipients, older workers, substance abusers, teenage parents, certain veterans, ethnic minorities, and those with limited English speaking ability or a criminal record or with a lack of education, work experience, credential, child care arrangements, transportation or alternative working parents.

**Campaign Badge veteran** - A veteran who served on active duty during the war (e.g., WWII), action (e.g., Korea, Vietnam), in a campaign, or an expedition for which a campaign badge of an expeditionary medal has been authorized (e.g. Bosnia, Grenada, Haiti, Panama, Southeast Asia, and Somalia).

**Case Management** - A client centered approach in the delivery of intensive services, designed to prepare and coordinate comprehensive employment plans for participants, to assure access to the necessary training and supportive services, and to provide support during program participation and after job placement.

**Case Manager** - One who coordinates, facilitates or provides direct services to a client or trainee from application through placement, post placement follow-up, or other case closing, exclusively, through periodic contact and the provision of appropriate assistance.

**Classroom Training** - Any training of the type normally conducted in an institutional setting, including vocational education, which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs. It may also include training designed to enhance the employability of individuals by upgrading basic skills, throughout the provision of courses such as remedial education, training in the primary language of persons with limited English language proficiency, or English as a second language training.

**Close Out** - Grant close out is the process by which the Federal grantor agency (in the case of VETS grants, Department of Labor) determines that all applicable administrative actions and all required work of the grant have been completed by the grantee and the grantor.

**Cognizant Federal Agency** - The federal agency that is assigned audit or indirect cost rate approval responsibility for a particular recipient organization by the Office of Management and Budget (OMB Circular A-87 and A-102 [20 CFR, Part 97]).

**Community Based Organization** - means a private non-profit organization that is representative of a community or a significant segment of a community and that has demonstrated expertise and effectiveness in the field of workforce investment. Faith-Based organizations are considered a subset.

**Cost Per Placement** - The cost per placement into unsubsidized employment is obtained by dividing the total funds expended by the total of direct placements plus assisted placements.

**Counseling** - A form of assistance which provides guidance in the development of a participant's vocational goals and the means to achieve those goals; and/or assist a participant with the solution to one or more individual problems which may pose a barrier (s) to sustained employment.

**Counselor** - (Employment/Vocational): A trained and qualified professional authorized to provide direct assistance (beyond advising and informing) through planning, testing, training and otherwise readying an individual for sustained employment.

**Customized Training** - A training program designed to meet the special requirements of an employer who has entered into an agreement with a Service Delivery Area to hire individuals who are trained to the employer's specifications. The training may occur at the employer's site or may be provided by a training vendor able to meet the employer's requirements. Such training usually requires a commitment from the employer to hire a specified number of trainees who satisfactorily complete the training.

**Direct Placements Into Unsubsidized Employment** - A direct placement into unsubsidized employment must be a placement made directly by staff with an established employer who covers all employment costs for 20 or more hours per week at or above the minimum wage. Day labor and other very short-term placements should not be recorded as placements into unsubsidized employment.

**Disabled Veteran** - A veteran who is entitled to compensation under laws administered by the Veterans Administration; or an individual who was medically discharged or otherwise released from active duty, due to service-connected disability.

**Disallowed Costs** - Disallowed costs are those charges to a grant that the grantor agency (or its representative) determines to be unallowable in accordance with the applicable Federal Cost Principles or other conditions in the grant.

**Disabled Veterans' Outreach Program** (DVOP) - A program of Federal assistance through grants to States to staff and support in accordance with 38 U.S.C. 4103A, appointed to perform a number of duties chief among which are direct employer contact, particularly with Federal contractors, Federal employers using individualized job development techniques, and with veterans (particularly with disabled veterans) using a case management approach to client-centered services.

**Economically Disadvantaged** - An individual who (a) receives, or is a member of a family which receives, cash welfare payments under a Federal, state, or local welfare program; (b) has, or is a member of a family which has, received a total family income for the six-month period prior to application for the program involved (exclusive of unemployment compensation, child support payments, and welfare payments) which, in relation to family size, was not in excess of the higher of (i) the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673 (2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 9902(2)), or (ii) 70 percent of the lower living standard income level; (c) is receiving (or has been determined within the 6-month period prior to the application for

program involved to be eligible to receive) food stamps pursuant to the Food Stamp Act of 1977; (d) qualifies as a homeless individual under section 103 of the Stewart B. McKinney Homeless Assistance Act; (e) is a foster child on behalf of whom state or local government payments are made or (f) in cases permitted by regulations of the Secretary, is an individual with a disability whose income meets the requirements of clause (a) or (b), but who is a member of a family whose income does not meet such requirements.

**Eligible** - Meeting the minimum requisite qualifications to be considered for the provision of services or entry into a position under a funded program or as required by law.

**Employability Development Services (EDS)** - This includes services and activities that will develop or increase the employability of the participant. Generally, this includes vocational counseling, classroom and on-the-job training, pre-employment services (such as job seeking skills and job search workshops), temporary or trial employment, sheltered work environments and other related services and activities. Planned services should assist the participant in addressing specific barriers to employment and finding a job. These activities may be provided by the applicant or by a Sub-grantee, contractor or another source such as the local Workforce Investment Act program or the DVOP personnel or LVERs. Such services are not mandatory but entries should reflect the services described in the application and the expected number of participants receiving or enrolled in such services during each quarter. Participants may be recorded more than once if they receive more than one service.

**Employment Development Plan (EDP)** - An individualized written plan or intervention strategy for serving an individual which, as a result of an assessment of the veteran's economic needs, vocational interests, aptitudes, work history, etc., defines a reasonable vocational or employment goal and the developmental services or steps required to reach the goal and which documents the accomplishments made by the individual.

**Employment Service** - the state level organization or public labor exchange system affiliated with the Department of Labor's United States Employment Service.

**Enlistments** - Individuals who have expressed an interest, signed up for a workshop or enrollment in the program.

**Entered Employment** - Applicants for service who were placed in jobs or otherwise obtained employment as a result of services used or received.

**Entered Employment Rate** - This is a method used to determine the percentage of participants who become employed. The percentage is calculated by dividing the number of total participants who were enrolled in the program by the number of participants who were placed or entered employment through the program.

**Enrolled Veteran** - Shall be synonymous with the term participant. A veteran who has been determined eligible for services at intake and who is receiving or scheduled to receive core training.



**Faith-Based Organization** – see “community-based organization”.

**Follow-up** - The tracking of clients for a period of time up to 180 days after initial placement, last referral date for services or completion of training programs to determine current status, outcome or whether to offer additional services (such as additional referral, job retention advisement, etc.).

**Full-Time Equivalent** (FTE) – a personnel charge to the grant equal to 2,080 hours per year.

**FY** - Fiscal Year. For federal government purposes, any twelve month period beginning on October 1 and ending on September 30.

**General Equivalency Diploma** (GED) – A high school equivalency diploma that is obtained by passing the General Educational Diploma Equivalency Test that measures the application of skills and knowledge generally associated with four (4) years of traditional high school instruction.

**Grant Officer's Technical Representative** (GOTR) - An individual (usually the DVET) serving on behalf of the Grant Officer who maintains and ensures the integrity of the approved grant agreement by reviewing and making recommendations regarding technical matters not involving a change in scope, cost, or conditions.

**Homeless or homeless individual** – includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either supervised public or private shelter designed to provide temporary living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. [Reference 42 U.S.C., Section 11302 (a)].

**Indirect cost** - A cost that is incurred for a common or joint purpose benefiting more than one cost objective and that is not readily assignable to the cost objective specifically benefited.

**In-kind Services** – Property or services which benefit federally assisted project or program and which are contributed without charge to the grantee.

**Institutional Skills Training** – training conducted in an institutional setting and designed to ensure that individuals acquire the skills, knowledge, and abilities necessary to perform a job or group of jobs in an occupation for which there is a demand.

**Intake** – A process for screening individual applicants for eligibility; making an initial determination whether the program can benefit the applicants; providing information about the program, its services and the availability of those services; and selecting individual applicants for participation in the program.

**Intensive Services** - The provision of concentrated staff services to clients who indicate the need for facilitation or interventions to secure lasting employment. The case management approach to service delivery is a viable model for successfully providing such services and obtaining the clients goals.

**Job Club Activities** - A form of job search assistance provided in a group setting. Usually job clubs provide instruction and assistance in completing job applications and developing resumes and focus on maximizing employment opportunities in the labor market and developing job leads. Many job clubs use telephone banks and provide group support to participants before and after they interview for job openings.

**Job Development** - The process of marketing a program participant to employers, including informing employers about what the participant can do and soliciting a job interview for that individual with the employer (targeted job development); and the development of one or more job openings or training opportunities with one or more employers using a variety of techniques and means of contact.

**Job Placement Services** - Job placement services are geared towards placing participants in jobs and may involve activities such as job search assistance, training, or job development. These services are initiated to enhance and expedite participants' transition from training to employment.

**Job Search Assistance** - An activity, which focuses on building practical skills and knowledge to identify and initiate employer contact and conduct successful interview with employers. Various approaches may be used to include participation in a job club, receive instruction in identifying personal strengths and goals, resume application preparation, learn interview techniques, and receive labor market information. Job search assistance is often self-service activity in which individuals obtain information about specific job openings or general jobs or occupational information.

**Labor Exchange** - Refers to the services provided to job seekers and employers by the State Employment Services Agencies, or other designated entities. Preparatory services to job seekers may include assessment, testing, counseling, provision of labor market information, targeted job development, resulting in job referral and follow-up with former applicants and prospective employers. Employer-oriented services may include accepting job orders, screening applicants, referring qualified applicants and providing follow-up to foster job retention and develop additional job openings or training opportunities.

**Labor Exchange Delivery System** (LEDS) - Describes the system of matching jobs and training opportunities with applicants operating with Federal employment and job training funds.

**Labor Force** - The sum of all civilians classified as employed and unemployed and members of the Armed Forces stationed in the United States. [Bureau of Labor Statistics Bulletin 2175].

**Labor Market Area** – an economically integrated geographic area within which individuals can reside and find employment within a reasonable distance or can readily change employment without changing their place of residence.

**Literacy and Bilingual Training** – See Adult Basic Education.

**Local Veterans' Employment Representative (LVER) Program** - A program of Federal assistance through grants to States to staff in accordance with 38 U.S.C.4104 to perform a number of duties, chief among which are the provision of intensive (case management) services to targeted eligible veterans with emphasis on VA, VR&E, and to functionally supervise without necessarily exercising line supervisor authority over the provision of services to veterans by SDP staff.

**Minimum Economic Need** – the level of wages paid to a program participant that will enable that participant to become economically self-sufficient.

**Minority Veterans** – for the purposes of the HVRP and VWIP programs, veterans who are Workforce Investment Act (WIA) eligible and are members of the following ethnic categories: African American, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander.

**National Veterans' Training Institute (NVTI)** - An agency contracted with USDOL/VETS to develop and provide skills development and enhancement training to individuals who are determined by the Assistant Secretary for Veterans' Employment and Training and who deliver or monitor the provision of employment and training services to veterans (38 U.S.C. 4109).

**Number Retaining Job for 90 Days** -To be counted as retaining a job for 90 days, continuous employment with one or more employers for at least 90 days must be verified and the definition for either direct placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 90 days as long as the client has been steadily employed for that length of time.

**Number Retaining Job For 180 Days** - To be counted as retaining a job for 180 days, continuous employment with one or more employers for at least 180 days must be verified, and the definition for either placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 180 days as long as the client has been steadily employed for that length of time.

**Occupational Skills Training** – Includes both (1) vocational education which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs, and (2) on-the-job training.

**Offender** – Any adult or juvenile who has been subject to any stage of the criminal justice process for whom services under this program may be beneficial or who requires assistance in overcoming artificial barriers to employment resulting from a record of arrest or conviction.

**On-the-Job Training (OJT)** – means training by an employer that is provided to a paid participant while engaged in productive work in a job that: (a) provides knowledge or skill essential to the full and adequate performance of the job; (b) provides reimbursement to the employer of up to 50 percent of the wage rate of the participant, for the extraordinary costs of providing the training and additional supervision related to the participant is being trained, taking into account the content of the training, the prior work experience of the participant, and the service strategy of the participant, as appropriate. Usually in the OJT agreement, there is a promise on the part of the employer to hire the trainee upon successful completion of the training.

**On-Site Industry-Specific Training** – This is training which is specifically tailored to the needs of a particular employer and/or industry. Participants may be trained according to specifications developed by an employer for an occupation or group of occupations at a job site. Such training is usually presented to a group of participants in an environment or job site representative of the actual job/occupation, and there is often an obligation on the part of the employer to hire a certain number of participants who successfully complete the training.

**Outreach** - An active effort by program staff to encourage individuals in the designated service delivery area to avail themselves of program services.

**Outside Funds** – Resources pledged to the grant program that have a quantified dollar value. Such resources may include training funds from programs such as WIA Title I that are put aside for the exclusive use by participants enrolled in a program. Outside funds do not include in-kind services.

**Participant** – means an individual who has been determined to be eligible to participate in and who is receiving services (except follow-up services) under the program. Participation shall be deemed to commence on the first day, following determination of eligibility, on which the individual began receiving subsidized employment, training, or other services provided under the program. An individual who receives only outreach and/or intake assessment services does not meet this definition.

**Participants Enrolled** - A client should be recorded as having been enrolled when an intake form has been completed, and services, referral, and/or employment has been received through the program. This should be an unduplicated count over the year, i.e., each participant is recorded only once, regardless of the number of times she or he receives assistance.

**Participants Services** - This cost includes supportive, training, or social rehabilitation services, which will assist in stabilizing the participant. This category should reflect all costs other than administrative.

**Placed Into Transitional Or Permanent Housing** - A placement into transitional or permanent housing should be recorded when a veteran served by the program upgrades his/her housing situation during the reporting period from shelter/streets to transitional housing or permanent housing or from transitional housing to permanent housing. Placements resulting from referrals by staff shall be counted. This item is however an unduplicated count over the year, except that a participant may be counted once upon entering transitional housing and again upon obtaining permanent housing.

**Placement** - the act of securing unsubsidized employment for or by a participant.

**Placement Rate** - This is a method used to determine the percentage of participants who become employed. The figure is calculated by dividing the number of total participants who were registered for services or enrolled in the program by the number of applicants or program participants who were placed or otherwise entered employment.

**Pre-apprenticeship Training** - Any training designed to increase or upgrade specific academic, or cognitive, or physical skills required as a prerequisite for entry into a specific trade or occupation.

**Pre-enrollment Assessment** - The process of determining the employability and training needs of individuals before enrolling them into the program. Individual factors usually addressed during pre-enrollment assessment include: an evaluation and/or measurement of vocational interests and aptitudes, present abilities, previous education and work experience, income requirements, and personal circumstances.

**Preference** - The application of priorities in the consideration and selection through appointment or assignment of staff to funded positions, or in the provision of direct services and order of referral to listed openings in the order designated by statute regulation, and grant agreement.

**Program Resources** - Includes the total of both program or grant and outside funds.

**Program Year (PY)** - The 12-month period beginning July 1 in the fiscal year for which the appropriation is made, and ending on the following June 30.

**Qualified** - An individual who has been determined to possess the requisite knowledge, skills, and abilities for positions within the context of the selection process used to identify and rank persons possessing those attributes.

**Rate of Placement Into Unsubsidized Employment** - The rate of placement into unsubsidized employment is obtained by dividing the number placed into unsubsidized employment, plus the number of assisted placements into unsubsidized employment by the number of clients enrolled.

**Recently Separated Veteran** - Refers to an individual who applies for program participation or assistance within 48 months of separation from active U.S. military service [29 U.S.C. 1503 (27) (c)].



**Remedial Education** – Education instruction, particularly in basic skills, to raise an individual's general competency level in order to succeed in vocational education or skill training programs, or employment.

**Service Connected Disabled** - Refers to (1) a veteran who is entitled to compensation under laws administered by the Department of Veterans' Affairs, or (2) an individual who was discharged or released from active duty because of a service-connected disability (38 U.S.C. 4211 (3); 29 U.S.C., Chapter 19, section 1503 (27) (C))

**Service Delivery Point (SDP)** - Includes offices of the public employment delivery system operated directly or by contract with the State Workforce Agency as grantee within a State and may include One -Stop Career Centers, local employment service offices, and any satellite or itinerant offices at which labor exchange services are available.

**Solicitation for Grant Applications (SGA)** - A document which provides the requirements and instructions for the submission by eligible applicants identified in the document's text of requests for Federal domestic assistance (funds) for one or more programs or grants-in-aid.

**State Workforce Agency (SWA)** - The State level organization, as affiliated with the former United States Employment Service.

**Subgrant** – An award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee.

**Subgrantee** – The government or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided.

**Suitable Employment** – See "Unsubsidized Employment".

**Substance Abuser** – An individual dependent on alcohol or drugs, especially narcotics, whose dependency constitutes or results in a substantial barrier to employment.

**Supportive Services** – means services which are necessary to enable an individual eligible for training, but who cannot afford to pay for such services, to participate in a training program funded under the grant. Such supportive services may include transportation, health care, financial assistance (except as a post-termination service), drug and alcohol abuse counseling and referral, individual and family counseling, special services and materials for individuals with disabilities, job coaches, child care and dependent care, temporary shelter, financial counseling, and other reasonable expenses required for participation in the training program and may be provided in-kind or through cash assistance.

**Targeted Job Development** - The identification and marketing of a group of qualified applicants with similar occupations or employment barriers requiring personal visitation/phone contact with those employers likely to employ these individuals.

**Total Planned Expenditures** - Identified forecasted financial needs to accomplish programmatic objectives broken down into fiscal quarters.

**Unsubsidized Employment** - Employment not financed from funds provided under the grant. In the grant program the term "adequate" or "suitable" employment is also used to mean placement in unsubsidized employment which pays an income adequate to accommodate the participants' minimum economic needs.

**Upgrading or Retraining** - Training given to an individual who needs such training to advance above an entry level or dead-end position. This training shall include assisting veterans in acquiring needed state certification to be employed in the same field as they were trained in the military (i.e., Commercial Truck Driving License (CDL), Emergency Medical Technician (EMT), Airframe & Power Plant (A&P), Teaching Certificate, etc.)

**Veteran** - An individual who served in the United States active military, naval, or air service, and who was discharged or released there from under conditions other than dishonorable (29 U.S.C. Chapter 19, section 1503 (27) (A) [for WIA, Section 168 (VWIP) and WIA, Title I training/services]).

**Veterans' Workforce Investment Program (VWIP)** - Competitively awarded employment and training grants to meet the needs of veterans with significant barriers to employment; with service-connected disabilities; who served on active duty in the armed forces during a campaign or expedition for which a campaign badge has been authorized; and recently separated veterans. The U.S. Department of Labor, Veterans' Employment and Training Service awards VWIP grants as authorized under the Workforce Investment Act (WIA), Section 168.

**Vocational Exploration Training** - Through assessments such as interest inventories and/or counseling, a process of identifying occupations or occupational areas in which a person may find satisfaction and potential, and for which his or her aptitudes and other qualifications may be appropriate.

**Vocational Guidance** - The provision of information, suggestions, and advice through discussion with individuals who are considering a geographical or vocational choice or change, relating to their career decision.

**Wartime Veteran** - See "campaign veteran above."

**Welfare and/or Public Assistance recipient** - An individual who, during the course of the program year, receives or is a member of a family who receives cash welfare or public assistance payments under a Federal, state, or local welfare program.

**Workforce Investment Act (WIA)** – The purpose of this Act is to establish programs to prepare youth and unskilled adults for entry into the labor force and to afford job training to those economically disadvantaged individuals and other individuals, including veterans, who face serious barriers to employment and who are in need of such training to obtain prospective employment. The Act requires the Assistant Secretary for Veterans' Employment and Training to consult with the Secretary of the Department of Veterans Affairs to ensure that programs funded under VWIP of this Act meet the employment and training needs of service-connected disabled, Campaign, and recently separated veterans and are coordinated, to the maximum extent feasible, with related programs and activities.

**Work Experience** – A temporary activity (six months or less) which provides an individual with the opportunity to acquire the skills and knowledge necessary to perform a job, including appropriate work habits and behaviors, and which may be combined with classroom or other training. When wages are paid to a participant on work experience and when such wages are wholly paid for under WIA, the participant may not receive this training under a private, for profit employer.

**Youth** – An individual between 20 and 24 years of age.

USDOL/VETSLIST OF COMMON ACRONYMS

ADVET	Assistant Director for Veterans' Employment and Training
ASVET	Assistant Secretary (of Labor) for Veterans' Employment and Training
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CWT	Compensated Work Therapy
DOD	Department of Defense
DV	Disabled Veteran
DVA	Department of Veterans Affairs (see also VA)
DVET	Director for Veterans' Employment and Training Service
DVOP	Disabled Veterans' Outreach Program
DTAP	Disabled Veterans' Transition Assistance Program
EDP	Employment Development Plan
ES	Employment Service
ETA	Employment and Training Administration
FARS	Financial Accounting and Reporting System
FCJL	Federal Contractor Job Listing
FCP	Federal Contracting Program
FEMA	Federal Emergency Management Administration
FY	Fiscal Year
GOTR	Grant Officer's Technical Representative
GPRA	Government Performance and Results Act of 1994
HHS	Department of Health and Human Services
HHS/PMS	Health and Human Services/Payment Management System
HUD	Department of Housing and Urban Development
HVCAA	Homeless Veterans' Comprehensive Assistance Act - Title 38 USC, Section 2001
HVRP	Homeless Veterans' Reintegration Project
IEP	Individual Employment Plan
ISS	Individual Support System
IV-TP	Incarcerated Veterans' Transition Program
LEDS	Labor Exchange Delivery System
LESO	Local Employment Service Office
LMI	Labor Market Information
LVER	Local Veterans' Employment Representative
MHAA	McKinney-Vento Homeless Assistance Act - Title 42 USC, Section 11302(a)
MOU	Memorandum of Understanding
NOGA	Notice of Grant Award
NVTI	National Veterans' Training Institute
OASAM	Office of the Assistant Secretary for Administration and Management
OASVET	Office of the Assistant Secretary (of Labor) for Veterans' Employment and Training
OCB	Office of Cost Determination
OMB	Office of Management and Budget
OPM	Office of Personnel Management
OJT	On-the-Job-Training
PAC	Post Award Conference
PB	Personnel Benefits
PL	Public Law
PS	Personal Services

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PY	Program Year
RAVET	Regional Administrator for Veterans' Employment and Training
SDP	Service Delivery Point
SDV	Special Disabled Veteran
SF	Standard Form
SGA	Solicitation For Grant Applications
SSA	Social Security Administration
SWA	State Workforce Agency
TAP	Transition Assistance Program
UCX	Unemployment Compensation (Insurance) for ex-service members
UI	Unemployment Insurance
USC	United States Code
USDOL	United States Department of Labor
VA	Department of Veterans Affairs
VARO	Veterans' Administration Regional Office
VAMC	Veterans' Administration Medical Center
VETS	Veterans' Employment and Training Service
VEV	Vietnam-Era Veteran
VOE	Veterans and Other Eligible Persons
VPL	Veterans Program Letter
VR&E	Vocational Rehabilitation and Employment (formerly VR&C)
VSO	Veteran Service Organization
VWIP	Veterans' Workforce Investment Program (WIA, Section 168)
WIA	Workforce Investment Act of 1998
WIB	Workforce Investment Board



Rank	Area Name	Census Population	
		April 1, 2000	April 1, 1990
1	New York--Northern New Jersey--Long Island, NY--NJ--CT--PA CMSA	21,199,865	19,549,649
2	Los Angeles--Riverside--Orange County, CA CMSA	16,373,645	14,531,529
3	Chicago--Gary--Kenosha, IL--IN--WI CMSA	9,157,540	8,239,820
4	Washington--Baltimore, DC--MD--VA--WV CMSA	7,608,070	6,727,050
5	San Francisco--Oakland--San Jose, CA CMSA	7,039,362	6,253,311
6	Philadelphia--Wilmington--Atlantic City, PA--NJ--DE--MD CMSA	6,188,463	5,892,937
7	Boston--Worcester--Lawrence, MA--NH--ME--CT CMSA	5,819,100	5,455,403
8	Detroit--Ann Arbor--Flint, MI CMSA	5,456,428	5,187,171
9	Dallas--Fort Worth, TX CMSA	5,221,801	4,037,282
10	Houston--Galveston--Brazoria, TX CMSA	4,669,571	3,731,131
11	Atlanta, GA MSA	4,112,198	2,959,950
12	Miami--Fort Lauderdale, FL CMSA	3,876,380	3,192,582
13	Seattle--Tacoma--Bremerton, WA CMSA	3,554,760	2,970,328
14	Phoenix--Mesa, AZ MSA	3,251,876	2,238,480
15	Minneapolis--St. Paul, MN--WI MSA	2,968,806	2,538,834
16	Cleveland--Akron, OH CMSA	2,945,831	2,859,644
17	San Diego, CA MSA	2,813,833	2,498,016
18	St. Louis, MO--IL MSA	2,603,607	2,492,525
19	Denver--Boulder--Greeley, CO CMSA	2,581,506	1,980,140
20	San Juan--Caguas--Arecibo, PR CMSA	2,450,292	2,270,808
21	Tampa--St. Petersburg--Clearwater, FL MSA	2,395,997	2,067,959
22	Pittsburgh, PA MSA	2,358,695	2,394,811
23	Portland--Salem, OR--WA CMSA	2,265,223	1,793,476
24	Cincinnati--Hamilton, OH--KY--IN CMSA	1,979,202	1,817,571
25	Sacramento--Yolo, CA CMSA	1,796,857	1,481,102
26	Kansas City, MO--KS MSA	1,776,062	1,582,875
27	Milwaukee--Racine, WI CMSA	1,689,572	1,607,183
28	Orlando, FL MSA	1,644,561	1,224,852
29	Indianapolis, IN MSA	1,607,486	1,380,491
30	San Antonio, TX MSA	1,592,383	1,324,749
31	Norfolk--Virginia Beach--Newport News, VA--NC MSA	1,569,541	1,443,244
32	Las Vegas, NV--AZ MSA	1,563,282	852,737
33	Columbus, OH MSA	1,540,157	1,345,450
34	Charlotte--Gastonia--Rock Hill, NC--SC MSA	1,499,293	1,162,093
35	New Orleans, LA MSA	1,337,726	1,285,270
36	Salt Lake City--Ogden, UT MSA	1,333,914	1,072,227
37	Greensboro--Winston-Salem--High Point, NC MSA	1,251,509	1,050,304
38	Austin--San Marcos, TX MSA	1,249,763	846,227
39	Nashville, TN MSA	1,231,311	985,026
40	Providence--Fall River--Warwick, RI--MA MSA	1,188,613	1,134,350
41	Raleigh--Durham--Chapel Hill, NC MSA	1,187,941	855,545
42	Hartford, CT MSA	1,183,110	1,157,585
43	Buffalo--Niagara Falls, NY MSA	1,170,111	1,189,288
44	Memphis, TN--AR--MS MSA	1,135,614	1,007,306
45	West Palm Beach--Boca Raton, FL MSA	1,131,184	863,518
46	Jacksonville, FL MSA	1,100,491	906,727
47	Rochester, NY MSA	1,098,201	1,062,470
48	Grand Rapids--Muskegon--Holland, MI MSA	1,088,514	937,891

49	Oklahoma City, OK MSA	1,083,346	958,839
50	Louisville, KY--IN MSA	1,025,598	948,829
51	Richmond--Petersburg, VA MSA	996,512	865,640
52	Greenville--Spartanburg--Anderson, SC MSA	962,441	830,563
53	Dayton--Springfield, OH MSA	950,558	951,270
54	Fresno, CA MSA	922,516	755,580
55	Birmingham, AL MSA	921,106	840,140
56	Honolulu, HI MSA	876,156	836,231
57	Albany--Schenectady--Troy, NY MSA	875,583	861,424
58	Tucson, AZ MSA	843,746	666,880
59	Tulsa, OK MSA	803,235	708,954
60	Syracuse, NY MSA	732,117	742,177
61	Omaha, NE--IA MSA	716,998	639,580
62	Albuquerque, NM MSA	712,738	589,131
63	Knoxville, TN MSA	687,249	585,960
64	El Paso, TX MSA	679,622	591,610
65	Bakersfield, CA MSA	661,645	543,477
66	Allentown--Bethlehem--Easton, PA MSA	637,958	595,081
67	Harrisburg--Lebanon--Carlisle, PA MSA	629,401	587,986
68	Scranton--Wilkes-Barre--Hazleton, PA MSA	624,776	638,466
69	Toledo, OH MSA	618,203	614,128
70	Baton Rouge, LA MSA	602,894	528,264
71	Youngstown--Warren, OH MSA	594,746	600,895
72	Springfield, MA MSA	591,932	587,884
73	Sarasota--Bradenton, FL MSA	589,959	489,483
74	Little Rock--North Little Rock, AR MSA	583,845	513,117
75	McAllen--Edinburg--Mission, TX MSA	569,463	383,545

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## DEPARTMENT OF LABOR

### Veterans' Employment and Training Service

#### Urban Homeless Veterans' Reintegration Program (HVRP) Grants for Program Year (PY) 2004; Funding Opportunity

*Announcement Type:* Initial Solicitation for Grant Applications (SGA).

*Funding Opportunity Number:* SGA 04-03.

*Catalogue of Federal Domestic Assistance Number:* 17-805.

*Dates:* Applications are due on May 13, 2004.

*Period of Performance* is PY 2004, July 1, 2004 through June 30, 2005.

*Executive Summary* (Applicants for Grant Funds Should Read This Notice In Its Entirety): The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with

the requirements of 38 U.S.C. Section 2021, as added by Section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to expedite the reintegration of homeless veterans into the labor force.

The Homeless Veterans' Reintegration Program (HVRP) grants are designated in three (3) award categories: urban, non-urban, and intermediaries. Separate Solicitations for Grant Applications (SGAs) are being issued for each grant category. This is the solicitation for "Urban HVRP grants." Previous HVRP grants have provided valuable information on approaches and techniques that work in the different environments. Due to limited funding and the high concentration of homeless veterans in the metropolitan areas of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico, the only jurisdictions eligible to be served through this urban competition for

HVRPs are those areas listed in Appendix I.

HVRP grants are intended to address two objectives: (1) To provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (2) to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans. Successful applicants will design programs that assist eligible veterans by providing job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. Successful programs will also be designed to be flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce.

Under this solicitation covering Fiscal Year (FY) 2004, VETS anticipates that up to \$3,600,000 will be available for grant awards up to a maximum of \$300,000 for each grant award. VETS expects to award approximately twelve (12) grants. This notice contains all of

the necessary information and forms to apply for grant funding. The period of performance for these PY 2004 grants will be July 1, 2004 through June 30, 2005. Two (2) optional years of funding may be available, depending upon Congressional funding appropriations, the agency's decision to exercise the optional year(s) of funding, and satisfactory grantee performance.

### I. Funding Opportunity Description

The U.S. Department of Labor (USDOL), Veterans' Employment and Training Service (VETS), announces a grant competition that complies with the requirements of 38 U.S.C. Section 2021, as added by Section 5 of Public Law 107-95, the Homeless Veterans Comprehensive Assistance Act of 2001 (HVCAA). Section 2021 requires the Secretary of Labor to conduct, directly or through grant or contract, such programs as the Secretary determines appropriate to provide job training, counseling, and placement services (including job readiness, literacy training, and skills training) to expedite the reintegration of homeless veterans into the labor force.

1. *Program Concept and Emphasis:* HVRP grants are intended to address two objectives: (a) To provide services to assist in reintegrating homeless veterans into meaningful employment within the labor force, and (b) to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

For this Fiscal Year (FY) 2004 grant solicitation, VETS seeks applicants that will provide direct services through a case management approach that networks with Federal, State, and local resources for veteran support programs. Successful applicants will have clear strategies for employment and retention of employment for homeless veterans. Successful applicants will design programs that assist eligible veterans by providing job placement services, job training, counseling, supportive services, and other assistance to expedite the reintegration of homeless veterans into the labor force. Successful applicants will also design programs that are flexible in addressing the universal as well as the local or regional problems that have had a negative impact on homeless veterans reentering the workforce. The HVRP in PY 2004 will seek to continue to strengthen development of effective service delivery systems, to provide comprehensive services through a case management approach that address complex problems facing eligible veterans trying to transition into gainful

employment, and to improve strategies for employment and retention in employment.

Due to the limited amount of funding and the high concentration of homeless veterans in the metropolitan areas of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico, the only jurisdictions eligible to be served through this urban competition for HVRP are those areas listed in Appendix I.

2. *Community Awareness Activities:* In order to promote networking between the HVRP funded program and local service providers (and thereby eliminate gaps or duplication in services and enhance the provision of assistance to participants), the grantee must provide project orientation workshops and/or program awareness activities that it determines are the most feasible for the types of providers listed below. Grantees are encouraged to demonstrate strategies for incorporating small faith-based and community organizations (defined as organizations with social services budgets of approximately \$300,000 or seven (7) or fewer full-time employees) into their outreach plans. Project orientation workshops conducted by grantees have been an effective means of sharing information and informing the community of the availability of other services; they are encouraged but not mandatory. Rather, grantees will have the flexibility to attend service provider meetings, seminars, and conferences, to outstation staff, and to develop individual service contracts as well as to involve other agencies in program planning.

*The grantee will be responsible for providing project awareness, program information, and orientation activities to the following:*

A. Direct providers of services to homeless veterans including shelter and soup kitchen operators: to make them aware of the services available to homeless veterans to make them job-ready and to aid their placement into jobs.

B. Federal, State, and local entitlement and social service agencies such as the Social Security Administration (SSA), Department of Veterans Affairs (DVA), State Workforce Agencies (SWAs) and their local One-Stop Centers (which integrate Workforce Investment Act (WIA), labor exchange, and other employment and social services), mental health services, and healthcare detoxification facilities: to familiarize them with the nature and needs of homeless veterans.

C. Civic and private sector groups, in particular Veterans' Service Organizations, support groups, job

training and employment services, and community-based organizations (including faith-based organizations): to provide information on homeless veterans and their needs.

The grantee will also be responsible for participating in "Stand Down" events. A "Stand Down" is an event held in a locality, usually for three (3) days, where services are provided to homeless veterans along with shelter, meals, clothing, employment services, and medical attention. This type of event is mostly a volunteer effort, which is organized within a community and brings service providers together such as the Department of Veterans Affairs, Disabled Veterans' Outreach Program Specialists and Local Veterans' Employment Representatives from the State Workforce Agencies, Veteran Service Organizations, military personnel, civic leaders, and a variety of other interested persons, groups, and organizations. Many services are provided on-site with referrals also made for continued assistance after the Stand Down event. These events can often be the catalyst that enables homeless veterans to get back into mainstream society. The Department of Labor has supported replication of these events and many have been held throughout the nation.

*In areas where an HVRP is operating, grantees are expected and encouraged to participate fully and offer their services for all locally planned Stand Down event(s).* Toward this end, up to \$5,000 of the currently requested HVRP grant funds may be used to supplement the Stand Down efforts, where funds are not otherwise available, and may be requested in the budget and explained in the budget narrative.

3. *Scope of Program Design:* The project design must include the following services:

A. Outreach, intake, assessment, peer counseling to the degree practical, employment services, and follow-up support services to enhance retention in employment. Program staff providing outreach services should have experience in dealing with, and an understanding of the needs of, homeless veterans.

B. Provision of or referral to employment services such as: job search workshops, job counseling, assessment of skills, resume writing techniques, interviewing skills, subsidized trial employment (work experience), job development services, job placement into unsubsidized employment, job placement follow-up services to enhance retention in employment.

C. Provision of or referral to training services such as: basic skills instruction,

remedial education activities, life skills and money management training, on-the-job training, classroom training, vocational training, specialized and/or licensing training programs, and other formal training programs as deemed appropriate to benefit the participant. At least 80% of the enrolled HVRP participants must participate in training activities.

D. Grantees will perform a preliminary assessment of each participant's eligibility for Department of Veterans Affairs (DVA) service-connected disability, compensation, and/or pension benefits. As appropriate, grantees will work with the Veterans Service Organizations or refer the participants to DVA in order to file a claim for compensation or pension. Grantees will track progress of claims and report outcomes in case management records.

E. Coordination with veterans' services programs, including: Disabled Veterans' Outreach Program Specialists (DVOPs), Local Veterans' Employment Representatives (LVERs) in the State Workforce Agencies (SWAs) or in the workforce development system's One-Stop Centers, as well as Veterans' Workforce Investment Programs (VWIPs), Department of Veterans Affairs (DVA) services, including its Health Care for Homeless Veterans, Domiciliary Care, Regional Benefits Assistance Program, and Transitional Housing under Homeless Provider Grant and per diem programs.

F. Networking with Veterans' Service Organizations such as: The American Legion, Disabled American Veterans, Veterans of Foreign Wars, Vietnam Veterans of America, the American Veterans (AMVETS).

G. Referral as necessary to health care, counseling, and rehabilitative services including, but not limited to: Alcohol and drug rehabilitation, therapeutic services, Post Traumatic Stress Disorder (PTSD) services, and mental health services as well as coordination with McKinney Homeless Assistance Act (MHAA) Title VI programs for health care for the homeless, and health care programs under the Homeless Veterans Comprehensive Assistance Act of 2001.

H. Referral to housing assistance, as appropriate, provided by: Local shelters, Federal Emergency Management Administration (FEMA) food and shelter programs, transitional housing programs and single room occupancy housing programs funded under MHAA Title IV (and under HVCAA), and permanent housing programs for disabled homeless persons funded under MHAA Title IV (and under HVCAA).

4. *Results-Oriented Model:* No specific model is mandatory, but successful applicants will design a program that is responsive to the needs of the local community and achieves the HVRP objectives. The HVRP objectives are to successfully reintegrate homeless veterans into the workforce and to stimulate the development of effective service delivery systems that will address the complex problems facing homeless veterans.

Under the Government Performance and Results Act (GPRA), Congress and the public are looking for program results rather than program processes. The outcome measurement established for HVRP grants is for grantees to meet a minimum entered employment rate of 58%, determined by dividing the number of entered employments by the number of HVRP enrollments. (Actual performance outcomes will be reported quarterly in spreadsheet format to be provided to grantees at the post award conference.) While the percentage of HVRP enrollments that enter employment is an important outcome, it is also necessary to evaluate and measure the program's long-term results, through the 90-day and 180-day follow-up period, to determine the quality and success of the program.

The applicant's program should be based on a results-oriented model. The first phase of activity should consist of the level of outreach necessary to introduce the program to eligible homeless veterans. Outreach also includes establishing contact with other agencies that encounter homeless veterans. Once the eligible homeless veterans have been identified, an assessment must be made of each individual's abilities, interests, needs, and barriers to employment. In some cases, participants may require referrals to services such as rehabilitation, drug or alcohol treatment, or a temporary shelter before they can be enrolled into the HVRP program. Once the eligible homeless veteran is "stabilized," the assessment must concentrate on the employability of the individual and whether the individual is to be enrolled into the HVRP program.

A determination should be made as to whether the HVRP enrolled participant would benefit from pre-employment preparation such as resume writing, job search workshops, related employment counseling, and case management, or possibly an initial entry into the job market through temporary jobs. Additionally, sheltered work environments, classroom training and/or on-the-job training must be evaluated. Such services should be noted in an Employability Development Plan to

facilitate the staff's successful monitoring of the plan. Entry into full-time employment or a specific job-training program should follow, in keeping with the overall objective of HVRP, to bring the participant closer to self-sufficiency. Supportive services may assist the HVRP enrolled participant at this point or even earlier.

Job development, a crucial part of the employability process, is usually when there are no competitive job openings that the HVRP enrolled participant is qualified to apply for, therefore, a job opportunity is created or developed specifically for that HVRP enrolled participant with an employer. HVRP enrolled participants who are ready to enter employment and/or who are in need of intensive case management services are to be referred to the DVOP and LVER staff at a One-Stop Center. DVOP and LVER staff are able to provide HVRP enrolled participants the following services: job development, employment services, case management and career counseling. Most DVOP and LVER staff received training in case management at the National Veterans' Training Institute. All DVOP and LVER staff provide employment related services to veterans who are most at a disadvantage in the labor market. VETS' urges working hand-in-hand with DVOP/LVER staff to achieve economies of resources.

The applicant's program must include tracking of program participants. Tracking should begin with the referral to employment and continue through the 90-day and 180-day follow-up periods after entering employment to determine whether the veteran is in the same or similar job. It is important that the grantee maintain contact with veterans after placement to ensure that employment-related problems are addressed. The 90-day and 180-day follow-ups are fundamental to assessing program results. Grantees need to budget for 90-day and 180-day follow-up activity so that it can be performed for those participants placed at or near the end of the grant performance period. All grantees, prior to the end of the grant performance period, must obligate sufficient funds to ensure that follow-up activities are completed. Such results will be reported in the final technical performance report.

## II. Award Information

1. *Type of Funding Instrument:* One (1) year grant.

2. *Funding Levels:* The total funding available for this Urban HVRP solicitation is up to \$3,600,000. It is anticipated that approximately twelve (12) awards will be made under this

solicitation. Awards are expected to range from \$200,000 to a maximum of \$300,000. The Department of Labor reserves the right to negotiate the amounts to be awarded under this competition. Please be advised that requests exceeding \$300,000 will be considered non-responsive.

3. *Period of Performance:* The period of performance will be for twelve (12) months from date of award unless modified by the Grant Officer. It is expected that successful applicants will begin program operations under this solicitation on July 1, 2004. All program funds must be obligated by June 30, 2005; a limited amount of funds may be obligated and reserved for follow-up activities and closeout.

4. *Optional Year Funding:* Should Congress appropriate additional funds for this purpose, VETS may consider an optional two (2) years of funding. The Government does not, however, guarantee optional year funding for any grantee. In deciding whether to exercise any optional year(s) of funding, VETS will consider grantee performance during the previous period of operations as follows:

A. The grantee must meet, at minimum, 85% of planned goals for Federal expenditures, enrollments, and placements in each quarter and/or at least 85% of planned cumulative goals by the end of the third quarter; and

B. The grantee must be in compliance with all terms identified in the Solicitation for Grant Application (SGA) and grant award document; and

C. All program and fiscal reports must have been submitted by the established due dates and must be verifiable for accuracy.

### III. Eligibility Information

1. *Eligible Applicants:* Applications for funds will be accepted from State and local Workforce Investment Boards, local public agencies, for-profit/commercial entities, and nonprofit organizations, including faith-based and community organizations. Applicants must have a familiarity with the area and population to be served and the ability to administer an effective and timely program.

Eligible applicants will generally fall into one of the following categories:

- State and local Workforce Investment Boards (WIBs), established under Sections 111 and 117 of the Workforce Investment Act.

- Public agencies, meaning any public agency of a State or of a general purpose political subdivision of a State that has the power to levy taxes and spend funds, as well as general corporate and police powers. (This

typically refers to cities and counties.) A State agency may propose in its application to serve one or more of the potential jurisdictions located in its State. This does not preclude a city or county agency from submitting an application to serve its own jurisdiction.

- For-profit/commercial entities.
- Nonprofit organizations. If claiming 501(c)(3) status, the Internal Revenue Service statement indicating 501(c)(3) status approval must be submitted.

**Note:** Qualifying applications from grantees in the below listed States that are not currently receiving HVRP funds (and are included on Appendix I) may receive priority funding over applicants in those States that are currently receiving HVRP funds: Arkansas, Delaware, Georgia, Kansas, Mississippi, Nebraska, New Hampshire, Rhode Island, Utah, Virginia, and West Virginia.

2. *Cost Sharing:* Cost sharing and/or matching funds are *not* required. However, we do encourage the use of sharing and/or matching funds.

3. *Other Eligibility Criteria:*

A. This SGA is for Urban HVRP grants. Separate SGAs for non-urban and intermediaries HVRP grants have been simultaneously issued.

B. The proposal must include an outreach component that uses either DVOP/LVER staff or a trained outreach cadre. Programs must be "employment focused." The services provided must be directed toward: (1) Increasing the employability of homeless veterans through training or arranging for the provision of services that will enable them to work; and (2) matching homeless veterans with potential employers.

C. Applicants are encouraged to utilize, through partnerships or sub-awards, experienced public agencies, private nonprofit organizations, private businesses, faith-based and community organizations, and colleges and universities (especially those with traditionally high enrollments of minorities) that have an understanding of unemployment and the barriers to employment unique to homeless veterans, a familiarity with the area to be served, and the capability to effectively provide the necessary services.

D. To be eligible for enrollment under this HVRP grant an individual must be homeless *and* a veteran defined as follows:

- The term "*homeless or homeless individual*" includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either a supervised public or private shelter designed to provide temporary

living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. [42 U.S.C. 11302 (a)].

- The term "*veteran*" means a person who served in the active military, naval, or air service, and who was discharged or released under conditions other than dishonorable. [38 U.S.C. 101(2)]

### IV. Application and Submission Information

1. *Address to Request an Application and Amendments:* Application announcements or forms will not be mailed. The **Federal Register** may be obtained from your nearest government office or library. Additional application packages may be obtained from the VETS Web site at <http://www.dol.gov/vets> and at <http://www.fedgrants.gov/>. The application forms and their instructions, and other pertinent materials are included in the Appendices. If copies of the standard forms are needed, they can also be downloaded from: [http://www.whitehouse.gov/omb/grants/grants\\_forms.html](http://www.whitehouse.gov/omb/grants/grants_forms.html).

To receive amendments to this Solicitation, all applicants must register their name and address in writing with the Grant Officer at the following address: U.S. Department of Labor, Procurement Services Center, Attn: Cassandra Mitchell, Reference SGA 04-03, 200 Constitution Avenue, NW., Room N-5416, Washington, DC 20210, Phone Number: (202) 693-4570 (not a toll free number).

2. *Content and Form of Application:* The grant application must consist of three (3) separate and distinct sections: the Executive Summary, the Technical Proposal, and the Cost Proposal. The information provided in these three (3) sections is essential to gain an understanding of the programmatic and fiscal contents of the grant proposal.

*A complete grant application package must include:*

- An original blue ink-signed and two (2) copies of the cover letter.
- An original and two (2) copies of the Executive Summary (see below).
- An original and two (2) copies of the Technical Proposal (see below) that includes a completed Technical Performance Goals Form (Appendix D).
- An original and two (2) copies of the Cost Proposal (see below) that includes an original blue ink-signed Application for Federal Assistance, SF-424 (Appendix A), a Budget Narrative, Budget Information Sheet SF-424A



(Appendix B), an original blue ink-signed and Assurances and Certifications Signature Page (Appendix C), a Direct Cost Description for Applicants and Sub-applicants (Appendix E), and a completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F).

A. *Section 1—Executive Summary:* A one to two page "Executive Summary" reflecting the grantees' overall strategy, timeline, and outcomes to be achieved in their grant proposal is required. This executive summary does not count against the 15-page limit. The executive summary should include:

- The proposed area to be served through the activities of this grant.
- Years of grantee's service to the residents in the proposed area to be served.

- Projects and activities that will expedite the reintegration of homeless veterans into the workforce.

- Summary of outcomes, benefits, and value added by the project.

B. *Section 2—Technical Proposal* consists of a narrative proposal that demonstrates the need for this particular grant program, the services and activities proposed to obtain successful outcomes for the homeless veterans to be served; and the applicant's ability to accomplish the expected outcomes of the proposed project design.

*The technical proposal narrative must not exceed fifteen (15) pages double-spaced, font size no less than 11 pt., and typewritten on one (1) side of the paper only. Note:* Resumes, charts, standard forms, transmittal letters, Memorandums of Understanding, agreements, lists of contracts and grants, and letters of support are not included in the page count. If provided, include these documents as attachments to the technical proposal.

*Required Content:* There are program activities that all applications must contain to be found technically acceptable under this SGA. Programs must be "employment focused" and must be responsive to the rating criteria in Section V(1). *The required program activities are:* Outreach, pre-enrollment assessments, employment development plans for each enrolled participant, case management, job placement, job retention follow-up (at 90 and 180 days) after individual enters employment, utilization/coordination of services with DVOP and LVER staff, and community linkages with other programs and services that provide support to homeless veterans.

*The following format for the technical proposal is recommended: Need for the program:* The applicant must identify the geographical area to be served and

provide an estimate of the number of homeless veterans in the designated geographical area. Include poverty and unemployment rates in the area and identify the disparities in the local community infrastructure that exacerbate the employment barriers faced by the targeted veterans. Include labor market information and job opportunities in the employment fields and industries that are in demand in the geographical area to be served.

*Approach or strategy to increase employment and job retention:* Applicants must be responsive to the Rating Criteria contained in Section V(1) and address all of the rating factors as thoroughly as possible in the narrative. *The applicant must:*

- Describe the specific supportive employment and training services to be provided under this grant and the sequence or flow of such services;

- Indicate the type(s) of training that will be provided under the grant and how it relates to the jobs that are in demand, length of training, training curriculum, and how the training will improve the eligible veterans' employment opportunities within that geographical area;

- Provide a follow-up plan that addresses retention after 90 and 180 days with participants who have entered employment;

- Include the completed Planned Quarterly Technical Performance Goals (and planned expenditures) form listed in Appendix D.

*Linkages with facilities that serve homeless veterans:* Describe program and resource linkages with other facilities that will be involved in identifying potential clients for this program. Describe any networks with other related resources and/or other programs that serve homeless veterans. Indicate how the program will be coordinated with any efforts that are conducted by public and private agencies in the community. Indicate how the applicant will coordinate with any "continuum of care" efforts for the homeless among agencies in the community. If a Memorandum of Understanding (MOU) or other service agreement with service providers exists, copies should be provided.

*Linkages with other providers of employment and training services to homeless veterans:* Describe the networks the program will have with other providers of services to homeless veterans; include a description of the relationship with other employment and training programs such as Disabled Veterans' Outreach Program (DVOP), the Local Veterans' Employment Representative (LVER) program, and

programs under the Workforce Investment Act such as the Veterans' Workforce Investment Program (VWIP); and list the type of services that will be provided by each. Note the type of agreement in place, if applicable. Linkages with the workforce development system must be delineated. Describe any networks with any other resources and/or other programs for homeless veterans. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

*Linkages with other Federal agencies:* Describe program and resource linkages with the Department of Housing and Urban Development (HUD), Department of Health and Human Services (HHS), and Department of Veterans Affairs (DVA), to include the Compensated Work Therapy (CWT) and per diem programs. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exists, copies should be provided.

*Proposed supportive service strategy for veterans:* Describe how supportive service resources for veterans will be obtained and used. If resources are provided by other sources or linkages, such as Federal, State, local, or faith-based and community programs, the applicant must fully explain the use of these resources and how they will be applied. If a Memorandum of Understanding (MOU) or other service agreements with other service providers exist, copies should be provided.

*Organizational capability to provide required program activities:* The applicant's relevant current or prior experience in operating employment and training programs should be clearly described. A summary narrative of program experience and employment and training performance outcomes is required. *The applicant should provide information showing outcomes of all past employment and training programs in terms of enrollments and placements.* An applicant that has operated a HVRP, other Homeless Employment and Training program, or VWIP program must include the final or most recent technical performance reports. The applicant must also provide evidence of key staff capability. It is preferred that the grantee be well established and not in the start-up phase or process.

*Proposed housing strategy for homeless veterans:* Describe how housing resources for eligible homeless veterans will be obtained or accessed. These resources must be from linkages or sources other than the HVRP grant such as HUD, HHS, community housing

resources, DVA leasing, or other programs.

**C. Section 3—The Cost Proposal must contain the following:** Applicants can expect that the cost proposal will be reviewed for allocability, allowability, and reasonableness.

(1) Standard Form SF-424, "Application for Federal Assistance" (with the original signed in blue-ink) (Appendix A) must be completed;

The Catalog of Federal Domestic Assistance number for this program is 17.805 and it must be entered on the SF-424, in Block 10.

The organizational unit section of Block 5 of the SF-424 must contain the Dun and Bradstreet Number (DUNS) of the applicant. Beginning October 1, 2003, all applicants for Federal grant funding opportunities are required to include a DUNS number with their application. See OMB Notice of Final Policy Issuance, 68 FR 38402 (June 27, 2003). Applicants' DUNS number is to be entered into Block 5 of SF-424. The DUNS number is a nine-digit identification number that uniquely identifies business entities. There is no charge for obtaining a DUNS number. To obtain a DUNS number call 1-866-705-5711 or access the following Web site: <http://www.dunandbradstreet.com/>. Requests for exemption from the DUNS number requirement must be made to the Office of Management and Budget.

(2) Standard Form SF-424A "Budget Information Sheet" (Appendix B) must be included;

(3) As an attachment to SF-424A, the applicant must provide a detailed cost breakout of each line item on the Budget Information Sheet. Please label this page or pages the "Budget Narrative" and ensure that costs reported on the SF-424A correspond accurately with the Budget Narrative;

*The Budget Narrative must include, at a minimum:*

- Breakout of all personnel costs by position, title, salary rates, and percent of time of each position to be devoted to the proposed project (including sub-grantees) by completing the "Direct Cost Descriptions for Applicants and Sub-Applicants" form (Appendix E);

- Explanation and breakout of extraordinary fringe benefit rates and associated charges (*i.e.*, rates exceeding 35% of salaries and wages);

- Explanation of the purpose and composition of, and method used to derive the costs of, each of the following: travel, equipment, supplies, sub-awards/contracts, and any other costs. The applicant must include costs of any required travel described in this Solicitation. Mileage charges may not

exceed 37.5 cents per mile, or the current Federal rate;

- All associated costs for retaining participant information pertinent to the follow-up survey, 180 days after the program performance period ends;

- Description/specification of, and justification for, equipment purchases, if any. Tangible, non-expendable, personal property having a useful life of more than one year and a unit acquisition cost of \$5,000 or more per unit must be specifically identified; and
- Identification of all sources of leveraged or matching funds and an explanation of the derivation of the value of matching/in-kind services. If resources/matching funds and/or the value of in-kind contributions are made available, please show in Section B of the Budget Information Sheet.

(4) A completed Assurance and Certification signature page (Appendix C) (signed in blue ink) must be submitted;

(5) All applicants must submit evidence of satisfactory financial management capability, which must include recent (within the last 18 months) financial and/or audit statements. Grantees are required to utilize Generally Accepted Accounting Practices (GAAP), maintain a separate accounting for these grant funds, and have a checking account;

(6) All applicants must include, as a separate appendix, a list of all employment and training government grants and contracts that it has had in the past three (3) years, including grant/contract officer contact information. VETS reserves the right to have a DOL representative review and verify this data;

(7) A completed Survey on Ensuring Equal Opportunity for Applicants (Appendix F) must be provided.

**3. Submission Dates and Times** (Acceptable Methods of Submission): The grant application package must be received at the designated place by the date and time specified or it will not be considered. Any application received at the Office of Procurement Services after 4:45 p.m. ET, May 13, 2004, will not be considered unless it is received before the award is made and:

- It is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the U.S. Department of Labor at the address indicated; or

- It was sent by registered or certified mail not later than the fifth calendar day before May 13, 2004; or

- It was sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee, not later than 5 p.m. at the place of mailing two (2)

working days, excluding weekends and Federal holidays, prior to May 13, 2004.

**4. Intergovernmental Review:** Not Applicable.

**5. Funding Restrictions:**

A. Proposals exceeding \$300,000 will be considered non-responsive.

B. There is a limit of one (1) application per submitting organization and location. If two (2) applications from the same organization for the same location are submitted, the application with the later date will be considered non-responsive.

C. Due to the limited availability of funding, if an organization was awarded Fiscal Year 2003 HVRP funds for a specific location and will be receiving second and possible third year funding, that organization at that specific location will be considered ineligible to compete for FY 2004 HVRP funds.

D. There will not be reimbursement of pre-award costs unless specifically agreed upon in writing by the Department of Labor.

E. Entities described in Section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities are not eligible to receive funds under this announcement because Section 18 of the Lobbying Disclosure Act of 1995, Public Law No. 104-65, 109 Stat. 691, prohibits the award of Federal funds to these entities.

F. The only potential areas that will be served through this urban competition for HVRPs in FY 2004 are the metropolitan areas of the 75 U.S. cities largest in population and the city of San Juan, Puerto Rico (see Appendix I).

G. The government is prohibited from directly funding religious activity.\* HVRP grants may not be used for religious instruction, worship, prayer, proselytizing or other inherently religious practices. Neutral, secular criteria that neither favor nor disfavor religion must be employed in the selection of grant and sub-grant recipients. In addition, under the Workforce Investment Act (WIA) and Department of Labor regulations implementing the WIA, a recipient may not train a participant in religious

\*The term "direct" funding is used to describe funds that are provided "directly" by a governmental entity or an intermediate organization with the same duties as the government entity, as opposed to funds that an organization receives as the result of the genuine and independent private choice of a beneficiary. In other contexts, the term "direct" funding may be used to refer to those funds that an organization receives directly from the Federal government (also known as "discretionary" funding), as opposed to funding that it receives from a State or local government (also known as "indirect" or "block grant" funding). In this SGA, the term "direct" has the former meaning.

activities, or permit participants to construct, operate, or maintain any part of a facility that is primarily used or devoted to religious instruction or worship. Under WIA, "no individual shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with, any such program or activity because of race, color, religion, sex (except as otherwise permitted under Title IX of the Education Amendments of 1972), national origin, age, disability, or political affiliation or belief."

#### H. Limitations on Administrative and Indirect Costs

- Administrative costs, which consist of all direct and indirect costs associated with the supervision and management of the program, are limited to and will not exceed 20% of the total grant award.

- Indirect costs claimed by the applicant must be based on a Federally approved rate. A copy of the negotiated approved and signed indirect cost negotiation agreement must be submitted with the application. Furthermore, indirect costs are considered a part of administrative costs for HVRP purposes and, therefore, may not exceed 20% of the total grant award.

- If the applicant does not presently have an approved indirect cost rate, a proposed rate with justification may be submitted. Successful applicants will be required to negotiate an acceptable and allowable rate within 90 days of grant award with the appropriate DOL Regional Office of Cost Determination or with the applicant's cognizant agency for indirect cost rates (See Office of Management and Budget Web site at <http://www.whitehouse.gov/omb/grants/attach.html>).

- Indirect cost rates traceable and trackable through the State Workforce Agency's Cost Accounting System represent an acceptable means of allocating costs to DOL and, therefore, can be approved for use in grants to State Workforce Agencies.

#### 6. Other Submission Requirements:

The only acceptable evidence to establish the date of mailing of a late application sent by registered or certified mail is the U.S. Postal Service postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. If the postmark is not legible, an application received after the above closing time and date shall be processed as if mailed late. "Postmark" means a printed, stamped or otherwise placed impression (not a postage meter machine impression) that is readily

identifiable without further action as having been applied and affixed by an employee of the U.S. Postal Service on the date of mailing. Therefore applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the date of mailing of a late application sent by U.S. Postal Service Express Mail Next Day Service-Post Office to Addressee is the date entered by the Post Office clerk on the "Express Mail Next Day Service-Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the U.S. Postal Service. "Postmark" has the same meaning as defined above. Therefore, applicants should request that the postal clerk place a legible hand cancellation "bull's-eye" postmark on both the receipt and the envelope or wrapper.

The only acceptable evidence to establish the time of receipt at the U.S. Department of Labor is the date/time stamp of the Procurement Services Center on the application wrapper or other documentary evidence or receipt maintained by that office. Applications sent by other delivery services, such as Federal Express, UPS, etc., will also be accepted.

*All applicants are advised that U.S. mail delivery in the Washington, DC area has been erratic due to security and anthrax concerns. All applicants must take this into consideration when preparing to meet the application deadline, as you assume the risk for ensuring a timely submission, that is, if, because of these mail problems, the Department does not receive an application or receives it too late to give proper consideration, even if it was timely mailed, the Department is not required to consider the application.*

#### V. Application Review Information

1. **Application Evaluation Criteria:** Applications will receive up to 100 total points based on the following criteria:

##### A. Need for the Project: 10 Points

The applicant will document the need for this project, as demonstrated by: (i) The potential number or concentration of homeless individuals and homeless veterans in the proposed project area relative to other similar areas; (ii) the rates of poverty and/or unemployment in the proposed project area as determined by the census or other surveys; and (iii) the extent of the gaps in the local infrastructure to effectively address the employment barriers that characterize the target population.

#### B. Overall Strategy To Increase Employment and Retention in Employment: 35 Points

The application must include a description of the approach to providing comprehensive employment and training services, including job training, job development, obtaining employer commitments to hire, placement, and post-placement follow-up services. Applicants must address how they will target occupations in emerging industries. Supportive services provided as part of the strategy of promoting job readiness and job retention must be indicated. The applicant must identify the local services and sources of training to be used for participants. At least 80% of enrolled participants must participate in training. A description of the relationship, if any, with other employment and training programs such as State Workforce Agencies (including DVOP and LVER Programs), One-Stops, VWIP, other WIA programs, and Workforce Investment or Development Boards or entities where in place, must be specified. Applicant must indicate how the activities will be tailored or responsive to the needs of homeless veterans. A participant flow chart may be used to show the sequence and mix of services.

**Note:** The applicant must complete Appendix D, the Technical Performance Goals Form, with proposed programmatic outcomes, including participants served, placement/entered employments and job retention. Of the 35 points possible in the strategy to increase employment and retention, 5 points will be awarded to grant proposals that demonstrate the ability to maintain a 180 day employment retention rate of 50 percent or greater. Applicants whose applications persuasively propose to use peer counselors who are themselves veterans will be awarded five (5) of the available points in the scoring criteria.

#### C. Quality and Extent of Linkages With Other Providers of Services to the Homeless and to Veterans: 20 Points

The application must provide information on the quality and extent of the linkages this program will have with other providers of services to homeless veterans in the local community including faith-based and community organizations. For each service, the applicant must specify who the provider is, the source of funding (if known), and the type of linkages/referral system established or proposed. Describe, to the extent possible, how the project would be incorporated into the community's continuum of care approach to respond to homelessness and show any linkages to HUD, HHS or DVA programs that will be advantageous to the proposed program.

**D. Demonstrated Capability in Providing Required Program Services, Including Programmatic Reporting and Participant Tracking: 25 Points**

The applicant must describe its relevant prior experience in operating employment and training programs and providing services to participants similar to those that are proposed under this solicitation. Specific outcomes previously achieved by the applicant must be described, such as job placements, benefits secured, network coalitions, etc. The applicant must also address its capacity for timely startup of the program, programmatic reporting, and participant tracking. The applicant should describe its staff experience and ability to manage the administrative, programmatic and financial aspects of a grant program. Include a recent (within the last 18 months) financial statement or audit. Final or most recent technical reports for other relevant programs must be submitted, if applicable. Because prior HVRP grant experience is not a requirement for this grant, some applicants may not have any technical performance reports to submit.

**E. Quality of Overall Housing Strategy: 10 Points**

The application must demonstrate how the applicant proposes to obtain or access housing resources for veterans in the program and entering the labor force. This discussion should specify the provisions made to access temporary, transitional, and permanent housing for participants through community resources, HUD, DVA lease, or other means. *HVRP funds may not be used for housing or vehicles.*

**2. Review and Selection Process:** Applications will initially be screened to ensure timeliness, completeness, and compliance with the SGA requirements. Applications that satisfy this initial screening will receive further review as explained below.

Technical proposals will be reviewed by a Department of Labor review panel using the point scoring system specified above in Section V(1). The review panel will assign scores after careful evaluation by each panel member and rank applications based on this score. The ranking will be the primary basis to identify applicants as potential grantees. The review panel may establish a competitive range and/or a minimum qualifying score, based upon the proposal evaluation, for the purpose of selecting qualified applicants. The review panel's conclusions are advisory in nature and not binding on the Grant Officer.

Cost proposals will be considered in two (2) ways. The Department of Labor review panel will screen all applicant cost proposals to ensure expenses are allocable, allowable, and reasonable. If the review panel concludes that the cost proposal contains an expense(s) that is not allocable, allowable; and/or reasonable, the application may be considered ineligible for funding. Further, VETS and the Grant Officer will consider applicant information concerning the proposed cost per placement, percentage of participants placed into unsubsidized employment, average wage at placement, and 180-day retention in employment percentage. The national average cost per placement for HVRP for last year was \$2,100.

The Government reserves the right to ask for clarification on any aspect of a grant application. The Government also reserves the right to discuss any potential grantee concerns amongst Department of Labor staff. The Government further reserves the right to select applicants out of rank order if such a selection would, in its opinion, result in the most effective and appropriate combination of funding, program, and administrative costs, e.g., cost per enrollment and placement, demonstration models, and geographic service areas. The Grant Officer's determination for award under SGA 04-03 is the final agency action. The submission of the same proposal from any prior year HVRP competition does not guarantee an award under this Solicitation.

**VI. Award Administration Information**

**1. Award Notices:**

A. The Notice of Award signed by the Grant Officer is the authorizing document and will be provided through postal mail and/or by electronic means to the authorized representative listed on the SF-424 Grant Application. Notice that an organization has been selected as a grant recipient does not constitute approval of the grant application as submitted. Before the actual grant award, The Grant Officer may enter into negotiations concerning such items as program components, funding levels, and administrative systems. If the negotiations do not result in an acceptable submittal, the Grant Officer reserves the right to terminate the negotiation and decline to fund the proposal.

B. A post-award conference will be held for those grantees awarded FY 2004 HVRP funds through this competition. The post-award conference is expected to be held in July or August 2004. Up to two (2) representatives must be present; a financial and a program

representative are recommended. The site of the post-award conference has not yet been determined, however, for planning and budgeting purposes, please allot five (5) days and use Washington, DC. as the conference site. The post-award conference will focus on providing information and assistance on reporting, record keeping, grant requirements, and also include best practices from past projects. Costs associated with attending this conference for up to two grantee representatives will be allowed as long as they are incurred in accordance with Federal travel regulations. Such costs must be charged as administrative costs and reflected in the proposed budget.

**2. Administrative and National Policy Requirements:** Unless specifically provided in the grant agreement, DOL's acceptance of a proposal and an award of Federal funds to sponsor any program(s) does not provide a waiver of any grant requirements and/or procedures. For example, the OMB circulars require that an entity's procurement procedures must provide all procurement transactions will be conducted, as practical, to provide open and free competition. If a proposal identifies a specific entity to provide the services, the DOL award does not provide the justification or basis to sole-source the procurement, i.e., avoid competition. All grants will be subject to the following administrative standards and provisions, as applicable to the particular grantee:

- 29 CFR part 93—Lobbying.
- 29 CFR part 95—Uniform

Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations, and with Commercial Organizations.

- 29 CFR part 96—Federal Standards for Audit of Federally Funded Grants, Contracts and Agreements.

- 29 CFR part 97—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

- 29 CFR part 98—Federal Standards for Government-wide Debarment and Suspension (Non procurement) and Government-wide Requirements for Drug-Free Workplace (Grants).

- 29 CFR part 99—Audit of States, Local Governments, and Nonprofit Organization.

- 29 CFR parts 30, 31, 32, 33 and 36—Equal Employment Opportunity in Apprenticeship and Training; Nondiscrimination in Federally Assisted Programs of the Department of Labor, Effectuation of Title VI of the Civil Rights Act of 1964; Nondiscrimination on the Basis of



Handicap in Programs and Activities; and Nondiscrimination on the Basis of Sex in Education Programs Receiving or Benefiting from Federal Financial Assistance.

3. *Reporting:* The grantee will submit the reports and documents listed below:

A. *Quarterly Financial Reports:* No later than 30 days after the end of each Federal fiscal quarter, the grantee must report outlays, program income, and other financial information on a federal fiscal quarterly basis using SF-269A, Financial Status Report, Short Form, and submit a copy of the HHS/PMS 272 draw down report. These reports must cite the assigned grant number and be submitted to the appropriate State Director for Veterans' Employment and Training (DVET).

B. *Quarterly Program Reports:* No later than 30 days after the end of each Federal fiscal quarter, grantees also must submit a Quarterly Technical Performance Report to the DVET that contains the following:

(1) A comparison of actual accomplishments to planned goals for the reporting period in spreadsheet format (to be provided to grantees after grant award) and any findings related to monitoring efforts;

(2) An explanation for variances of plus or minus 15% of planned program and/or expenditure goals, to include: identification of corrective action that will be taken to meet the planned goals, if required; and a timetable for accomplishment of the corrective action.

C. *90-Day Follow-Up Report:* No later than 120 days after the grant performance expiration date, the grantee must submit a follow-up report showing results and performance as of the 90th day after the grant period, and containing the following:

(1) Final Financial Status Report SF-269A Short Form (that zeros out all unliquidated obligations); and

(2) Technical Performance Report including updated goals chart.

D. *180-Day Follow-Up Report:* No later than 210 days after the grant performance expiration date, the grantee must submit a follow-up report showing results and performance as of the 180th day after the grant period, and containing the following:

(1) Final Financial Status Report SF-269A Short Form (if not previously submitted); and

(2) Final Narrative Report identifying:

(a) The total combined (directed/assisted) number of veterans placed into employment during the entire grant period;

(b) The number of veterans still employed after the 180 day follow-up period;

(c) If the veterans are still employed at the same or similar job, and if not, what are the reason(s);

(d) Whether training received was applicable to jobs held;

(e) Wages at placement and during follow-up period;

(f) An explanation regarding why those veterans placed during the grant, but not employed at the end of the follow-up period, are not so employed; and

(g) Any recommendations to improve the program.

#### VII. Agency Contact

*Questions and applications are to be forwarded to:* Department of Labor, Procurement Services Center, Attention: Cassandra Mitchell, Reference SGA 04-03, 200 Constitution Avenue NW., Room N-5416, Washington, DC 20210, Phone Number: (202) 693-4570 (this is not a toll free number).

*Resources for the Applicant:* Applicants may review "VETS' Guide to Competitive and Discretionary Grants" located at [http://www.dol.gov/vets/grants/Final\\_VETS\\_Guide-linked.pdf](http://www.dol.gov/vets/grants/Final_VETS_Guide-linked.pdf). Applicants may also find these resources useful: America's Service

Locator <http://www.servicelocator.org/> provides a directory of our nation's One-Stop Career Centers; the National Association of Workforce Boards maintains an Internet site (<http://www.nawb.org/asp/wibdir.asp>) that contains contact information for the State and local Workforce Investment Boards; and the homepage for the Department of Labor, Center for Faith-Based & Community Initiatives (<http://www.dol.gov/cfbci>).

*Comments:* Comments are to be submitted to the Veterans' Employment and Training Service (VETS), U.S. Department of Labor, Room S-1312, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-4701. Written comments are limited to ten (10) pages or fewer and may be transmitted by facsimile to (202) 693-4755. Receipt of submissions, whether by U.S. mail, e-mail, or facsimile transmittal, will not be automatically acknowledged; however, the sender may request confirmation that a submission has been received, by telephoning VETS at (202) 693-4701 or (202) 693-4753 (TTY/TDD).

Signed at Washington, DC this 6th day of April, 2004.

Lisa Harvey,  
Acting Grant Officer.

#### Appendices

Appendix A: Application for Federal Assistance SF-424  
Appendix B: Budget Information Sheet SF-424A  
Appendix C: Assurances and Certifications Signature Page  
Appendix D: Quarterly Technical Performance Goals Form  
Appendix E: Direct Cost Descriptions for Applicants and Sub-Applicants  
Appendix F: Survey on Ensuring Equal Opportunity for Applicants  
Appendix G: The Glossary of Terms  
Appendix H: List of Common Acronyms  
Appendix I: List of 75 Largest Cities Nationwide

BILLING CODE 4510-79-P



**APPLICATION FOR FEDERAL ASSISTANCE**

Version 7/03

<b>1. TYPE OF SUBMISSION:</b> Application		<b>2. DATE SUBMITTED</b>	Applicant Identifier
<input type="checkbox"/> Construction	Pre-application	<b>3. DATE RECEIVED BY STATE</b>	State Application Identifier
<input type="checkbox"/> Non-Construction	<input type="checkbox"/> Construction	<b>4. DATE RECEIVED BY FEDERAL AGENCY</b>	Federal Identifier
	<input type="checkbox"/> Non-Construction		
<b>5. APPLICANT INFORMATION</b>			
Legal Name:		Organizational Unit:	
		Department:	
Organizational DUNS:		Division:	
<b>Address:</b>		Name and telephone number of person to be contacted on matters involving this application (give area code)	
Street:		Prefix:	First Name:
City:		Middle Name	
County:		Last Name	
State:	Zip Code	Suffix:	
Country:		Email:	
<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN):</b>		Phone Number (give area code)	Fax Number (give area code)
□□-□□□□□□□□			
<b>8. TYPE OF APPLICATION:</b>		<b>7. TYPE OF APPLICANT:</b> (See back of form for Application Types)	
<input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		Other (specify)	
If Revision, enter appropriate letter(s) in box(es) (See back of form for description of letters.)			
Other (specify)			
<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</b>		<b>9. NAME OF FEDERAL AGENCY:</b>	
TITLE (Name of Program):			
□□-□□□□			
<b>12. AREAS AFFECTED BY PROJECT</b> (Cities, Counties, States, etc.):		<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</b>	
<b>13. PROPOSED PROJECT</b>		<b>14. CONGRESSIONAL DISTRICTS OF:</b>	
Start Date:	Ending Date:	a. Applicant	b. Project
<b>15. ESTIMATED FUNDING:</b>		<b>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</b>	
a. Federal	\$ .00	a. Yes. <input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON	
b. Applicant	\$ .00	DATE:	
c. State	\$ .00	b. No. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E. O. 12372	
d. Local	\$ .00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW	
e. Other	\$ .00	<b>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</b>	
f. Program Income	\$ .00	<input type="checkbox"/> Yes if "Yes" attach an explanation. <input type="checkbox"/> No	
g. TOTAL	\$ .00		
<b>18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.</b>			
<b>a. Authorized Representative</b>			
Prefix	First Name	Middle Name	
Last Name			Suffix
b. Title			c. Telephone Number (give area code)
d. Signature of Authorized Representative			e. Date Signed

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## INSTRUCTIONS FOR THE SF-424

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0043), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

This is a standard form used by applicants as a required face sheet for pre-applications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item:	Entry:	Item:	Entry:																
1.	Select Type of Submission.	11.	Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.																
2.	Date application submitted to Federal agency (or State if applicable) and applicant's control number (if applicable).	12.	List only the largest political entities affected (e.g., State, counties, cities).																
3.	State use only (if applicable).	13.	Enter the proposed start date and end date of the project.																
4.	Enter Date Received by Federal Agency Federal Identifier number: If this application is a continuation or revision to an existing award, enter the present Federal Identifier number. If for a new project, leave blank.	14.	List the applicant's Congressional District and any District(s) affected by the program or project																
5.	Enter legal name of applicant, name of primary organizational unit (including division, if applicable), which will undertake the assistance activity, enter the organization's DUNS number (received from Dun and Bradstreet), enter the complete address of the applicant (including country), and name, telephone number, e-mail and fax of the person to contact on matters related to this application.	15.	Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.																
6.	Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.	16.	Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.																
7.	Select the appropriate letter in the space provided. <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">A. State</td> <td style="width: 50%;">I. State Controlled Institution of Higher Learning</td> </tr> <tr> <td>B. County</td> <td>J. Private University</td> </tr> <tr> <td>C. Municipal</td> <td>K. Indian Tribe</td> </tr> <tr> <td>D. Township</td> <td>L. Individual</td> </tr> <tr> <td>E. Interstate</td> <td>M. Profit Organization</td> </tr> <tr> <td>F. Intermunicipal</td> <td>N. Other (Specify)</td> </tr> <tr> <td>G. Special District</td> <td>O. Not for Profit Organization</td> </tr> <tr> <td>H. Independent School District</td> <td></td> </tr> </table>	A. State	I. State Controlled Institution of Higher Learning	B. County	J. Private University	C. Municipal	K. Indian Tribe	D. Township	L. Individual	E. Interstate	M. Profit Organization	F. Intermunicipal	N. Other (Specify)	G. Special District	O. Not for Profit Organization	H. Independent School District		17.	This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
A. State	I. State Controlled Institution of Higher Learning																		
B. County	J. Private University																		
C. Municipal	K. Indian Tribe																		
D. Township	L. Individual																		
E. Interstate	M. Profit Organization																		
F. Intermunicipal	N. Other (Specify)																		
G. Special District	O. Not for Profit Organization																		
H. Independent School District																			
8.	Select the type from the following list: <ul style="list-style-type: none"> <li>• "New" means a new assistance award.</li> <li>• "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.</li> <li>• "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. If a revision enter the appropriate letter: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">A. Increase Award</td> <td style="width: 50%;">B. Decrease Award</td> </tr> <tr> <td>C. Increase Duration</td> <td>D. Decrease Duration</td> </tr> </table> </li> </ul>	A. Increase Award	B. Decrease Award	C. Increase Duration	D. Decrease Duration	18.	To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)												
A. Increase Award	B. Decrease Award																		
C. Increase Duration	D. Decrease Duration																		
9.	Name of Federal agency from which assistance is being requested with this application.																		
10.	Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.																		

OMB Approval No. 0346-0044

**BUDGET INFORMATION - Non-Construction Programs**  
**SECTION A - BUDGET SUMMARY**

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		Total (g)
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	
1.		\$	\$	\$	\$	0.00
2.						0.00
3.						0.00
4.						0.00
5. Totals		\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	0.00

**SECTION B - BUDGET CATEGORIES**

Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1)	(2)	(3)	(4)	
a. Personnel	\$	\$	\$	\$	0.00
b. Fringe Benefits					0.00
c. Travel					0.00
d. Equipment					0.00
e. Supplies					0.00
f. Contractual					0.00
g. Construction					0.00
h. Other					0.00
i. Total Direct Charges (sum of 6a-6h)	0.00	0.00	0.00	0.00	0.00
j. Indirect Charges					0.00
k. TOTALS (sum of 6i and 6j)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	0.00

7. Program Income	\$	\$	\$	\$	0.00
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SECTION C - NON-FEDERAL RESOURCES					
(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS	
8.	\$	\$	\$	\$	0.00
9.					0.00
10.					0.00
11.					0.00
12. TOTAL (sum of lines 8-11)	\$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	FUTURE FUNDING PERIODS (Years)			4th Quarter
		1st Quarter	2nd Quarter	3rd Quarter	
13. Federal	\$ 0.00 \$	\$	\$	\$	\$
14. Non-Federal	0.00				
15. TOTAL (sum of lines 13 and 14)	\$ 0.00 \$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT					
(a) Grant Program	FUTURE FUNDING PERIODS (Years)				
	(b) First	(c) Second	(d) Third	(e) Fourth	
16.	\$	\$	\$	\$	
17.					
18.					
19.					
20. TOTAL (sum of lines 16-19)	\$	0.00 \$	0.00 \$	0.00 \$	0.00
SECTION F - OTHER BUDGET INFORMATION					
21. Direct Charges:					
22. Indirect Charges:					
23. Remarks:					

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Public reporting burden for this collection of information is estimated to average 180 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0044), Washington, DC 20503.

**PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.**

## General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

## Section A. Budget Summary Lines 1-4 Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the Catalog program title and the Catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the Catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the Catalog program title on each line in Column (a) and the respective Catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

## Lines 1-4, Columns (c) through (g)

For *new applications*, leave Column (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For *continuing grant program applications*, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For *supplemental grants and changes* to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 - Show the totals for all columns used.

## Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Line 6a-1 - Show the totals of Lines 6a to 6h in each column.

Line 6j - Show the amount of indirect cost.

Line 6k - Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7 - Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount, Show under the program



**INSTRUCTIONS FOR THE SF-424A (continued)**

narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

**Section C. Non-Federal Resources**

**Lines 8-11** Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

**Column (a)** - Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

**Column (b)** - Enter the contribution to be made by the applicant.

**Column (c)** - Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

**Column (d)** - Enter the amount of cash and in-kind contributions to be made from all other sources.

**Column (e)** - Enter totals of Columns (b), (c), and (d).

**Line 12** - Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

**Section D. Forecasted Cash Needs**

**Line 13** - Enter the amount of cash needed by quarter from the grantor agency during the first year.

**Line 14** - Enter the amount of cash from all other sources needed by quarter during the first year.

**Line 15** - Enter the totals of amounts on Lines 13 and 14.

**Section E. Budget Estimates of Federal Funds Needed for Balance of the Project**

**Lines 16-19** - Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

**Line 20** - Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

**Section F. Other Budget Information**

**Line 21** - Use this space to explain amounts for individual direct object class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

**Line 22** - Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

**Line 23** - Provide any other explanations or comments deemed necessary.

**CERTIFICATIONS AND ASSURANCES****ASSURANCES AND CERTIFICATIONS SIGNATURE PAGE**

The Department of Labor will not award a grant or agreement where the grantee/recipient has failed to accept the ASSURANCES AND CERTIFICATIONS contained in this section. By signing and returning this signature page, the grantee/recipient is providing the certifications set forth below:

- A. Certification Regarding Lobbying, Debarment, Suspension, Other Responsibility Matters - Primary Covered Transactions and Certifications Regarding Drug-Free/Tobacco-Free Workplace,
- B. Certification of Release of Information
- C. Assurances - Non-Construction Programs
- D. Applicant is not a 501(c)(4) organization

APPLICANT NAME and LEGAL ADDRESS:

If there is any reason why one of the assurances or certifications listed cannot be signed, please explain. Applicant need only submit and return this signature page with the grant application. All other instruction shall be kept on file by the applicant.

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SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL

TITLE

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APPLICANT ORGANIZATION

DATE SUBMITTED

**Please Note:** This signature page and any pertinent attachments which may be required by these assurances and certifications shall be attached to the applicant's Cost Proposal.

**RECOMMENDED FORMAT FOR PLANNED  
QUARTERLY TECHNICAL PERFORMANCE GOALS**  
(data entered cumulatively)

**Performance Goals**

**Assessments**

Participants Enrolled

Placed Into Transitional Or Permanent Housing

Direct Placements Into Unsubsidized Employment

Assisted Placements Into Unsubsidized Employment

Combined Placements Into Unsubsidized Employment  
(Direct & Assisted)

1ST QTR	2ND QTR	3RD QTR	4TH QTR

**Cost Per Placement**

Number Retaining Jobs For 90 Days

Number Retaining Jobs For 180 Days

Rate of Placement Into Unsubsidized Employment

Average Hourly Wage At Placement


**Employability Development Services - (As Applicable)**

Classroom Training

On-The-Job Training

Remedial Education

Vocational Counseling

Pre-employment Services

Occupational Skills Training

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_


**Planned Expenditures**

Total Expenditures

Administrative Costs

Participant Services\*

	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Total Expenditures	\$	\$	\$	\$
Administrative Costs	\$	\$	\$	\$
Participant Services*	\$	\$	\$	\$

\*Services may include training and/or supportive.

Direct Cost Descriptions For Applicants and Sub-Applicants\*

Position Title(s)	Annual Salary/Wage Rate	% of Time Charged to Grant	Proposed Administration Costs **	Proposed Program Costs

Sub-Total

	Administration	Program
Fringe Benefits For All Positions	_____	_____
Contractual	_____	_____
Travel	_____	_____
Indirect Costs	_____	_____
Equipment	_____	_____
Supplies	_____	_____

Total Costs -----

Administration      Program

\*\* Administrative costs are associated with the supervision and management of the program and do not directly or immediately affect participants.

\* Direct costs for all funded positions for both applicant and sub-applicant(s) must be provided.



## SURVEY ON ENSURING EQUAL OPPORTUNITY

*Federal Agency Use Only*

OMB No. 1225-0083 Exp. 02/28/2006

**NOTE:** Please place survey form directly behind the Standard Application for Federal Assistance (SF 424) fact sheet.

**Purpose:** This form is for applicants that are private nonprofit organizations (not including private universities). Please complete it to assist the federal government in ensuring that all qualified applicants, small or large, non-religious or faith-based, have an equal opportunity to compete for federal funding. Information provided on this form will not be considered in any way in making funding decisions and will not be included in the federal grants database.

1. Does the applicant have 501(c)(3) status?
  - Yes
  - No
2. How many full-time equivalent employees does the applicant have? (Check only one box).
  - 3 or Fewer
  - 4-5
  - 6-14
  - 15-50
  - 51-100
  - over 100
3. What is the size of the applicant's annual budget? (Check only one box.)
  - Less Than \$150,000
  - \$150,000 - \$299,999
  - \$300,000 - \$499,999
  - \$500,000 - \$999,999
  - \$1,000,000 - \$4,999,999
  - \$5,000,000 or more
4. Is the applicant a faith-based/religious organization?
  - Yes
  - No
5. Is the applicant a non-religious community-based organization?
  - Yes
  - No
6. Is the applicant an intermediary that will manage the grant on behalf of other organizations?
  - Yes
  - No
7. Has the applicant ever received a government grant or contract (Federal, State, or local)?
  - Yes
  - No
8. Is the applicant a local affiliate of a national organization?
  - Yes
  - No



### Survey Instructions on Ensuring Equal Opportunity for Applicants

1. 501(c)(3) status is a legal designation provided on application to the Internal Revenue Service by eligible organizations. Some grant programs may require nonprofit applicants to have 501(c)(3) status. Other grant programs do not.
2. For example, two part-time employees who each work half-time equal one full-time equivalent employee. If the applicant is a local affiliate of a national organization, the responses to survey questions 2 and 3 should reflect the staff and budget size of the local affiliate.
3. Annual budget means the amount of money your organization spends each year on all of its activities.
4. Self-identify.
5. An organization is considered a community-based organization if its headquarters/service location shares the same zip code as the clients you serve.
6. An "intermediary" is an organization that enables a group of small organizations to receive and manage government funds by administering the grant on their behalf.
7. Self-explanatory.
8. Self-explanatory.

#### **Paperwork Burden Statement**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is **1225-0083**. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. **If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to:** Departmental Clearance Officer, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-1301, Washington, D.C. 20210. **If you have comments or concerns regarding the status of your individual submission of this form, write directly to:** Joyce I. Mays, Application Control Center, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210.

**U.S. Department of Labor**  
**Veterans' Employment and Training Service**

**GLOSSARY OF TERMS**

**Adequate Employment** – See Unsubsidized Employment.

**Administrative Costs** - Administrative costs shall consist of all direct and indirect costs associated with the supervision and management of the program. These costs shall include the administrative costs, both direct and indirect, of sub-recipients and contractors.

**Adult Basic Education** - Education for adults whose inability to speak, read, or write the English language or to effectively reason mathematically, constitutes a substantial impairment of their ability to get or retain employment commensurate with their real ability, which is designed to help eliminate such inability and raise the level, of education of such individuals with a view to making them less likely to become dependent on others, to improve their ability to benefit from occupational training and otherwise increase their opportunities for more productive and profitable employment, and to make them better able to meet their adult responsibilities.

**Ancillary Services** – Employment and training related activities other than core training that may enhance a participant's employability.

**Apprenticeship Training** – A formal occupational training program that combines on-the-job training and related instruction and in which workers learn the practical and conceptual skills required for a skilled occupation, craft, or trade. It may be registered or unregistered.

**Assessment/Intake** - A process for screening individual applicants for program eligibility making the level of need determinations; making an initial determination what services or programs can best benefit the applicants; providing information about services, program eligibility, and the availability of those services, and the routing or selecting individual applicants for particular service delivery or program participation.

**Assisted Placements Into Unsubsidized Employment** - Assisted placements into unsubsidized employment should be recorded where the definition for placement with unsubsidized employment above is met, but the placement was arranged by an agency to which the homeless veteran was referred to.

**Average Hourly Wage At Placement** - The average hourly wage at placement is the average hourly wage rates at placement of all assisted placements plus direct placements.

**Assurance and Certifications** - The act of signifying intent to comply with applicable federal and State laws and regulations as a condition for receiving and expanding USDOL grant funds.

**Barriers to Employment** - Characteristics that may hinder an individual's hiring promotion or participation in the labor force. Identification of these barriers will vary by location and labor market. Some examples of individuals who may face barriers to employment include: single parents, women, displaced homemakers, youth, public assistance recipients, older workers, substance abusers, teenage parents, certain veterans, ethnic minorities, and those with limited English speaking ability or a criminal record or with a lack of education, work experience, credential, child care arrangements, transportation or alternative working parents.

**Campaign Badge veteran** - A veteran who served on active duty during the war (e.g., WWII), action (e.g., Korea, Vietnam), in a campaign, or an expedition for which a campaign badge of an expeditionary medal has been authorized (e.g. Bosnia, Grenada, Haiti, Panama, Southeast Asia, and Somalia).

**Case Management** - A client centered approach in the delivery of intensive services, designed to prepare and coordinate comprehensive employment plans for participants, to assure access to the necessary training and supportive services, and to provide support during program participation and after job placement.

**Case Manager** - One who coordinates, facilitates or provides direct services to a client or trainee from application through placement, post placement follow-up, or other case closing, exclusively, through periodic contact and the provision of appropriate assistance.

**Classroom Training** - Any training of the type normally conducted in an institutional setting, including vocational education, which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs. It may also include training designed to enhance the employability of individuals by upgrading basic skills, throughout the provision of courses such as remedial education, training in the primary language of persons with limited English language proficiency, or English as a second language training.

**Close Out** - Grant close out is the process by which the Federal grantor agency (in the case of VETS grants, Department of Labor) determines that all applicable administrative actions and all required work of the grant have been completed by the grantee and the grantor.

**Cognizant Federal Agency** - The federal agency that is assigned audit or indirect cost rate approval responsibility for a particular recipient organization by the Office of Management and Budget (OMB Circular A-87 and A-102 [20 CFR, Part 97]).

**Community Based Organization** - means a private non-profit organization that is representative of a community or a significant segment of a community and that has demonstrated expertise and effectiveness in the field of workforce investment. Faith-Based organizations are considered a subset.

**Cost Per Placement** - The cost per placement into unsubsidized employment is obtained by dividing the total funds expended by the total of direct placements plus assisted placements.

**Counseling** - A form of assistance which provides guidance in the development of a participant's vocational goals and the means to achieve those goals; and/or assist a participant with the solution to one or more individual problems which may pose a barrier (s) to sustained employment.

**Counselor** - (Employment/Vocational): A trained and qualified professional authorized to provide direct assistance (beyond advising and informing) through planning, testing, training and otherwise readying an individual for sustained employment.

**Customized Training** - A training program designed to meet the special requirements of an employer who has entered into an agreement with a Service Delivery Area to hire individuals who are trained to the employer's specifications. The training may occur at the employer's site or may be provided by a training vendor able to meet the employer's requirements. Such training usually requires a commitment from the employer to hire a specified number of trainees who satisfactorily complete the training.

**Direct Placements Into Unsubsidized Employment** - A direct placement into unsubsidized employment must be a placement made directly by staff with an established employer who covers all employment costs for 20 or more hours per week at or above the minimum wage. Day labor and other very short-term placements should not be recorded as placements into unsubsidized employment.

**Disabled Veteran** - A veteran who is entitled to compensation under laws administered by the Veterans Administration; or an individual who was medically discharged or otherwise released from active duty, due to service-connected disability.

**Disallowed Costs** - Disallowed costs are those charges to a grant that the grantor agency (or its representative) determines to be unallowable in accordance with the applicable Federal Cost Principles or other conditions in the grant.

**Disabled Veterans' Outreach Program (DVOP)** - A program of Federal assistance through grants to States to staff and support in accordance with 38 U.S.C. 4103A, appointed to perform a number of duties chief among which are direct employer contact, particularly with Federal contractors, Federal employers using individualized job development techniques, and with veterans (particularly with disabled veterans) using a case management approach to client-centered services.

**Economically Disadvantaged** - An individual who (a) receives, or is a member of a family which receives, cash welfare payments under a Federal, state, or local welfare program; (b) has, or is a member of a family which has, received a total family income for the six-month period prior to application for the program involved (exclusive of unemployment compensation, child support payments, and welfare payments) which, in relation to family size, was not in excess of the higher of (i) the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673 (2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 9902(2)), or (ii) 70 percent of the lower living standard income level; (c) is receiving (or has been determined within the 6-month period prior to the application for

program involved to be eligible to receive) food stamps pursuant to the Food Stamp Act of 1977; (d) qualifies as a homeless individual under section 103 of the Stewart B. McKinney Homeless Assistance Act; (e) is a foster child on behalf of whom state or local government payments are made or (f) in cases permitted by regulations of the Secretary, is an individual with a disability whose income meets the requirements of clause (a) or (b), but who is a member of a family whose income does not meet such requirements.

**Eligible** - Meeting the minimum requisite qualifications to be considered for the provision of services or entry into a position under a funded program or as required by law.

**Employability Development Services (EDS)** - This includes services and activities that will develop or increase the employability of the participant. Generally, this includes vocational counseling, classroom and on-the-job training, pre-employment services (such as job seeking skills and job search workshops), temporary or trial employment, sheltered work environments and other related services and activities. Planned services should assist the participant in addressing specific barriers to employment and finding a job. These activities may be provided by the applicant or by a Sub-grantee, contractor or another source such as the local Workforce Investment Act program or the DVOP personnel or LVERs. Such services are not mandatory but entries should reflect the services described in the application and the expected number of participants receiving or enrolled in such services during each quarter. Participants may be recorded more than once if they receive more than one service.

**Employment Development Plan (EDP)** - An individualized written plan or intervention strategy for serving an individual which, as a result of an assessment of the veteran's economic needs, vocational interests, aptitudes, work history, etc., defines a reasonable vocational or employment goal and the developmental services or steps required to reach the goal and which documents the accomplishments made by the individual.

**Employment Service** - the state level organization or public labor exchange system affiliated with the Department of Labor's United States Employment Service.

**Enlistments** - Individuals who have expressed an interest, signed up for a workshop or enrollment in the program.

**Entered Employment** - Applicants for service who were placed in jobs or otherwise obtained employment as a result of services used or received.

**Entered Employment Rate** - This is a method used to determine the percentage of participants who become employed. The percentage is calculated by dividing the number of total participants who were enrolled in the program by the number of participants who were placed or entered employment through the program.

**Enrolled Veteran** - Shall be synonymous with the term participant. A veteran who has been determined eligible for services at intake and who is receiving or scheduled to receive core training.



**Faith-Based Organization** – see “community-based organization”.

**Follow-up** - The tracking of clients for a period of time up to 180 days after initial placement, last referral date for services or completion of training programs to determine current status, outcome or whether to offer additional services (such as additional referral, job retention advisement, etc.).

**Full-Time Equivalent (FTE)** – a personnel charge to the grant equal to 2,080 hours per year.

**FY** - Fiscal Year. For federal government purposes, any twelve month period beginning on October 1 and ending on September 30.

**General Equivalency Diploma (GED)** – A high school equivalency diploma that is obtained by passing the General Educational Diploma Equivalency Test that measures the application of skills and knowledge generally associated with four (4) years of traditional high school instruction.

**Grant Officer's Technical Representative (GOTR)** - An individual (usually the DVET) serving on behalf of the Grant Officer who maintains and ensures the integrity of the approved grant agreement by reviewing and making recommendations regarding technical matters not involving a change in scope, cost, or conditions.

**Homeless or homeless individual** – includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either supervised public or private shelter designed to provide temporary living accommodations; an institution that provides a temporary residence for individuals intended to be institutionalized; or a private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. [Reference 42 U.S.C., Section 11302 (a)].

**Indirect cost** - A cost that is incurred for a common or joint purpose benefiting more than one cost objective and that is not readily assignable to the cost objective specifically benefited.

**In-kind Services** – Property or services which benefit federally assisted project or program and which are contributed without charge to the grantee.

**Institutional Skills Training** – training conducted in an institutional setting and designed to ensure that individuals acquire the skills, knowledge, and abilities necessary to perform a job or group of jobs in an occupation for which there is a demand.

**Intake** – A process for screening individual applicants for eligibility; making an initial determination whether the program can benefit the applicants; providing information about the program, its services and the availability of those services; and selecting individual applicants for participation in the program.

**Intensive Services** - The provision of concentrated staff services to clients who indicate the need for facilitation or interventions to secure lasting employment. The case management approach to service delivery is a viable model for successfully providing such services and obtaining the clients goals.

**Job Club Activities** - A form of job search assistance provided in a group setting. Usually job clubs provide instruction and assistance in completing job applications and developing resumes and focus on maximizing employment opportunities in the labor market and developing job leads. Many job clubs use telephone banks and provide group support to participants before and after they interview for job openings.

**Job Development** - The process of marketing a program participant to employers, including informing employers about what the participant can do and soliciting a job interview for that individual with the employer (targeted job development); and the development of one or more job openings or training opportunities with one or more employers using a variety of techniques and means of contact.

**Job Placement Services** - Job placement services are geared towards placing participants in jobs and may involve activities such as job search assistance, training, or job development. These services are initiated to enhance and expedite participants' transition from training to employment.

**Job Search Assistance** - An activity, which focuses on building practical skills and knowledge to identify and initiate employer contact and conduct successful interview with employers. Various approaches may be used to include participation in a job club, receive instruction in identifying personal strengths and goals, resume application preparation, learn interview techniques, and receive labor market information. Job search assistance is often self-service activity in which individuals obtain information about specific job openings or general jobs or occupational information.

**Labor Exchange** - Refers to the services provided to job seekers and employers by the State Employment Services Agencies, or other designated entities. Preparatory services to job seekers may include assessment, testing, counseling, provision of labor market information, targeted job development, resulting in job referral and follow-up with former applicants and prospective employers. Employer-oriented services may include accepting job orders, screening applicants, referring qualified applicants and providing follow-up to foster job retention and develop additional job openings or training opportunities.

**Labor Exchange Delivery System (LEDS)** - Describes the system of matching jobs and training opportunities with applicants operating with Federal employment and job training funds.

**Labor Force** - The sum of all civilians classified as employed and unemployed and members of the Armed Forces stationed in the United States. [Bureau of Labor Statistics Bulletin 2175].

**Labor Market Area** – an economically integrated geographic area within which individuals can reside and find employment within a reasonable distance or can readily change employment without changing their place of residence.

**Literacy and Bilingual Training** – See Adult Basic Education.

**Local Veterans' Employment Representative (LVER) Program** - A program of Federal assistance through grants to States to staff in accordance with 38 U.S.C.4104 to perform a number of duties, chief among which are the provision of intensive (case management) services to targeted eligible veterans with emphasis on VA, VR&E, and to functionally supervise without necessarily exercising line supervisor authority over the provision of services to veterans by SDP staff.

**Minimum Economic Need** – the level of wages paid to a program participant that will enable that participant to become economically self-sufficient.

**Minority Veterans** – for the purposes of the HVRP and VWIP programs, veterans who are Workforce Investment Act (WIA) eligible and are members of the following ethnic categories: African American, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander.

**National Veterans' Training Institute (NVTI)** - An agency contracted with USDOL/VETS to develop and provide skills development and enhancement training to individuals who are determined by the Assistant Secretary for Veterans' Employment and Training and who deliver or monitor the provision of employment and training services to veterans (38 U.S.C. 4109).

**Number Retaining Job for 90 Days** -To be counted as retaining a job for 90 days, continuous employment with one or more employers for at least 90 days must be verified and the definition for either direct placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 90 days as long as the client has been steadily employed for that length of time.

**Number Retaining Job For 180 Days** - To be counted as retaining a job for 180 days, continuous employment with one or more employers for at least 180 days must be verified, and the definition for either placement or assisted placement into unsubsidized employment above is met. This allows clients who have moved into a position with a different employer to be recorded as retaining the job for 180 days as long as the client has been steadily employed for that length of time.

**Occupational Skills Training** – Includes both (1) vocational education which is designed to provide individuals with the technical skills and information required to perform a specific job or group of jobs, and (2) on-the-job training.

**Offender** – Any adult or juvenile who has been subject to any stage of the criminal justice process for whom services under this program may be beneficial or who requires assistance in overcoming artificial barriers to employment resulting from a record of arrest or conviction.

**On-the-Job Training (OJT)** – means training by an employer that is provided to a paid participant while engaged in productive work in a job that: (a) provides knowledge or skill essential to the full and adequate performance of the job; (b) provides reimbursement to the employer of up to 50 percent of the wage rate of the participant, for the extraordinary costs of providing the training and additional supervision related to the participant is being trained, taking into account the content of the training, the prior work experience of the participant, and the service strategy of the participant, as appropriate. Usually in the OJT agreement, there is a promise on the part of the employer to hire the trainee upon successful completion of the training.

**On-Site Industry-Specific Training** – This is training which is specifically tailored to the needs of a particular employer and/or industry. Participants may be trained according to specifications developed by an employer for an occupation or group of occupations at a job site. Such training is usually presented to a group of participants in an environment or job site representative of the actual job/occupation, and there is often an obligation on the part of the employer to hire a certain number of participants who successfully complete the training.

**Outreach** - An active effort by program staff to encourage individuals in the designated service delivery area to avail themselves of program services.

**Outside Funds** – Resources pledged to the grant program that have a quantified dollar value. Such resources may include training funds from programs such as WIA Title I that are put aside for the exclusive use by participants enrolled in a program. Outside funds do not include in-kind services.

**Participant** – means an individual who has been determined to be eligible to participate in and who is receiving services (except follow-up services) under the program. Participation shall be deemed to commence on the first day, following determination of eligibility, on which the individual began receiving subsidized employment, training, or other services provided under the program. An individual who receives only outreach and/or intake assessment services does not meet this definition.

**Participants Enrolled** - A client should be recorded as having been enrolled when an intake form has been completed, and services, referral, and/or employment has been received through the program. This should be an unduplicated count over the year, i.e., each participant is recorded only once, regardless of the number of times she or he receives assistance.

**Participants Services** - This cost includes supportive, training, or social rehabilitation services, which will assist in stabilizing the participant. This category should reflect all costs other than administrative.

**Placed Into Transitional Or Permanent Housing** - A placement into transitional or permanent housing should be recorded when a veteran served by the program upgrades his/her housing situation during the reporting period from shelter/streets to transitional housing or permanent housing or from transitional housing to permanent housing. Placements resulting from referrals by staff shall be counted. This item is however an unduplicated count over the year, except that a participant may be counted once upon entering transitional housing and again upon obtaining permanent housing.

**Placement** - the act of securing unsubsidized employment for or by a participant.

**Placement Rate** - This is a method used to determine the percentage of participants who become employed. The figure is calculated by dividing the number of total participants who were registered for services or enrolled in the program by the number of applicants or program participants who were placed or otherwise entered employment.

**Pre-apprenticeship Training** - Any training designed to increase or upgrade specific academic, or cognitive, or physical skills required as a prerequisite for entry into a specific trade or occupation.

**Pre-enrollment Assessment** - The process of determining the employability and training needs of individuals before enrolling them into the program. Individual factors usually addressed during pre-enrollment assessment include: an evaluation and/or measurement of vocational interests and aptitudes, present abilities, previous education and work experience, income requirements, and personal circumstances.

**Preference** - The application of priorities in the consideration and selection through appointment or assignment of staff to funded positions, or in the provision of direct services and order of referral to listed openings in the order designated by statute regulation, and grant agreement.

**Program Resources** - Includes the total of both program or grant and outside funds.

**Program Year (PY)** - The 12-month period beginning July 1 in the fiscal year for which the appropriation is made, and ending on the following June 30.

**Qualified** - An individual who has been determined to possess the requisite knowledge, skills, and abilities for positions within the context of the selection process used to identify and rank persons possessing those attributes.

**Rate of Placement Into Unsubsidized Employment** - The rate of placement into unsubsidized employment is obtained by dividing the number placed into unsubsidized employment, plus the number of assisted placements into unsubsidized employment by the number of clients enrolled.

**Recently Separated Veteran** - Refers to an individual who applies for program participation or assistance within 48 months of separation from active U.S. military service [29 U.S.C. 1503 (27) (c)].



**Remedial Education** – Education instruction, particularly in basic skills, to raise an individual's general competency level in order to succeed in vocational education or skill training programs, or employment.

**Service Connected Disabled** - Refers to (1) a veteran who is entitled to compensation under laws administered by the Department of Veterans' Affairs, or (2) an individual who was discharged or released from active duty because of a service-connected disability (38 U.S.C. 4211 (3); 29 U.S.C., Chapter 19, section 1503 (27) (C))

**Service Delivery Point (SDP)** - Includes offices of the public employment delivery system operated directly or by contract with the State Workforce Agency as grantee within a State and may include One-Stop Career Centers, local employment service offices, and any satellite or itinerant offices at which labor exchange services are available.

**Solicitation for Grant Applications (SGA)** - A document which provides the requirements and instructions for the submission by eligible applicants identified in the document's text of requests for Federal domestic assistance (funds) for one or more programs or grants-in-aid.

**State Workforce Agency (SWA)** - The State level organization, as affiliated with the former United States Employment Service.

**Subgrant** – An award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee.

**Subgrantee** – The government or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided.

**Suitable Employment** – See "Unsubsidized Employment".

**Substance Abuser** – An individual dependent on alcohol or drugs, especially narcotics, whose dependency constitutes or results in a substantial barrier to employment.

**Supportive Services** – means services which are necessary to enable an individual eligible for training, but who cannot afford to pay for such services, to participate in a training program funded under the grant. Such supportive services may include transportation, health care, financial assistance (except as a post-termination service), drug and alcohol abuse counseling and referral, individual and family counseling, special services and materials for individuals with disabilities, job coaches, child care and dependent care, temporary shelter, financial counseling, and other reasonable expenses required for participation in the training program and may be provided in-kind or through cash assistance.

**Targeted Job Development** - The identification and marketing of a group of qualified applicants with similar occupations or employment barriers requiring personal visitation/phone contact with those employers likely to employ these individuals.

**Total Planned Expenditures** - Identified forecasted financial needs to accomplish programmatic objectives broken down into fiscal quarters.

**Unsubsidized Employment** - Employment not financed from funds provided under the grant. In the grant program the term "adequate" or "suitable" employment is also used to mean placement in unsubsidized employment which pays an income adequate to accommodate the participants' minimum economic needs.

**Upgrading or Retraining** - Training given to an individual who needs such training to advance above an entry level or dead-end position. This training shall include assisting veterans in acquiring needed state certification to be employed in the same field as they were trained in the military (i.e., Commercial Truck Driving License (CDL), Emergency Medical Technician (EMT), Airframe & Power Plant (A&P), Teaching Certificate, etc.)

**Veteran** - An individual who served in the United States active military, naval, or air service, and who was discharged or released there from under conditions other than dishonorable (29 U.S.C. Chapter 19, section 1503 (27) (A) [for WIA, Section 168 (VWIP) and WIA, Title I training/services]).

**Veterans' Workforce Investment Program (VWIP)** - Competitively awarded employment and training grants to meet the needs of veterans with significant barriers to employment; with service-connected disabilities; who served on active duty in the armed forces during a campaign or expedition for which a campaign badge has been authorized; and recently separated veterans. The U.S. Department of Labor, Veterans' Employment and Training Service awards VWIP grants as authorized under the Workforce Investment Act (WIA), Section 168.

**Vocational Exploration Training** - Through assessments such as interest inventories and/or counseling, a process of identifying occupations or occupational areas in which a person may find satisfaction and potential, and for which his or her aptitudes and other qualifications may be appropriate.

**Vocational Guidance** - The provision of information, suggestions, and advice through discussion with individuals who are considering a geographical or vocational choice or change, relating to their career decision.

**Wartime Veteran** - See "campaign veteran above."

**Welfare and/or Public Assistance recipient** - An individual who, during the course of the program year, receives or is a member of a family who receives cash welfare or public assistance payments under a Federal, state, or local welfare program.

**Workforce Investment Act** (WIA) – The purpose of this Act is to establish programs to prepare youth and unskilled adults for entry into the labor force and to afford job training to those economically disadvantaged individuals and other individuals, including veterans, who face serious barriers to employment and who are in need of such training to obtain prospective employment. The Act requires the Assistant Secretary for Veterans' Employment and Training to consult with the Secretary of the Department of Veterans Affairs to ensure that programs funded under VWIP of this Act meet the employment and training needs of service-connected disabled, Campaign, and recently separated veterans and are coordinated, to the maximum extent feasible, with related programs and activities.

**Work Experience** – A temporary activity (six months or less) which provides an individual with the opportunity to acquire the skills and knowledge necessary to perform a job, including appropriate work habits and behaviors, and which may be combined with classroom or other training. When wages are paid to a participant on work experience and when such wage are wholly paid for under WIA, the participant may not receive this training under a private, for profit employer.

**Youth** – An individual between 20 and 24 years of age.

USDOL/VETSLIST OF COMMON ACRONYMS

ADVET	Assistant Director for Veterans' Employment and Training
ASVET	Assistant Secretary (of Labor) for Veterans' Employment and Training
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CWT	Compensated Work Therapy
DOD	Department of Defense
DV	Disabled Veteran
DVA	Department of Veterans Affairs (see also VA)
DVET	Director for Veterans' Employment and Training Service
DVOP	Disabled Veterans' Outreach Program
DTAP	Disabled Veterans' Transition Assistance Program
EDP	Employment Development Plan
ES	Employment Service
ETA	Employment and Training Administration
FARS	Financial Accounting and Reporting System
FCJL	Federal Contractor Job Listing
FCP	Federal Contracting Program
FEMA	Federal Emergency Management Administration
FY	Fiscal Year
GOTR	Grant Officer's Technical Representative
GPRA	Government Performance and Results Act of 1994
HHS	Department of Health and Human Services
HHS/PMS	Health and Human Services/Payment Management System
HUD	Department of Housing and Urban Development
HVCAA	Homeless Veterans' Comprehensive Assistance Act - Title 38 USC, Section 2001
HVRP	Homeless Veterans' Reintegration Project
IEP	Individual Employment Plan
ISS	Individual Support System
IV-TP	Incarcerated Veterans' Transition Program
LEDS	Labor Exchange Delivery System
LESO	Local Employment Service Office
LMI	Labor Market Information
LVER	Local Veterans' Employment Representative
MHAA	McKinney-Vento Homeless Assistance Act - Title 42 USC, Section 11302(a)
MOU	Memorandum of Understanding
NOGA	Notice of Grant Award
NVTI	National Veterans' Training Institute
OASAM	Office of the Assistant Secretary for Administration and Management
OASVET	Office of the Assistant Secretary (of Labor) for Veterans' Employment and Training
OCB	Office of Cost Determination
OMB	Office of Management and Budget
OPM	Office of Personnel Management
OJT	On-the-Job-Training
PAC	Post Award Conference
PB	Personnel Benefits
PL	Public Law
PS	Personal Services

PY	Program Year
f RAVET	Regional Administrator for Veterans' Employment and Training
SDP	Service Delivery Point
SDV	Special Disabled Veteran
SF	Standard Form
SGA	Solicitation For Grant Applications
SSA	Social Security Administration
SWA	State Workforce Agency
TAP	Transition Assistance Program
UCX	Unemployment Compensation (Insurance) for ex-service members
UI	Unemployment Insurance
USC	United States Code
USDOL	United States Department of Labor
VA	Department of Veterans Affairs
VARO	Veterans' Administration Regional Office
VAMC	Veterans' Administration Medical Center
VETS	Veterans' Employment and Training Service
VEV	Vietnam-Era Veteran
VOE	Veterans and Other Eligible Persons
VPL	Veterans Program Letter
VR&E	Vocational Rehabilitation and Employment (formerly VR&C)
VSO	Veteran Service Organization
VWIP	Veterans' Workforce Investment Program (WIA, Section 168)
WIA	Workforce Investment Act of 1998
WIB	Workforce Investment Board



Rank	Area Name	Census Population	
		April 1, 2000	April 1, 1990
1	New York--Northern New Jersey--Long Island, NY--NJ--CT--PA CMSA	21,199,865	19,549,649
2	Los Angeles--Riverside--Orange County, CA CMSA	16,373,645	14,531,529
3	Chicago--Gary--Kenosha, IL--IN--WI CMSA	9,157,540	8,239,820
4	Washington--Baltimore, DC--MD--VA--WV CMSA	7,608,070	6,727,050
5	San Francisco--Oakland--San Jose, CA CMSA	7,039,362	6,253,311
6	Philadelphia--Wilmington--Atlantic City, PA--NJ--DE--MD CMSA	6,188,463	5,892,937
7	Boston--Worcester--Lawrence, MA--NH--ME--CT CMSA	5,819,100	5,455,403
8	Detroit--Ann Arbor--Flint, MI CMSA	5,456,428	5,187,171
9	Dallas--Fort Worth, TX CMSA	5,221,801	4,037,282
10	Houston--Galveston--Brazoria, TX CMSA	4,669,571	3,731,131
11	Atlanta, GA MSA	4,112,198	2,959,950
12	Miami--Fort Lauderdale, FL CMSA	3,876,380	3,192,582
13	Seattle--Tacoma--Bremerton, WA CMSA	3,554,760	2,970,328
14	Phoenix--Mesa, AZ MSA	3,251,876	2,238,480
15	Minneapolis--St. Paul, MN--WI MSA	2,968,806	2,538,834
16	Cleveland--Akron, OH CMSA	2,945,831	2,859,644
17	San Diego, CA MSA	2,813,833	2,498,016
18	St. Louis, MO--IL MSA	2,603,607	2,492,525
19	Denver--Boulder--Greeley, CO CMSA	2,581,506	1,980,140
20	San Juan--Caguas--Arecibo, PR CMSA	2,450,292	2,270,808
21	Tampa--St. Petersburg--Clearwater, FL MSA	2,395,997	2,067,959
22	Pittsburgh, PA MSA	2,358,695	2,394,811
23	Portland--Salem, OR--WA CMSA	2,265,223	1,793,476
24	Cincinnati--Hamilton, OH--KY--IN CMSA	1,979,202	1,817,571
25	Sacramento--Yolo, CA CMSA	1,796,857	1,481,102
26	Kansas City, MO--KS MSA	1,776,062	1,582,875
27	Milwaukee--Racine, WI CMSA	1,689,572	1,607,183
28	Orlando, FL MSA	1,644,561	1,224,852
29	Indianapolis, IN MSA	1,607,486	1,380,491
30	San Antonio, TX MSA	1,592,383	1,324,749
31	Norfolk--Virginia Beach--Newport News, VA--NC MSA	1,569,541	1,443,244
32	Las Vegas, NV--AZ MSA	1,563,282	852,737
33	Columbus, OH MSA	1,540,157	1,345,450
34	Charlotte--Gastonia--Rock Hill, NC--SC MSA	1,499,293	1,162,093
35	New Orleans, LA MSA	1,337,726	1,285,270
36	Salt Lake City--Ogden, UT MSA	1,333,914	1,072,227
37	Greensboro--Winston-Salem--High Point, NC MSA	1,251,509	1,050,304
38	Austin--San Marcos, TX MSA	1,249,763	846,227
39	Nashville, TN MSA	1,231,311	985,026
40	Providence--Fall River--Warwick, RI--MA MSA	1,188,613	1,134,350
41	Raleigh--Durham--Chapel Hill, NC MSA	1,187,941	855,545
42	Hartford, CT MSA	1,183,110	1,157,585
43	Buffalo--Niagara Falls, NY MSA	1,170,111	1,189,288
44	Memphis, TN--AR--MS MSA	1,135,614	1,007,306
45	West Palm Beach--Boca Raton, FL MSA	1,131,184	863,518
46	Jacksonville, FL MSA	1,100,491	906,727
47	Rochester, NY MSA	1,098,201	1,062,470
48	Grand Rapids--Muskegon--Holland, MI MSA	1,088,514	937,891

49	Oklahoma City, OK MSA	1,083,346	958,839
50	Louisville, KY--IN MSA	1,025,598	948,829
51	Richmond--Petersburg, VA MSA	996,512	865,640
52	Greenville--Spartanburg--Anderson, SC MSA	962,441	830,563
53	Dayton--Springfield, OH MSA	950,558	951,270
54	Fresno, CA MSA	922,516	755,580
55	Birmingham, AL MSA	921,106	840,140
56	Honolulu, HI MSA	876,156	836,231
57	Albany--Schenectady--Troy, NY MSA	875,583	861,424
58	Tucson, AZ MSA	843,746	666,880
59	Tulsa, OK MSA	803,235	708,954
60	Syracuse, NY MSA	732,117	742,177
61	Omaha, NE--IA MSA	716,998	639,580
62	Albuquerque, NM MSA	712,738	589,131
63	Knoxville, TN MSA	687,249	585,960
64	El Paso, TX MSA	679,622	591,610
65	Bakersfield, CA MSA	661,645	543,477
66	Allentown--Bethlehem--Easton, PA MSA	637,958	595,081
67	Harrisburg--Lebanon--Carlisle, PA MSA	629,401	587,986
68	Scranton--Wilkes-Barre--Hazleton, PA MSA	624,776	638,466
69	Toledo, OH MSA	618,203	614,128
70	Baton Rouge, LA MSA	602,894	528,264
71	Youngstown--Warren, OH MSA	594,746	600,895
72	Springfield, MA MSA	591,932	587,884
73	Sarasota--Bradenton, FL MSA	589,959	489,483
74	Little Rock--North Little Rock, AR MSA	583,845	513,117
75	McAllen--Edinburg--Mission, TX MSA	569,463	383,545

[FR Doc. 04-8190 Filed 4-12-04; 8:45 am]

BILLING CODE 4510-79-C

## MEDICARE PAYMENT ADVISORY COMMISSION

### Commission Meeting

**AGENCY:** Medicare Payment Advisory Commission.

**ACTION:** Notice of meeting.

**SUMMARY:** The Commission will hold its next public meeting on Thursday, April 22, 2004, and Friday, April 23, 2004, at the Ronald Reagan Building, International Trade Center, 1300 Pennsylvania Avenue, NW., Washington, DC. The meeting is tentatively scheduled to begin at 10 a.m. on April 22, and at 10 a.m. on April 23.

*Topics for discussion include:* long-term care hospitals; the Medicare hospice program; chronic care improvement for chronic kidney disease; beneficiaries' financial resources; private insurers' strategies for purchasing imaging and other services; prescription drug implementation issues; and the Medicare dual-eligible

population. The Commission will also discuss congressionally mandated reports on specialty hospitals, the usefulness of the IRS Form 990 in reporting on hospitals' access to capital, and an assessment of the strengths and weaknesses of available data to judge total financial circumstances of hospitals and other providers of Medicare services.

Agendas will be e-mailed approximately one week prior to the meeting. The final agenda will be available on the Commission's Web site (<http://www.MedPAC.gov>).

**ADDRESSES:** MedPAC's address is: 601 New Jersey Avenue, NW., Suite 9000, Washington, DC 20001. The telephone number is (202) 220-3700.

**FOR FURTHER INFORMATION CONTACT:** Diane Ellison, Office Manager, (202) 220-3700.

**Mark E. Miller.**

*Executive Director.*

[FR Doc. 04-8334 Filed 4-12-04; 8:45 am]

BILLING CODE 6820-BW-M

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Advisory Committee on Preservation; Meeting

**AGENCY:** National Archives and Records Administration.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2) and implementing regulation 41 CFR 101.6, the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on Preservation. NARA uses the Committee's recommendations on NARA's implementation of strategies for preserving the permanently valuable records of the Federal Government.

**DATES:** June 15, 2004, from 9 a.m. to 4 p.m.

**ADDRESSES:** National Archives and Records Administration, 8601 Adelphi Road, lecture rooms C & D, College Park, MD 20740-6001.

**FOR FURTHER INFORMATION CONTACT:** Alan Calmes, Preservation Officer, 301-837-1567.

**SUPPLEMENTARY INFORMATION:**

The agenda for the meeting will be Options for the Preservation and Duplication of the November 22, 1963, Dallas Police Dictation Belts.

1. Background
2. Preservation of the original dictation belts
3. Reproduction of the dictation belts for preservation and access
4. Recommendations

This meeting will be open to the public, but seating may be limited.

Dated: April 6, 2004.

Mary Ann Hadyka,

*Committee Management Officer.*

[FR Doc. 04-8253 Filed 4-12-04; 8:45 am]

BILLING CODE 7515-01-P

**NATIONAL SCIENCE FOUNDATION****Sunshine Act Meeting**

**AGENCY HOLDING MEETING:** National Science Foundation, National Science Board, Committee on Nominations.

**DATE AND TIME:** April 12, 11:30 a.m. to 12:30 p.m.

**PLACE:** National Science Foundation, Room 1220, 4201 Wilson Boulevard, Arlington, VA 22230.

**STATUS:** This meeting will be closed to the public.

**MATTERS TO BE CONSIDERED:** Monday, April 12, 2004. Closed Session (11:30 a.m. to 12:30 p.m.)

Selection of committee chairman;  
Discussion of candidates for NSB Chairman and Vice Chairman;  
Discussion of candidates for two vacancies on the NSB Executive Committee.

**FOR INFORMATION CONTACT:** Michael P. Crosby, Ph.D., Director, National Science Board Office and Executive Officer, (703) 292-7000, [www.nsf.gov/nsb](http://www.nsf.gov/nsb).

Michael P. Crosby,

*Director, National Science Board Office and Executive Officer.*

[FR Doc. 04-8449 Filed 4-9-04; 12:20 pm]

BILLING CODE 7555-01-M

**UNITED STATES NUCLEAR REGULATORY COMMISSION**

[Docket Nos. 50-266 and 50-301]

**Nuclear Management Company, LLC, Point Beach Nuclear Plant, Units 1 and 2; Notice of Acceptance for Docketing of the Application and Notice of Opportunity for Hearing Regarding Renewal of Facility Operating License Nos. DPR-24 and DPR-27 for an Additional 20-Year Period**

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering application for the renewal of Operating License Nos. DPR-24 and DPR-27, which authorize the Nuclear Management Company, LLC, to operate the Point Beach Nuclear Plant, Units 1 and 2 at 1540 megawatts thermal for each unit. The renewed licenses would authorize the applicant to operate the Point Beach Nuclear Plant, Units 1 and 2, for an additional 20 years beyond the period specified in the current licenses. The current operating license for the Point Beach Nuclear Plant, Unit 1 expires on October 5, 2010, and the current operating license for the Point Beach Nuclear Plant, Unit 2 expires on March 8, 2013.

On February 26, 2004, the Commission's staff received an application from Nuclear Management Company, LLC filed pursuant to 10 CFR Part 54, to renew the Operating License Nos. DPR-24 and DPR-27 for Point Beach Nuclear Plant, Units 1 and 2, respectively. A Notice of Receipt and Availability of the license renewal application, "Nuclear Management Company, LLC: Notice of Receipt and Availability of Application for Renewal of Point Beach Nuclear Plant, Units 1 and 2, Facility Operating License Nos. DPR-24 and DPR-27 for Additional 20-Year Period," was published in the **Federal Register** on March 8, 2004 (69 FR 10765).

The Commission's staff has determined that Nuclear Management Company, LLC has submitted sufficient information in accordance with 10 CFR 54.19, 54.21, 54.22, 54.23, and 51.53(c) that is acceptable for docketing. The current Docket Nos. 50-266 and 50-301 for Operating License Nos. DPR-24 and DPR-27, respectively, will be retained. The docketing of the renewal application does not preclude requesting additional information as the review proceeds, nor does it predict whether the Commission will grant or deny the application.

Before issuance of each requested renewed license, the NRC will have made the findings required by the Atomic Energy Act of 1954, as amended

(the Act), and the Commission's rules and regulations. In accordance with 10 CFR 54.29, the NRC will issue a renewed license on the basis of its review if it finds that actions have been identified and have been or will be taken with respect to: (1) Managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring aging management review, and (2) time-limited aging analyses that have been identified as requiring review, such that there is reasonable assurance that the activities authorized by the renewed licenses will continue to be conducted in accordance with the current licensing basis (CLB), and that any changes made to the plant's CLB comply with the Act and the Commission's regulations.

Additionally, in accordance with 10 CFR 51.95(c), the NRC will prepare an environmental impact statement that is a supplement to the Commission's NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Power Plants," dated May 1996. Pursuant to 10 CFR 51.26, and as part of the environmental scoping process, the staff intends to hold a public scoping meeting. Detailed information regarding this meeting will be the subject of a separate **Federal Register** notice.

Within 60 days after the date of publication of this **Federal Register** Notice, the requestor/petitioner may file a request for a hearing, and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene with respect to the renewal of the licenses. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852 and is accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff at 1-800-397-4209, or by email at [pdr@nrc.gov](mailto:pdr@nrc.gov). If a request for a hearing or a petition for leave to intervene is filed within the 60-

day period, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order. In the event that no request for a hearing or petition for leave to intervene is filed within the 60-day period, the NRC may, upon completion of its evaluations and upon making the findings required under 10 CFR parts 51 and 54, renew the licenses without further notice.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding, taking into consideration the limited scope of matters that may be considered pursuant to 10 CFR parts 51 and 54. The petition must specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the requestor's/petitioner's right under Act to be made a party to the proceeding; (2) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases of each contention and a concise statement of the alleged facts or the expert opinion that supports the contention on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the requestor/petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The requestor/petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact.<sup>1</sup> Contentions shall be limited to matters within the scope of the action under consideration. The contention must be one that, if proven, would

entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Each contention shall be given a separate numeric or alpha designation within one of the following groups and all like subject-matters shall be grouped together:

1. Technical—primarily concerns issues relating to technical and/or health and safety matters discussed or referenced in the Point Beach Nuclear Plant, Units 1 and 2 safety analysis for the application (including issues related to emergency planning and physical security to the extent that such matters are discussed or referenced in the application).

2. Environmental—primarily concerns issues relating to matters discussed or referenced in the Environmental Report for the license renewal application

3. Miscellaneous—does not fall into one of the categories outlined above.

As specified in 10 CFR 2.309, if two or more requestors/petitioners seek to co-sponsor a contention or propose substantially the same contention, the requestors/petitioners will be required to jointly designate a representative who shall have the authority to act for the requestors/petitioners with respect to that contention within ten (10) days after advised of such contention.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to participate fully in the conduct of the hearing. A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) Email addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, [HEARINGDOCKET@NRC.GOV](mailto:HEARINGDOCKET@NRC.GOV); or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at 301-415-1101, verification number is 301-415-1966. A copy of the request for hearing and petition for leave to intervene must also be sent to the Office of the General

Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301-415-3725 or by email to [OGCMailCenter@nrc.gov](mailto:OGCMailCenter@nrc.gov). A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee. Attorney for the Applicant: David R. Lewis, Esq., Shaw Pittman, 2300 N Street, NW., Washington, DC 20037.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition, request and/or contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)-(viii).

Detailed information about the license renewal process can be found under the Nuclear Reactors icon at <http://www.nrc.gov/reactors/operating/licensing/renewal.html> on the NRC's Web page. Copies of the application to renew the operating licenses for the Point Beach Nuclear Plant, Units 1 and 2, are available for public inspection at the Commission's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, 20855-2738, and at <http://www.nrc.gov/reactors/operating/licensing/renewal/applications/point-beach.html> the NRC's Web page while the application is under review. The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html> under ADAMS accession number ML040580020. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, may contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

The staff has verified that a copy of the license renewal application is also available to local residents near the Point Beach Nuclear Plant at the Lester Public Library, at 1001 Adams Street, Two Rivers, Wisconsin 54241.

Dated at Rockville, Maryland, this the 7th day of April 2004

For the Nuclear Regulatory Commission.

**Pao-Tsin Kuo,**

*Program Director, License Renewal and Environmental Impacts, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.*

[FR Doc. 04-8286 Filed 4-12-04; 8:45 am]

BILLING CODE 7590-01-U

## NUCLEAR REGULATORY COMMISSION

### Advisory Committee on Nuclear Waste; Revised

The agenda for the 149th meeting of the Advisory Committee on Nuclear Waste (ACNW) scheduled for April 20-22, 2004, 11545 Rockville Pike, Rockville, Maryland, has been revised to include a presentation on the Scientific and Technical Priorities at Yucca Mountain on Wednesday, April 21, 2004, as follows:

4 p.m.-5 p.m.: *Scientific and Technical Priorities at Yucca Mountain (Open)*—The Committee will hear presentations by and hold discussions with representatives of the Electric Power Research Institute regarding their December 2003 report on scientific and technical priorities at Yucca Mountain.

All other items pertaining to this meeting remain the same as previously published in the **Federal Register** on Thursday, April 1, 2004 (69 FR 17243).

For further information, contact Mr. Howard J. Larson, Special Assistant, ACNW, (Telephone: 301-415-6805), between 7:30 a.m. and 4:15 p.m., ET.

Dated: April 7, 2004.

**J. Samuel Walker,**

*Acting Secretary of the Commission.*

[FR Doc. 04-8285 Filed 4-12-04; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

### Sunshine Act Meeting

**DATES:** Weeks of April 12, 19, 26, May 3, 10, 17, 2004.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and closed.

**MATTERS TO BE CONSIDERED:**

#### Week of April 12, 2004

*Tuesday, April 13, 2004*

9:30 a.m. Briefing on Status of Office of Nuclear Regulatory Research (RES) Programs, Performance, and Plans (Public Meeting) (Contact: Alan Levin, 301-415-6656).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

#### Week of April 19, 2004—Tentative

There are no meetings scheduled for the Week of April 19, 2004.

#### Week of April 26, 2004—Tentative

*Wednesday, April 28, 2004*

9:30 a.m. Discussion of Security Issues (Closed—Ex. 1)

#### Week of May 3, 2004—Tentative

*Tuesday, May 4, 2004*

9:30 a.m. Briefing on Results of the Agency Action Review Meeting (Public Meeting) (Contact: Bob Pascarelli, 301-415-1245).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

*Thursday, May 6, 2004*

1:30 p.m. Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: John Larkins, 301-415-7360).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

#### Week of May 10, 2004—Tentative

*Monday, May 10, 2004*

1:30 p.m. Briefing on Grid Stability and Offsite Power Issues (Public Meeting) (Contact: Cornelius Holden, 301-415-3036).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

*Tuesday, May 11, 2004*

9:30 a.m. Briefing on Status of Office of International Programs (OIP) Programs, Performance, and Plans (Public Meeting) (Contact: Ed Baker, 301-415-2344).

This meeting will be webcast live at the Web address—<http://www.nrc.gov>.

1:30 p.m. Briefing on Threat Environment Assessment (Closed—Ex. 1).

#### Week of May 17, 2004—Tentative

There are no meetings scheduled for the Week of May 17, 2004.

\* The scheduled 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.

**SUPPLEMENTARY INFORMATION:** By a vote of 3-0 on April 1, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Discussion of Security Issues (Closed—Ex. 1)" be held April 7, and on

less than one week's notice to the public.

\* \* \* \* \*

The NRC Commission Meeting Schedule can be found on the Internet at <http://www.nrc.gov/what-we-do/policy-making/schedule.html>.

\* \* \* \* \*

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](mailto:dkw@nrc.gov).

Dated: April 8, 2004.

**Dave Gamberoni,**

*Office of the Secretary.*

[FR Doc. 04-8419 Filed 4-9-04; 9:24 am]

BILLING CODE 7590-01-M

## NUCLEAR REGULATORY COMMISSION

### Biweekly Notice; Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

#### I. Background

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from, March 19 through April 1, 2004. The last biweekly notice was published on March 30, 2004 (69 FR 16615).

#### Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve



no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration *Determination*, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may

also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in

the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the

Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov); or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415-1101, verification number is (301) 415-1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301-415-3725 or by e-mail to [OGCMailCenter@nrc.gov](mailto:OGCMailCenter@nrc.gov). A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)-(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdrc@nrc.gov](mailto:pdrc@nrc.gov).

**AmerGen Energy Company, LLC, et al., Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey**

*Date of amendment request:* February 27, 2004.

**Description of amendment request:** The licensee proposed to relocate the average power range monitor (APRM)-based stability protection settings for Option II stability solution to the Core Operating Limits Report (COLR). The Option II solution demonstrates that existing quadrant-based APRM trip systems will initiate a reactor scram for postulated reactor instability and avoid violating the minimum critical power ratio safety limit. Use of Option II was previously approved by the Nuclear Regulatory Commission staff thru Amendment No. 235, dated October 18, 2002.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed changes will relocate the Average Power Range Monitor (APRM) based stability protection settings for the Option II stability solution from the Technical Specifications (TS) to the Core Operating Limits Report (COLR). The APRM based stability protection settings are not an initiator or a precursor to an accident. Furthermore, changes to the stability protection settings do not physically modify or change the function, or system interfaces, of the APRM Neutron Flux Scram and Neutron Flux Control Rod Block systems or components. The APRM based stability protection settings provide automatic protection to assure that anticipated coupled neutronic/thermal-hydraulic instabilities will not compromise established fuel safety limits. The proposed TS changes cannot increase the consequences of a previously evaluated accident because the changes do not alter any Limiting Safety System Setting, but only relocate the applicable stability protection settings to the COLR. The applicable stability protection settings will continue to be determined by an NRC approved methodology.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed changes will relocate the APRM based stability protection settings for the Option II stability solution from the TS to the COLR. The APRM based stability protection settings for the Option II stability solution assure anticipated coupled neutronic/thermal-hydraulic instabilities will not compromise established fuel safety limits. These changes do not introduce any

new accident precursors and do not involve any alterations to plant configurations which could initiate a new or different kind of accident. The proposed changes do not affect the intended function of the APRM system nor do they affect the operation of the system in a way which would create a new or different kind of accident.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change will relocate the APRM based stability protection settings for the Option II stability solution from the TS to the COLR. The APRM based stability protection settings for protection against reactor instability assure anticipated coupled neutronic/thermal-hydraulic instabilities will not compromise established fuel safety limits. No fuel thermal limits or other design and licensing basis acceptance criteria are adversely affected. No other events are adversely affected. The margin of safety, as defined in the TS, for all events is maintained.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendment involves no significant hazards consideration.

*Attorney for licensee:* Kevin P. Gallen, Morgan, Lewis & Bockius, LLP, 1800 M Street, NW., Washington, DC 20036-5869.

*NRC Section Chief:* Richard J. Laufer.

**AmerGen Energy Company, LLC, et al., Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey**

*Date of amendment request:* March 8, 2004.

**Description of amendment request:** The proposed amendment would delete Operating License Condition 2.C.(6) "Long Range Planning Program." The original objective of this requirement was to enable the licensee to better control and manage resources regarding major activities. The license condition does not have any direct effect on plant design or operation. Since imposition of this requirement on May 27, 1988, the licensee has developed internal processes to control and manage work activities, thus leading the licensee to determine that this license condition is no longer needed.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the

issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the three standards of 10 CFR 50.92(c). The NRC staff's analysis is presented below:

The first standard requires that operation of the unit in accordance with the proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated. The subject license condition was not a factor in the scenario of any previously analyzed postulated design-basis accident or anticipated operational transient. No hardware design change is involved with the proposed amendment. Thus, the proposed deletion of the license condition would create no adverse effect on the functional performance of any plant structure, system, or component (SSC). All SSCs will continue to perform their design functions with no decrease in their capabilities to mitigate the previously analyzed consequences of postulated accidents and anticipated operational transients. Accordingly, the deletion of the license condition will lead to no increase in the consequences of an accident previously evaluated, and no increase in the probability of an accident previously evaluated.

The second standard requires that operation of the unit in accordance with the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed amendment is not the result of a hardware design change, nor does it lead to the need for a hardware design change. There is no change in the methods the unit is operated. As a result, all SSCs will continue to perform as previously analyzed by the licensee, and previously evaluated and accepted by the NRC staff. Therefore, the proposed amendment will not create the possibility of a new or different kind of accident from any previously evaluated.

The third standard requires that operation of the unit in accordance with the proposed amendment will not involve a significant reduction in a margin of safety. Since the proposed deletion of the license condition will not lead the licensee to exceed or alter a design basis or safety limit, and will not result in operating any component in a less conservative manner, the proposed amendment will not affect in any way the performance characteristics and intended functions of any SSC. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

Based on the NRC staff's analysis, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Kevin P. Gallen, Morgan, Lewis & Bockius, LLP, 1800 M Street, NW., Washington, DC 20036-5869.

*NRC Section Chief:* Richard J. Laufer.

**AmerGen Energy Company, LLC,  
Docket No. 50-289, Three Mile Island  
Nuclear Station, Unit 1 (TMI-1),  
Dauphin County, Pennsylvania**

*Date of amendment request:* March 8, 2004.

*Description of amendment request:* The proposed amendment would delete Operating License Condition 2.C.(9) "Long Range Planning Program." The original objective of this requirement was to enable the licensee to better control and manage resources regarding major activities. The license condition does not have any direct effect on plant design or operation. Since imposition of this requirement on May 27, 1988, the licensee has developed internal processes to control and manage work activities, thus leading the licensee to determine that this license condition is no longer needed.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the three standards of 10 CFR 50.92(c). The NRC staff's analysis is presented below:

The first standard requires that operation of the unit in accordance with the proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated. The subject license condition was not a factor in the scenario of any previously analyzed postulated design-basis accident or anticipated operational transient. No hardware design change is involved with the proposed amendment. Thus, the proposed deletion of the license condition would create no adverse effect on the functional performance of any plant structure, system, or component (SSC). All SSCs will continue to perform their design functions with no decrease in their capabilities to mitigate the previously analyzed consequences of postulated accidents and anticipated operational transients. Accordingly, the deletion of the license condition will lead to no increase in the consequences

of an accident previously evaluated, and no increase in the probability of an accident previously evaluated.

The second standard requires that operation of the unit in accordance with the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed amendment is not the result of a hardware design change, nor does it lead to the need for a hardware design change. There is no change in the methods the unit is operated. As a result, all SSCs will continue to perform as previously analyzed by the licensee, and previously evaluated and accepted by the NRC staff. Therefore, the proposed amendment will not create the possibility of a new or different kind of accident from any previously evaluated.

The third standard requires that operation of the unit in accordance with the proposed amendment will not involve a significant reduction in a margin of safety. Since the proposed deletion of the license condition will not lead the licensee to exceed or alter a design basis or safety limit, and will not result in operating any component in a less conservative manner, the proposed amendment will not affect in any way the performance characteristics and intended functions of any SSC. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

Based on the NRC staff's analysis, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Edward J. Cullen, Jr., Esquire, Vice President, General Counsel and Secretary, Exelon Generation Company, LLC, 300 Exelon Way, Kennett Square, PA 19348.

*NRC Section Chief:* Richard J. Laufer.

**Calvert Cliffs Nuclear Power Plant, Inc.,  
Docket Nos. 50-317 and 50-318, Calvert  
Cliffs Nuclear Power Plant, Unit Nos. 1  
and 2, Calvert County, Maryland**

*Date of amendments request:* December 12, 2003.

*Description of amendments request:* The proposed amendment would delete Technical Specification (TS) Section 5.5.3, "Post-Accident Sampling," requirements to maintain a Post-Accident Sampling System (PASS). Licensees were generally required to implement PASS upgrades as a result of NUREG-0737, "Clarification of TMI [Three Mile Island] Action Plan Requirements," and Regulatory Guide 1.97, Revision 3, "Instrumentation for Light-Water-Cooled Nuclear Power

Plants to Access Plant and Environs Conditions During and Following an Accident." Implementation of these upgrades was an outcome of the NRC's lessons learned from the accident that occurred at TMI Unit 2. Requirements related to PASS were imposed by Order for many facilities and were added to or included in the TS for nuclear power reactors currently licensed to operate. Lessons learned and improvements implemented over the last 20 years have shown that the information obtained from PASS can be readily obtained through other means or is of little use in the assessment and mitigation of accident conditions.

The NRC staff issued a notice of opportunity for comment in the **Federal Register** on August 11, 2000 (65 FR 49271) on possible amendments to eliminate PASS, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the consolidated line item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in a license amendment application in the **Federal Register** on October 31, 2000 (65 FR 65018). The licensee affirmed the applicability of the following NSHC determination in its application dated December 12, 2003.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The PASS was originally designed to perform many sampling and analysis functions. These functions were designed and intended to be used in post accident situations and were put into place as a result of the TMI-2 accident. The specific intent of the PASS was to provide a system that has the capability to obtain and analyze samples of plant fluids containing potentially high levels of radioactivity, without exceeding plant personnel radiation exposure limits. Analytical results of these samples would be used largely for verification purposes in aiding the plant staff in assessing the extent of core damage and subsequent offsite radiological dose projections. The system was not intended to and does not serve a function for preventing accidents and its elimination would not affect the probability of accidents previously evaluated.

In the 20 years since the TMI-2 accident and the consequential promulgation of post accident sampling requirements, operating experience has demonstrated that a PASS provides little actual benefit to post accident

mitigation. Past experience has indicated that there exists in-plant instrumentation and methodologies available in lieu of a PASS for collecting and assimilating information needed to assess core damage following an accident. Furthermore, the implementation of Severe Accident Management Guidance (SAMG) emphasizes accident management strategies based on in-plant instruments. These strategies provide guidance to the plant staff for mitigation and recovery from a severe accident. Based on current severe accident management strategies and guidelines, it is determined that the PASS provides little benefit to the plant staff in coping with an accident.

The regulatory requirements for the PASS can be eliminated without degrading the plant emergency response. The emergency response, in this sense, refers to the methodologies used in ascertaining the condition of the reactor core, mitigating the consequences of an accident, assessing and projecting offsite releases of radioactivity, and establishing protective action recommendations to be communicated to offsite authorities. The elimination of the PASS will not prevent an accident management strategy that meets the initial intent of the post-TMI-2 accident guidance through the use of the SAMGs, the emergency plan (EP), the emergency operating procedures (EOP), and site survey monitoring that support modification of emergency plan protective action recommendations (PARs).

Therefore, the elimination of PASS requirements from Technical Specifications (TS) (and other elements of the licensing bases) does not involve a significant increase in the consequences of any accident previously evaluated.

**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated**

The elimination of PASS related requirements will not result in any failure mode not previously analyzed. The PASS was intended to allow for verification of the extent of reactor core damage and also to provide an input to offsite dose projection calculations. The PASS is not considered an accident precursor, nor does its existence or elimination have any adverse impact on the pre-accident state of the reactor core or post accident confinement of radionuclides within the containment building.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in [a] Margin of Safety**

The elimination of the PASS, in light of existing plant equipment, instrumentation, procedures, and programs that provide effective mitigation of and recovery from reactor accidents, results in a neutral impact to the margin of safety. Methodologies that are not reliant on PASS are designed to provide rapid assessment of current reactor core conditions and the direction of degradation while effectively responding to

the event in order to mitigate the consequences of the accident. The use of a PASS is redundant and does not provide quick recognition of core events or rapid response to events in progress. The intent of the requirements established as a result of the TMI-2 accident can be adequately met without reliance on a PASS.

Therefore, this change does not involve a significant reduction in [a] margin of safety.

Based upon the reasoning presented above and the previous discussion of the amendment request, the requested change does not involve a significant hazards consideration.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* James M. Petro, Jr., Esquire, Counsel, Constellation Energy Group, Inc., 750 East Pratt Street, 5th floor, Baltimore, MD 21202.

*NRC Section Chief:* Richard J. Laufer.

**Duke Energy Corporation, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina**

*Date of amendment request:* June 25, 2003.

*Description of amendment request:*

The proposed amendments would correct two inadvertent editorial changes made by Duke during the submittal of Technical Specification (TS) Amendment 194/175 which revised TS 3.3.1 (Reactor Trip System Instrumentation) and TS Amendment 197/178 which revised TS 4.2.1 (Design Features, Fuel Assemblies).

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does this LAR [License Amendment Request] involve a significant increase in the probability or consequences of an accident previously evaluated?

No. Approval and implementation of this LAR will have no effect on accident probabilities or consequences since the proposed changes are editorial in nature and were previously reviewed and approved by the NRC [Nuclear Regulatory Commission].

2. Does this LAR create the possibility of a new or different kind of accident from any accident previously evaluated?

No. This LAR does not involve any physical changes to the plant. Therefore, no new accident causal mechanisms will be generated. The proposed changes are editorial in nature and were previously reviewed and approved by the NRC. Consequently, plant accident analyses will not be affected by these changes.

3. Does this LAR involve a significant reduction in a margin of safety?

No. Margin of safety is related to the confidence in the ability of the fission



product barriers to perform their design functions during and following accident conditions. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The performance of these barriers will not be affected by the proposed changes since they are editorial in nature and have been previously reviewed and approved by the NRC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Ms. Lisa F. Vaughn, Duke Energy Corporation, 422 South Church Street, Charlotte, North Carolina 28201-1006.

*NRC Section Chief:* John A. Nakoski.

**Duke Energy Corporation, Docket Nos. 50-269, 50-270, and 50-287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina**

*Date of amendment request:* January 15, 2004, as supplemented by letter dated March 15, 2004.

*Description of amendment request:* The proposed amendments would revise the Technical Specifications associated with the control rod drive (CRD) trip devices. These amendments are needed to support implementation of the reactor trip breaker (RTB) replacement.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated[.]

The proposed LAR [license amendment request] modifies the Technical Specifications [TS] to incorporate new TS requirements associated with the new Control Rod Drive (CRD)/Reactor Trip Breaker (RTB) configuration. The proposed LAR will continue to ensure that the CRD trip devices will be operable to ensure that the reactor remains capable of being tripped at any time it is critical. Reliable CRD reactor trip circuit breakers and associated support circuitry provides assurance that a reactor trip will occur when initiated. The new RTBs will have the same seismic and quality group qualifications as the existing components in the CRDCS [CRD control system] system [sic]. The new RTBs will enhance the reliability of the system by resolving age-related degradation issues and replacing obsolete equipment. Therefore, the proposed LAR does not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different kind of accident from any kind of accident previously evaluated[.]

The proposed LAR modifies the Technical Specifications to incorporate new TS requirements associated with the new CRD/RTB configuration. The systems affected by implementing the proposed changes to the TS are not assumed to initiate design basis accidents. Rather, the systems affected by the changes are used to mitigate the consequences of an accident that has already occurred. The proposed TS changes do not affect the mitigating function of these systems. The reliability of the mitigating systems will be improved by implementation of the RTB Upgrade. Consequently, these changes do not alter the nature of events postulated in the Safety Analysis Report nor do they introduce any unique precursor mechanisms. Therefore, the proposed amendment will not create the possibility of a new or different kind of accident from any previously evaluated.

(3) Involve a significant reduction in a margin of safety.

The proposed TS changes do not unfavorably affect any plant safety limits, set points, or design parameters. The changes also do not unfavorably affect the fuel, fuel cladding, RCS [reactor coolant system], or containment integrity. Therefore, the proposed TS change, which adds TS requirements associated with the CRD/RTB upgrade, do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Anne W. Cottingham, Winston and Strawn, 1200 17th Street, NW., Washington, DC 20005.

*NRC Section Chief:* John A. Nakoski.

**Entergy Nuclear Operations, Docket Nos. 50-247 and 50-286, Indian Point Nuclear Generating Unit Nos. 2 and 3, Westchester County, New York**

*Date of amendment request:* March 3, 2004.

*Description of amendment request:* The proposed amendments would revise the administrative Technical Specifications (TSs) for the Reactor Coolant Pump Flywheel Inspection Program to extend the allowable inspection interval to 20 years.

The NRC staff issued a notice of opportunity for comment in the *Federal Register* on June 24, 2003 (68 FR 37590), on possible amendments to extend the inspection interval for reactor coolant pump (RCP) flywheels, including a model safety evaluation and model no significant hazards consideration (NSHC) determination,

using the consolidated line-item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the *Federal Register* on October 22, 2003 (68 FR 60422). The licensee affirmed the applicability of the model NSHC determination in its application dated March 3, 2004.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The proposed change to the RCP flywheel examination frequency does not change the response of the plant to any accidents. The RCP will remain highly reliable and the proposed change will not result in a significant increase in the risk of plant operation. Given the extremely low failure probabilities for the RCP motor flywheel during normal and accident conditions, the extremely low probability of a loss-of-coolant accident (LOCA) with loss of offsite power (LOOP), and assuming a conditional core damage probability (CCDP) of 1.0 (complete failure of safety systems), the core damage frequency (CDF) and change in risk would still not exceed the NRC's acceptance guidelines contained in Regulatory Guide (RG) 1.174 ( $<1.0E-6$  per year). Moreover, considering the uncertainties involved in this evaluation, the risk associated with the postulated failure of an RCP motor flywheel is significantly low. Even if all four RCP motor flywheels are considered in the bounding plant configuration case, the risk is still acceptably low.

The proposed change does not adversely affect accident initiators or precursors, nor alter the design assumptions, conditions, or configuration of the facility, or the manner in which the plant is operated and maintained; alter or prevent the ability of structures, systems, components (SSCs) from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits; or affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. Further, the proposed change does not increase the type or amount of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposure. The proposed change is consistent with the safety analysis assumptions and resultant consequences. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.



**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Accident Previously Evaluated**

The proposed change in flywheel inspection frequency does not involve any change in the design or operation of the RCP. Nor does the change to examination frequency affect any existing accident scenarios, or create any new or different accident scenarios. Further, the change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or alter the methods governing normal plant operation. In addition, the change does not impose any new or different requirements or eliminate any existing requirements, and does not alter any assumptions made in the safety analysis. The proposed change is consistent with the safety analysis assumptions and current plant operating practice. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in a Margin of Safety**

The proposed change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined. The safety analysis acceptance criteria are not impacted by this change. The proposed change will not result in plant operation in a configuration outside of the design basis. The calculated impact on risk is insignificant and meets the acceptance criteria contained in RG 1.174. There are no significant mechanisms for inservice degradation of the RCP flywheel. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

*NRC Section Chief:* Richard J. Laufer.

**Entergy Nuclear Operations, Inc.,  
Docket No. 50-286, Indian Point  
Nuclear Generating Unit No. 3,  
Westchester County, New York**

*Date of amendment request:* March 9, 2004.

*Description of amendment request:* The proposed amendment would extend the completion time (CT) from 1 hour to 24 hours for Condition B of Technical Specification (TS) 3.5.1, "Accumulators." The accumulators are part of the emergency core cooling system and consist of tanks partially filled with borated water and pressurized with nitrogen gas. The contents of the tank are discharged to the reactor coolant system (RCS) if, as during a loss-of-coolant accident, the coolant pressure decreases to below the

accumulator pressure. Condition B of TS 3.5.1 specifies a CT to restore an accumulator to operable status when it has been declared inoperable for a reason other than the boron concentration of the water in the accumulator not being within the required range. This change was proposed by the Westinghouse Owners Group participants in the TS Task Force (TSTF) and is designated TSTF-370. TSTF-370 is supported by NRC-approved Topical Report WCAP-15049-A, "Risk-Informed Evaluation of an Extension to Accumulator Completion Times," submitted on May 18, 1999. The NRC staff issued a notice of opportunity for comment in the **Federal Register** on July 15, 2002 (67 FR 46542), on possible amendments concerning TSTF-370, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the consolidated line item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on March 12, 2003 (68 FR 11880). The licensee affirmed the applicability of the following NSHC determination in its application dated March 9, 2004.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The basis for the accumulator limiting condition for operation (LCO), as discussed in Bases Section 3.5.1.1, is to ensure that a sufficient volume of borated water will be immediately forced into the core through each of the cold legs in the event the RCS pressure falls below the pressure of the accumulators, thereby providing the initial cooling mechanism during large RCS pipe ruptures. As described in Section 9.2 of WCAP-15049-A, the proposed change will allow plant operation with an inoperable accumulator for up to 24 hours, instead of 1 hour, before the plant would be required to begin shutting down. The impact of the increase in the accumulator CT on core damage frequency for all the cases evaluated in WCAP-15049-A is within the acceptance limit of 1.0E-06/yr for a total plant core damage frequency (CDF) less than 1.0E-03/yr. The incremental conditional core damage probabilities calculated in WCAP-15049-A for the accumulator CT increase meet the criterion of 5E-07 in Regulatory Guides (RG) 1.174, "An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," and 1.177, "An Approach for Plant-

Specific, Risk-Informed Decisionmaking: Technical Specifications," for all cases except those that are based on design basis success criteria. As indicated in WCAP-15049-A, design basis accumulator success criteria are not considered necessary to mitigate large break loss-of-coolant accident (LOCA) events, and were only included in the WCAP-15049-A evaluation as a worst case data point. In addition, WCAP-15049-A states that the NRC has indicated that an incremental conditional core damage frequency (ICDP) greater than 5E-07 does not necessarily mean the change is unacceptable.

The proposed technical specification change does not involve any hardware changes nor does it affect the probability of any event initiators. There will be no change to normal plant operating parameters, engineered safety feature (ESF) actuation setpoints, accident mitigation capabilities, accident analysis assumptions or inputs.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From any Previously Evaluated**

No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures are introduced as a result of the proposed change. As described in Section 9.1 of the WCAP-15049-A evaluation, the plant design will not be changed with this proposed technical specification CT increase. All safety systems still function in the same manner and there is no additional reliance on additional systems or procedures. The proposed accumulator CT increase has a very small impact on core damage frequency. The WCAP-15049-A evaluation demonstrates that the small increase in risk due to increasing the CT for an inoperable accumulator is within the acceptance criteria provided in RGs 1.174 and 1.177. No new accidents or transients can be introduced with the requested change and the likelihood of an accident or transient is not impacted.

The malfunction of safety related equipment, assumed to be operable in the accident analyses, would not be caused as a result of the proposed technical specification change. No new failure mode has been created and no new equipment performance burdens are imposed.

Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in a Margin of Safety**

The proposed change does not involve a significant reduction in a margin of safety. There will be no change to the departure from nucleate boiling ratio (DNBR) correlation limit, the design DNBR limits, or the safety analysis DNBR limits.

The basis for the accumulator LCO, as discussed in Bases Section 3.5.1.1, is to ensure that a sufficient volume of borated

water will be immediately forced into the core through each of the cold legs in the event the RCS pressure falls below the pressure of the accumulators, thereby providing the initial cooling mechanism during large RCS pipe ruptures. As described in Section 9.2 of WCAP-15049-A, the proposed change will allow plant operation with an inoperable accumulator for up to 24 hours, instead of 1 hour, before the plant would be required to begin shutting down. The impact of this on plant risk was evaluated and found to be very small. That is, increasing the time the accumulators will be unavailable to respond to a large LOCA event, assuming accumulators are needed to mitigate the design basis event, has a very small impact on plant risk.

Since the frequency of a design basis large LOCA (a large LOCA with loss of offsite power) would be significantly lower than the large LOCA frequency of the WCAP-15049-A evaluation, the impact of increasing the accumulator CT from 1 hour to 24 hours on plant risk due to a design basis large LOCA would be significantly less than the plant risk increase presented in the WCAP-15049-A evaluation.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. John Fulton, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

*NRC Section Chief:* Richard J. Laufer.

**Entergy Nuclear Operations, Inc.,  
Docket No. 50-293, Pilgrim Nuclear  
Power Station, Plymouth County,  
Massachusetts**

*Date of amendment request:*  
December 24, 2003.

*Description of amendment request:* The proposed amendment would delete requirements in the Pilgrim Nuclear Power Station Technical Specifications (TSs) 3.7.A.7.c and 4.7.A.7.c, associated with hydrogen analyzers. The NRC staff issued a notice of opportunity for comment in the *Federal Register* on August 2, 2002 (67 FR 50374), on possible amendments to eliminate the hydrogen analyzers from TSs, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the Consolidated Line Item Improvement Process (CLIP). The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the *Federal Register* on September 25, 2003 (68 FR 55416). The licensee affirmed the applicability of the relevant portions of the model NSHC determination in its application dated December 24, 2003.

*Basis for proposed no significant hazards consideration determination:*

As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The revised 10 CFR 50.44 no longer defines a design-basis loss-of-coolant accident (LOCA) hydrogen release, and eliminates requirements for hydrogen control systems to mitigate such a release. The installation of hydrogen recombiners and/or vent and purge systems required by 10 CFR 50.44(b)(3) was intended to address the limited quantity and rate of hydrogen generation that was postulated from a design-basis LOCA. The Commission has found that this hydrogen release is not risk-significant because the design-basis LOCA hydrogen release does not contribute to the conditional probability of a large release up to approximately 24 hours after the onset of core damage. In addition, these systems were ineffective at mitigating hydrogen releases from risk-significant accident sequences that could threaten containment integrity.

With the elimination of the design-basis LOCA hydrogen release, hydrogen monitors are no longer required to mitigate design-basis accidents and, therefore, the hydrogen monitors do not meet the definition of a safety-related component as defined in 10 CFR 50.2. RG [Regulatory Guide] 1.97 Category 1, is intended for key variables that most directly indicate the accomplishment of a safety function for design-basis accident events. The hydrogen monitors no longer meet the definition of Category 1 in RG 1.97. As part of the rulemaking to revise 10 CFR 50.44, the Commission found that Category 3, as defined in RG 1.97, is an appropriate categorization for the hydrogen monitors because the monitors are required to diagnose the course of beyond design-basis accidents.

The regulatory requirements for the hydrogen monitors can be relaxed without degrading the plant emergency response. The emergency response, in this sense, refers to the methodologies used in ascertaining the condition of the reactor core, mitigating the consequences of an accident, assessing and projecting offsite releases of radioactivity, and establishing protective action recommendations to be communicated to offsite authorities. Classification of the hydrogen monitors as Category 3, and removal of the hydrogen monitors from TS will not prevent an accident management strategy through the use of the SAMGs [Severe Accident Management Guidelines], the emergency plan (EP), the emergency operating procedures (EOP), and site survey monitoring that support modification of emergency plan protective action recommendations (PARs).

Therefore, the elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, does not involve a significant increase in the probability or the

consequences of any accident previously evaluated.

**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From any Previously Evaluated.**

The elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, will not result in any failure mode not previously analyzed. The hydrogen recombiner and hydrogen monitor equipment was intended to mitigate a design-basis hydrogen release. The hydrogen recombiner and hydrogen monitor equipment are not considered accident precursors, nor does their existence or elimination have any adverse impact on the pre-accident state of the reactor core or post accident confinement of radionuclides within the containment building.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety.**

The elimination of the hydrogen recombiner requirements and relaxation of the hydrogen monitor requirements, including removal of these requirements from TS, in light of existing plant equipment, instrumentation, procedures, and programs that provide effective mitigation of and recovery from reactor accidents, results in a neutral impact to the margin of safety.

The installation of hydrogen recombiners and/or vent and purge systems required by 10 CFR 50.44(b)(3) was intended to address the limited quantity and rate of hydrogen generation that was postulated from a design-basis LOCA. The Commission has found that this hydrogen release is not risk-significant because the design-basis LOCA hydrogen release does not contribute to the conditional probability of a large release up to approximately 24 hours after the onset of core damage.

Category 3 hydrogen monitors are adequate to provide rapid assessment of current reactor core conditions and the direction of degradation while effectively responding to the event in order to mitigate the consequences of the accident. The intent of the requirements established as a result of the TMI, Unit 2 accident can be adequately met without reliance on safety-related hydrogen monitors.

Therefore, this change does not involve a significant reduction in the margin of safety. Removal of hydrogen monitoring from TS will not result in a significant reduction in their functionality, reliability, and availability.

Based upon the reasoning presented above, the requested change does not involve a significant hazards consideration. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* J.M. Fulton, Esquire, Assistant General Counsel,

Pilgrim Nuclear Power Station, 600 Rocky Hill Road, Plymouth, Massachusetts 02360-5599.

*NRC Section Chief:* Darrell J. Roberts, Acting.

**Entergy Operations Inc., Docket No. 50-382, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana**

*Date of amendment request:* March 15, 2004.

*Description of amendment request:* The amendment proposes to move the Waterford Steam Electric Station, Unit 3 (Waterford 3) Technical Specification (TS) 3.4.8.2, pressurizer heatup and cooldown limits to the Technical Requirements Manual (TRM), which is reviewed in accordance with Section 50.59 of Title 10 of the Code of Federal Regulations (10 CFR), "Changes, tests, and experiments." The associated action statement, surveillance requirement, and bases are also proposed for relocation.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The probability of an accident is unchanged as a result of the proposed change to delete the Waterford 3 pressurizer heatup and cooldown rates and associated action, surveillance requirement, and bases from the TS. The cooldown and heatup rates are not initiators to any accidents or pressurizer transients discussed in the Waterford 3 Final Safety Analysis Report (FSAR). Therefore, the probability of an accident is not changed.

The purpose of the pressurizer heatup and cooldown limits is to ensure that given transient events will not negatively affect the pressurizer structural integrity beyond Code allowables. These limits will be maintained within ASME [American Society of Mechanical Engineers] Code allowables in the TRM in accordance with 10 CFR 50.59. Therefore, the consequences of an accident are not increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The limitations imposed on the pressurizer heatup and cooldown rates are provided to assure that the pressurizer is operated within the design criteria assumed for the flaw evaluation and fatigue analysis performed in accordance with the ASME Code Section XI,

subsection IWB-3600 requirements. The Waterford 3 FSAR has analyzed the conditions that would result from a thermal or pressurization transient on the Waterford 3 pressurizer. The proposed deletion of the pressurizer heatup and cooldown rates and relocation of the limits to the TRM does not change the way that the pressurizer is designed or operated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The margin of safety is established by the rules contained in the ASME Section III Code. Any future changes to the cooldown or heatup rates will be evaluated using 10 CFR 50.59 and are required to meet the ASME Code margins.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* N.S. Reynolds, Esquire, Winston & Strawn 1400 L Street NW., Washington, DC 20005-3502.

*NRC Section Chief:* Robert A. Gramm.

**Exelon Generation Company, LLC, Docket Nos. 50-373 and 50-374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois**

*Date of amendment request:* March 12, 2004.

*Description of amendment request:* The proposed amendments would modify the Technical Specifications (TS) to eliminate selected response time testing (RTT) requirements associated with Reactor Protection System instrumentation and Primary Containment Isolation instrumentation for Main Steam Line Isolation functions. The proposed changes are consistent with the Boiling Water Reactor Owners Group (BWROG) Licensing Topical Report "System Analyses for the Elimination of Selected Response Time Testing Requirements," NEDO-32291-A, Supplement 1, dated October 1999, as approved by the NRC on June 11, 1999.

The original Licensing Topical Report (LTR) NEDO-32291-A, dated October 1995, established a generic basis for elimination of many RTTs for instrument loops that had good performance histories and longer response time requirements. The justification was based on the adequacy

of surveillance tests other than RTTs to assure that response time requirements were met for sensors in those loops. Supplement 1 to NEDO-32291-A was prepared to document an analysis to extend the conclusions of the original study to cover the logic components in selected instrumentation loops that have intermediate length response time requirements. The intent was to demonstrate that elimination of the RTT requirements for the logic portions of those loops is of no safety significance. Supplement 1 concludes, for instrument loops meeting the application criteria of the Licensing Topical Report, that performance of ongoing TS required surveillance tests other than RTTs (*i.e.*, calibration tests, functional tests, and logic system functional tests) provides adequate assurance that those instrument loops will meet their respective response time requirements.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in probability or consequences of an accident previously evaluated.

The proposed amendment to the TS eliminates selected RTT requirements in accordance with the NRC approved BWROG LTR. Elimination of RTT for selected instrumentation in the Reactor Protection System and Primary Containment Isolation Instrumentation does not result in the alteration of the design, material, or construction standards that were applicable prior to the proposed change. The response time assumptions used in the accident analyses remain unchanged. Only the methodology used for response time verification is changed. All component models used in the affected trip channels were analyzed for a bounding response time. As documented in the BWROG LTR and supplement, a degraded response time will be detected by other TS required tests. The bounding response time of the relays discussed in the supplement to the LTR can be used in place of actual measured response times to ensure that the instrumentation systems will meet the response time requirements of the accident analysis.

The proposed change will not result in the modification of any system interface that would increase the likelihood of an accident since these events are independent of the proposed change. In addition, the proposed amendment will not change, degrade, or prevent actions, or alter any assumptions previously made in evaluating the radiological consequences of an accident.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed action does not involve physical alteration of the station. No new equipment is being introduced, and installed equipment is not being operated in a new or different manner. There is no change being made to the parameters within which LaSalle is operated. There are no setpoints at which protective or mitigative actions are initiated that are affected by this proposed action. All Reactor Protection System and Primary Containment Isolation Instrumentation channels affected by the proposed change will continue to have an initial response time verified by test before initially placing the channel in service and after any maintenance that could affect response time.

The proposed change does not alter assumptions made in the safety analysis. A review of the failure modes of the affected sensors and relays indicates that a sluggish response of the instruments can be detected by other TS surveillances. Changing the method of periodically verifying instrument response for the selected instrument channels will not create any new accident initiators or scenarios. Periodic surveillance of these instruments will detect significant degradation in the channel characteristic. This proposed action will not alter the manner in which equipment operation is initiated, nor will the function demands on credited equipment be changed. No change is being made to procedures relied upon to respond to an off-normal event. As such, no new failure modes are being introduced.

The sensors and relays in the affected channels will be able to meet the bounding response times as defined and presented in the LTR Supplement. It has been found acceptable to use component bounding response times in place of actual measured response times to ensure that instrumentation systems will meet response time requirements of the accident analyses. In addition, [Exelon Generation Company, LLC] EGC's adherence to the conditions listed in the NRC Safety Evaluations for the LTR and Supplement provides additional assurance that the instrumentation systems will meet the response time requirements of the accident analyses.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

Implementation of the BWROG LTR methodologies for eliminating selected response time testing requirements does not involve a significant reduction in the margin of safety. The current response time limits are based on the maximum values assumed in the plant safety analyses. The analyses conservatively establish the margin of safety. The elimination of the selected response time testing does not affect the capability of the associated systems to perform their intended function within the allowed response time used as the basis for plant safety analyses. Plant and system response to an initiating event will remain in compliance within the

assumptions of the safety analyses, and therefore, the margin of safety is not affected. This is based on the ability to detect a degraded response time of an instrument or relay by the other required TS tests, component reliability, and redundancy and diversity of the affected functions, as justified in the reviewed and approved LTR and Supplement.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

*Attorney for licensee:* Mr. Edward J. Cullen, Deputy General Counsel, Exelon BSC—Legal, 2301 Market Street, Philadelphia, PA 19101.

*NRC Section Chief:* Anthony J. Mendiola.

**Exelon Generation Company, LLC, and PSEG Nuclear LLC, Dockets Nos. 50-277 and 50-278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania**

*Date of application for amendments:* February 27, 2004.

*Description of amendment request:* The proposed change to the Technical Specifications (TSs) supports the activation of the trip outputs of the previously-installed Oscillation Power Range Monitor (OPRM) portion of the Power Range Neutron Monitoring (PRNM) system. Specifically, this proposed change will revise TS Sections 3.3.1.1, "Reactor Protection System Instrumentation," and 3.4.1, "Recirculation Loops Operating Reporting Requirements," and their associated TS Bases, and TS Section 5.6.5, "Core Operating Limits Report (COLR)." In addition, the proposed change deletes the Interim Corrective Action requirements from the Recirculation Loops Operating TSs.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No. This modification has no impact on any of the previously installed PRNM functions. Plant operation in portions of the former restricted region may potentially cause a marginal increase in the probability of occurrence of an instability

event. This potential increase in probability is acceptable because the OPRM function will automatically detect the condition and initiate a reactor scram before the Minimum Critical Power Ratio (MCPR) Safety Limit is reached. Consequences of the potential instability event are reduced because of the more reliable automatic detection and suppression of an instability event, and the elimination of dependence on the manual operator actions.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No. The modification replaces procedural actions that were established to avoid operating conditions where reactor instabilities might occur with an NRC approved automatic detect and suppress function.

Potential failures in the OPRM Upscale function could result in either failure to take the required mitigating action or an unintended reactor scram. These are the same potential effects of failure of the operator to take the correct appropriate action under the current procedural actions. The net effect of the modification changes the method by which an instability event is detected and by which mitigating action is initiated, but does not change the type of stability event that could occur. The effects of failure of the OPRM equipment are limited to reduced or failed mitigation, but such failure cannot cause an instability event or other type of accident.

Therefore, since no radiological barrier will be challenged as a result of activating the OPRM trip function, it is concluded that this proposed activity does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No. The current safety analyses assume that the existing procedural actions are adequate to prevent an instability event. As a result, there is currently no quantitative or qualitative assessment of an instability event with respect to its impact on MCPR.

The OPRM trip function is being implemented to automate the detection (via direct measurement of neutron flux) and subsequent suppression (via scram) of an instability event prior to exceeding the MCPR Safety Limit. The OPRM trip provides a trip output of the same type as currently used for the Average Power Range Monitor (APRM). Its failure modes and types are identical to those for the present APRM output. Currently, the MCPR Safety Limit is not impacted by an instability event since the event is "mitigated" by manual means via the procedural actions, which prevent plant operating conditions where an instability event is possible. In both methods of mitigation (manual and automated), the margin of safety associated with the MCPR Safety Limit is maintained.

Therefore, since the MCPR Safety Limit will not be exceeded as a result of an



instability event following implementation of the OPRM trip function, it is concluded that the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for Licensee:* Mr. Edward Cullen, Vice President and General Counsel, Exelon Generation Company, LLC, 2301 Market Street, S23-1, Philadelphia, PA 19101.

*NRC Section Chief:* Darrell Roberts, Acting.

**Florida Power Corporation, et al., Docket No. 50-302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida**

*Date of amendment request:* February 27, 2004.

*Description of amendment request:* The proposed amendment would delete Technical Specification (TS) Section 5.6.2.6, "Post Accident Sampling," requirements to maintain a Post Accident Sampling System (PASS). Licensees were generally required to implement PASS upgrades as described in NUREG-0737, "Clarification of TMI [Three Mile Island] Action Plan Requirements," and Regulatory Guide 1.97, Revision 3, "Instrumentation for Light-Water-Cooled Nuclear Power Plants to Access Plant and Environs Conditions During and Following an Accident." Implementation of these upgrades was an outcome of the NRC's lessons learned from the accident that occurred at TMI Unit 2. Requirements related to PASS were imposed by Order for many facilities and were added to or included in the TS for nuclear power reactors currently licensed to operate. Lessons learned and improvements implemented over the last 20 years have shown that the information obtained from PASS can be readily obtained through other means or is of little use in the assessment and mitigation of accident conditions.

The NRC staff issued a notice of opportunity for comment in the **Federal Register** on March 3, 2003 (68 FR 10052) on possible amendments to eliminate PASS, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the consolidated line item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in a license amendment application in the **Federal**

**Register** on May 13, 2003 (68 FR 25664). The licensee affirmed the applicability of the following NSHC determination in its application dated February 27, 2004.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The PASS was originally designed to perform many sampling and analysis functions. These functions were designed and intended to be used in post accident situations and were put into place as a result of the TMI-2 accident. The specific intent of the PASS was to provide a system that has the capability to obtain and analyze samples of plant fluids containing potentially high levels of radioactivity, without exceeding plant personnel radiation exposure limits. Analytical results of these samples would be used largely for verification purposes in aiding the plant staff in assessing the extent of core damage and subsequent offsite radiological dose projections. The system was not intended to and does not serve a function for preventing accidents and its elimination would not affect the probability of accidents previously evaluated.

In the 20 years since the TMI-2 accident and the consequential promulgation of post accident sampling requirements, operating experience has demonstrated that a PASS provides little actual benefit to post accident mitigation. Past experience has indicated that there exists in-plant instrumentation and methodologies available in lieu of a PASS for collecting and assimilating information needed to assess core damage following an accident. Furthermore, the implementation of Severe Accident Management Guidance (SAMG) emphasizes accident management strategies based on in-plant instruments. These strategies provide guidance to the plant staff for mitigation and recovery from a severe accident. Based on current severe accident management strategies and guidelines, it is determined that the PASS provides little benefit to the plant staff in coping with an accident.

The regulatory requirements for the PASS can be eliminated without degrading the plant emergency response. The emergency response, in this sense, refers to the methodologies used in ascertaining the condition of the reactor core, mitigating the consequences of an accident, assessing and projecting offsite releases of radioactivity, and establishing protective action recommendations to be communicated to offsite authorities. The elimination of the PASS will not prevent an accident management strategy that meets the initial intent of the post-TMI-2 accident guidance through the use of the SAMGs, the emergency plan (EP), the emergency operating procedures (EOP), and site survey monitoring that support modification of

emergency plan protective action recommendations (PARs).

Therefore, the elimination of PASS requirements from Technical Specifications (TS) (and other elements of the licensing bases) does not involve a significant increase in the consequences of any accident previously evaluated.

**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From any Previously Evaluated**

The elimination of PASS related requirements will not result in any failure mode not previously analyzed. The PASS was intended to allow for verification of the extent of reactor core damage and also to provide an input to offsite dose projection calculations. The PASS is not considered an accident precursor, nor does its existence or elimination have any adverse impact on the pre-accident state of the reactor core or post accident confinement of radioisotopes within the containment building.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety**

The elimination of the PASS, in light of existing plant equipment, instrumentation, procedures, and programs that provide effective mitigation of and recovery from reactor accidents, results in a neutral impact to the margin of safety. Methodologies that are not reliant on PASS are designed to provide rapid assessment of current reactor core conditions and the direction of degradation while effectively responding to the event in order to mitigate the consequences of the accident. The use of a PASS is redundant and does not provide quick recognition of core events or rapid response to events in progress. The intent of the requirements established as a result of the TMI-2 accident can be adequately met without reliance on a PASS.

Therefore, this change does not involve a significant reduction in the margin of safety.

Based upon the reasoning presented above and the previous discussion of the amendment request, the requested change does not involve a significant hazards consideration.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Steven R. Carr, Associate General Counsel—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602-1551.

*NRC Section Chief:* William F. Burton, Acting.

**Nuclear Management Company, LLC, Docket No. 50-331, Duane Arnold Energy Center, Linn County, Iowa**

*Date of amendment request:* January 28, 2004.

*Description of amendment request:* Duane Arnold Energy Center



implemented improved technical specifications in 1998 via Amendment 223 using NUREG 1433, "Standard Technical Specifications—General Electric Plants BWR/4," Revision 1, as a model. The proposed amendment would revise Technical Specification Sections 5.5.11, 1.4, 3.3.1.1, and 5.5.2 to adopt the following selected NRC approved generic changes to the improved technical specification NUREG.

- Technical Specification Task Force (TSTF)-273, Revision 2, Safety Function Determination Program Clarifications.

- TSTF-284, Revision 3, Add "Met" versus "Perform" to Specification 1.4, Frequency.

- TSTF-264, Deletion of Flux Monitors Specific Overlap Surveillance Requirements.

- TSTF-299, Administrative Controls Program 5.5.2.b Test Interval Defined and Allowance for 25 Percent Extension of Frequency.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

#### Adoption of TSTF-273, Revision 2, and TSTF-284, Revision 3

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change involves reformatting, renumbering, and rewording the existing Technical Specifications. The reformatting, renumbering, and rewording process involves no technical changes to the existing Technical Specifications. As such, this change is administrative in nature and does not affect initiators of analyzed events or assumed mitigation of accident or transient events. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or changes in methods governing normal plant operation. The proposed change will not impose any new or eliminate any old requirements. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does this change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change will not reduce a margin of safety because it has no effect on any safety analyses' assumptions. This

change is administrative in nature. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

#### Adoption of TSTF-264, Revision 0

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change deletes Surveillance Requirements. Surveillances are not initiators to any accident previously evaluated. Consequently, the probability of an accident previously evaluated is not significantly increased. The equipment being tested is still required to be Operable and capable of performing the accident mitigation functions assumed in the accident analysis. As a result, the consequences of any accident previously evaluated are not significantly affected. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The remaining Surveillance Requirements are Consistent with industry practice and are considered to be sufficient to prevent the removal of the subject Surveillances from creating a new or different type of accident. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does this change involve a significant reduction in a margin of safety?

*Response:* No.

The deleted Surveillance Requirements do not result in a significant reduction in the margin of safety. As provided in the justification, the change has been evaluated to ensure that the deleted Surveillance Requirements are not necessary for verification that the equipment used to meet the LCO [limiting condition for operation] can perform its required functions. Thus, appropriate equipment continues to be tested in a manner and at a frequency necessary to give confidence that the equipment can perform its assumed safety function. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

#### Adoption of TSTF-299, Revision 0

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed change provides more stringent requirements for operation of the facility. These more stringent requirements do not result in operation that will increase the probability of initiating an analyzed event and do not alter assumptions relative to mitigation of an accident or transient event. The more restrictive requirements continue to ensure process variables, structures,

systems, and components are maintained consistent with the safety analyses and licensing basis. Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or changes in methods governing normal plant operation. The proposed change does impose different requirements. However, these changes are consistent with the assumptions in the safety analyses and licensing basis. Thus, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does this change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed change provides additional restrictions which enhance plant safety. This change maintains requirements within the safety analyses and licensing basis. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jonathan Rogoff, Morgan Lewis, 1111 Pennsylvania Avenue NW., Washington, DC 20004.  
*NRC Section Chief:* L. Raghavan.

**Nuclear Management Company, LLC,  
Docket No. 50-331, Duane Arnold  
Energy Center, Linn County, Iowa**

*Date of amendment request:* February 27, 2004.

*Description of amendment request:* The proposed amendment would remove license condition 2.C.(2)(b) to perform large transient testing as part of the extended power uprate (EPU) power ascension testing program at the Duane Arnold Energy Center (DAEC).

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The requested licensing action would remove the current requirement to perform specific large transient tests as part of the DAEC EPU power ascension testing program. No other changes are proposed. Therefore,

the probability of an accident previously evaluated is not significantly increased.

The proposed action will not affect any System, Structure, or Component designed for the mitigation of previously analyzed events. The proposed change does not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Thus, the proposed change will not increase the consequences of any previously evaluated accident.

(2) The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The requested licensing action would remove the current requirement to perform specific large transient tests as part of the DAEC EPU power ascension testing program. No other changes are proposed. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

(3) The proposed amendment will not involve a significant reduction in a margin of safety.

Performance of these specific large transient tests is not necessary to ensure acceptable plant operation at the higher thermal power level. Simple, integrated systems tests are performed in lieu of the complex, challenging large transient tests. Other required testing of the specific SSCs that have been modified for EPU ensures that the plant will respond as expected during any abnormal operating event, including these specific transients. Thus, the proposed elimination of the large transient tests will not significantly reduce any margin of safety from that previously approved for EPU operation at the DAEC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jonathan Rogoff, Morgan Lewis, 1111 Pennsylvania Avenue, NW., Washington, DC 20004.

*NRC Section Chief:* L. Raghavan.

**Nuclear Management Company, LLC, Docket No. 50-263, Monticello Nuclear Generating Plant, Wright County, Minnesota**

*Date of amendment request:* January 30, 2004.

*Description of amendment request:* The proposed amendment would revise Monticello Nuclear Generating Plant (MNGP) Technical Specifications (TS) to (1) clarify the permissive set point for the source range monitor (SRM) detector not-fully-inserted rod block bypass, (2) correct a typographical error in the surveillance requirement for suppression pool temperature monitoring, (3) clarify the set point for

the pressure suppression chamber-reactor building vacuum breakers instrumentation, (4) clarify the operating force requirements for the pressure suppression chamber—drywell vacuum breakers surveillance test, and (5) make corrections resulting from License Amendments (LAs) 130 and 132.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The SRM Detector-not-fully-inserted rod block bypass set point, the Pressure Suppression Chamber—Reactor Building Vacuum Breakers actuation instrumentation set point requirement and the Pressure Suppression Chamber—Drywell Vacuum Breakers surveillance test requirements are being clarified in the MNGP TS to ensure these functions will adequately support safe operation of the facility. Typographical errors are being corrected along with corrections resulting from omissions and an oversight from previous LAs. The proposed TS changes do not introduce new equipment or new equipment operating modes, nor do the proposed changes alter existing system relationships. The changes do not affect plant operation, design function or any analysis that verifies the capability of a SSC [structure, system or component] to perform a design function. Further, the proposed changes do not increase the likelihood of the malfunction of any structure, system or component (SSC) or impact any analyzed accident. Consequently, the probability of an accident previously evaluated is not affected.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The SRM Detector-not-fully-inserted rod block bypass set point, the Pressure Suppression Chamber—Reactor Building Vacuum Breakers actuation instrumentation set point requirement and the Pressure Suppression Chamber—Drywell Vacuum Breakers surveillance test requirements are being clarified in the MNGP TS to ensure these functions will adequately support safe operation of the facility. Typographical errors are being corrected along with corrections resulting from omissions and an oversight from previous LAs. The changes do not create the possibility of new credible failure mechanisms, or malfunctions. These changes do not modify the design function or operation of any SSC. Further the changes do not involve physical alterations of the plant;

no new or different type of equipment will be installed. The proposed changes do not introduce new accident initiators. Consequently, the changes cannot create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

3. Does the proposed amendment involve a significant reduction in the margin of safety?

The SRM Detector-not-fully-inserted rod block bypass set point, the Pressure Suppression Chamber—Reactor Building Vacuum Breakers actuation instrumentation set point requirement and the Pressure Suppression Chamber—Drywell Vacuum Breakers surveillance test requirements are being clarified in the MNGP TS to ensure these functions will adequately support safe operation of the facility. Typographical errors are being corrected along with corrections resulting from omissions and an oversight from previous LAs. These changes do not exceed or alter a design basis or a safety limit for a parameter established in the MNGP Updated Safety Analysis Report (USAR) or the MNGP facility license. Consequently, the changes do not result in a significant reduction in the margin of safety.

Therefore, the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

*NRC Section Chief:* L. Raghavan.

**Nuclear Management Company, LLC, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin**

*Date of amendment request:* February 10, 2004.

*Description of amendment request:* The proposed change involves the extension from 1 hour to 24 hours of the completion time (CT) for Action (a) of Technical Specification (TS) 3.5.1.1, which defines requirements for accumulators. Accumulators are part of the emergency core cooling system and consist of tanks partially filled with borated water and pressurized with nitrogen gas. The contents of the tank are discharged to the reactor coolant system (RCS) if, as during a loss-of-coolant accident, the coolant pressure

decreases to below the accumulator pressure. Action (a) of TS 3.5.1.1 specifies a CT to restore an accumulator to operable status when it has been declared inoperable for a reason other than the boron concentration of the water in the accumulator not being within the required range. This change was proposed by the Westinghouse Owners Group participants in the TS Task Force (TSTF) and is designated TSTF-370. TSTF-370 is supported by NRC-approved topical report WCAP-15049-A, "Risk-Informed Evaluation of an Extension to Accumulator Completion Times," submitted on May 18, 1999. The NRC staff issued a notice of opportunity for comment in the **Federal Register** on July 15, 2002 (67 FR 46542), on possible amendments concerning TSTF-370, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the consolidated line item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on March 12, 2003 (68 FR 11880). The licensee included in its application several minor changes to make the plant specific TS more consistent with the STS and TSTF-370. The licensee affirmed the applicability of the following NSHC determination in its application dated February 10, 2004.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of no significant hazards consideration is presented below:

**Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated**

The basis for the accumulator limiting condition for operation (LCO), as discussed in Basis Section 3.5.1.1, is to ensure that a sufficient volume of borated water will be immediately forced into the core through each of the cold legs in the event the RCS pressure falls below the pressure of the accumulators, thereby providing the initial cooling mechanism during large RCS pipe ruptures. As described in Section 9.2 of WCAP-15049-A, the proposed change will allow plant operation with an inoperable accumulator for up to 24 hours, instead of 1 hour, before the plant would be required to begin shutting down. The impact of the increase in the accumulator CT on core damage frequency for all the cases evaluated in WCAP-15049-A is within the acceptance limit of 1.0E-06/yr for a total plant core damage frequency (CDF) less than 1.0E-03/yr. The incremental conditional core damage probabilities calculated in WCAP-15049-A for the accumulator CT increase meet the

criterion of 5E-07 in Regulatory Guides (RG) 1.174, "An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," and 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," for all cases except those that are based on design basis success criteria. As indicated in WCAP-15049-A, design basis accumulator success criteria are not considered necessary to mitigate large break loss-of-coolant accident (LOCA) events, and were only included in the WCAP-15049-A evaluation as a worst case data point. In addition, WCAP-15049-A states that the NRC has indicated that an incremental conditional core damage frequency (ICCDP) greater than 5E-07 does not necessarily mean the change is unacceptable.

The proposed technical specification change does not involve any hardware changes nor does it affect the probability of any event initiators. There will be no change to normal plant operating parameters, engineered safety feature (ESF) actuation setpoints, accident mitigation capabilities, accident analysis assumptions or inputs.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

**Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident From Any Previously Evaluated**

No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures are introduced as a result of the proposed change. As described in Section 9.1 of the WCAP-15049-A evaluation, the plant design will not be changed with this proposed technical specification CT increase. All safety systems still function in the same manner and there is no additional reliance on additional systems or procedures. The proposed accumulator CT increase has a very small impact on core damage frequency. The WCAP-15049-A evaluation demonstrates that the small increase in risk due to increasing the CT for an inoperable accumulator is within the acceptance criteria provided in RGs 1.174 and 1.177. No new accidents or transients can be introduced with the requested change and the likelihood of an accident or transient is not impacted.

The malfunction of safety related equipment, assumed to be operable in the accident analyses, would not be caused as a result of the proposed technical specification change. No new failure mode has been created and no new equipment performance burdens are imposed.

Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

**Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety**

The proposed change does not involve a significant reduction in a margin of safety. There will be no change to the departure from nucleate boiling ratio (DNBR)

correlation limit, the design DNBR limits, or the safety analysis DNBR limits.

The basis for the accumulator LCO, as discussed in Basis Section 3.5.1.1, is to ensure that a sufficient volume of borated water will be immediately forced into the core through each of the cold legs in the event the RCS pressure falls below the pressure of the accumulators, thereby providing the initial cooling mechanism during large RCS pipe ruptures. As described in Section 9.2 of WCAP-15049-A, the proposed change will allow plant operation with an inoperable accumulator for up to 24 hours, instead of 1 hour, before the plant would be required to begin shutting down. The impact of this on plant risk was evaluated and found to be very small. That is, increasing the time the accumulators will be unavailable to respond to a large LOCA event, assuming accumulators are needed to mitigate the design basis event, has a very small impact on plant risk.

Since the frequency of a design basis large LOCA (a large LOCA with loss of offsite power) would be significantly lower than the large LOCA frequency of the WCAP-15049-A evaluation, the impact of increasing the accumulator CT from 1 hour to 24 hours on plant risk due to a design basis large LOCA would be significantly less than the plant risk increase presented in the WCAP-15049-A evaluation.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

*NRC Section Chief:* L. Raghavan.

**Southern Nuclear Operating Company, Inc., et al., Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia**

*Date of amendment request:* February 20, 2004.

*Description of amendment request:* The proposed amendments would revise Vogtle Electric Generating Plant, Units 1 and 2 Administrative Controls Section 5.2.2.g of Technical Specification to limit the requirement of the Shift Technical Advisor function to Modes 1-4 in accordance with NUREG 0737.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change to TS [Technical Specification] 5.2.2.g does not significantly

increase the probability or consequences of an accident previously evaluated in the FSAR [Final Safety Analysis Report]. This revision does not have any effect on the probability of any accident initiators. The consequences of accidents previously evaluated in the FSAR are not adversely affected by this proposed change because the STA [Shift Technical Advisor] is not credited for mitigation of any accidents. The proposed change which requires the STA function to be available while in Modes 1-4 is in accordance with the requirements of NUREG 0737, Item I.A.1.1. Consequently, the probability or consequences of an accident previously evaluated are not significantly increased.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

The proposed change to TS 5.2.2.g does not create the possibility of a new or different kind of accident from any previously evaluated. No new accident scenarios, failure mechanism, or limiting single failures are introduced as a result of the proposed change. The proposed Technical Specifications change does not challenge the performance or integrity of any safety-related systems. The proposed change to TS 5.2.2.g is in accordance with NUREG 0737.

3. Does the proposed change involve a significant reduction in a margin of safety?

The proposed change to TS 5.2.2.g will not reduce a margin of safety because it has no direct effect on any safety analyses assumptions. The STA function is to evaluate plant conditions and provide advice to the shift supervisor during plant transients and accidents. The proposed change limits the requirements for the STA function to Modes 1-4 in accordance with NUREG 0737. The STA function is not credited for the mitigation of any accidents previously evaluated.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. Arthur H. Domy, Troutman Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2216.

*NRC Section Chief:* John A. Nakoski.

**Southern Nuclear Operating Company, Inc., et al., Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia**

*Date of amendment request:* February 26, 2004.

*Description of amendment request:* The proposed amendments would revise Technical Specification (TS) 5.6.6, "Reactor Coolant System (RCS) Pressure and Temperature Limits Report (PTLR)", to reference the NRC-approved methodology for developing Pressure-

Temperature limits and Cold Overpressure Protection System setpoints and the methodology used to justify eliminating the reactor vessel closure head/vessel flange requirements. The proposed amendment would also revise TS 3.4.12, "Cold Overpressure Protection System (COPS)", to change the Reactor Coolant System vent size.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed changes to the Technical Specifications [TS] and PTLRs [Pressure and Temperature Limits Reports] do not affect any plant equipment, test methods, or plant operation, and are not initiators of any analyzed accident sequence. Operation in accordance with the proposed TS will ensure that all analyzed accidents will continue to be mitigated by the SSCs [systems, structures and components] as previously analyzed.

2. Do the proposed changes create the possibility of a new or different kind of accident from any previously evaluated?

No. The proposed changes do not introduce any new equipment, create new failure modes for existing equipment, or create any new limiting single failures. The changes to the P-T [pressure-temperature] limits and COPS [Cold Overpressure Protection Systems] setpoints will ensure that appropriate fracture toughness margins are maintained to protect against reactor vessel failure during both normal and low temperature operation. The changes to the P-T limits and COPS setpoints are consistent with the methodology approved by the NRC [Nuclear Regulatory Commission] in WCAP-14040, Rev. 4. Plant operation will not be altered, and all safety functions will continue to perform as previously assumed in accident analyses.

3. Do the proposed changes involve a significant reduction in a margin of safety?

No. The proposed changes will not adversely affect the operation of plant equipment or the function of any equipment assumed in the accident analysis. The utilization of ASME [American Society of Mechanical Engineers] Code Case N-640 maintains the relative margin of safety commensurate with that which existed at the time that ASME B&PV [Boiler and Pressure Vessel] Code, Section XI, Appendix G was approved in 1974 and will ensure an acceptable margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. Arthur H. Domy, Troutman Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2216.

*NRC Section Chief:* John A. Nakoski.

**Tennessee Valley Authority, Docket No. 50-259, Browns Ferry Nuclear Plant (BFN), Unit 1, Limestone County, Alabama**

*Date of amendments request:* March 9, 2004 (TS 434).

*Description of amendments request:* The proposed amendment would lower the current Reactor Vessel Water Level—Low, Level 3 Allowable Value in the Unit 1 Technical Specifications for several instrument functions to reduce the likelihood of unnecessary reactor scrams and the resultant engineered safety feature actuations by increasing the operating range between the normal reactor vessel water level and Level 3 trip functions.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The Reactor Vessel Water Level—Low, Level 3 functions are in response to water level transients and are not involved in the initiation of accidents or transients. Therefore, reducing the BFN, Unit 1, Level 3 Allowable Value does not increase the probability of an accident previously evaluated.

Additionally, the results of the safety evaluation associated with the lowering of the Level 3 Allowable Value concludes that the previously evaluated transient and accident consequences are not significantly affected by the change. Therefore, the proposed amendment does not involve a significant increase in the probability of consequences or an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed amendment to lower the BFN, Unit 1, Reactor Vessel Water Level—Low, Level 3 Allowable Value does not involve a hardware change and the purpose of the Level 3 function is not affected. The Level 3 functions will continue to fulfill their design objective. The proposed changes do not create the possibility of any new failure mechanisms. No new external threats or release pathways are created. Therefore, reduction of the Allowable Value does not result in the possibility of a new or different kind of accident.

3. Does the proposed amendment involve a significant reduction in a margin of safety?



No. The results of the safety evaluation associated with the reducing the BFN, Unit 1, Reactor Vessel Water Level—Low, Level 3 Allowable Value concluded that transient and accident consequences remain within the required acceptance criteria. Therefore, the margin of safety is not reduced for any event evaluated.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

*NRC Section Chief:* William F. Burton, Acting.

**Tennessee Valley Authority (TVA), Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee**

*Date of amendment request:* March 5, 2004.

*Description of amendment request:* The proposed amendments would delete Technical Specifications (TSs) 3.6.4.1, "Hydrogen Monitors," and 3.6.4.2, "Electric Hydrogen Recombiners-W." The proposed changes support Title 10, Code of Federal Regulations, Part 50, Section 44 (10 CFR 50.44), "Standards for Combustible Gas Control system in Light-Water-Cooled Power Reactors" and are consistent with the Industry/Technical Specification Task Force (TSTF) Standard TS Change Traveler, TSTF-447, "Elimination of Hydrogen Recombiners and change to Hydrogen and Oxygen Monitors."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

TVA has reviewed the proposed no significant hazards consideration determination published on September 25, 2003, (68 FR 55416) as part of the consolidated line item improvement process (CLIIP). TVA has concluded that the proposed determination presented in the notice is applicable to SQN, and the determination is hereby incorporated by reference to satisfy the requirements of 10 CFR 50.91(a).

The United States Nuclear Regulatory Commission (NRC) staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff

proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

*NRC Section Chief:* William F. Burton, Acting.

**Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee**

*Date of amendment request:* March 5, 2004.

*Description of amendment request:* The proposed amendments would delete surveillance requirement (SR) 4.9.2.c and SRs 4.10.3.2 and 4.10.4.2 from the Technical Specifications (TSs). SR 4.9.2.c requires channel functional tests for each Source Range neutron flux monitor within 8 hours prior to initial core alterations. SRs 4.10.3.2 and 4.10.4.2 require channel functional tests for each Power Range and Intermediate Range neutron flux monitor within 12 hours prior to the initiation of a physics test. In addition, the proposed changes include revisions to the associated TS bases (3/4.9.2, 3/4.10.3, and 3/4.10.4).

*Basis for proposed no significant hazards consideration determination:* As required by Title 10, Code of Federal Regulations, Part 50, Section 91(a) (10 CFR 50.91(a)), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed amendment removes the requirement to perform an additional CHANNEL FUNCTIONAL TEST (CFT) on the Intermediate and Power Range functions within 12 hours of performing a PHYSICS TEST. The Intermediate and Power Range instrumentation is determined to be OPERABLE by periodic SRs which must be confirmed to be within frequency prior to making the reactor critical. The proposed amendment also removes the requirement to perform an additional CFT on the Source Range monitors. The Source Range instrumentation is determined to be OPERABLE by periodic SRs, which must be confirmed to be within frequency prior to Mode 6, prior to CORE ALTERATIONS, and must remain OPERABLE. A CFT for the Source Range, Intermediate Range, or Power Range instrumentation is not a precursor to, or assumed to be an initiator of any analyzed accident. Therefore, this change does not involve a significant increase in the probability of an accident previously evaluated.

Regarding a significant increase in the consequences of an accident, several factors

must be considered. First the PHYSICS TESTS are performed in accordance with the TSs in Mode 2. Therefore, the power level of the reactor is limited to 5 percent or less. Along with this, the reactor trip function of the Intermediate Range detectors will be unaffected by the proposed amendment and therefore, will be available to mitigate a reactivity transient at low power. Further, the trip setpoint for the Power Range monitors are decreased during startup. This setpoint reduction provides an additional measure to limit a reactivity excursion. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed changes permit the conduct of normal operating evolutions during limited periods when additional controls over reactivity margin are imposed by the TSs. The proposed change does not introduce any new equipment into the plant or significantly alter the manner in which existing equipment will be operated. The proposed changes are not based on a change in the design or configuration of the plant. The changes to operating allowances are minor and are only applicable during certain conditions. The operating allowances are consistent with those acceptable at other times. The proposed changes delete the requirements for the performance of a CFT for the Source Range, Intermediate Range, and Power Range instrumentation within 8 hours of initiating CORE ALTERATIONS for the Source Range monitors and within 12 hours of starting a PHYSICS TEST for the Intermediate Range and Power Range instrumentation. Since the proposed changes only allow activities that are presently approved and routinely conducted, no possibility exists for a new or different kind of accident from those previously evaluated. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. As stated previously, the proposed change deletes the requirement to perform an additional CFT for the Source Range, Intermediate Range, and Power Range instrumentation within 8 hours of initiating CORE ALTERATIONS for the Source Range monitors and within 12 hours of starting a PHYSICS TEST for the Intermediate Range and Power Range instrumentation. The Source Range, Intermediate Range, and Power Range instrumentation channels are determined to be OPERABLE by meeting the requirements of the periodic surveillance. These SRs are not affected by the proposed amendment. The proposed changes do not involve a significant reduction in a margin of safety because the ability to monitor the reactor during the applicable operating conditions and modes of operation will be maintained. The proposed changes do not affect these operating restrictions and the margin of safety which assures the ability to



monitor the reactor is not affected. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The United States Nuclear Regulatory Commission (NRC) staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

*NRC Section Chief:* William F. Burton, Acting.

**Tennessee Valley Authority (TVA), Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant (SQN), Units 1 and 2, Hamilton County, Tennessee**

*Date of amendment request:* March 5, 2004.

*Description of amendment request:* The proposed amendments would change Technical Specification (TS) 4.0.5.c. Specifically, the proposed change would extend the examination frequency for the reactor coolant pump (RCP) motor flywheel from a 10-year interval to an interval not to exceed 20 years. This proposed change is consistent with the Industry/Technical Specification Task Force (TSTF) Standard Technical Specification Change Traveler, TSTF-421, "Revision to RCP Flywheel Inspection Program (WCAP-15666)."

*Basis for proposed no significant hazards consideration determination:* As required by Title 10, *Code of Federal Regulations*, Part 50, Section 91(a) (10 CFR 50.91(a)), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

TVA has reviewed the proposed no significant hazards consideration determination published on June 24, 2003 (68 FR 37590), as part of the consolidated line item improvement process (CLIP). TVA has concluded that the proposed determination presented in the notice is applicable to SQN, and the determination is hereby incorporated by reference to satisfy the requirements of 10 CFR 50.91(a).

The United States Nuclear Regulatory Commission (NRC) staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority,

400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

*NRC Section Chief:* William F. Burton, Acting.

**Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Unit Nos. 1 and 2, Louisa County, Virginia**

*Date of amendment request:* March 4, 2004.

*Description of amendment request:* The proposed amendments would delete the note in Improved Technical Specification Surveillance Requirement 3.4.12.7 that permitted the performance of the Channel Operational Test within 12 hours of entering a mode in which the power-operated relief valves (PORVs) are required to be operable for low temperature overpressure protection (LTOP).

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do changes involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed changes to perform a Channel Operational Test on each required PORV at least 31 days prior to entering the LTOP Mode will continue to ensure verification and adjustment, if required, of its lift setpoint. Changes will not affect the probability of occurrence of any accident previously analyzed; nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. Therefore, the proposed changes do not involve a significant increase in the consequences of any previously analyzed accident.

2. Do changes create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed changes to perform a Channel Operational Test on each required PORV at least 31 days prior to entering the LTOP Mode will not create any new accident or event initiators. No systems, structures, or components are being physically modified such that the design function is being altered. The proposed changes do not impose any new or different requirements for the performance of the Channel Operational Test. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from those previously analyzed.

3. Do changes involve a significant reduction in a margin of safety?

The proposed changes do not involve any change to the safety analysis limits. The level of safety of facility operation is unaffected by the proposed changes since there is no change in the intent for the performance of the Channel Operational Test. Therefore, it is concluded that the margin of safety will not

be reduced by the implementation of the changes.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Ms. Lillian M. Cuoco, Esq., Senior Counsel, Dominion Resources Services, Inc., Millstone Power Station, Building 475, 5th Floor, Rope Ferry Road, Rt. 156, Waterford, Connecticut 06385.

*NRC Section Chief:* John A. Nakoski.

**Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing**

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

**Calvert Cliffs Nuclear Power Plant, Inc., Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland**

*Date of application for amendment:* February 25, 2004.

*Brief description of amendments:* The amendment would extend the implementation date for Amendment Nos. 261 and 238 for Calvert Cliffs Units 1 and 2, respectively, to July 1, 2004. The changes to the reactor pressure vessel pressure-temperature limits cooldown rates that were approved by Amendment Nos. 261 and 238 are more conservative than the plants existing rates and result in a longer cooldown period. The existing cooldown rates are acceptable through the end of 2004.

*Date of publication of individual notice in Federal Register:* March 5, 2004 (69 FR 10487).

*Expiration date of individual notice:* May 5, 2004.

### Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

### AmerGen Energy Company, LLC, et al., Docket No. 50-219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

*Date of application for amendment:* December 23, 2003, as supplemented by letter dated January 30, 2004.

*Brief description of amendment:* The amendment modified Technical Specification (TS) requirements for mode change limitations to adopt the TS Task Force (TSTF) change TSTF-359, "Increase Flexibility in Mode Restraints."

*Date of issuance:* March 29, 2004.

*Effective date:* As of the date of issuance to be implemented within 60 days.

*Amendment No.:* 241.

*Facility Operating License No. NPF-69:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* January 20, 2004 (69 FR 2738).

The January 30, 2004, letter provided clarifying information within the scope of the original application and did not change the staff's initial proposed no significant hazards consideration determination. The staff's related evaluation of the amendment is contained in a Safety Evaluation dated March 29, 2004.

No significant hazards consideration comments received: No.

### Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units Nos. 1, 2, and 3, Maricopa County, Arizona

*Date of application for amendments:* October 7, 2003, and its supplement dated December 18, 2003.

*Brief description of amendments:* The amendments revise Technical Specification (TS) Section 5.5.6, "Containment Tendon Surveillance Program," for consistency with the requirements of 10 CFR 50.55a(g)(4) for components classified as Code Class CC. The amendments also delete the provisions of Surveillance Requirement (SR) 3.0.2 from this TS. In addition, the amendments revise TS 5.5.16, "Containment Leakage Rate Testing Program," to add exceptions to Regulatory Guide 1.163, "Performance-Based Containment Leak-Testing Program." Also, the paragraphs in Section 5.5.16 have been sequenced to more clearly separate the requirements of the program. This is considered an administrative change and is consistent with the guidance in NUREG-1432, "Standard Technical Specifications Combustion Engineering Plants," Revision 2.

*Date of issuance:* March 19, 2004.

*Effective date:* March 19, 2004, and shall be implemented within 90 days of the date of issuance.

*Amendment Nos.:* Unit 1-151, Unit 2-151, Unit 3-151.

*Facility Operating License Nos. NPF-41, NPF-51, and NPF-74:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* December 9, 2003 (68 FR 68659) The December 18, 2003, supplemental letter provided revised technical specification pages to reflect changes that were approved in Amendment No. 149, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 19, 2004.

No significant hazards consideration comments received: No.

### Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units Nos. 1, 2, and 3, Maricopa County, Arizona

*Date of application for amendments:* September 17, 2003 as supplemented by letter dated February 20, 2004.

*Brief description of amendments:* The amendments revise the technical specifications to support the replacement of part-length control element assemblies (CEAs) with a new design, referred to as part-strength CEAs. The two designs are geometrically very similar and contain essentially the same amount and type of neutron absorber in the lower half of the assemblies, which is the region of the CEAs inserted into the reactor core during normal operations.

*Date of issuance:* March 23, 2004.

*Effective date:* March 23, 2004, and shall be implemented within 60 days of the date of issuance.

*Amendment Nos.:* Unit 1-152, Unit 2-152, Unit 3-152.

*Facility Operating License Nos. NPF-41, NPF-51, and NPF-74:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* December 9, 2003 (68 FR 68657). The February 20, 2004, supplemental letter provided additional clarifying information, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 23, 2004.

No significant hazards consideration comments received: No.

**Carolina Power & Light Company, Docket No. 50-325, Brunswick Steam Electric Plant, Unit 1, Brunswick County, North Carolina**

*Date of application for amendment:* October 31, 2003, as supplemented March 4, March 12, and March 19, 2004.

*Brief description of amendment:* The amendment revised the Minimum Critical Power Ratio Safety Limit contained in Technical Specification 2.1.1.2.

*Date of issuance:* March 26, 2004.

*Effective date:* Effective as of the date of issuance and shall be implemented prior to startup for Unit 1, Cycle 15, operation.

*Amendment No.:* 231.

*Facility Operating License Nos. DPR-71:* Amendment changes the Technical Specifications.

*Date of initial notice in Federal Register:* January 6, 2004 (69 FR 693). The March 4, March 12, and March 19, 2004, supplemental letters provided clarifying information that did not change the scope of the proposed amendment as described in the original notice of proposed action published in the **Federal Register** and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 26, 2004.

No significant hazards consideration comments received: No.

**Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina**

*Date of application for amendment:* February 14, 2003, as supplemented by letters dated November 10 and December 10, 2003, and January 30, 2004.

*Brief description of amendment:* This amendment revises Technical Specification (TS) 5.6.3.d to allow an increase in the decay heat load from 1.0 MBTU/hr to 7.0 MBTU/hr for fuel stored in Spent Fuel Pools C and D at Shearon Harris Nuclear Power Plant, Unit 1.

*Date of issuance:* March 26, 2004.

*Effective date:* March 26, 2004.

*Amendment No.:* 115.

*Facility Operating License No. NPF-63:* Amendment revises the Technical Specifications.

*Date of initial notice in Federal Register:* March 18, 2003 (68 FR

12948). The November 10 and December 10, 2003, and January 30, 2004, supplements provided clarifying information that did not change the scope of the proposed amendment as described in the original notice of proposed action published in the **Federal Register** and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 26, 2004.

No significant hazards consideration comments received: No.

**Consumers Energy Company, Docket No. 50-155, Big Rock Point Nuclear Plant, Charlevoix County, Michigan**

*Date of application for amendment:* November 20, 2002, and August 6, 2003, as supplemented by letters dated December 1, 2003, and February 20, 2004.

*Brief description of amendment:* The amendment revises the Big Rock Point License and Defueled Technical Specifications to remove reactor operational and administrative requirements that are no longer applicable due to the transfer of all spent fuel from the spent fuel pool into dry cask storage at the Big Rock Point Independent Spent Fuel Storage Installation.

*Date of issuance:* March 19, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 45 days.

*Amendment No.:* 125.

*Facility Operating License No. DPR-6:* Amendment revises the Defueled Technical Specifications.

*Date of initial notice in Federal Register:* January 21, 2003 (68 FR 2800), and November 25, 2003 (68 FR 66133). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 19, 2004.

No significant hazards consideration comments received: No.

**Dominion Nuclear Connecticut, Inc., Docket No. 50-423, Millstone Power Station, Unit No. 3, New London County, Connecticut**

*Date of application for amendment:* March 4, 2003, as supplemented May 13 and September 18, 2003, and February 12 and March 10, 2004.

*Brief description of amendment:* The amendment revised selected sections of the Technical Specifications (TSs) based upon a re-analysis of fuel handling accidents (FHAs). The revised analysis is based upon selective implementation of the alternative source term methodology of Regulatory Guide 1.183,

and in accordance with Title 10 of the Code of Federal Regulations, Section 50.67. Specifically, the amendment revised: TS 3.7.8, "Plant Systems, Control Room Envelope Pressurization System;" TS 3.9.4, "Refueling Operations, Containment Building Penetrations;" TS 3.9.9, "Refueling Operations, Containment Purge and Exhaust Isolation System," and TS 3.9.12, "Refueling Operations, Fuel Building Exhaust Filter System."

*Date of issuance:* March 17, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 90 days from the date of issuance.

*Amendment No.:* 219.

*Facility Operating License No. NPF-49:* The amendment revised the TSs.

*Date of initial notice in Federal Register:* March 4, 2003 (68 FR 40711). The May 13 and September 18, 2003, and February 12 and March 10, 2004, supplements contained clarifying information and did not change the staff's initial proposed finding of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 17, 2004.

No significant hazards consideration comments received: No.

**Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Docket No. 50271, Vermont Yankee Nuclear Power Station, Vernon, Vermont**

*Date of application for amendment:* December 5, 2003, as supplemented on February 9, 2004.

*Brief description of amendment:* The amendment revised the Safety Limit Minimum Critical Power Ratio values in Technical Specification 1.1.A.1 to incorporate the results of the cycle-specific core reload analysis for Vermont Yankee Nuclear Power Station Cycle 24 operation.

*Date of Issuance:* March 22, 2004.

*Effective date:* As of the date of issuance, and shall be implemented within 60 days.

*Amendment No.:* 217.

*Facility Operating License No. DPR-28:* The amendment revised the TSs.

*Date of initial notice in Federal Register:* January 20, 2004 (69 FR 2741). The supplement dated February 9, 2004, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated March 22, 2004.

No significant hazards consideration comments received: No.

**Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont**

*Date of application for amendment:* March 26, 2003, as supplemented on July 24, 2003.

*Brief description of amendment:* The amendment revised the Technical Specifications (TSs) regarding reactor pressure vessel (RPV) fracture toughness and material surveillance requirements (SRs). Specifically, the amendment revised the pressure-temperature limits for the RPV as specified in TS Figures 3.6.1, 3.6.2, and 3.6.3. In addition, the amendment deleted TS 4.6.A.5, which specifies plant-specific RPV material SRs. These plant-specific SRs are being replaced by implementing the Boiling Water Reactor Vessel and Internals Project (BWRVIP) RPV integrated surveillance program (ISP). The details of the BWRVIP ISP will be added to the Vermont Yankee Nuclear Power Station Updated Final Safety Analysis Report.

*Date of Issuance:* March 29, 2004.

*Effective date:* As of the date of issuance, and shall be implemented within 60 days.

*Amendment No.:* 218.

*Facility Operating License No. DPR-28:* Amendment revised the TSs.

*Date of initial notice in Federal Register:* April 29, 2003 (68 FR 22747). The supplement dated July 24, 2003, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated March 29, 2004.

No significant hazards consideration comments received: No.

**Exelon Generation Company, LLC, Docket Nos. STN 50-454 and STN 50-455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois**

**Docket Nos. STN 50-456 and STN 50-457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois**

*Date of application for amendments:* June 11, 2003, as supplemented on December 5, December 30, 2003, and February 18, 2004.

*Brief description of amendments:* The amendments revise technical specification 3.7.8 to permit a one-time extension from 72 hours to 144 hours for the completion time required to

restore a unit specific essential service water train to operable status.

*Date of issuance:* March 18, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 30 days.

*Amendment Nos.:* 136/136, 130/130. *Facility Operating License Nos. NPF-37, NPF-66, NPF-72 and NPF-77:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* September 30, 2003.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 18, 2004.

No significant hazards consideration comments received: No.

**Exelon Generation Company, LLC, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania**

*Date of application for amendments:* September 8, 2003.

*Brief description of amendments:* The amendments modified Technical Specifications requirements to adopt the provisions of Industry/Technical Specification Task Force (TSTF) change 359, "Increase Flexibility in Mode Restraints."

*Date of issuance:* March 12, 2004.

*Effective date:* As of date of issuance and shall be implemented within 60 days.

*Amendment Nos.:* 169 and 132. *Facility Operating License Nos. NPF-39 and NPF-85:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* December 9, 2003 (68 FR 68668).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 12, 2004.

No significant hazards consideration comments received: No.

**FPL Energy Seabrook, LLC, Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire**

*Date of amendment request:* April 15, 2002, as supplemented by letter dated January 14, 2004.

*Description of amendment request:* The amendment revises the Technical Specifications (TSs) to relocate the boron concentration limits and "Safety Limits" figures to the Core Operating Limits Report. Some limiting conditions and actions are revised to be consistent with the Improved Standard Technical Specifications.

*Date of issuance:* March 23, 2004.

*Effective date:* As of its date of issuance, and shall be implemented within 90 days.

*Amendment No.:* 96.

*Facility Operating License No. NPF-86:* The amendment revises the TS.

*Date of initial notice in Federal Register:* May 28, 2002 (67 FR 36931). The January 14, 2004, letter provided clarifying information that did not change the initial proposed no significant hazards consideration determination or expand the amendment beyond the scope of the initial notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 23, 2004.

No significant hazards consideration comments received: No.

**Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska**

*Date of amendment request:* August 25, 2003.

*Brief description of amendment:* The amendment revises the Technical Specification (TS) for Limiting Condition for Operation requirement 3.5.1 to incorporate TS Task Force Traveler 318 to allow one low pressure coolant injection pump inoperable in each of the two emergency core cooling system divisions.

*Date of issuance:* March 31, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 60 days of issuance.

*Amendment No.:* 203.

*Facility Operating License No. DPR-46:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* October 14, 2003 (68 FR 59218).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 31, 2004.

No significant hazards consideration comments received: No.

**Nuclear Management Company, LLC, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin**

*Date of application for amendments:* March 27, 2003, as supplemented on November 3, 2003, and January 28, 2004.

*Brief description of amendments:* The amendment revises Technical Specification Surveillance Requirement 3.2.4.2, "Rod Group Alignment Limits." The revision expands the alignment limits on allowable rod cluster control assembly, or rod, deviation from demanded position. The change applies in Mode 1, when operating at greater than 85 percent of rated thermal power.

*Date of issuance:* March 29, 2004.



*Effective date:* As of the date of issuance and shall be implemented within 45 days.

*Amendment Nos.:* 212 and 217.

*Facility Operating License Nos. DPR-24 and DPR-27:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* April 29, 2003 (68 FR 22749).

The supplemental letters contained clarifying information and did not change the initial no significant hazards consideration determination and did not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 29, 2004.

No significant hazards consideration comments received: No.

**Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California**

*Date of application for amendments:* June 11, 2003.

*Brief description of amendments:* The amendments revise the technical specifications to allow use of the power distribution monitoring system (PDMS) for power distribution measurements as described in Topical Report WCAP-12462-P-A, "BEACON: Core Monitoring and Support System."

*Date of issuance:* March 31, 2004.

*Effective date:* March 31, 2004, and shall be implemented within 180 days from the date of issuance.

*Amendment Nos.:* Unit 1—164; Unit 2—166.

*Facility Operating License Nos. DPR-80 and DPR-82:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* July 8, 2003 (68 FR 40717).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 31, 2004.

No significant hazards consideration comments received: No.

**Tennessee Valley Authority, Docket Nos. 50-260 and 50-296, Browns Ferry Nuclear Plant, Units 2 and 3, Limestone County, Alabama**

*Date of application for amendments:* September 18, 2003, as supplemented December 8, 2003, and February 24, 2004.

*Description of amendment request:* The amendments revised the pressure-temperature limit curves in Technical Specification (TS) 3.4.9.

*Date of issuance:* March 10, 2004.

*Effective date:* March 10, 2004.

*Amendment Nos.:* 288 & 247.

*Facility Operating License No. DPR-52 and DPR-68:* Amendments revised the TSs.

*Date of initial notice in Federal Register:* October 28, 2003 (68 FR 61480).

The December 8, 2003, and February 24, 2004, letters provided clarifying information that did not change the scope of the original request or the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 10, 2004.

No significant hazards consideration comments received: No.

**Tennessee Valley Authority, Docket No. 50-390, Watts Bar Nuclear Plant, Unit 1, Rhea County, Tennessee**

*Date of application for amendment:* March 24, 2003, as supplemented December 4, 2003, and February 12, 2004.

*Brief description of amendment:* The amendment revises the design and licensing basis failure modes and effects analysis for specific valves in the essential raw cooling water system, component cooling water system, and control air system to address a condition in which containment integrity, accident flood levels, and sump boron concentrations subsequent to a high-energy line break could not be automatically ensured, and, therefore, manual actions are required.

*Date of issuance:* March 29, 2004.

*Effective date:* As of the date of issuance and shall be implemented in conjunction with the next update to the Updated Final Safety Analysis Report required by 10 CFR 50.71(e).

*Amendment No.:* 51.

*Facility Operating License No. NPF-90:* Amendment revises the Updated Final Safety Analysis Report.

*Date of initial notice in Federal Register:* April 15, 2003 (68 FR 18287).

The supplemental letters provided clarifying information that was within the scope of the initial notice and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 29, 2004.

No significant hazards consideration comments received: No.

**TXU Generation Company LP, Docket No. 50-445, Comanche Peak Steam Electric Station, Unit No. 1, Somervell County, Texas**

*Date of amendment request:* July 21, 2003, as supplemented by letters dated January 8, January 21, and March 8, 2004.

*Brief description of amendments:* The Amendment revises the Technical Specification 5.5.9, "Steam Generator (SG) Tube Surveillance Program," to allow the use of Westinghouse (Westinghouse Electric Station LLC) leak limiting Alloy 800 sleeves for repair of degraded SG tubes.

*Date of issuance:* March 24, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 30 days from the date of issuance.

*Amendment Nos.:* 112.

*Facility Operating License No. NPF-87:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* July 21, 2003. Supplemental letters dated January 8, January 21, and March 8, 2004 provided clarifying information that did not change the scope of the original **Federal Register** notice or the original no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 24, 2004.

No significant hazards consideration comments received: No.

**Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri**

*Date of application for amendment:* December 8, 2003.

*Brief description of amendment:* The amendment revises Technical Specification (TS) Section 5.5.6, "Containment Tendon Surveillance Program," for consistency with the requirements of 10 CFR 50.55a(g)(4) for components classified as Code Class CC. The amendment also deletes the provisions of Surveillance Requirement (SR) 3.0.2 from this TS. In addition, the amendment revises TS 5.5.16, "Containment Leakage Rate Testing Program," to add exceptions to Regulatory Guide 1.163, "Performance-Based Containment Leak-Testing Program."

*Date of issuance:* March 17, 2004.

*Effective date:* March 17, 2004, and shall be implemented within 90 days from the date of issuance.

*Amendment No.:* 160.

*Facility Operating License No. NPF-30:* The amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* January 6, 2004 (69 FR 700).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 17, 2004.

No significant hazards consideration comments received: No.



**Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas**

*Date of amendment request:* October 17, 2003.

*Brief description of amendment:* The amendment revises Technical Specification (TS) Section 5.5.6, "Containment Tendon Surveillance Program," for consistency with the requirements of 10 CFR 50.55a(g)(4) for components classified as Code Class CC. The amendment also deletes the provisions of Surveillance Requirement (SR) 3.0.2 from this TS. In addition, the amendment revises TS 5.5.16, "Containment Leakage Rate Testing Program," to add exceptions to Regulatory Guide 1.163, "Performance-Based Containment Leak-Testing Program."

*Date of issuance:* March 17, 2004.

*Effective date:* March 17, 2004, and shall be implemented within 90 days from the date of issuance.

*Amendment No.:* 152.

*Facility Operating License No. NPF-42:* The amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* November 12, 2003 (68 FR 64140).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated March 17, 2004.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 5th day of April 2004.

For the Nuclear Regulatory Commission,  
**Ledyard B. Marsh,**  
*Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 04-8047 Filed 4-12-04; 8:45 am]

BILLING CODE 7590-01-P

**NUCLEAR REGULATORY COMMISSION**

**Regulatory Guide; Issuance, Availability**

The Nuclear Regulatory Commission (NRC) has issued errata sheets for two guides in its Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in its review of applications for permits and licenses, and data needed by the NRC staff in its review of applications for permits and licenses.

Errata sheets have been issued for Regulatory Guide 1.184, "Decommissioning of Nuclear Power Reactors," and Regulatory Guide 1.185, "Standard Format and Content for Post-Shutdown Decommissioning Activities Report." These errata sheets update Reference 1 in both guides to Supplement 1, "Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities" (Volumes 1 and 2) to NUREG-0586 (November 2002), which supersedes the previous version of NUREG-0586, issued in August 1988.

Comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time. Written comments may be submitted to the Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Questions on the content of this guide may be directed to Mr. T. Smith, (301) 415-6721; e-mail [tbs1@nrc.gov](mailto:tbs1@nrc.gov).

Regulatory guides are available for inspection or downloading at the NRC's Web site at <http://www.nrc.gov> under NRC Documents and in NRC's ADAMS System at the same site. Single copies of regulatory guides may be obtained free of charge by writing the Reproduction and Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to (301) 415-2289, or by e-mail to [distribution@nrc.gov](mailto:distribution@nrc.gov). Issued guides may also be purchased from the National Technical Information Service (NTIS) on a standing order basis. Details on this service may be obtained by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; telephone 1-800-553-6847; <http://www.ntis.gov/>. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

—(5 U.S.C. 552(a))

Dated at Rockville, MD, this 31st day of March 2004.

For the Nuclear Regulatory Commission,  
**Ashok C. Thadani,**  
*Director, Office of Nuclear Regulatory Research.*

[FR Doc. 04-8287 Filed 4-12-04; 8:45 am]

BILLING CODE 7590-01-P

**SECURITIES AND EXCHANGE COMMISSION**

[File No. 1-31703]

**Issuer Delisting; Notice of Application of Essex Corporation, To Withdraw Its Common Stock, No Par Value, From Listing and Registration on the American Stock Exchange LLC**

April 7, 2004.

Essex Corporation, a Virginia corporation ("Issuer"), has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 12d2-2(d) thereunder,<sup>2</sup> to withdraw its Common Stock, no par value ("Security"), from listing and registration on the American Stock Exchange LLC ("Amex" or "Exchange").

The Board of Directors ("Board") of the Issuer approved a resolution on March 15, 2004 to withdraw the Issuer's Security from listing on the Amex and to list the Security on Nasdaq National Market System ("Nasdaq NMS"). The Board states that the reasons it is taking such action are to offer shareholders a broader market, including liquidity and increased visibility. The Issuer expects to trade the Security on the Nasdaq NMS on March 31, 2004.

The Issuer stated in its application that it has met the requirements of Amex Rule 18 by complying with all applicable laws in the State of Virginia, in which it is incorporated, and with the Amex's rules governing an issuer's voluntary withdrawal of a security from listing and registration.

The Issuer's application relates solely to the withdrawal of the Securities from listing on the Amex and from registration under section 12(b) of the Act<sup>3</sup> and shall not affect its obligation to be registered under section 12(g) of the Act.<sup>4</sup> Any interested person may, on or before April 30, 2004, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. All comment letters should refer to File No. 1-31703. Comments may also be submitted electronically at the following e-mail address: [rule-comments@sec.gov](mailto:rule-comments@sec.gov). The

<sup>1</sup> 15 U.S.C. 78l(d).

<sup>2</sup> 17 CFR 240.12d2-2(d).

<sup>3</sup> 15 U.S.C. 781(b).

<sup>4</sup> 15 U.S.C. 781(g).

Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>5</sup>

Jonathan G. Katz,  
Secretary.

[FR Doc. 04-8323 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

## SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

### Whispering Oaks International, Inc., D/b/a BioCurex, Inc.; Order of Suspension of Trading

April 8, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Whispering Oaks International, d/b/a BioCurex, Inc. ("BioCurex"), because of questions regarding the accuracy of assertions by BioCurex and by others, in press releases and e-mails to investors concerning, among other things, (1) a study confirming the effectiveness of its primary product and (2) approval of its main product by the Food and Drug Administration.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above listed company.

Therefore, it is ordered, pursuant to section 12(k) of the Securities Exchange Act of 1934, that trading in the above listed company is suspended for the period from 3 p.m. EDT on April 8, 2004 through 11:59 p.m. EDT on April 22, 2004.

By the Commission.

J. Lynn Taylor,

Assistant Secretary.

[FR Doc. 04-8407 Filed 4-8-04; 8:45 am]

BILLING CODE 8010-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49529; File No. SR-CHX-2004-04]

### Self-Regulatory Organizations; Notice of Filing of Proposed Rule by the Chicago Stock Exchange, Incorporated, To Revise Its Article VI, Rule 5 To Correct a Reference to the Form Used for the Registration of New Branch Offices

April 6, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on January 7, 2004, the Chicago Stock Exchange, Incorporated ("CHX" or "Exchange"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

This proposal would update the reference to a form used by certain CHX member firms for the registration of new branch offices. The text of the proposed rule change is set forth below. Proposed new language is in *italics*; proposed deletions are in [brackets].

\* \* \* \* \*

#### Chicago Stock Exchange Rules Article VI Restrictions and Requirements

\* \* \* \* \*

#### Supervision of Members and Member Organizations and Their Branch and Resident Offices

\* \* \* \* \*

Rule 5. No change to text.

\* \* \* Interpretations and Policies

.01 Registration of new branch offices.—

Outlined below are the steps to be taken when registering new branch offices.

(1) *Each member organization must forward a[A] completed Schedule E to Form BD [MW-B form will be forwarded] to the Exchange.*

(2) Before approval of the branch office is granted, the office manager or the registered representative in charge

must have completed the Exchange requirements for registration.

The office may begin operating as a branch on receipt of written approval from the Exchange.

(3) Firms that are also members of the New York Stock Exchange are not subject to these requirements. However, New York Stock Exchange members will be required to notify the Exchange in writing of any openings and closings of a branch office, along with the name of the office manager.

\* \* \* \* \*

#### 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 CHX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received regarding the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX 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 Exchange's rules, a member firm for which the Exchange is the designated examining authority must notify the Exchange before opening a new branch office.<sup>3</sup> The Exchange's rules currently require that a firm provide this notice by completing and submitting a MW-B form.

The Exchange represents, however, that it currently asks its member firms to submit Schedule E to Form BD for that purpose. The proposed rule would correct the reference to the form in its Article VI, Rule 5 and would make other non-substantive changes to the text.

###### 2. Statutory Basis

The CHX believes that the proposed rule change is consistent with Section 6(b) of the Act,<sup>4</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>5</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market

<sup>3</sup> See CHX Rule 5 of Article VI.

<sup>4</sup> 15 U.S.C. 78f(b).

<sup>5</sup> 15 U.S.C. 78f(b)(5).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>5</sup> 17 CFR 200.30-3(a)(1).

system, and, in general, to protect investors and the public interest.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 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 90 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, as amended, or

B. Institute proceedings to determine whether the proposed rule change, as amended, 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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Comments may also be submitted electronically at the following e-mail address: [rule-comments@sec.gov](mailto:rule-comments@sec.gov). All comment letters should refer to File No. SR-CHX-2004-04. 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, comments should be sent in hardcopy or by e-mail but not by both methods. 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 will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR-CHX-2004-04 and should be submitted by May 4, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>6</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04-8326 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49534; File No. SR-NASD-2004-060]

#### **Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc., Regarding the Nasdaq Closing Cross**

April 7, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on April 5, 2004, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. Nasdaq has designated the proposed rule change as "non-controversial" under Section 19(b)(3)(A) of the Act<sup>3</sup> and Rule 19b-4(f)(6) thereunder,<sup>4</sup> which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The proposed rule change would make two amendments to NASD Rule 4709 governing the Nasdaq Closing Cross. Specifically, the proposed rule change would: (1) Change Rule 4709(a)(2) to change the order entry time for Imbalance Only Orders ("IOs")

to start at 3:30 p.m. e.s.t., rather than 9:30 a.m., and (2) amend Rule 4709(b) to change the frequency with which Nasdaq would disseminate the Nasdaq Order Imbalance Indicator ("NOII").

The text of the proposed rule change is set forth below. Proposed new language is in *italics*; proposed deletions are in [brackets].

\* \* \* \* \*

#### 4709. Nasdaq Closing Cross

(a) Definitions. For the purposes of this rule the term:

(1) No Change.  
(2) "Imbalance Only Order" or "IO" shall mean an order to buy or sell at a specified price or better that may be executed only during the Nasdaq Closing Cross and only against MOC or LOC orders. IO orders can be entered between [9:30:01 a.m.] 3:30 p.m. and 3:59:59 p.m., but they cannot be cancelled or modified after 3:50:00 except to increase the number of shares or to increase (decrease) the buy (sell) limit price. IO sell (buy) orders will only execute at or above (below) the 4:00:00 SuperMontage offer (bid). All IO orders must be available for automatic execution.

(3) "Limit On Close Order" or "LOC" shall mean an order to buy or sell at a specified price or better that is to be executed only during the Nasdaq Closing Cross. LOC orders can be entered, cancelled, and corrected between 9:30:01 a.m. and 3:50:00 p.m. [and] LOC Orders will execute only at the price determined by the Nasdaq Closing Cross. All LOC orders must be available for automatic execution.

(4) "Market on Close Order" shall mean an order to buy or sell at the market that is to be executed only during the Nasdaq Closing Cross. MOC orders can be entered, cancelled, and corrected between 9:30:01 a.m. and 3:50:00 p.m. [and] MOC orders will execute only at the price determined by the Nasdaq Closing Cross. All MOC orders must be available for automatic execution.

(5) No Change.

(6) No Change.

(b) Order Imbalance Indicator. Beginning at 3:50 p.m., Nasdaq shall disseminate by electronic means an Order Imbalance Indicator every 30 seconds until 3:55, and then *beginning at 3:55*, every 15 seconds until [3:58] 3:59, and then *beginning at 3:59*, every 5 seconds until [3:59, and then every second until] market close. The Order Imbalance Indicator shall contain the following real time information:

(1)-(4) No Change.

(c) No Change.

\* \* \* \* \*

<sup>6</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>4</sup> 17 CFR 240.19b-4(f)(6).

*II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

**1. Purpose**

Nasdaq is proposing two amendments to NASD Rule 4709 governing the Nasdaq Closing Cross. Specifically, Nasdaq proposes to modify subsection (a)(2) which defines an IO and currently permits market participants to enter such orders beginning at 9:30:01 a.m. E.S.T. Nasdaq has determined that it is inefficient to accept and retain such orders early in the trading day because IOs do not impact the market or the Closing Cross until 3:50 p.m. and market participants derive little benefit from entering them that early. Accordingly, Nasdaq proposes to change the order entry time for IOs to start at 3:30 p.m. E.S.T. in order to better allocate order processing resources.

Nasdaq is also proposing to amend subsection (b) of Rule 4709 to change the frequency with which Nasdaq will disseminate the NOII. Currently, the rule provides for the following dissemination: beginning at 3:50 p.m., Nasdaq will disseminate the NOII every 30 seconds until 3:55, and then every 15 seconds until 3:58, and then every 5 seconds until 3:59, and then every second until market close. Nasdaq has determined that this dissemination would be an unnecessary drain on system resources. Nasdaq proposes to change that dissemination to the following: beginning at 3:50 p.m., Nasdaq would disseminate the NOII every 30 seconds until 3:55, then beginning at 3:55 every 15 seconds until 3:59, and then beginning at 3:59 every 5 seconds until market close.

**2. Statutory Basis**

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,<sup>5</sup> in general, and with Section 15A(b)(6) of

<sup>5</sup> 15 U.S.C. 78o-3.

the Act,<sup>6</sup> in particular, in that Section 15A(b)(6) requires, among other things, that a national securities association's rules be designed to protect investors and the public interest. Nasdaq believes that the proposed rule change is consistent with the obligations under these provisions of the Act because it would result in the public dissemination of information that more accurately reflects the trading in a particular security at the close. Furthermore, to the extent a security is a component of an index, Nasdaq believes the index would more accurately reflect the value of the market, or segment of the market, the index is designed to measure. Nasdaq believes the corresponding result should be trades, or other actions, executed at prices more reflective of the current market when the price of an execution, or other action, is based on the last sale, the high price or low price of a security, or the value of an index.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

Written comments were neither solicited nor received.

**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,<sup>7</sup> it has become effective pursuant to Section 19(b)(3)(A) of the

<sup>6</sup> 15 U.S.C. 78o-3(b)(6).

<sup>7</sup> The Commission revised this section to reflect that the proposed rule change does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate. Telephone conversation between Jeffrey S. Davis, Associate Vice President and Associate General Counsel, Nasdaq, and Ann E. Leddy, Special Counsel, Division of Market Regulation ("Division"), Commission (April 6, 2004).

Act<sup>8</sup> and Rule 19b-4(f)(6) thereunder.<sup>9</sup> At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

Nasdaq has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow Nasdaq to effect the proposed amendments to the Nasdaq Closing Cross prior to the launch of the Nasdaq Closing Cross scheduled for Wednesday, April 7, 2004.<sup>10</sup> For these reasons, the Commission designates the proposal to be effective and operative upon filing with the Commission.<sup>11</sup>

**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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Comments may also be submitted electronically at the following e-mail address: [rule-comments@sec.gov](mailto:rule-comments@sec.gov). All comment letters should refer to File No. SR-NASD-2004-060. 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, comments should be sent in hardcopy or by e-mail but not by both methods. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

<sup>8</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>9</sup> 17 CFR 240.19b-4(f)(6). The Commission notes that Nasdaq provided written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change at least five business days prior to the date of filing of the proposed rule change.

<sup>10</sup> The Commission revised this sentence to clarify that the launch date of the Nasdaq Closing Cross is Wednesday, April 7, 2004. Telephone conversation between Jeffrey S. Davis, Associate Vice President and Associate General Counsel, Nasdaq, and Ann E. Leddy, Special Counsel, Division, Commission (April 6, 2004).

<sup>11</sup> For purposes only of waiving the 30-day operative delay of the proposed rule change, the Commission considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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 will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR-NASD-2004-060 and should be submitted by May 4, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>12</sup>

**Margaret H. McFarland,**  
Deputy Secretary.

[FR Doc. 04-8266 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49537; File Nos. SR-NASD-2002-108 and SR-NYSE-2002-35]

### Self-Regulatory Organizations; National Association of Securities Dealers, Inc. and New York Stock Exchange, Inc.; Order Approving Proposed Rule Changes Relating to Business Continuity Planning of Members and Notice of Filing and Order Granting Accelerated Approval of NASD Amendment Nos. 6, 7, and 8

April 7, 2004.

#### I. Introduction

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> the National Association of Securities Dealers, Inc. ("NASD") on August 7, 2002, and the New York Stock Exchange, Inc. ("NYSE") on August 16, 2002, filed with the Securities and Exchange Commission ("SEC" or "Commission") proposed rule changes that would require every member to establish and maintain a business continuity plan ("BCP") and to provide either NASD or NYSE, as appropriate, with certain emergency contact information. On September 9, 2002, the Commission published notice of both proposals in the **Federal Register** ("Original Notices").<sup>3</sup> The Commission received four comments in response to

the Original Notices.<sup>4</sup> Thereafter, NASD and NYSE submitted amendments to their respective proposals, which contained their responses to the comment letters.<sup>5</sup> The Commission published notice of the amended proposals in the **Federal Register** ("Second Notices").<sup>6</sup> The Commission received four comment letters in response to the Second Notices.<sup>7</sup> Subsequently, NYSE submitted a fourth amendment<sup>8</sup> and NASD submitted its fourth and fifth amendments, which amended the proposals as published in the Second Notices and responded to the comments received in response to

<sup>4</sup> One commenter submitted a single letter that addressed both Original Notices. See letter from Melvyn Musson, Business Continuity Planning Manager, Edward D. Jones & Co., to Jonathan G. Katz, Secretary, SEC, dated September 30, 2002 ("Edward Jones 1"). A second commenter submitted two letters that addressed each proposal separately. See letters from Jerry W. Klawitter, Securities Industry Association ("SIA") Business Continuity Planning Committee and Bond Market Association ("BMA") Business Continuity Management Council, to Margaret H. McFarland, Deputy Secretary, SEC, dated September 30, 2002 (collectively, "SIA/BMA 1"). A third commenter submitted a letter that addressed only the NASD Original Notice. See letter from Frances M. Stadler, Deputy Senior Counsel, Investment Company Institute, to Jonathan G. Katz, Secretary, SEC, dated September 30, 2002 ("ICI").

<sup>5</sup> See letters from Brian J. Woldow, Office of General Counsel, NASD, to Katherine A. England, Division of Market Regulation ("Division"), SEC, dated December 11, 2002 ("NASD Amendment No. 1"); January 8, 2003 ("NASD Amendment No. 2"); and February 19, 2003 ("NASD Amendment No. 3"). See also letters from Darla C. Stuckey, Corporate Secretary, NYSE, to Nancy Sanow, Division, SEC, dated January 10, 2003 ("NYSE Amendment No. 1"); March 6, 2003 ("NYSE Amendment No. 2"); and March 26, 2003 ("NYSE Amendment No. 3"). NYSE Amendment No. 3 incorporated and superseded NYSE Amendments No. 1 and 2.

<sup>6</sup> See Securities Exchange Act Release Nos. 47441 (March 4, 2003), 68 FR 11432 (March 10, 2003) (noticing Amendments No. 1, 2, and 3 of NASD proposal); and 48502 (March 27, 2003), 68 FR 16334 (April 3, 2003) (noticing Amendment No. 3 of NYSE proposal).

<sup>7</sup> Two commenters addressed only the NASD Second Notice. See letters from Melvyn Musson, Business Continuity Planning Manager, Edward D. Jones & Co., to Jonathan G. Katz, Secretary, SEC, dated March 28, 2003 ("Edward Jones 2"); Thomas K. Heard, Associate Vice President & Director of Contingency Planning, A.G. Edwards & Sons, Inc., to Jonathan G. Katz, Secretary, SEC, dated March 31, 2003 ("A.G. Edwards"). One commenter submitted separate letters to each of the NASD and NYSE Second Notices. See letters from Jerry W. Klawitter, SIA Business Continuity Planning Committee and BMA Business Continuity Management Council, to Jonathan G. Katz, Secretary, SEC, dated March 31, 2003 (responding to NASD Second Notice); Jerry W. Klawitter, SIA Business Continuity Planning Committee and BMA Business Continuity Management Council, to Jonathan G. Katz, Secretary, SEC, dated April 24, 2003 (responding to NYSE Second Notice) (collectively, "SIA/BMA 2").

<sup>8</sup> See letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Katherine A. England, Division, SEC, dated September 11, 2003 ("NYSE Amendment No. 4").

the Second Notices.<sup>9</sup> The Commission published notice of these amendments on September 26, 2003 ("Third Notices").<sup>10</sup> The Commission received 14 comments in response to the Third Notices.<sup>11</sup> On February 10, 2004, NASD submitted a sixth amendment, which responded to the issues raised by the commenters in response to the Third Notice.<sup>12</sup> NASD submitted its seventh and eighth amendments on March 23, 2004, and April 5, 2004, respectively, which made minor changes to its proposal.<sup>13</sup> Finally, on March 24, 2004,

<sup>9</sup> See letters from Brian J. Woldow, Office of General Counsel, NASD, to Katherine A. England, Division, SEC, dated September 3, 2003 ("NASD Amendment No. 4") and September 16, 2003 ("NASD Amendment No. 5").

<sup>10</sup> See Securities Exchange Act Release Nos. 48502 (September 17, 2003), 68 FR 55691 (NYSE); and 48503 (September 17, 2003), 68 FR 55686 (NASD).

<sup>11</sup> One comment letter addressed the Third Notices of both the NASD and the NYSE. See letter from Jerry W. Klawitter, SIA Business Continuity Planning Committee, to Jonathan G. Katz, Secretary, SEC, dated October 16, 2003 ("SIA 3"). Eight comment letters were nearly identical and addressed only the NASD Third Notice. See letters from Jack R. Handy, Jr., President & CEO, Financial Network Investment Corporation, dated October 14, 2003; Patrick H. McEvoy, President/CEO, IFG Network Securities, Inc., undated but received by the Commission on October 15, 2003; Patrick H. McEvoy, President/CEO, Multi-Financial Securities Corporation, undated but received by the Commission on October 15, 2003; Patrick H. McEvoy, President/CEO, Vestax Securities Corporation, undated but received by the Commission on October 15, 2003; Ronald R. Barhorst, President, ING Financial Advisers, LLC, undated but received by the Commission on October 16, 2003; Karl Lindberg, President, Locust Street Securities Inc., undated but received by the Commission on October 16, 2003; Kevin P. Maas, Chief Compliance Officer, PrimeVest Financial Services, undated but received by the Commission on October 15, 2003; Barbara Stewart, President, Washington Square Securities, Inc., undated but received by the Commission on October 15, 2003, to Secretary, SEC (collectively, "Joint Commenters"). Three additional comment letters addressed only the NASD Third Notice. See letters from Henry H. Hopkins, Vice President and Chief Legal Counsel, and John R. Gilner, Vice President & Associate Legal Counsel, T. Rowe Price Investment Services, Inc., to Jonathan G. Katz, Secretary, SEC, dated October 16, 2003 ("T. Rowe Price"); Joseph H. Moglia, CEO, Ameritrade Holding Corporation, to Margaret H. McFarland, Deputy Secretary, SEC, dated October 17, 2003 ("Ameritrade"); W. Thomas Boulter, Vice President & Chief Compliance Officer, Jefferson Pilot Securities Corporation, to Jonathan G. Katz, Secretary, SEC, dated October 17, 2003 ("Jefferson Pilot"). One commenter submitted separate but nearly identical letters to both the NASD Third Notice and the NYSE Third Notice. See letters from Barry S. Augenbraun, Senior Vice President and Corporate Secretary, Raymond James Financial, Inc., to Jonathan G. Katz, Secretary, SEC, dated October 16, 2003 (collectively, "Raymond James").

<sup>12</sup> See letter from Brian J. Woldow, Office of General Counsel, NASD, to Katherine A. England, Division, SEC, dated February 10, 2004 ("NASD Amendment No. 6").

<sup>13</sup> See letters from Shirley H. Weiss, Associate General Counsel, NASD, to Katherine A. England, Division, SEC, dated March 23, 2004 ("NASD Amendment No. 7"), and April 5, 2004 ("NASD Amendment No. 8").

<sup>12</sup> 17 CFR 200.30-3(a)(12).

<sup>15</sup> U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release Nos. 46443 (August 30, 2002), 67 FR 57264 (File No. SR-NYSE-2002-35); and 46444 (August 30, 2002), 67 FR 57257 (File No. SR-NASD-2002-108).



NYSE submitted a letter responding to the issues raised by the commenters in response to the Third Notice.<sup>14</sup>

This order approves the NASD and NYSE proposals, as amended, and approves NASD Amendment Nos. 6, 7, and 8 on an accelerated basis. In addition, the Commission solicits comment from interested persons on NASD Amendment Nos. 6, 7, and 8.

## II. Description of the Proposals

Proposed NASD Rule 3510(a) and proposed NYSE Rule 446(a) set forth a basic requirement for NASD and NYSE members and member organizations to create, maintain, review, and update a written BCP that identifies procedures relating to an emergency or significant business disruption. Under the proposed rules, members' BCPs "must be reasonably designed to enable the member to meet its existing obligations to customers" and address members' existing relationships with other broker-dealers and counter-parties. A member of NASD or NYSE is required to make its BCP available to its respective self-regulatory organization ("SRO") upon request.<sup>15</sup>

Proposed NASD Rule 3510(b) and proposed NYSE Rule 446(b) require each member to update its BCP in the event of any material change to the member's operations, structure, business, or location. In addition, the proposed rules require every member to conduct, at a minimum, an annual review of its BCP to determine whether any modifications are necessary in light of changes to the member's operations, structure, business, or location.

Both proposed rules require that a BCP be approved by the member. Proposed NASD Rule 3510(d) requires a member of senior management, who must be a registered principal, to approve a BCP and be responsible for conducting the annual review. Proposed NYSE Rule 446(g) requires a senior officer, as defined in NYSE Rule 351(e), to approve and review the BCP on an annual basis.

The proposed rules set forth the elements that a BCP must address, if applicable,<sup>16</sup> which shall be tailored to the size and needs of the member.<sup>17</sup>

<sup>14</sup> See letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Katherine A. England, Division SEC, dated March 23, 2004 ("NYSE Response Letter").

<sup>15</sup> See proposed NASD Rule 3510(a) and proposed NYSE Rule 446(a).

<sup>16</sup> The proposed rules provide that if an element is not applicable to a member the BCP must contain the rationale as to why such element is not included in the BCP. See proposed NASD Rule 3510(c) and proposed NYSE Rule 446(b).

<sup>17</sup> See proposed NASD Rule 3510(c) and proposed NYSE Rule 446(c).

Specifically, each BCP must address data back-up and recovery (hard copy and electronic); mission critical systems;<sup>18</sup> financial and operational assessments;<sup>19</sup> alternate communications between customers and the member; alternate communications between the member and its employees; alternate physical location of employees;<sup>20</sup> critical business constituent, bank, and counterparty impact; regulatory reporting; communications with regulators; and how the member will assure customers' prompt access to their funds and securities in the event that the member determines that it is unable to continue its business. Finally, if a member relies on another entity for any of the required elements, the BCP must address the relationship with the third party.<sup>21</sup>

Proposed NASD Rule 3510(e) and proposed NYSE Rule 446(d) each require a member to disclose to its customers how its BCP addresses the possibility of a future significant business disruption and how the member plans to respond to events of varying scope. Such disclosure, at a minimum, must be made in writing to customers at account opening, posted on the member's Web site (if the member maintains a Web site), and mailed to customers upon request. As proposed, an NASD or NYSE member would not be required to disclose its actual plan. Instead, the member would be required to disclose only a summary of how its BCP addressed the possibility

<sup>18</sup> NASD and NYSE proposed substantively the same definition for "mission critical system." The proposed rules define "mission critical system" as any system that is necessary, depending on the nature of a member's business, to ensure prompt and accurate processing of securities transactions, including, but not limited to, order taking, order entry, execution, comparison, allocation, clearance and settlement of securities transactions, the maintenance of customer accounts, access to customer accounts and the delivery of funds and securities. See proposed NASD Rule 3510(f)(1) and proposed NYSE Rule 446(e).

<sup>19</sup> NASD and NYSE proposed substantively the same definition for "financial and operation assessment." As defined, a "financial and operational assessment" means a set of written procedures that allows a member to identify changes in its operational, financial, and credit risk exposure. See proposed NASD Rule 3510(f)(2) and proposed NYSE Rule 446(f).

<sup>20</sup> NASD's added this element in its Amendment No. 8. Therefore, under the final proposals, NASD and NYSE will require their members to address the exact same aspects of business continuity.

<sup>21</sup> NASD and NYSE stated that this provision would permit a member that is a subsidiary of another entity to satisfy its obligations under the rules by participation in a corporate-wide BCP of the parent, even if the parent were not itself a member. However, the parent company's BCP would be required to comply with the requirements of the BCP rule and would have to be available to NASD and/or NYSE (as appropriate) upon request.

of significant business disruptions and generally how the member planned to respond.

Proposed NASD Rule 3520(a) requires each member to report to NASD emergency contact information, which includes the designation of two emergency contact persons.<sup>22</sup> The emergency contact persons must be members of senior management and registered principals. Proposed NASD Rule 3520(b) requires members to promptly update emergency contact information in the event of a material change and requires the member's Executive Representative, or his or her designee, to review and update such emergency contact information within 17 days after the end of each calendar quarter.

Proposed NYSE Rule 446(g) requires a member or member organization to designate one or more emergency contact persons who must be senior officers of the firm; to provide the name, title, mailing address, e-mail address, telephone number, and fax number of such person(s); and to notify NYSE promptly of any change in such designations.

NASD proposes that the effectiveness of its new rules be calculated from the date of publication of the Commission's approval order, with different effective dates for clearing firms and introducing firms. Each NASD-member clearing firm must establish a BCP, as required under proposed NASD Rule 3510, within 120 days of the publication of the Commission's approval order. An NASD-member introducing firm must establish a BCP, as required under proposed NASD Rule 3510, within 150 days of the publication of the Commission's approval order. All NASD members (both clearing and introducing firms) must designate their emergency contact persons, as required in proposed NASD Rule 3520, within 60 days of publication of the Commission's approval order. NYSE proposes that its rule will take effect 120 days after Commission approval.

Finally, NASD proposes to offer an optional repository service for its members' BCPs. In its Amendment No. 8, however, NASD stated that this online repository service would be operated through an outside vendor and that any NASD members wishing to use

<sup>22</sup> NASD originally proposed to require certain additional emergency information, such as location of books and records (including back-up locations), clearance and settlement information, identification of key banking relationships, and alternative communication plans for investors. In its Amendment No. 8, NASD withdrew this portion of the proposal and deleted the words "Among other things" from proposed NASD Rule 3520(a).

this service would pay a monthly fee directly to the repository.

### III. Summary of Comments

In total, the Commission received 22 comment letters on the proposed rule changes.<sup>23</sup> Generally, the commenters supported the proposed new rules.<sup>24</sup> As noted above, NASD and NYSE generally addressed the issues raised in the comment letters received in response to the Original Notices and the Second Notices in subsequent amendments.<sup>25</sup> These amendments, including NASD's and NYSE's responses to the comment letters, were published by the Commission in the *Federal Register*.<sup>26</sup> In response to the Third Notices, the Commission received 14 comment letters.<sup>27</sup> NASD and NYSE submitted responses to the issues raised in the comments letters the Commission received in response to the Third Notices.<sup>28</sup> The issues raised by the commenters in response to the Third Notices and NASD and NYSE responses are summarized below.

#### A. Meeting Existing Obligations to Customers

In the Third Notices, NASD and NYSE amended their respective proposals to provide that the procedures set forth in a BCP should be reasonably designed to enable a member to meet its existing obligations to customers and address existing relationships with other broker-dealers and counter-parties. A majority of commenters<sup>29</sup> advocated returning to the language published in the Second Notices, which stated that each member's plan must be "reasonably designed to enable the member to continue its business." Specifically, the Joint Commenters argued that the phrase "meet its existing obligation to customers" was vague and did not adequately clarify that a member would not be required to continue its business. They also argued that the phrase "address their existing relationships with other broker-dealers and counter-parties" did not stipulate what level of detail would be required in the BCP and appeared to add new requirements to the BCP rather than clarifying that a member would not be required to stay in business.

NASD and NYSE, in response, declined to amend their proposals as suggested. In explaining their decision not to amend this provision of the proposed rules, NASD and NYSE noted the following statement made by the Commission:

The decision by a broker-dealer to risk capital or provide brokerage services on an ongoing basis is, in essence, a matter of business judgment. Given the competitive nature of the securities business, however, the Commission expects there to be incentives for broker-dealers to be prepared to participate in the markets following a wide-scale disruption as soon as the markets' trading facilities become available.<sup>30</sup>

In its Amendment No. 4, NASD stated that it did not intend members to interpret its rule to require them to continue their business in the event of a significant business disruption. NYSE stated that it believed that further amendment was not warranted because its position that members are not required to continue its business is clear and that this position is consistent with the Commission's Policy Statement.

#### B. Plan Elements

##### 1. Critical Business Constituent, Banks, and Counter-Party Impact

In responding to the Third Notices, one commenter commended the revision to limit the scope of this provision to "critical" counter-parties.<sup>31</sup> However, the commenter requested that NASD and NYSE communicate any criteria that they develop to define such critical relationships at the earliest opportunity. Another commenter argued that the proposal appeared to impose on members the "impossible requirement" of addressing how they would remedy the possible failure of industry-wide systems on which all parties must rely, such as the Depository Trust Company.<sup>32</sup> Several commenters argued that because the terms are not defined the intent of the rule language was vague and ambiguous.<sup>33</sup> Finally, one commenter recommended that NASD and NYSE should use the same rule language to avoid confusion.<sup>34</sup>

In its Amendment No. 6, NASD responded that it believed that members should be responsible for identifying those relationships that it deems critical for purposes of complying with the rule.

NASD, however, did state that it would consider, based on its experience with the rule following its adoption, whether to enumerate specific relationships that it views critical to all members. In addition, NASD amended its proposal to read "critical business constituent, bank, and counter-party impact" so that it is identical to the NYSE proposal.

##### 2. Customer Access to Funds and Securities

As noted above, proposed NASD Rule 3510(c)(9) and proposed NYSE 446(c)(10) requires a member's BCP to address "[h]ow the member will assure customers" prompt access to their funds and securities in the event that the member determines that it is unable to continue its business." This new language was published in the Third Notices. NASD and NYSE stated that this new category should help to ensure that, if a member is unable to continue its business following a significant business disruption, customers could access their funds or securities held through the member.

In response to the Third Notices, one commenter argued that the obligations placed on a firm under the proposed rules might conflict with the obligations of the firm imposed by the Securities Investor Protection Corporation ("SIPC").<sup>35</sup> NASD and NYSE stated that they did not believe that the provisions conflict with SIPC rules and did not intend for the proposed rule change to have any effect on a member's obligations under such rules. The new provisions require a member only to address how it would assure such access. NASD and NYSE continued that, if a member believed that SIPC rules might affect a member's response to this subsection, the member should address SIPC rules in its BCP. Finally, NASD and NYSE noted that a member could not rely on SIPC membership, by itself, to satisfy its obligations under the proposed rules, because SIPC involvement in the liquidation of a broker-dealer is limited to SIPC's authority under the Securities Investor Protection Act of 1970.

#### C. Disclosure

In the Third Notices, NASD and NYSE proposed that members disclose to their customers how their BCPs address a future significant business disruption. Several commenters argued that the disclosure provision would be burdensome and costly.<sup>36</sup> The Joint Commenters, for example, maintained

<sup>23</sup> See *supra* notes 4, 7 and 11.

<sup>24</sup> See Ameritrade, Edward Jones 1, ICI, Jefferson Pilot, Joint Commenters, Raymond James, and SIA/BMA 1.

<sup>25</sup> See *supra* notes 5, 8, and 9 and accompanying text.

<sup>26</sup> See *supra* notes 6 and 10.

<sup>27</sup> See *supra* note 11.

<sup>28</sup> See *supra* notes 12 and 14.

<sup>29</sup> See Ameritrade and Joint Commenters.

<sup>30</sup> *Business Continuity Planning for Trading Markets*, Securities Exchange Act Release No. 48545 (September 25, 2003), 68 FR 56656, 56658 (October 1, 2003) ("Policy Statement").

<sup>31</sup> See SIA 3.

<sup>32</sup> See Raymond James.

<sup>33</sup> See Joint Commenters.

<sup>34</sup> See SIA 3.

<sup>35</sup> See *id.*

<sup>36</sup> See Jefferson Pilot, Joint Commenters, and Raymond James.

that the cost of delivering the summary BCP to customers at account opening outweighed any benefits. The Joint Commenters also noted that a customer receives large amounts of information at account opening and, "as more information is added, the import of the information becomes lost and the customer becomes increasingly frustrated with the account opening process." Another commenter echoed that "providing a summary that is not easily understood will lead to customer confusion."<sup>37</sup> This commenter argued that "deficient business continuity plans by member firms can be detected and deterred sufficiently through the regulatory audit process" rather than through public disclosure. In the alternative, the commenter recommended that it would be sufficient for a firm to post its summary BCP on its Web site and provide it on demand rather than to provide it to every customer at account opening.<sup>38</sup> Another commenter—noting that it had identified over 200 mission critical functions in its various departments and developed a response plan for each of these functions—argued that it would be impossible to summarize these plans in any meaningful way.<sup>39</sup>

Two comments raised concerns about disclosing potentially confidential and proprietary information.<sup>40</sup> One commenter also argued that a firm might be subject to liability for breach of contract or misrepresentation if it determined to vary a course of action from what was disclosed in its summary BCP in order to react more appropriately in a recovery situation.<sup>41</sup>

In their responses, NASD and NYSE stated that they continued to believe that this requirement was necessary to enable customers to make educated decisions about whether to place their funds and securities at a specific broker-dealer. NASD and NYSE also stated that they believe that these provisions would encourage members to create adequate contingency plans. In response to one commenter's concern about disclosing confidential and proprietary information, NYSE stated that a member would be required only to summarize the manner in which its BCP addresses the possibility of significant business disruptions. NASD and NYSE reiterated that members would not be required to disclose the specific location of any back-up facilities, any proprietary information contained in the plan, or

the parties with whom the member has back-up arrangements.

In order to make the disclosure meaningful, NASD and NYSE stated that, when addressing events of varying scope, a member should: (1) Provide specific scenarios of varying severity (e.g., a firm-only business disruption, a disruption to a single building, a disruption to a business district, a city-wide disruption and a regional disruption); (2) state whether it plans to continue business during that scenario and, if so, its planned recovery time; and (3) provide general information on its intended response. Furthermore, NASD and NYSE stated that the disclosure requirement was necessary to enable customers to make educated decisions about whether to place their funds and securities at a specific firm. Finally, in response to the liability concern, NASD and NYSE stated that a member could include in its BCP cautionary language to the effect that the plan was subject to modification, that an updated plan would be promptly posted on the member's website, and that customers also could obtain an updated plan by requesting a written copy by mail. Plans also can be flexible enough to provide for individualized responses to various events.

#### D. Emergency Contact Information

In response to the NASD Third Notice, one commenter asserted that NASD's discussion in its Amendment No. 4 suggests that the Executive Representative should have the authority to make potentially time sensitive decisions on behalf of the firm, which may conflict with the governing charter of many member firms.<sup>42</sup> In its Amendment No. 6, however, NASD stated it "in no way sought to alter the scope of authority of a member's Executive Representative to make these types of decisions."

#### E. Implementation

In response to the Second Notices, one commenter recommended that the proposed rules should become effective 360 days from the publication of the final rules in the *Federal Register*.<sup>43</sup> After the Third Notices, this commenter reiterated its view that the proposed implementation schedule was too aggressive, suggesting instead that NASD and NYSE should follow the Commission's implementation dates for trading markets set forth in the Policy Statement.<sup>44</sup> NASD and NYSE both responded that they do not believe that

this comparison is appropriate. The Policy Statement sets forth the Commission's view that self regulatory organizations ("SROs") that operate trading markets and electronic communications networks ("ECNs") should, among other things, plan to resume trading operations by the next business day in response to a wide-scale business disruption. The current proposals require a member only to create and maintain a BCP that is reasonably designed to meet the member's obligations to its customers and that addresses certain enumerated areas. NYSE also noted that many firms, as a matter of best practices, have already established BCPs. Therefore, NASD and NYSE declined to amend the effective dates.

#### IV. Discussion

One of the critical "lessons learned" from the events of September 11, 2001, is the need for more rigorous business continuity planning in the financial services industry. Since September 11, the resilience of the U.S. securities markets has been a matter of principal concern to the Commission and to other regulators. In April 2003, for example, the Commission—together with the Office of the Comptroller of the Currency and the Board of Governors of the Federal Reserve System—issued an *Interagency Paper on Sound Practices to Strengthen the Resilience of the U.S. Financial System*,<sup>45</sup> which noted that, "because of the interdependent nature of the U.S. financial markets, all financial firms have a role in improving the overall resilience of the financial system. It therefore is appropriate for all financial firms to review their business continuity plans \* \* \*".<sup>46</sup>

Subsequently, the Commission issued the Policy Statement,<sup>47</sup> which set forth the Commission's view that SROs that operate trading markets and ECNs should apply certain basic principles in their business continuity planning within a specified timeframe. Specifically, the Commission stated that it expected each SRO market and ECN, among other things, to have a BCP that anticipates the resumption of trading no later than the next business day following a wide-scale business disruption, and that this generally requires geographic diversity between primary and back-up sites. In the Policy

<sup>45</sup> Securities Exchange Act Release No. 47638 (April 7, 2003), 68 FR 17809 (April 11, 2003) ("Interagency Paper").

<sup>46</sup> The Interagency Paper sets forth sound practices for business continuity planning for the clearance and settlement systems of the U.S. financial markets.

<sup>47</sup> See *supra* note .

<sup>37</sup> See Jefferson Pilot.

<sup>38</sup> See *id.*

<sup>39</sup> See Raymond James.

<sup>40</sup> See Ameritrade and Joint Commenters.

<sup>41</sup> See Ameritrade.

<sup>42</sup> See SIA 3.

<sup>43</sup> See SIA/BMA 2.

<sup>44</sup> See *supra* SIA 3.

Statement, the Commission declined to establish new regulatory requirements for non-ECN broker-dealers but did state:

The establishment of a next-business day resumption goal for the SRO Markets and ECNs should serve as a useful resumption benchmark for securities firms as well. The decision by a broker-dealer to risk capital or provide brokerage services on an ongoing basis is, in essence, a matter of business judgment. Given the competitive nature of the securities business, however, the Commission expects there to be incentives for broker-dealers to be prepared to participate in the markets following a wide-scale disruption as soon as the markets' trading facilities become available.<sup>48</sup>

With their respective proposals, NASD and NYSE are taking an important step in setting forth business continuity planning requirements for broker-dealers that allow for flexibility and the exercise of business judgment, yet at the same time assure that investors have sufficient information to evaluate the level of a firm's BCP and, in any event, that all customers have prompt access to their funds and securities. For the reasons discussed below, the Commission finds that the proposed rule changes, as amended, are consistent with the requirements of the Act and the regulations thereunder.<sup>49</sup> In particular, the Commission believes that NASD's proposal is consistent with Section 15A(b)(6) of the Act<sup>50</sup> which requires, among other things, that the rules of a national securities association be 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 a national market system, and in general to protect investors and the public interest. The Commission also believes that NYSE's proposal is consistent with Section 6(b)(5) of the Act<sup>51</sup> which requires, among other things, that the rules of a national securities exchange be 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 a national market

system, and in general to protect investors and the public interest.

The proposed rules will require member firms to establish written plans that address general areas of business continuity. Requiring every NASD and NYSE member to address how it would handle business disruptions of varying scope is an important first step in reducing the impact of any such disruptions. Although no plan can reasonably be expected to mitigate the effects of every crisis, a firm that has a BCP meeting the requirements of the proposed rules should be in a much better position to respond to a significant event. Furthermore, implementation of the proposed rules by all NASD and NYSE members collectively should reduce the adverse systemic consequences of a disruption that affects multiple firms in a particular area. Therefore, the Commission believes that the new rules should enhance the resilience of the U.S. financial markets generally.

The Commission agrees with the approach taken by the SROs to allow each member the flexibility to tailor its BCP to the nature, type, and scope of its business. The new rules require each member's BCP, at a minimum, to address various aspects of business continuity planning. Thus, the new rules envisage a planning *process* but do not—except with respect to customer access to funds and securities, described below—dictate the content of the plans that result from that process. For example, although a member firm would be required in its plan to address its mission critical systems and the back-up for such systems, the rules do not require a member to take specific actions such as establishing a back-up facility or obtaining a specified amount of redundant telecommunications capacity.

The Commission believes that NASD and NYSE have identified important elements that must be addressed in each member's BCP. While the new rules are primarily procedures-based rather than standards-based, they include an important provision to encourage NASD and NYSE members to develop thoughtful and robust plans: An obligation to disclose a summary of their BCPs to their customers. This obligation should harness market forces to improve the emergency preparedness of particular firms as well as the securities industry as a whole. The information contained in these public disclosures will allow individual customers (and potential customers) to compare the emergency preparedness of a broker-dealer to that of its competitors and help them to decide where to place

their funds and securities. While the new rules establish few minimum standards that the BCP of every NASD or NYSE member must meet, a customer will be in a much better position to evaluate whether a particular firm's emergency preparedness meets his or her expectations.

The summary of the member's BCP that is disclosed to customers should include a discussion of how the broker-dealer intends to respond to events of varying scope (e.g., a firm-only disruption, a disruption to a single building, a disruption to a business district, a city-wide disruption, and a regional disruption); whether the broker-dealer intends to continue its business during each scenario and, if so, the planned recovery time; and how the broker-dealer intends to respond to each scenario. This requirement should give the summary BCP a basic framework against which it can readily be compared to other BCPs. The Commission believes that it is important for customers to understand the capabilities and plans of the NASD or NYSE member with which they choose to do business, and this disclosure should provide investors with such information.

Although the new NASD and NYSE rules are fundamentally process-based, every member is required to include one element in its BCP: A discussion of how the member will assure its customers' prompt access to their funds and securities in the event that the member is unable to operate. A broker-dealer that holds funds and securities on behalf of its customers is acting as the customers' agent. The Commission believes that it is reasonable and consistent with the Act for NASD and NYSE to require that a member address how it will assure customers' access to their funds and securities even if the member cannot operate or determines that it is not economically feasible to continue its business during or after a significant business disruption. The Commission expects that a discussion of this subject will appear on the summary BCP, as a likely concern of any customer is how to recover funds and securities if the broker-dealer is incapacitated.

The Commission believes that it is reasonable and consistent with the Act for NASD and NYSE to require each member to designate emergency contact persons and to provide NASD and NYSE (as appropriate) with emergency contact information for such persons. This information should facilitate efforts to coordinate efforts between NASD or NYSE and its members to resume operations after a significant business disruption. The Commission also

<sup>48</sup> Policy Statement, 68 FR at 56658.

<sup>49</sup> In approving these proposals, the Commission considered the proposed rules' impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>50</sup> 15 U.S.C. 78o-3(b)(6).

<sup>51</sup> 15 U.S.C. 78f(b)(5).

believes that it is reasonable and consistent with the Act for NASD and NYSE to require each member to review and update its BCPs and its emergency contact information in the manner and at the times specified in the new rules.

The Commission believes that the implementation timeframes proposed by NASD and NYSE are reasonable and consistent with the Act. In particular, the Commission believes that it is reasonable for NASD to grant its NASD-member introducing firms 30 days more than NASD-member clearing firms, as introducing firms may need to incorporate the business recovery strategies of their clearing firms into their own plans.

The Commission believes that it is reasonable for NASD to arrange with an outside vendor to serve as a repository for its members' BCPs. Use of this service would be voluntary and subject to a monthly fee payable by a member directly to the repository. The Commission believes that this service may be beneficial to members during emergency situations. Specifically, it will enable a member to get a copy of its BCP even if its offices are not accessible.

Pursuant to Section 19(b)(2) of the Act,<sup>52</sup> the Commission finds good cause for approving NASD Amendment Nos. 6, 7, and 8 prior to the thirtieth day after the date of publication of notice thereof in the *Federal Register*. These amendments make only minor revisions to the rule text that clarify the NASD proposal and do not alter its substance. In addition, the Commission believes that NASD's proposal should be approved, as amended by Amendments Nos. 6, 7, and 8, at the same time as the NYSE proposal to provide consistent regulation among NASD and NYSE members. Accordingly, the Commission believes that good cause exists to approve Amendment Nos. 6, 7, and 8 on an accelerated basis.

#### V. Solicitation of Comments on NASD Amendment Nos. 6, 7, and 8

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether NASD Amendment Nos. 6, 7, and 8 are consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW, Washington, DC 20549-0609. Comments may also be submitted electronically at the following e-mail address: [rule-comments@sec.gov](mailto:rule-comments@sec.gov). All comment letters should refer to File No.

SR-NASD-2002-108. The 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, comments should be sent in hardcopy or by e-mail but not by both methods. 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 will also be available for inspection and copying at the principal office of NASD. All submissions should refer to the File No. SR-NASD-2002-108 and should be submitted by May 4, 2004.

#### VI. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>53</sup> that the proposed rule changes (SR-NASD-2002-108 and SR-NYSE-2002-35), as amended, are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>54</sup>

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04-8324 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

#### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49535; File No. SR-NASD-2004-018]

#### Self-Regulatory Organizations; Order Approving Proposed Rule Change and Amendment No. 1 Thereto by the National Association of Securities Dealers, Inc. To Amend the Procedures for the Review of Nasdaq Listing Determinations

April 7, 2004.

On January 28, 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")<sup>1</sup> and Rule

19b-4<sup>2</sup> thereunder, a proposal to amend the procedures for the review of Nasdaq listing determinations. On February 20, 2004, Nasdaq submitted Amendment No. 1 to the proposal,<sup>3</sup> which replaced the original proposal in its entirety. On March 1, 2004, the Commission published the proposed rule change, as amended, in the *Federal Register*.<sup>4</sup> The Commission received no comments on the proposal. This order approves the amended proposal.

The Commission believes that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities association.<sup>5</sup> In particular, the Commission believes that the proposal is consistent with Section 15A(b)(6) of the Act<sup>6</sup> which requires, among other things, that the rules of an association be designed to promote just and equitable principles of trade and to protect investors and the public interest. NASD Rule 4830 provides that all hearings before the Nasdaq Listing Qualifications Panel be conducted by at least two persons designated by the Nasdaq board of directors. Nasdaq's practice is to conduct such hearings before panels composed of two members. Currently, NASD Rule 4830 does not make provision for a deadlock between the two members of the panel. Under new paragraph (d) of NASD Rule 4830, in the event of a deadlock, the issuer would be afforded the opportunity for a new hearing before a new Listing Qualifications Panel comprised of three members. The issuer and Nasdaq staff would be afforded the opportunity to supplement the record on review, including any information that was not available at the time of the first hearing before the Listing Qualifications Panel. There would be no fee for the second hearing.

Among other things, the rule change also: (1) Allows the Listing Qualifications Panel or the Nasdaq Listing Council to reconsider its decision, but only if there were a mistake of material fact in the decision; (2) clarifies when the Nasdaq Listing Council may assert jurisdiction over a decision or permit the Listing Qualifications Panel to proceed with the

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See letter from Mary M. Dunbar, Vice President and Deputy General Counsel, Nasdaq, to Katherine A. England, Division of Market Regulation, Commission, dated February 20, 2004 ("Amendment No. 1").

<sup>4</sup> See Securities Exchange Act Release No. 49306 (February 23, 2004), 69 FR 9662 (March 1, 2004).

<sup>5</sup> In approving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>6</sup> 15 U.S.C. 78o-3(b)(6).

<sup>53</sup> *Id.*

<sup>54</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>52</sup> 15 U.S.C. 78s(b)(2).



reconsideration; and (3) allows documents required by the NASD Rule 4800 process to be delivered by e-mail, if the issuer consents to such method of delivery.

The Commission believes that these proposals will improve the efficiency and fairness of the process by which Nasdaq makes listing determinations and, therefore, are reasonable and consistent with the Act.

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act,<sup>7</sup> that the proposed rule change (SR-NASD-2004-013), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority,<sup>8</sup>

Margaret H. McFarland,  
Deputy Secretary.

[FR Doc. 04-8325 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49515; File No. SR-NYSE-2004-17]

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto by the New York Stock Exchange, Inc. Relating to the Listing of Income Deposit Securities (Sections 102.01C, 202.05 and 802.01B of the Listed Company Manual)

April 1, 2004.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on March 17, 2004, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. On March 29, 2004, the Exchange amended the proposed rule change.<sup>3</sup> The Exchange filed the proposed rule change

pursuant to Section 19(b)(3)(A) of the Act<sup>4</sup> and Rule 19b-4(f)(6) thereunder,<sup>5</sup> which renders the proposal effective upon filing.<sup>6</sup> The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend the Listed Company Manual ("LCM") Sections 102.01C, 202.05 and 802.01B to clarify that income deposit securities intended to be traded as a unit will, as a general matter, be listed if each of the component parts of the unit meets the applicable requirements for listing.

#### 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 NYSE included statements concerning the purpose of and basis for the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange is considering the listing of units comprised of common stock and a debt security, sometimes referred to as income deposit securities ("IDS"). In contrast to a typical unit, an IDS unit can be expected to trade as a unit for an extended period of time, although holders can have certain rights to separate the IDS unit into its component parts (or to combine the components into an IDS).

In order to provide clarity and transparency with respect to the listing standards applicable to IDS units, the Exchange is proposing to amend LCM Section 102.01C to clarify that each component of a unit must meet the applicable listing standards. A comparable amendment is proposed to

LCM Section 802.01B with respect to applicable continued listing standards.

Additionally, the Exchange is proposing an addition to LCM Section 202.05 to specify publication requirements regarding any change in the terms of a listed unit, such as changes to the terms and conditions of any of the components or to the ratio of the components within the unit, and to specify that the issuer must provide current information in this regard on its website, or if it does not maintain a website, in its annual report to unit holders. Changes that should be publicized would include those resulting from a stock split or an automatic exchange of one or more components of the unit (e.g., as a result of a secondary offering of units). The issuer would be expected to provide public disclosure as soon as practicable regarding the nature and effective date of the change. For example, changes resulting from a stock split should be subject to prior disclosure, while changes with respect to original issue discount should be disclosed as soon as such information is available. Disclosure of this nature is appropriate to ensure that sufficient information regarding the attributes of IDS units is publicly available and readily accessible on a timely basis.<sup>7</sup>

###### 2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,<sup>8</sup> in general, and Section 6(b)(5) of the Act,<sup>9</sup> in particular, in that it will promote just and equitable principles of trade; facilitate transactions in securities, remove impediments to and perfect the mechanisms of a free and open market and a national market system; and protect investors and the public interest.

##### 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 on the proposed rule change were neither solicited nor received.

<sup>7</sup> 15 U.S.C. 78s(b)(2).

<sup>8</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated March 26, 2004 ("Amendment No. 1"). In Amendment No. 1, the Exchange made certain changes to Section 7 of the form 19b-4 and Section III of Exhibit 1 of the proposed rule change and confirmed that the original and continuing equity distribution standards set out in the Listed Company Manual Sections 102.01A and 802.01A will be applied to units listed as income deposit securities.

<sup>4</sup> 15 U.S.C. 78s(b)(1).

<sup>5</sup> 17 CFR 240.19b-4.

<sup>6</sup> The NYSE asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. See Rule 19b-4(f)(6)(iii). 17 CFR 240.19b-4(f)(6)(iii).

<sup>7</sup> The Commission notes that Amendment No. 1 also set forth the standards applicable to the units as a whole. See *supra* at footnote 3.

<sup>8</sup> 15 U.S.C. 78f(b).

<sup>9</sup> 15 U.S.C. 78f(b)(5).

### 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, it has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>10</sup> and Rule 19b-4(f)(6) thereunder.<sup>11</sup>

The NYSE has asked the Commission to waive the five-day pre-filing notice requirement and the 30-day operative delay. The Commission believes waiving the five-day pre-filing notice requirement and the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes that it recently approved a similar proposal by the American Stock Exchange LLC ("Amex"), which the NYSE's proposal is based upon.<sup>12</sup> The Amex proposal was published for comment and the Commission received no comments on it.<sup>13</sup> Finally, the Commission does not believe the NYSE's proposal raises any new regulatory issues. For these reasons, the Commission designates the proposal to be effective and operative upon filing of the amended proposal with the Commission.<sup>14</sup>

At any time within 60 days of the filing of the amended proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.<sup>15</sup>

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written

submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549-0609. Comments may also be submitted electronically at the following e-mail address: *rule-comments@sec.gov*. All comment letters should refer to File No. SR-NYSE-2004-17. This file number should be included on the subject line if e-mail is used. To help the Commission process and review comments more efficiently, comments should be sent in hardcopy or by e-mail but not by both methods. 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 will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR-NYSE-2004-17, and should be submitted by May 4, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>16</sup>

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04-8263 Filed 4-12-04; 8:45 am]

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### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49532; File No. SR-PCX-2004-01]

#### Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendment Nos. 1 and 2 Thereto by the Pacific Exchange, Inc. To Trade, Either By Listing or Pursuant to Unlisted Trading Privileges, Index-Linked Exchangeable Notes

April 7, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Commission Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on February 6, 2004, the Pacific Exchange, Inc. ("PCX" or "Exchange"),

through its wholly owned subsidiary PCX Equities, Inc. ("PCXE"), filed with the Securities Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. On March 3, 2004, the Exchange submitted Amendment No. 1 to the proposed rule change.<sup>3</sup> On March 22, 2004, the Exchange submitted Amendment No. 2 to the proposed rule change.<sup>4</sup> The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval to the proposed rule change.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules governing the Archipelago Exchange ("ArcaEx"), the equities trading facility of PCXE. The Exchange proposed to adopt listing standards for index-linked exchangeable notes. With this filing, PCX proposes to add PCXE Rule 5.2(j)(4) to permit for listing or pursuant to unlisted trading privileges ("UTPs"), index-linked exchangeable notes. The text of the proposed rule change appears below. Proposed new language is in italics.

\* \* \* \* \*

Rule 5.2(a)-(i)—No change. (j)(1)-(3)—No change.

#### Index-Linked Exchangeable Notes

(4) *Index-linked exchangeable notes which are exchangeable debt securities that are exchangeable at the option of the holder (subject to the requirement that the holder in most circumstances exchange a specified minimum amount of notes), on call by the issuer or at maturity for a cash amount (the "Cash Value Amount") based on the reported market prices of the Underlying Stocks of an Underlying Index will be considered for listing and trading by the*

<sup>3</sup> On March 3, 2004, the Exchange filed a Form 19b-4, which replaced the original filing in its entirety ("Amendment No. 1").

<sup>4</sup> See letter to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, from Tania J.C. Blanford, Staff Attorney, Regulatory Policy, PCX, dated March 19, 2004 ("Amendment No. 2"). In Amendment No. 2, the Exchange made a change to the proposed rule text to conform it to those previously approved by both the American Stock Exchange LLC ("Amex"), Philadelphia Stock Exchange, Inc. ("Phlx"), and the Chicago Board Options Exchange, Inc. ("CBOE"). See Securities Exchange Act Release Nos. 46370 (August 16, 2002), 67 FR 54509 (August 22, 2002) (Order granting accelerated approval to SR-CBOE-2002-29); 45082 (November 19, 2001), 66 FR 59282 (November 27, 2001) (Order granting accelerated approval to SR-Phlx-2001-92); and 44621 (July 30, 2001), 66 FR 41064 (August 6, 2001) (Order granting accelerated approval to SR-Amex-2001-29).

<sup>10</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>11</sup> 17 CFR 240.19b-4(f)(6).

<sup>12</sup> See Securities Exchange Act Release No. 48666 (October 21, 2003); 68 FR 61239 (October 27, 2003) (SR-Amex-2003-83).

<sup>13</sup> See *id.*

<sup>14</sup> For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>15</sup> Because the proposed rule change became effective on March 29, 2004, the date on which Amendment No. 1 was filed, the 60-day abrogation period began on March 29, 2004.

<sup>16</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> CFR 240.19b-4.

Corporation pursuant to Rule 19b-4(e) under the Securities Exchange Act of 1934, provided:

(a) Both the issue and the issuer of such security meet the criteria set forth above in "Other Securities" (PCXE Rule 5.2(j)(1)), except that the minimum public distribution shall be 150,000 notes with a minimum of 400 public note-holders, except, if traded in thousand dollar denominations, then no minimum number of holders.

(b) The issue has a minimum term of one year.

(c) The issuer will be expected to have a minimum tangible net worth in excess of \$250,000,000, and to otherwise substantially exceed the earnings requirements set forth in PCXE Rule 5.2(j)(1). In the alternative, the issuer will be expected: (i) to have a minimum tangible net worth of \$150,000,000 and to otherwise substantially exceed the earnings requirements set forth in PCXE Rule 5.2(j)(1); and (ii) not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth.

(d) The index to which an exchangeable-note is linked shall either be (i) indices that have been created by a third party and been reviewed and have been approved for the trading of options or other derivatives securities (each, a "Third-Party Index") either by the Commission under Section 19(b)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and rules thereunder or by the Corporation under rules adopted pursuant to Rule 19b-4(e); or (ii) indices which the issuer has created and for which the Corporation will have obtained approval from either the Commission pursuant to Section 19(b)(2) and rules thereunder or from the Corporation under rules adopted pursuant to Rule 19b-4(e) (each an "Issuer Index"). The Issuer Indices and their underlying securities must meet one of the following:

(i) The procedures and criteria set forth PCX Rule 7.3(b)-(c); or

(ii) The criteria set forth in subsection (C) and (D) of PCXE Rule 5.2(j)(2), the index concentration limits set forth in PCX Rule 7.3(b)(6), and PCX Rule 7.3(b)(12) in so far as it relates to PCX Rule 7.3(b)(6).

(e) Index-linked Exchangeable Notes will be treated as equity instruments;

(f) Beginning twelve months after the initial issuance of a series of index-linked exchangeable notes, the

Corporation will consider the suspension of trading in or removal from listing of that series of index-linked exchangeable notes under any of the following circumstances:

(i) If the series has fewer than 50,000 notes issued and outstanding;

(ii) If the market value of all index-linked exchangeable notes of that series issued and outstanding is less than \$1,000,000; or

(iii) If such other event shall occur or such other condition exists which in the opinion of the Corporation makes further dealings on the Corporation inadvisable.

\* \* \* \* \*

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The purpose of this proposed rule change is to enact listing standards for index-linked exchangeable notes. Under PCXE Rule 5.2(j)(1), the Exchange may approve for listing and trading, securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures, or warrants. The Exchange now proposes to list for trading, whether by listing or pursuant to UTPs, under new PCXE Rule 5.2(j)(4), index-linked exchangeable notes that are intended to allow investors to hold a single, exchange-listed note exchangeable for the cash value of the underlying stocks ("Underlying Stocks") of an index ("Underlying Index," "Index," "Underlying Indices," or "Indices"), and thereby acquire—in a single security and single trade—exposure to a specific index of equity securities.

Each Underlying Index must be:

- An index that has been created by a third party and approved for the trading of options or other derivative securities (each, a "Third-Party Index") by the Commission under Section

19(b)(2) of the Act,<sup>5</sup> and the rules thereunder, or by the Exchange under rules adopted pursuant to Rule 19b-4(e) of the Act;<sup>6</sup> or

- An index which the issuer has created and for which an Exchange will have obtained approval from the Commission pursuant to Section 19(b)(2) of the Act<sup>7</sup> and the rules thereunder, or from the Exchange under rules adopted pursuant to Rule 19b-4(e) of the Act<sup>8</sup> (each, an "Issuer Index").

In addition, each Underlying Stock will meet the following criteria:

- Each issuer of an Underlying Stock shall be an Exchange Act reporting company that is listed on a national securities exchange or is traded through the facilities of a national securities association and is subject to last sale reporting;

- Each Underlying Stock of a Third-Party Index will meet the standards set forth in the Commission's Section 19(b)(2) of the Act order approving the index, or the Exchange rules under which it was approved, as the case may be; and

- Each Underlying Stock of an Issuer Index will meet (with minor modifications set forth below) the criteria in PCX Rule 7.3(b)-(c); or (with minor modifications set forth below) the criteria for underlying securities in PCXE Rule 5.2(j)(1) and the index concentration limits in PCX Rule 7.3(b)(6) and PCX Rule 7.3(b)(12) in so far as it relates to PCX Rule 7.3(b)(6).

### Description of Index-Linked Exchangeable Notes

Index-linked exchangeable notes are exchangeable debt securities that are exchangeable at the option of the holder (subject to the requirement that the holder in most circumstances exchange a specified minimum amount of notes), on call by the issuer, or at maturity for a cash amount (the Cash Value Amount<sup>9</sup>) based on the reported market prices of the Underlying Stocks of an Underlying Index. Each index-linked exchangeable note is intended to provide investors with an instrument that closely tracks the Underlying Index. Notwithstanding that the notes are linked to an index, they will trade as a single security. The linkage is on a 1-to-1 basis so that a holder of notes is fully exposed to depreciation and appreciation of the Underlying Stocks. The Exchange will disseminate, on a real time basis for each series of index-linked exchangeable notes, an estimate,

<sup>5</sup> 15 U.S.C. 78s(b)(2).

<sup>6</sup> 17 CFR 240.19b-4(e).

<sup>7</sup> 15 U.S.C. 78s(b)(2).

<sup>8</sup> 17 CFR 240.19b-4(e).

updated every 15 seconds, of the value of a note of that series.<sup>9</sup> This will be based, for example, upon current information regarding the value of the Underlying Index. The value for any newly created index shall be disseminated by the Exchange on a real-time basis and updated every 15 seconds.

Index-linked exchangeable notes are expected to trade at a lower cost than the cost of trading each of the Underlying Stocks separately (because of reduced commission and custody costs) and also give investors the ability to maintain index exposure without any management or administrative fees and ongoing expenses. The initial offering price for an index-linked exchangeable note will be established on the date the note is priced for sale to the public. In addition, index-linked exchangeable notes will not include embedded options or leverage. Because index-linked exchangeable notes are debt securities, holders will not be recognized by issuers of the Underlying Stocks as the owner of those stocks and will have no rights as a stockholder with respect to those stocks.

Additional issuances of a series of index-linked exchangeable notes may be made subsequent to the initial issuance of that series (and prior to the maturity of that series) for purposes of providing market liquidity. Each series of index-linked exchangeable notes may or may not provide for quarterly interest coupons based on dividends or other cash distributions paid on the Underlying Stocks during a prescribed period and an annual supplemental coupon based on the value of the Underlying Index during a prescribed period. Index-linked exchangeable notes will generally be acquired, held, or transferred only in round-lot amounts (or round-lot multiples) of 100 notes, although odd-lot orders are permissible.

Beginning on a specified date and up to a specified date prior to the maturity date or any call date, the holder of an index-linked exchangeable note may exchange some or all of its index-linked exchangeable notes for their Cash Value Amount, plus any accrued but unpaid quarterly interest coupons. Holders will generally be required to exchange a certain specified minimum amount of index-linked exchangeable notes, although this minimum requirement may be waived following a downgrade in the issuer's credit rating below

specified thresholds or the occurrence of other specified events.

Index-linked exchangeable notes may be subject to call by the issuer on specified dates or during specified periods, upon at least 30, but not more than 60, days notice to holders. The call price would be equal to the Cash Value Amount, plus any accrued but unpaid quarterly interest coupons.

At maturity, the holder of an index-linked exchangeable note will receive cash amount equal to the Cash Value Amount, plus any accumulated but unpaid quarterly and annual supplemental interest coupons. Although a specific maturity date will not be established until the time of the initial offering of a series of index-linked exchangeable notes, the index-linked exchangeable notes will provide for maturity within a period of not less than one nor more than thirty years from the date of issue.

In connection with the initial listing of each series of index-linked exchangeable notes, the Exchange has established that a minimum of 150,000 notes held by at least 400 holders be required to be outstanding when trading begins. Beginning twelve months after the initial issuance of a series of index-linked exchangeable notes, the Exchange will consider the suspension of trading in or removal from listing of that series of index-linked exchangeable notes under any of the following circumstances: (i) If the series has fewer than 50,000 notes issued and outstanding; (ii) if the market value of all index-linked exchangeable notes of that series issued and outstanding is less than \$1 million; or (iii) if such other event shall occur or such other condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

#### *Eligibility Standards for Issuers*

The following standards shall apply to each issuer of index-linked exchangeable notes:

(A) **Assets/Equity**—The issuer shall have assets in excess of \$100 million and stockholders' equity of at least \$10 million. In the case of an issuer that is unable to satisfy the earnings criteria set forth in PCXE Rule 5.2(j)(1)(C), the Exchange generally will require the issuer to have the following: (i) Assets in excess of \$200 million and stockholders' equity of at least \$10 million; or (ii) assets in excess of \$100 million and stockholders' equity of at least \$20 million.

(B) **Distribution**—Minimum public distribution of 150,000 notes with a minimum of 400 public noteholders, except, if traded in thousand dollar

denominations, then no minimum number of holders.

(C) **Principal Amount/Aggregate Market Value**—Not less than \$4 million.

(D) **Tangible Net Worth**—The issuer will be expected to have a minimum tangible net worth in excess of \$250 million, and to otherwise substantially exceed the earnings requirements set forth in PCXE Rule 5.2(j)(1)(C). In the alternative, the issuer will be expected: (i) to have a minimum tangible net worth of \$150 million, and to otherwise substantially exceed the earnings requirements set forth in PCXE Rule 5.2(j)(1)(C); and (ii) not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth.

#### *Description of the Underlying Indices*

Underlying Indices will either be: (i) Indices that have been created by a third party and have been reviewed and approved for the trading of options or other derivative securities (each, a "Third-Party Index") either by the Commission under Section 19(b)(2) of the Act,<sup>10</sup> and the rules thereunder, or by the Exchange under rules adopted pursuant to Rule 19b-4(e)<sup>11</sup>; or (ii) indices which the issuer has created and for which an Exchange will have obtained approval either from the Commission pursuant to section 19(b)(2) of the Act<sup>12</sup> and rules thereunder or from the Exchange under rules adopted pursuant to Rule 19b-4(e)<sup>13</sup> (each, an "Issuer Index").

All changes to an Underlying Index, including the deletion and addition of Underlying Stocks, index rebalancing, and changes to the calculation of the index, will be made in accordance with the Commission's section 19(b)(2) of the Act<sup>14</sup> order or the Exchange rules under which that index was approved, as the case may be.

The Underlying Index will be calculated based on either the market capitalization, modified market capitalization, price, equal-dollar, or modified equal-dollar weighting methodology. If the issuer or a broker-dealer is responsible for maintaining (or has a role in maintaining) the Underlying Index, it would be required

<sup>9</sup> In cases where the issuer of the index-linked exchangeable note disseminates the estimate of the note through another exchange, the PCX will ensure that such value is being disseminated by such other exchange on a real-time basis and updated every 15 seconds.

<sup>10</sup> 15 U.S.C. 78s(b).

<sup>11</sup> 17 CFR 240.19b-4(e).

<sup>12</sup> 15 U.S.C. 78s(b)(2).

<sup>13</sup> 17 CFR 240.19b-4(e).

<sup>14</sup> 15 U.S.C. 78s(b)(2).



to erect and maintain a "Fire Wall," in a form satisfactory to the Exchange, to prevent the flow of information regarding the Underlying Index from the index production personnel to the sales and trading personnel, and the index must be calculated by a third party who is not a broker-dealer.<sup>15</sup>

#### *Eligibility Standards for Underlying Stocks*

The following standards shall apply to each Underlying Stock:

(A) General Criteria—Each issuer of an Underlying Stock shall be an Exchange Act reporting company that is listed on a national securities exchange or is traded through the facilities of a national securities association and is subject to last sale reporting.

(B) Criteria Applicable to Underlying Stocks of Third-Party Indices—In addition to meeting the "General Criteria" set forth under clause (A) above, each Underlying Stock of a Third-Party Index shall also meet the criteria specified for Underlying Stocks of that index in the Commission's Section 19(b)(2) order approving that index or the Exchange rules under which it was approved.

(C) Criteria Applicable to Underlying Stocks of Issuer Indices—In addition to meeting the "General Criteria" set forth under clause (A) above, each Underlying Stock of an Issuer Index shall also meet the criteria specified in (1) or (2) below:

(1) Each Underlying Stock of an Issuer Index shall meet each of the following criteria:

(a) A minimum market value of at least \$75 million, except that for each of the lowest weighted Underlying Stocks in the index that in aggregate account for no more than 10% of the weight of the index, the market value can be at least \$50 million;

(b) Trading volume in each of the last six months of not less than 1 million shares, except that for each of the lowest weighted Underlying Stocks in the index that in the aggregate account for no more than 10% of the weight of the index, the trading volume shall be at least 500,000 shares in each of the last six months;

(c) In a capitalization-weighted index, the lesser of the five highest weighted Underlying Stocks in the index or the highest weighted Underlying Stocks in the index that in the aggregate represent at least 30% of the total number of Underlying Stocks in the index, each have an average monthly trading volume of at least 2 million shares over the previous six months;

(d) 90% of the index's numerical index value and at least 80% of the total number of Underlying Stocks will meet the then current criteria for standardized option trading set forth in PCX Rule 3.6;

(e) American Depositary Receipts ("ADRs") that are not subject to comprehensive surveillance agreements do not in the aggregate represent more than 20% of the weight of the index;

(f) All component stocks or ADRs will either be listed on the Amex or the New York Stock Exchange, Inc. ("NYSE") or traded through the facilities of the National Association of Securities Dealers Automated Quotation System ("Nasdaq") and reported National Market System securities; and

(g) No Underlying Stock will represent more than 25% of the weight of the index, and the five highest weighted Underlying Stocks in the index will not in the aggregate account for more than 50% of the weight of the index (60% for an index consisting of fewer than 25 Underlying Stocks).

The standards set forth in clauses (a) to (g) above must be continuously maintained, except that:

(a) The criteria that no single Underlying Stock represent more than 25% of the weight of the index and the five highest weighted Underlying Stocks in the index cannot represent more than 50% (or 60% of indices with less than 25 Underlying Stocks) of the weight of the index, need only be satisfied for capitalization-weighted and price-weighted indices as of the first day of January and July in each year;

(b) The total number of Underlying Stocks in the index may not increase or decrease by more than 33 1/3% from the number of Underlying Stocks in the index at the time of its initial listing, and in no event may be fewer than nine Underlying Stocks;

(c) The trading volume of each Underlying Stock in the index must be at least 500,000 shares for each of the last six months, except that for each of the lowest weighted Underlying Stocks in the index that in the aggregate account for no more than 10% of the weight of the index trading volume must be at least 400,000 shares for each of the last six months; and

(d) In a capitalization-weighted index, the lesser of the five highest weighted Underlying Stocks in the index or the highest weighted Underlying Stocks in the index that in the aggregate represent at least 30% of the total number of stocks in the index have had an average monthly trading volume of at least 1 million shares over the previous six months.

(2) In the alternative, each Underlying Stock of an Issuer Index shall meet each of the following criteria:

(a)(i) A minimum market capitalization of \$3 billion and during the 12 months preceding listing is shown to have traded at least 2.5 million shares; (ii) a minimum market capitalization of \$500 million and during the 12 months preceding listing is shown to have traded at least 10 million shares; or (iii) a minimum market capitalization of \$500 million and during the 12 months preceding listing is shown to have traded at least 15 million shares;

(b) No Underlying Stock will represent more than 25% of the weight of the index, and the five highest weighted component securities in the index do not in the aggregate account for more than 50% of the weight of the index (60% for an index consisting of fewer than 25 component securities), except that for capitalization-weighted and price-weighted indices these standards need be satisfied only as of the first day of January and July in each year;

(c) If any Underlying Stock is the stock of a non-U.S. company that is traded in the U.S. market as sponsored American Depositary Shares ("ADS") or ADRs then for each such security the Exchange shall either:

(i) Have in place a comprehensive surveillance sharing agreement with the primary exchange on which each security underlying the ADS or ADR is traded;

(ii) The combined trading volume of each non-U.S. security and other related non-U.S. securities occurring in the U.S. market or in markets with which the Exchange has in place a comprehensive surveillance sharing agreement represents (on a share equivalent basis for any ADSs) at least 50% of the combined worldwide trading volume in each non-U.S. security, other related non-U.S. securities, and other classes of common stock related to each non-U.S. security over the six-month period preceding the date of listing of the related index-linked exchangeable note; or

(iii) (A) the combined trading volume of each non-U.S. security and other related non-U.S. securities occurring in the U.S. market represents (on a share equivalent basis) at least 20% of the combined world-wide trading volume in each non-U.S. security and in other related non-U.S. securities over the six-month period preceding the date of listing of the related index-linked exchangeable note; (B) the average daily trading volume for each non-U.S. security in the U.S. markets over the six

<sup>15</sup> See PCX Rule 7.3(b)(12).



months preceding the date of listing of the related index-linked exchangeable note is 100,000 or more shares; and (C) the trading volume is at least 60,000 shares per day in the U.S. markets on a majority of the trading days for the six months preceding the date of listing of the related index-linked exchangeable note.

(d) An Underlying Stock may not exceed 5% of the total outstanding common shares of the issuer of that Underlying Stock, however, if any Underlying Stock is a non-U.S. security represented by ADSs, common shares, or otherwise, then for each such index-linked exchangeable note the instrument may not exceed:

(i) 2% of the total shares outstanding worldwide provided at least 20% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six month period preceding the date of listing occurs in the U.S. market;

(ii) 3% of the total worldwide shares outstanding provided at least 50% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six-month period preceding the date of listing occurs in the U.S. market; and

(iii) 5% of the total shares outstanding worldwide provided at least 70% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six-month period preceding the date of listing occurs in the U.S. market.

(e) If any non-U.S. security and related securities have less than 20% of the worldwide trading volume occurring in the U.S. market during the six-month period preceding the date of listing, then the instrument may not be linked to that non-U.S. security.

If an issuer proposes to list an index-linked exchangeable note that relates to more than the allowable percentages set forth above, the Exchange, with the concurrence of the staff of the Market Regulation Division ("Division"), will evaluate the maximum percentage of index-linked exchangeable note that may be issued on a case-by-case basis.

If an Underlying Stock to which an index-linked exchangeable note is to be linked is the stock of a non-U.S. company which is traded in the U.S. market as a sponsored ADS, ordinary shares or otherwise, then the minimum number of holders of such Underlying Stock shall be 2,000.

#### *Exchange Rules Applicable to Index-Linked Exchangeable Notes*

Index-linked exchangeable notes will be treated as equity instruments. Index-linked exchangeable notes will be

subject to all Exchange rules governing the trading of equity securities,<sup>16</sup> including provisions of PCXE Rule 7.56 (trade-through rule), which prohibits ETP Holders and Sponsored Participants (hereinafter "Users") from initiating trade-throughs for ITS securities, as well as Exchange rules governing priority, parity and precedence of orders, market volatility related trading halt provisions, and responsibilities of Market Makers.<sup>17</sup> Exchange equity margin rules and the three trading sessions<sup>18</sup> of the Exchange will apply to trading in index-linked exchangeable notes.

Prior to the commencement of trading in index-linked exchangeable notes, the Exchange will distribute a circular to its Users highlighting the characteristics of index-linked exchangeable notes, including, but not limited to: that the notes are subject to call by the issuer; that Users must adhere to the procedures established under PCXE Rules 9.2(a) and 9.2(b); that the Exchange may consider factors such as those set forth in PCX Rule 7.10(b) in exercising its discretion to halt or suspend trading; and that trading will be halted in the event that market volatility parameters set forth in PCXE Rule 7.12 have been reached.

In addition, pursuant to Rule 10A-3 of the Act<sup>19</sup> and section 3 of the Sarbanes-Oxley Act of 2002,<sup>20</sup> the Exchange will prohibit the initial or continued listing of any security of an issuer that is not in compliance with the requirements set forth therein.

Lastly, the Exchange's surveillance procedures for index-linked exchangeable notes will be similar to the procedures used for equity-linked term notes, index portfolio receipts trust issued receipts, and other equity non-option products traded on the Exchange and will incorporate and rely upon existing Exchange surveillance systems. The Exchange will closely monitor activity in index-linked exchangeable notes to identify and deter any potential improper trading activity in the index-linked exchangeable notes.

<sup>16</sup> See PCXE Rule 7 *et seq.* for a discussion of the rules governing equity trading.

<sup>17</sup> However, the Exchange represents that if index-linked exchangeable notes are traded only in round lots (or round-lot multiples), the Exchange rules relating to odd-lot executions will not apply.

<sup>18</sup> The Exchange operates three trading sessions each day it is open. The three trading sessions are (1) the Opening Session; (2) the Core Trading Session; and (3) the Late Trading Session. See PCXE Rule 7.34(a).

<sup>19</sup> 17 CFR 240.10A-3.

<sup>20</sup> See Section 3 of Pub. L. 107-204, 116 Stat. 745 (2002).

## 2. Statutory Basis

The proposed rule change, as amended, is consistent with section 6(b) of the Act,<sup>21</sup> in general, and furthers the objectives of section 6(b)(5),<sup>22</sup> in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

### *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.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

Written comments on the proposed rule change were neither solicited nor received.

## III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549-0609. Comments may also be submitted electronically at the following e-mail address: [rule-comments@sec.gov](mailto:rule-comments@sec.gov). All comment letters should refer to File No. SR-PCX-2004-01. The 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, comments should be sent in hardcopy or by e-mail but not by both methods. 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 will also be available for inspection and copying at the principal office of the Exchange. All

<sup>21</sup> 15 U.S.C. 78f(b).

<sup>22</sup> 15 U.S.C. 78f(b)(5).

submissions should refer to the File No. SR-PCX-2004-01 and should be submitted by May 4, 2004.

#### IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of section 6(b)(5) of the Act<sup>23</sup> and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission believes the Exchange's proposal to list to trade, whether by listing or unlisted trading privileges,<sup>24</sup> index-linked exchangeable notes will provide an instrument for investors to achieve desired investment objectives through the purchase of debt securities—index-linked exchangeable notes—exchangeable for the cash value of the Underlying Stocks of an Underlying Index.<sup>25</sup> Accordingly, the Commission finds that the Exchange's proposal will facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national system, and, in general, protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.<sup>26</sup>

<sup>23</sup> 15 U.S.C. 78f(b)(5). In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>24</sup> The Commission notes that, pursuant to Rule 12f-5 under the Act, prior to trading a particular class or type of security pursuant to unlisted trading privileges, the Exchange must have listing standards comparable to those of the primary market on which the security is listed. 17 CFR 240.12f-5. The Commission finds that adequate rules and procedures exist to govern the trading of index-linked exchangeable notes on the Exchange, pursuant to unlisted trading privileges.

<sup>25</sup> Index-linked exchangeable notes will generally be acquired, held or transferred only in round-lot amounts (or round-lot multiples) of 100 notes although odd-lot orders are permissible. Although these notes will have features similar to other index related products, they differ from other products with respect to their exchangeability feature. The Commission notes that the holder of the note may exchange the notes at his or her option, on call by the issuer, or at maturity for the cash value based upon the reported market prices of the Underlying Stocks of an Underlying Index. Holders, however, will generally be required to exchange a certain specified minimum amount of index-linked exchangeable notes, although this minimum requirement may be waived following a downgrade in the issuer's credit rating below specified thresholds or the occurrence of other specified events.

<sup>26</sup> Pursuant to Section 6(b)(5) of the Act, the Commission must predicate approval of exchange trading for new products upon a finding that the introduction of the product is in the public interest. Such a finding would be difficult with respect to a product that served no investment, hedging or other economic functions, because any benefits that might be derived by market participants would likely be outweighed by the potential for manipulation, diminished public confidence in the

Furthermore, the Commission has approved the trading of identical products on the Amex, Phlx, and CBOE.<sup>27</sup>

The Commission notes that the initial offering price of an index-linked exchangeable note will be determined on the date that the note is priced for sale to the public. The Commission believes that index-linked exchangeable notes will be attractive to investors because they are expected to trade at lower cost than the cost of trading each of the Underlying Stocks separately. The Commission also notes that the Exchange will disseminate an estimate of the value of a note for each series of index-linked exchangeable notes, on a real time basis, every 15 seconds. The value of any Underlying Index will also be publicly available to investors on a real time basis. The Exchange, for example, has stated that to the extent there is an existing Index, it will ensure its value is publicly available, and if it is a new Index, that the Exchange would publish the value itself on a real time basis. This will ensure investors receive up-to-date information on the value of the note and the Underlying Index. Accordingly, index-linked exchangeable notes should allow investors to: (i) Respond quickly to market changes through intra-day trading opportunities; (ii) engage in hedging strategies not currently available to retail investors; and (iii) reduce transaction costs for trading a group or index of securities.

Although the value of index-linked exchangeable notes will be based on the value of the Underlying Stocks in an Underlying Index, index-linked exchangeable notes are not leveraged instruments.<sup>28</sup> In essence, index-linked exchangeable notes are debt securities based on the Underlying Stocks of an Underlying Index; the holders of such notes will not be considered owners of the Underlying Stocks and will not have the rights of a stockholder in those stocks. However, index-linked

integrity of the markets, and other valid regulatory concerns.

<sup>27</sup> See Securities Exchange Act Release Nos. 46370 (August 16, 2002), 67 FR 54509 (August 22, 2002) (Order granting accelerated approval to SR-CBOE-2002-29); 45082 (November 19, 2001), 66 FR 59282 (November 27, 2001) (Order granting accelerated approval to SR-Phlx-2001-92); and 44621 (July 30, 2001), 66 FR 41064 (August 6, 2001) (Order granting accelerated approval to SR-Amex-2001-29).

<sup>28</sup> In contrast, proposals to list exchange-traded derivative products that contain a built-in leverage feature or component raise additional regulatory issues, including heightened concerns regarding manipulation, market impact, and customer suitability. See, e.g., Securities Exchange Act Release No. 36165 (August 29, 1995), 65 FR 46653 (September 7, 1995) (relating to the establishment of uniform listing and trading guidelines for stock index, currency, and currency index warrants).

exchangeable notes will be regulated as equity instruments and will be subject to all of the Exchange's rules governing the trading of equity securities. Nevertheless, the Commission believes that the unique nature of index-linked exchangeable notes, related to, among other things, the exchangeability feature,<sup>29</sup> raise certain product design, disclosure, trading, and other issues that must be addressed.

#### A. Index-Linked Exchangeable Notes Generally

The Commission believes that the proposed index-linked exchangeable notes are reasonably designed to provide investors with an investment vehicle that substantially reflects the value of the Underlying Stocks of an Underlying Index. Index-linked exchangeable notes will be treated as equity instruments subject to Exchange rules governing the trading of equity securities. As such, the Commission finds that adequate rules and procedures exist to govern the trading of index-linked exchangeable notes. In this regard, the Commission notes that the Exchange will impose specific criteria in the selection of issuers, the Underlying Stocks, and the Underlying Indices.

As noted above, the Exchange rules for index-linked exchangeable notes contain specific criteria for issuers. For example, the issuer must have a minimum tangible net worth in excess of \$250 million and substantially exceed the earnings requirements in PCXE Rule 5.2(j)(1)(C); or a minimum tangible value of \$150 million, substantially exceed the earnings requirements in PCXE Rule 5.2(j)(1)(C), and not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth. These criteria are in part intended to ensure that the issuer has enough assets to meet its obligations under the terms of the note and should help to reduce systematic risk.

The minimum issue requirements for the issue of index-linked exchangeable notes should also serve to establish a minimum level of liquidity for the product. These issues requirements include: (i) A minimum public distribution of 150,000 notes with a minimum of 400 public noteholders (no minimum number of holders if traded in

<sup>29</sup> See *supra* note 25.

one thousand dollar denominations), and (ii) market value of \$4 million.

The Exchange rules applicable to the index-linked exchangeable notes also contain minimum requirements for the Indices the note can be linked to and the underlying components of those Indices. For example, because all components of an Underlying Index must be a U.S. reporting company, there will be information of available Index component stocks. Further, the Exchange's proposed rules for the Indices underlying index-linked exchangeable notes are linked to other approved criteria for index related products. Accordingly, any Underlying Index would have to follow the criteria adopted by the Commission for that Index, including the criteria for component stocks already in Exchange's rules. These requirements will generally contain, among other things, minimum market capitalization, trading volume, and concentration requirements that are designed to reduce manipulation concerns and ensure a minimum level of liquidity for component securities.

In summary, the rules for selecting components of Indices are intended to make the Underlying Stocks and the Underlying Indices representative of the market they are intended to reflect as well as to reduce manipulation concerns by setting forth minimum liquidity standards for Underlying Stocks. Accordingly, the Commission believes that these criteria should serve to ensure that the Underlying Stocks of Underlying Indices are well capitalized and actively traded.

#### B. Disclosure

The Commission believes that the Exchange's proposal should ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading index-linked exchangeable notes. The Commission notes that upon the initial listing of any class of index-linked exchangeable notes, the Exchange will issue a circular to its Users explaining the unique characteristics and risks of this type of security.<sup>30</sup> The circular will also note Exchange User's responsibilities under PCXE Rules 9.2(a) and 9.2(b) regarding transactions in index-linked exchangeable notes. PCXE Rule 9.2(a) generally requires that Users use due diligence to learn the essential facts relative to every customer, every order or account accepted.<sup>31</sup> Exchange Rule

9.2 generally requires that members be personally informed of the essential facts of each customer prior to giving the required written approval for the opening of that customer account.<sup>32</sup>

#### C. Trading of Index-Linked Exchangeable Notes

The Commission finds that adequate rules and procedures exist to govern the trading of index-linked exchangeable notes. Index-linked exchangeable notes will be treated as equity instruments subject to all Exchange rules governing the trading of equity securities. These rules include: rules governing priority, parity and precedence of orders, market volatility related trading halt provisions pursuant to PCXE Rule 7.12, Responsibilities of Specialists, Users dealing for their own accounts, specialists, odd-lot brokers, and registered traders, and handling of orders and reports. In addition, the Exchange's equity margin rules and the three trading sessions<sup>33</sup> of the Exchange will apply to transactions in index-linked exchangeable notes.

The Commission is satisfied with the Exchange's development of specific listing and delisting criteria for index-linked exchangeable notes. For example, in connection with the initial listing of each series of index-linked exchangeable notes, the Exchange has established that a minimum of 150,000 notes held by at least 400 holders be required to be outstanding when trading begins. These criteria should help ensure that a minimum level of liquidity will exist in each series of index-linked exchangeable notes to allow for maintenance of fair and orderly markets. The delisting criteria also allows the Exchange to consider suspension of trading and the delisting of a series of index-linked exchangeable notes if an event were to occur that made further dealings in such series inadvisable. This will give the Exchange flexibility to delist index-linked exchangeable notes if circumstances warrant such action. Further, Exchange rules have specific criteria that allow them to delist if there is fewer than 50,000 notes issued and outstanding, or if the market value of the index-exchangeable notes is less than \$100,000. This should ensure a minimum level of liquidity for these products. Accordingly, the Commission believes that the rules governing the trading of index-linked exchangeable notes, consistent with section 6(b)(5) of

the Act,<sup>34</sup> provide adequate safeguards to protect investors and the public interest. While the index-linked exchangeable notes have certain call and redemption features that make them different from other products, the Exchange has addressed any concerns by adopting the existing criteria used in other index related products. In addition, the Exchange will highlight these different features in the circular to members.

#### D. Dissemination of Information

The Commission believes that the value of index-linked exchangeable notes that the Exchange proposes to disseminate will provide investors with timely and useful information concerning the value of the index-linked exchangeable notes based on current information regarding the value of the Underlying Index. The value of the Underlying Index will also be publicly disseminated. This information will be disseminated and updated every 15 seconds during regular New York trading hours of 9:30 a.m. to 4 p.m.

#### E. Surveillance

The Commission believes that the surveillance procedures developed by the Exchange for index-linked exchangeable notes should be adequate to address concerns associated with the listing and trading of index-linked such notes. In this regard, the Exchange has developed procedures to monitor activity in index-linked exchangeable notes to identify and deter improper trading activity.

The Commission also notes that concerns are raised when a broker-dealer is involved in the development and maintenance of an Underlying Index upon which a product, such as index-linked exchangeable notes is based, in that case, the broker-dealer and its affiliate should have procedures designed specifically to address the improper sharing of information. The Commission notes that the Exchange requires the implementation of procedures that are satisfactory to the Exchange to prevent the misuse of material, non-public information regarding changes to Underlying Stocks of an Underlying Index in a particular series of index-linked exchangeable notes. In addition, the Commission notes that if a broker-dealer is involved in developing or maintaining an Underlying Index, the Index must be calculated by a third party who is not a broker-dealer.<sup>35</sup> The Commission

<sup>32</sup> *Id.* See also PCXE Rule 9.2(b).

<sup>33</sup> The Exchange operates three trading sessions each day it is open. The three trading sessions are (1) the Opening Session; (2) the Core Trading Session; and (3) the Late Trading Session. See PCXE Rule 7.34(a).

<sup>30</sup> The Exchange represents that it will highlight the exchangeability feature of index-linked exchangeable notes in its circular to Users.

<sup>31</sup> See PCXE Rule 9.2(a).

<sup>34</sup> 15 U.S.C. 78(f)(6)(5).

<sup>35</sup> See PCX Rule 7.3(b)(12).

believes that such information barrier procedures will address the unauthorized transfer and misuse of material, non-public information.

Lastly, the Exchange has represented pursuant to Rule 10A-3 of the Act<sup>36</sup> and Section 3 of the Sarbanes-Oxley Act of 2002,<sup>37</sup> that it will prohibit the initial or continued listing of any security of an issuer that is not in compliance with the requirements set forth therein.

#### F. Scope of the Commission's Order

The Commission is approving the Exchange's proposed listing and trading standards for the index-linked exchangeable notes as discussed herein. Index-linked exchangeable notes addressed in this order can be listed pursuant to Rule 19b-4(e)<sup>38</sup> if they meet the standards discussed above in the Exchange rules. The Commission notes that with respect to any future rules adopted by the Exchange pursuant to Rule 19b-4(e),<sup>39</sup> the Exchange has indicated that in its Section 19(b)(2) filings to adopt such new rules, it will state and discuss whether or not it proposes to apply the new rule standards to index-linked exchangeable notes.

#### G. Accelerated Approval

The Commission finds good cause for approving the proposal, as amended, prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The proposal establishes listing and trading standards for a new product, index-linked exchangeable notes. Granting accelerated approval will allow the Exchange to immediately begin listing and trading series of index-linked exchangeable notes under these new standards. While the structure of the product is different from those previously reviewed by the Commission, the Exchange proposes to apply existing criteria used for other index related products. In addition, the Commission has approved the trading of identical products on the Amex, Phlx, and CBOE.<sup>40</sup> Accordingly, the Commission believes that there is good cause, consistent with Sections 6(b)(5)

and 19(b) of the Act,<sup>41</sup> to approve the proposed rule change, as amended, on an accelerated basis.

#### IV. Conclusion

*It is therefore ordered*, pursuant to section 19(b)(2) of the Act,<sup>42</sup> that the proposed rule change, as amended, (SR-PCX-2004-01) is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>43</sup>

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04-8265 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-49523; File No. SR-Phlx-2003-71]

#### Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Participation Guarantees for Floor Brokers Representing Crossing and Facilitation Orders in Index Options

April 2, 2004.

On October 20, 2003, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to amend Phlx Rule 1064, Crossing, Facilitation and Solicited Orders, with respect to index options. On January 9, 2004, Phlx filed Amendment No. 1 to the proposed rule change.<sup>3</sup> The proposed rule change, as amended, was published for comment in the **Federal Register** on February 18, 2004.<sup>4</sup> The Commission received no comments on the proposal.

Phlx Rule 1064 sets forth, among other things, the procedures by which a floor broker holding an option order ("original order") may cross it with another order or orders he or she is holding, or, in the case of a public customer order, with a contra side order

provided by the originating firm from its own proprietary account ("facilitation order"). Under certain conditions, Rule 1064 provides "participation guarantees" in such crossing or facilitation transactions, entitling the floor broker to cross a certain percentage of the original order with the other order or orders ahead of members of the trading crowd.<sup>5</sup> These participation guarantees currently apply to transactions in equity options only. The Exchange proposes to amend Rule 1064 to provide a participation guarantee for trading in index options, and to set the guaranteed percentage in such options at 20%.<sup>6</sup>

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,<sup>7</sup> and, in particular, the requirements of section 6(b)(5) of the Act.<sup>8</sup> The Exchange believes that establishing a participation guarantee of 20% for crossing and facilitation transactions in index options would make the Exchange more competitive by providing an incentive to index options order flow providers to bring order flow to the Exchange. The Commission believes that participation guarantees are reasonable and within the business judgment of the Exchange, as long as they do not restrict competition and do not harm investors.<sup>9</sup> The Commission has found, with respect to participation guarantees in other contexts, that guarantees of as much as 40% of an order in options trading are not inconsistent with statutory standards of

<sup>5</sup> The percentage of the order that a floor broker is entitled to cross after all public customer orders have been satisfied is: (1) 20% of the remaining contracts in the order if the order is traded at the best bid or offer given by the crowd in response to the floor broker's initial request for a market; and (2) 40% of the remaining contracts in the order if the order is traded between the best bid or offer given by the crowd in response to the floor broker's initial request for a market. These guarantees apply when the original order is of an eligible size as determined by the Phlx Options Committee on an option-by-option basis, but in no case less than 500 contracts. See Phlx Rule 1064, Commentary .02(ii)-(iii).

<sup>6</sup> The 20% guarantee would apply whether the order is traded at or between the best bid or offer given by the crowd in response to the floor broker's initial request for a market. All other provisions in Rule 1064 concerning participation guarantees in equity options would apply to index options in the same manner as they apply to equity options. See Notice.

<sup>7</sup> In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

<sup>8</sup> 15 U.S.C. 78(b)(5).

<sup>9</sup> See, e.g., Securities Exchange Act Release No. 47729 (April 24, 2003), 68 FR 23344 (May 1, 2003).

<sup>36</sup> 17 CFR 240.10A-3.

<sup>37</sup> See Section 3 of Pub. L. 107-204, 116 Stat. 745 (2002).

<sup>38</sup> 17 CFR 240.19b-4(e).

<sup>39</sup> *Id.*

<sup>40</sup> See Securities Exchange Act Release Nos. 46370 (August 16, 2002), 67 FR 54509 (August 22, 2002) (Order granting accelerated approval to SR-CBOE-2002-29); 45082 (November 19, 2001), 66 FR 59282 (November 27, 2001) (Order granting accelerated approval to SR-Phlx-2001-92); and 44621 (July 30, 2001), 66 FR 41064 (August 6, 2001) (Order granting accelerated approval to SR-Amex-2001-29).

<sup>41</sup> 15 U.S.C. 78f(b)(5) and 78s(b).

<sup>42</sup> 15 U.S.C. 78s(b)(2).

<sup>43</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See letter from Richard S. Rudolph, Director and Counsel, Phlx, to Ira Brandriss, Special Counsel, Division of Market Regulation, Commission, dated January 8, 2004.

<sup>4</sup> See Securities Exchange Act Release No. 49215 (February 9, 2004), 69 FR 7662 ("Notice").



competition and free and open markets.<sup>10</sup>

The Commission notes that, pursuant to Phlx Rule 1064, Commentary .02(vi), if a crossing or facilitation trade takes place in a situation in which the specialist is entitled to an Enhanced Specialist Participation (specialist guarantee), the percentage received by the specialist, combined with the percentage crossed by the floor broker, may be no more than 40% of the original order (after public customer orders have been satisfied).

It is therefore ordered, pursuant to section 19(b)(2) of the Act,<sup>11</sup> that the proposed rule change (File No. SR-Phlx-2003-71) be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>12</sup>

Margaret H. McFarland,  
Deputy Secretary.

[FR Doc. 04-8264 Filed 4-12-04; 8:45 am]

BILLING CODE 8010-01-P

## SMALL BUSINESS ADMINISTRATION

### Data Collection Available for Public Comments and Recommendations

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

**DATES:** Submit comments on or before June 14, 2004.

**ADDRESSES:** Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to Veronica Johnson, Program Analyst, Office of Business Development, Small Business Administration, 409 3rd Street, SW., Suite 8800, Washington, DC 20416.

**FOR FURTHER INFORMATION CONTACT:** Veronica Johnson, Program Analyst, 202-619-0472 or Curtis B. Rich, Management Analyst, 202-205-7030.

#### SUPPLEMENTARY INFORMATION:

<sup>10</sup> See, e.g., Securities Exchange Act Release Nos. 42455 (February 24, 2000), 65 FR 11388 (March 2, 2000) at 11398; and 43100 (July 31, 2000), 65 FR 48778 (August 9, 2000) at notes 96-99 and accompanying text.

<sup>11</sup> 15 U.S.C. 78s(b)(2).

<sup>12</sup> 17 CFR 200.30-3(a)(12).

**Title:** "BusinessLINC Program."  
**Description of Respondents:** Small Business Owners.

**Form No:** N/A.

**Annual Responses:** 81.

**Annual Burden:** 4,200.

**ADDRESSES:** Send all comments regarding whether this information collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collection, to Radwan Saade, Economist, Office of Advocacy, Small Business Administration, 409 3rd Street, SW., Suite 7800, Washington, DC 20416.

**FOR FURTHER INFORMATION CONTACT:** Radwan Saade, Economist, 202-205-6878 or Curtis B. Rich, Management Analyst, 202-205-7030.

#### SUPPLEMENTARY INFORMATION:

**Title:** "Evaluation of State Efforts to Review and Alleviate State Regulatory Burdens on Small Businesses."

**Description of Respondents:** The Office of Advocacy is surveying states to gain a better understanding of what states are doing to help small businesses overcome state regulatory burdens.

**Form No:** 2196.

**Annual Responses:** 130.

**Annual Burden:** 120.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 04-8380 Filed 4-12-04; 8:45 am]

BILLING CODE 8025-01-P

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

[Docket No. OST-04-17391]

### Notice of Request for Renewal of a Previously Approved Collection

**AGENCY:** Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork reduction Act of 1995, this notice announces the U.S. Department of Transportation's (DOT) intention to request extension of a previously approved information collection.

**DATES:** Comments on this notice must be received by June 14, 2004.

**ADDRESSES:** You may submit comments (identified by DOT DMS Docket Number OST-04-17391) by any of the following methods:

- Web site: <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1-202-493-2251.

- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001.

- 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 on Federal holidays.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Instructions:** All submissions must include the agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the SUPPLEMENTARY INFORMATION section of this document. Note that all comments received will be posted without change to <http://dms.dot.gov> including any personal information provided.

Please see the Privacy Act heading under Regulatory Notes.

**Docket:** For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to 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 FURTHER INFORMATION CONTACT:** Ladd Hakes, Business Policy Division, M-61, Office of the Senior Procurement Executive, Office of the Secretary, (202) 366-4268. Refer to OMB Control Number 2105-0520.

#### SUPPLEMENTARY INFORMATION:

**Title:** Uniform Administrative Requirements For Grants and Cooperative Agreements to State and Local Governments.

**OMB Control Number:** 2105-0520.

**Type of Request:** Extension without change, of a previously approved collection.

**Abstract:** The requested extension of the approved control number covers the information and collection requirements imposed by Office of Management and Budget (OMB) Circular A-102, Grants and Cooperative Agreements with State and Local Governments, which the Department of Transportation codified at 49 CFR part 18. The information collected, retained and provided by the State and local government grantees is required to ensure grantee eligibility and their conformance with Federally mandated reporting requirements. OMB



provides management and oversight of the circular. OMB also provides for a standard figure of 70 burden hours per grantee for completion of required forms. This collection covers only those DOT programs that utilize the standard OMB forms SF 269, SF 270, SF 271, SF 272 and SF 424.

**Respondents:** State and local governments receiving Federal financial assistance from the Department of Transportation (DOT).

**Estimated Number of Respondents:** 1,795.

**Estimated Total Burden on Respondents:** 125,650 hours.

**Comments are invited on:** (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information collection; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

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.

Issued in Washington, DC on April 6, 2004.

**David J. Litman,**

*Senior Procurement Executive.*

[FR Doc. 04-8347 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-62-P

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

[Docket No. OST-04-17390]

#### Notice of Request for Renewal of a Previously Approved Collection

**AGENCY:** Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork reduction Act of 1995, this notice announces the U.S. Department of Transportation's (DOT) intention to request extension of a previously approved information collection.

**DATES:** Comments on this notice must be received by June 14, 2004.

**ADDRESSES:** You may submit comments (identified by DOT DMS Docket Number OST-04-7390) by any of the following methods:

- Web site: <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1-202-493-2251.

- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001.

- 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 on Federal holidays.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Instructions:** All submissions must include the agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the SUPPLEMENTARY INFORMATION section of this document. Note that all comments received will be posted without change to <http://dms.dot.gov> including any personal information provided. Please see the Privacy Act heading under Regulatory Notes.

**Docket:** For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to 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 FURTHER INFORMATION CONTACT:

Ladd Hakes, Business Policy Division, M-61, Office of the Senior Procurement Executive, Office of the Secretary, (202) 366-4272. Refer to OMB Control Number 2105-0531.

#### SUPPLEMENTARY INFORMATION:

**Title:** Uniform Administrative Requirements for Grants and Cooperative Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

**OMB Control Number:** 2105-0531.

**Type of Request:** Extension without change, of a previously approved collection.

**Abstract:** The requested extension of the approved control number covers the information and collection requirements imposed by the Office of Management and Budget (OMB) Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, which the Department of Transportation codified at 49 CFR part 19. The information collected, retained

and provided by the nonprofit grantees is required to ensure grantee eligibility and their conformance with Federally mandated reporting requirements. OMB provides management and oversight of the circular. OMB also provides for a standard figure of 70 burden hours per grantee annually for completion of required forms. This collection covers only those DOT programs that utilize the standard OMB forms SF 269, SF 270, SF 271, SF 272 and SF 424.

**Respondents:** Individuals or households and business or others for profit organizations.

**Estimated Number of Respondents:** 150.

**Estimated Total Burden on Respondents:** 10,500 hours.

**Comments are invited on:** (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information collection; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

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.

Issued in Washington, DC on April 6, 2004.

**David J. Litman,**

*Senior Procurement Executive.*

[FR Doc. 04-8348 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-62-P

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

#### Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending April 2, 2004

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart B (formerly subpart Q) of the Department of Transportation's procedural regulations (see 14 CFR 301.201 *et seq.*). The due date for answers, conforming applications, or motions to modify scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption

of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

*Docket Number:* OST-2004-17451.

*Date Filed:* March 29, 2004.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* April 19, 2004.

*Description:* Application of Clay Lacy Aviations, Inc., requesting a certificate of public convenience and necessity to engage in foreign charter air transportation of persons, property and mail.

*Docket Number:* OST-2004-17452.

*Date Filed:* March 29, 2004.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* April 19, 2004.

*Description:* Application of Clay Lacy Aviation, Inc., requesting a certificate of public convenience and necessity authorizing it to engage in interstate charter air transportation of persons, property and mail.

*Docket Number:* OST-2004-17461.

*Date Filed:* March 31, 2004.

*Due Date for Answers, Conforming Applications, or Motion to Modify Scope:* April 21, 2004.

*Description:* Application of Air Tahoma, Inc., requesting a certificate of public convenience and necessity to engage in interstate charter air transportation.

**Maria Gulczewski,**

*Supervisory Dockets Officer, Docket Operations, Alternate Federal Register Liaison.*

[FR Doc. 04-8349 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-62-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Advisory Circular 25.869-1, Electrical System Fire and Smoke Protection

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of availability of Advisory Circular (AC) 25.869-1.

**SUMMARY:** The AC provides methods acceptable to the Administrator for showing compliance with revised airworthiness standards for fire protection of electrical system components on transport category airplanes. The guidance provided in the AC supplements the engineering and operational judgment that must form the basis of any compliance findings relative to electrical system fire and smoke protection to minimize the hazards to an airplane.

**EFFECTIVE DATES:** March 25, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Stephen Slotte, Airplane and Flightcrew Interface Branch ANM-111, Transport Airplane Directorate, Aircraft Certification Service, FAA, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (425) 227-2315; fax (425) 227-1320; e-mail [steve.slotte@faa.gov](mailto:steve.slotte@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Availability of AC

The AC can be found and downloaded from the AC from the Internet at the link titled <http://www.airweb.faa.gov/rgl>. A paper copy may be obtained by contacting the person named above under the caption **FOR FURTHER INFORMATION CONTACT**.

##### Discussion

Advisory Circular 25.869-1 has been prepared to provide guidance on one means of demonstrating compliance with the requirements of § 25.869, "Electrical System Fire and Smoke Protection," of Title 14, Code of Federal Regulations (CFR). Part 25 contains the airworthiness standards applicable to transport category airplanes.

The means of compliance described in AC 25.869-1 is intended to provide guidance to supplement the engineering and operational judgment that must form the basis of any compliance findings relative to paragraph 25.869(a). This paragraph concerns the protection of electrical systems from fire and smoke.

##### Harmonization of Standards and Guidance

The AC is based on recommendations submitted to the FAA by the Aviation Rulemaking Advisory Committee (ARAC). We initiated this action under the "Fast Track Harmonization Program" (64 FR 66522, November 26, 1999). The goal of "harmonization tasks," such as this, is to ensure that:

- Where possible, standards and guidance do not require domestic and foreign parties to manufacture or operate to different standards for each country involved; and
- The standards and guidance adopted are mutually acceptable to the FAA and the foreign aviation authorities.

The guidance contained in the AC has been harmonized with that of the JAA, and provides a method of compliance that has been found acceptable to both the FAA and JAA.

Issued in Renton, Washington, on March 25, 2004.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*  
[FR Doc. 04-8368 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Advisory Circular 25.1353-1, Electrical Equipment and Installations

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of availability of Advisory Circular (AC) 25.1353-1.

**SUMMARY:** This AC provides methods acceptable to the Administrator for showing compliance with the revised airworthiness standards for electrical equipment and installation on transport category airplanes. The guidance provided in the AC supplements the engineering and operational judgment that must form the basis of any compliance findings relative to electrical installation and nickel cadmium installation to minimize the hazards to an airplane.

**EFFECTIVE DATE:** March 25, 2004.

#### FOR FURTHER INFORMATION CONTACT:

Stephen Slotte, Airplane and Flightcrew Branch, Transport Airplane Directorate, FAA, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone (425) 227-2315; fax (425) 227-1320; e-mail [steve.slotte@faa.gov](mailto:steve.slotte@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Availability of AC

The AC can be found and downloaded from the Internet at the link titled <http://www.airweb.faa.gov/rgl>. A paper copy of the AC may be obtained by contacting the person named above under the caption **FOR FURTHER INFORMATION CONTACT**.

##### Discussion

Advisory circular 25.1353-1, "Electrical Equipment and Installations," has been prepared to provide guidance on one means of demonstrating compliance with the requirements of § 25.1353, "Electrical Equipment and Installations," of Title 14, Code of Federal Regulations (CFR) part 25. Part 25 contains the airworthiness standards applicable to transport category airplanes.

The means of compliance described in AC 25.1353-1 is intended to provide guidance to supplement the engineering

and operational judgment that must form the basis of any compliance findings relative to paragraph §§ 25.1353(a) and 25.1353(c)(6). These paragraphs concern electrical equipment, nickel cadmium battery installations, and nickel cadmium battery storage.

#### Harmonization of Standards and Guidance

The AC is based on recommendations submitted to the FAA by the Aviation Rulemaking Advisory Committee (ARAC). The FAA tasked ARAC (63 FR 50954, September 23, 1998) to provide advice and recommendations on "harmonizing" certain sections of part 25 with the counterpart standards contained in Joint Aviation Requirements (JAR) 25. The goal of "harmonization tasks," such as this, is to ensure that:

- Where possible, standards and guidance do not require domestic and foreign parties to manufacture or operate to different standards for each country involved; and
- The standards and guidance adopted are mutually acceptable to the FAA and the foreign aviation authorities.

The guidance contained in the AC has been harmonized with that of the JAA, and provides a method of compliance that has been found acceptable to both the FAA and JAA.

Issued in Renton, Washington, on March 25, 2004.

**Kalene C. Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04-8369 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Public Notice for a Change in Use of Aeronautical Property at Martin County Airport/Witham Field in Stuart, FL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Request for public comment.

**SUMMARY:** The Federal Aviation Administration is requesting public comment on the Martin County Board of County Commissioners (Sponsor) request to change approximately 30 acres of airport property from aeronautical use to non-aeronautical use.

The property is located on the west side of the airport and is bordered by Monterey Road to the North, Taxiway D

to the East, Runway 7-25 to the south, and Runway 12-30 to the West. The property is currently designated as future aeronautical use on the currently approved Airport Layout Plan. The Sponsor proposes changing the land-use to non-aeronautical/commercial development for the purposes of generating revenue to cover operational and capital expenses of the airport. The property would remain airport property under the ownership of the sponsor.

Documents reflecting the sponsor's request are available, by appointment only, for inspection at the Airport Manager's office and the FAA Airports District Office.

**DATES:** Comments must be received on or before May 13, 2004.

**ADDRESSES:** Documents are available for review at the Airport Manager's office, Martin County Airport/Witham Field, 1805 SE Airport Road, Stuart, FL 34996 and the FAA Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, FL 32822. Written comments on the sponsor's request must be delivered or mailed to: Matthew J. Thys, Assistant Manager, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, FL 32822-5024.

**FOR FURTHER INFORMATION CONTACT:** Matthew J. Thys, Assistant Manager, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, FL 32822-5024.

**SUPPLEMENTARY INFORMATION:** Section 125 of The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR-21) requires the FAA to provide an opportunity for public notice and comment prior to the "waiver" or "modification" of a sponsor's Federal obligation to use certain airport land for non-aeronautical purposes.

The property is located on the west side of the airport and is bordered by Monterey Road to the North, Taxiway D to the East, Runway 7-25 to the South, and Runway 12-30 to the West.

The property was owned by Martin County and leased to the Federal Government on May 27, 1943. The Federal Government transferred the property back to the Martin County Board of County Commissioners through a Surplus Property Agreement under Regulation 16-War Asset Administration, dated July 1, 1949.

The property is currently designated as future aeronautical use on the currently approved Airport Layout Plan. The Sponsor proposes changing the land-use to non-aeronautical/commercial development for the purposes of generating revenue to cover operational and capital expenses of the

airport. The property is currently vacant. The property would remain airport property under the ownership of the sponsor and leased for the purposes of revenue generation.

**Matthew J. Thys,**

*Acting Manager, Orlando Airports District Office, Southern Region.*

[FR Doc. 04-8367 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Commercial Space Transportation; Waiver of Public Notice Requirement for Suborbital Rocket Launch

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of waiver.

**SUMMARY:** The FAA has determined to waive the public notice requirement of 14 CFR part 431 for Reusable Launch Vehicle (RLV) missions to be conducted by Scaled Composites, LLC, under License No. LRLS 04-067, issued by the FAA on April 1, 2004. The FAA finds that waiving the public notice requirement is in the public interest and will not jeopardize public health and safety, safety of property, and national security and foreign policy interests of the United States.

**FOR FURTHER INFORMATION CONTACT:** George Nield, Deputy Associate Administrator for Commercial Space Transportation and Acting Manager, Licensing and Safety Division, Office of the Associate Administrator for Commercial Space Transportation, Federal Aviation Administration, U.S. Department of Transportation, 800 Independence Avenue SW., Washington, DC 20591, (202) 267-9222.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Federal Aviation Administration (FAA) licenses the launch of a launch vehicle, reentry of a reentry vehicle and the operation of a launch or reentry site under authority granted to the Secretary of Transportation in the Commercial Space Launch Act of 1984, as amended (CSLA), codified in 49 U.S.C. Subtitle IX, chapter 701, and delegated to the FAA Administrator. Licensing authority under the CSLA is carried out by the Associate Administrator for Commercial Space Transportation.

The CSLA allows the FAA to waive a requirement for an individual license applicant if the Administrator decides that the waiver is in the public interest and will not jeopardize public health

and safety, safety of property, and national security and foreign policy interests of the United States. 49 U.S.C. 70105(b)(3).

On April 1st, the FAA issued the first commercial Reusable Launch Vehicle (RLV) mission license authorizing Scaled Composites, LLC, to conduct manned suborbital RLV missions. The license, issued in accordance with licensing requirements under 14 CFR part 431, is valid for up to one year or until the authorized missions are completed, whichever occurs first.

Scaled Composites, LLC (Scaled Composites) plans to conduct piloted RLV missions using its SpaceShipOne vehicle, an RLV that is operated at all times under an Experimental Airworthiness Certificate (EAC). SpaceShipOne is an air-launched, winged, hybrid rocket-powered, horizontal landing vehicle that is a suborbital rocket as defined by the FAA. See **Federal Register Notice**, 68 FR 59977-59980, issued October 20, 2003, as corrected. It is carried aloft using a carrier aircraft, known as the White Knight. The White Knight is operated under an EAC. At the designated altitude, the SpaceShipOne is released from the White Knight, and after a brief glide for vehicle separation, the pilot ignites its rocket motor. Licensed activity commences upon rocket motor ignition.

Scaled Composites plans to conduct flight activities commencing upon take-off of the White Knight carrier aircraft from Mojave Airport, East Kern Airport District (EKAD). Licensed launch activity will commence, under the terms and conditions of the RLV mission license, in R-2515 airspace within the shared use areas of the R-2508 complex around and above Edwards Air Force Base, and will conclude, for nominal flight, upon landing at Mojave Airport.

As specified in the license, rocket-powered ballistic flight will occur over unpopulated area east of Mojave Airport. Ballistic flight resembles a parabolic arc with steep ascent, followed by a coast period during which weightlessness occurs, and then atmospheric entry. Following atmospheric entry, SpaceShipOne will circle down in a glide phase containment area, defined in the license, and must avoid identified population centers. In a nominal situation, the SpaceShipOne operates as a glider after its ballistic flight profile is concluded, having used up its fuel supply. It will fly back to Mojave Airport, where it will land on the designated Mojave Airport runway.

Under 14 CFR part 431, a licensee is required to maintain an emergency

response plan that contains procedures for informing the affected public of a planned RLV mission. 14 CFR 431.45(a). The FAA has determined to waive the public notice requirement for SpaceShipOne flights, relieving Scaled Composites of the requirement to issue local notice of planned launch events. While risk to public safety from SpaceShipOne launches is within allowable limits under 14 CFR part 431, and is expected to be highly remote, the FAA is concerned that public notice may have the unintended effect of drawing spectators to the launch area thereby increasing risk to public safety and the safety of property. Accordingly, the FAA has determined that waiver of the public notice requirement is in the public interest.

Waiving the public notice requirement will not jeopardize public health and safety or the safety of property, and is consistent with U.S. national interests. Public notice is intended to alert the public in the vicinity of an RLV mission that a launch event will be occurring that includes ascent and descent flight. Without notice, the public may be alarmed at the sight of a launch vehicle and believe it to be unauthorized activity. Concerned persons may wish to seek shelter. However, for SpaceShipOne launches, the FAA has determined that because the most hazardous operations will occur in remote, unpopulated area, there should be little opportunity for the public to be alarmed at the sight of the vehicle. During glide flight, when the vehicle will briefly pass over populated area, the vehicle will be in a safe, non-explosive configuration and should not pose unusual risk to the local population. Moreover, Scaled Composites has conducted limited test flights using the SpaceShipOne vehicle, up to 15-second rocket motor burn-time, and has performed return glide flight to Mojave Airport. On all occasions, return glide flight of the SpaceShipOne vehicle to Mojave Airport has been uneventful from a public safety perspective and has not been hazardous to public health and safety or the safety of property.

In accordance with RLV mission licensing requirements under 14 CFR part 431, proposed SpaceShipOne launch missions have undergone an interagency policy review. The review identified no concerns relating to national security or foreign policy considerations. The FAA has determined that waiving the public notice requirement will not jeopardize U.S. national security or foreign policy.

For the foregoing reasons, the FAA has waived the public notice requirement with respect to the conduct

by Scaled Composites of RLV missions authorized by License No. LRLS 04-067.

Issued in Washington DC, on April 8, 2004.

**Patricia Grace Smith,**

*Associate Administrator for Commercial Space Transportation.*

[FR Doc. 04-8308 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### **Notice of Public Hearing and Availability of a Draft Environmental Assessment (EA) for Installation of Category II/III Approaches at O'Hare International Airport at Chicago, IL**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice to hold a public hearing and of availability of a draft Environmental Assessment for Installation of Category II/III approaches at Chicago O'Hare International Airport.

**SUMMARY:** The Federal Aviation Administration (FAA) has prepared and is making available the Draft Environmental Assessment (DEA) for the following proposed action at O'Hare International Airport: the upgrade of Runways 27LK and 27R from a category I approach to a Category II/III approach, the installation of an Approach Lighting System with Sequenced Flashing Lights (ALSF-2) system to Runways 27L and 27R, the construction of localizer buildings and associated equipment including removal of the existing buildings, installation of 1,000-gallon underground storage tanks at the localizer buildings, the replacement or potential relocation of the localizer antennae on Runway 27R, the installation of an Inner Marker and Far Field Monitor on Runways 27L and 27R, the removal of existing Medium Intensity Approach Lighting System with Runway Alignment Indicator Lights (MALSR) systems from Runway 27L and 27R, the removal of the Runways 27L and 27R Middle Marker, shelter, and antenna, the replacement of the glide slope antenna and equipment for Runway 27R, the installation of taxiway centerline lights in the apron north of Gates B-17 through B-22, the installation of Runway Guard Lights (RGLs) at connecting taxiways to Runways 27L and 27R, the expansion of lease areas, by the FAA, from the City 8 of Chicago on airport property, the development of Category II/III instrument approach procedures for Runways 27L and 27R, and the issuance of National Airspace System (NAS)

Change Proposal (NCP) waivers associated with design and installation of the preceding.

The Draft EA is being prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended, FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts," and FAA Order 5050.4A, "Airport Environmental Handbook." The proposed development action is consistent with the National Airspace System Plan prepared by the U.S. Department of Transportation, Federal Aviation Administration (FAA).

A Draft Environmental Assessment will be available for public review 30 days prior to the Public Hearing during normal business hours at the following locations:

Arlington Heights Memorial Library, 500 N. Dunton Ave., Arlington Heights, IL 60004  
 Bensenville Public Library, 200 S. Church Rd., Bensenville, IL 60106  
 Chicago Department of Aviation Office, Terminal 2 E/F Concourse, Mezzanine Level Chicago O'Hare International Airport 60016  
 Des Plaines Public Library, 1501 Ellinwood St., Des Plaines, IL 60016  
 Eisenhower Public Library, 4652 N. Olcott Ave., Harwood Heights, IL 60706  
 Elk Grove Village Public Library, 1001 Wellington Ave., Elk Grove Village, IL 60007  
 Elmhurst Public Library, 211 Prospect Ave., Elmhurst, IL 60126  
 Franklin Park Public Library, 10311 Grand Ave., Franklin Park, IL 60131  
 Harold Washington Library, 400 South State St., 5th Floor, Chicago, IL 60605  
 Norridge Village Hall, Office of the Village Clerk, 4000 N. Olcott Ave., Norridge, IL 60706  
 Northlake Public Library, 231 N. Wolf Rd., Northlake, IL 60164  
 Oakton Community College Library, Des Plaines, IL 60016  
 Park Ridge Public Library, 20 S. Prospect Ave., Park Ridge, IL 60068  
 Rosemont village Hall, Office of the Village Clerk, 9501 Devon Avenue, Rosemont, IL 60018  
 Schiller Park Public Library, 4200 Old River Rd., Schiller Park, IL 60176  
 Wood Dale Public Library, 520 N. Wood Dale Rd., Wood Dale, IL 60191  
 Northeast Illinois Planning Commission (NIPC), 222 South Riverside Plaza, Suite 1800, Chicago, Illinois 60606  
*Dates, Times and Place:* Oral or written comments may also be given at a Public Hearing that will be held on Tuesday, May 18, 2004, 2 p.m. to 7 p.m. at the Fountain Blue Banquets and Conference Center, 2300 Mannheim Road, Des Plaines, IL 60018.

**ADDRESSES:** Written comments are encouraged from persons or interested parties unable to attend the public hearing or who do not wish to make public statements. Written comments concerning the Draft EA will be accepted until 5 p.m. CST, Tuesday, June 1, 2004. Written comments may be sent to: Ms. Virginia Marcks, ANI-430, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018.

**FOR FURTHER INFORMATION CONTACT:** Ms. Virginia Marcks, Environmental Engineer, ANI-430, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Telephone number: 847-294-7494.

**SUPPLEMENTARY INFORMATION:**

**Background**

O'Hare, the world's busiest airport in terms of aircraft operations in 2003, functions as both a gateway for international passengers and as a key component in the domestic network of the national air transportation system. In its domestic role, O'Hare is unique in that it serves as the nation's only dual major airline hub (for both United and American Airlines) and, due to its geographic location, serves as a logical connecting point for significant passenger flows across the United States. However, increasing traffic has resulted in record level delays at O'Hare, particularly during IFR or inclement weather conditions, placing O'Hare last in on-time performance among the 31 busiest U.S. airports. Since the mid-70's, the installation of Category II/III capability has been examined for the potential to benefit arrival and departure capabilities during poor weather conditions. The FAA's Proposed Action will allow existing scheduled operations to occur during IFR weather conditions, thereby reducing cancellations and delays benefiting the entire National Airspace System.

**Meeting Procedures**

- (a) Persons wishing to speak at the meeting are asked to limit their comments to five minutes. This could be extended depending on the number of person wishing to speak.
- (b) Persons wishing to make oral presentations will be required to identify themselves for the record.
- (c) Proceedings of the meeting will be documented and recorded.
- (d) Any person who wishes to submit a position paper or other written comments for the record may do so.
- (e) The sessions may be adjourned at any time if persons present have had an opportunity to speak.

(f) This meeting is designed for listening carefully to public statements. As such, there will be no rebuttal from persons facilitating the meeting.

Issued in Des Plaines, Illinois April 7, 2004.

**Vincent Bridgeworth,**

*Manager, Chicago NAS Implementation Center, ANI-400, Great Lakes Region.*

[FR Doc. 04-8372 Filed 4-12-04; 8:45 am]

**BILLING CODE 4910-13-M**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

[Summary Notice No. PE-2004-25]

**Petitions for Exemption; Dispositions of Petitions Issued**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of dispositions of prior petitions.

**SUMMARY:** Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains the dispositions of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

**FOR FURTHER INFORMATION CONTACT:** John Linsenmeyer, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Tel. (202) 267-5174.

This notice is published pursuant to 14 CFR §§ 11.85 and 11.91.

Issued in Washington, DC, on April 8, 2004.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

**Dispositions of Petitions**

*Docket No.:* FAA-2004-17072.  
*Petitioner:* Cessna Aircraft Company.  
*Section of 14 CFR Affected:* 14 CFR 25.161(d).

*Description of Relief Sought/Disposition:* To grant relief concerning the engine-out lateral/directional trim requirements for Cessna Model 680 airplanes.

*Grant of Exemption, 03/24/2004, Exemption No. 8280*

[FR Doc. 04-8365 Filed 4-12-04; 8:45 am]

**BILLING CODE 4910-13-P**



**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration**

[Summary Notice No. PE-2004-17474]

**Petitions for Exemption; Summary of Petitions Received****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of petition for exemption received.

**SUMMARY:** Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption, part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of a certain petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

**DATES:** Comments on petitions received must identify the petition docket number involved and must be received on or before April 27, 2004.

**ADDRESSES:** You may submit comments identified by DOT DMS Docket Number FAA-2004-17474 by any of the following methods:

- *Web site:* <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- *Fax:* 1-202-493-2251.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-0001.

- *Hand Delivery:* Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal holidays.

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

**Docket:** For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Susan Boylon (425-227-1152), Transport Airplane Directorate (ANM-

113), Federal Aviation Administration, 1601 Lind Ave SW., Renton, WA 98055-4056; or John Linsenmeyer (202-267-5174), Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on April 8, 2004.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

**Petitions for Exemption**

*Docket No.:* FAA-2004-17474.

*Petitioner:* Zero Gravity Corporation.

*Sections of 14 CFR Affected:* 14 CFR 25.785 and 25.1447(c)(1).

*Description of Relief Sought:* To allow an interior configuration which includes a "floating area" where persons can experience weightless flight on a specially modified Boeing Model 727 airplane.

[FR Doc. 04-8366 Filed 4-12-04; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****Research, Engineering and Development Advisory Committee**

Pursuant to section 10(A)(2) of the Federal Advisory Committee Act (Public Law 92-463; 5 U.S.C. App. 2), notice is hereby given of a meeting of the FAA Research, Engineering and Development (R,E&D) Advisory Committee.

**AGENCY:** Federal Aviation Administration.

**ACTION:** Notice of meeting.

*Name:* Research, Engineering & Development Advisory Committee.

*Time and Date:* May 4, 2004-8:30 a.m. to 4:30 p.m.

*Place:* Federal Aviation Administration, 800 Independence Avenue, SW—Bessie Coleman Room, Washington, DC 20591.

*Purpose:* On May 4 from 8:30 a.m. to 4:30 p.m. the meeting agenda will include receiving from the Committee guidance for FAA's research and development investments in the areas of air traffic services, airports, aircraft safety, human factors and environment and energy.

Attendance is open to the interested public but seating is limited. Persons wishing to attend the meeting or obtain information should contact Gloria Dunderman at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591

(202) 267-8937 or [gloria.dunderman@faa.gov](mailto:gloria.dunderman@faa.gov).

Members of the public may present a written statement to the Committee at any time.

Issued in Washington, DC on April 7, 2004.

**Joan Bauerlein,**

*Director of Operations Planning Research & Development.*

[FR Doc. 04-8370 Filed 4-12-04; 8:45 am]

**BILLING CODE 4910-13-M**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****Notice of Passenger Facility Charge (PFC) Approvals and Disapprovals**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Monthly Notice of PFC Approvals and Disapprovals. In February 2004, there were 11 applications approved. This notice also includes information on two applications, one approved in November 2002, and the other approved in October 2003, inadvertently left off the November 2002 and October 2003 notices, respectively. Additionally, three approved amendments to previously approved applications are listed.

**SUMMARY:** The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Bus Reconciliation Act of 1990) (Pub. L. 101-508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

**PFC Applications Approved**

*Public Agency:* City of Portland, Maine.

*Application Number:* 02-03-C-00-PWM.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$3.00.

*Total PFC Revenue Approved in this Decision:* \$14,214,483.

*Earliest Charge Effective Date:* February 1, 2004.

*Estimated Charge Expiration Date:* December 1, 2010.

*Class of Air Carriers Not Required to Collect PFC's:* Air taxi/commercial operators.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the

total annual enplanements at Portland International Jetport.

*Brief Description of Projects Approved for Collection and Use:*

Terminal canopy completion.  
Passenger boarding bridge acquisition.  
Passenger boarding bridge—regional jet modifications.  
Runway 11/29 upgrade/relocation.  
Taxiway improvements.  
Terminal roadway system expansion.  
Snow removal equipment acquisition.  
PFC application preparation and program administration.

*Brief Description of Projects Approved for Collection:* Baggage claim expansion and improvements.

*Decision Date:* November 29, 2002.

**FOR FURTHER INFORMATION CONTACT:** Priscilla Scott, New England Region Airports Division, (718) 238-7614.

*Public Agency:* Broome County Department of Aviation, Binghamton, New York.

*Application Number:* 03-06-C-00-BGM.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$7,996.

*Earliest Charge Effective Date:* February 1, 2005.

*Estimated Charge Expiration Date:* March 1, 2005.

*Class of Air Carriers Not Required to Collect PFC's:* Part 135 (air taxi) operators.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Greater Binghamton Airport.

*Brief Description of Projects Approved for Use:*

Aircraft rescue and firefighting facility refurbishment.

Passenger boarding bridge purchase.

*Brief Description of Projects Approved for Collection and Use:*

Airport security access control system enhancement.

Airport security fence improvements.

*Decision Date:* October 9, 2003.

**FOR FURTHER INFORMATION CONTACT:** Robert Levine, New York Airports District Office, (516) 227-3807.

*Public Agency:* City of Klamath Falls, Oregon.

*Application Number:* 03-02-C-00-LMT.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$877,799.

*Earliest Charge Effective Date:* August 1, 2004.

*Estimated Charge Expiration Date:* December 1, 2011.

*Class of Air Carriers Not Required to Collect PFC's:* None.

*Brief Description of Projects Approved for Collection and Use:*

Runway safety area design and construction.

Construct northwest apron.

Master plan.

Parking expansion.

Security improvements.

Acquire security equipment.

Rehabilitation of west side apron including associated taxiway.

*Decision Date:* February 2, 2004.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Lee-Pang, Seattle Airports District Office, (425) 227-2654.

*Public Agency:* Cedar Rapids Airport Commission, Cedar Rapids, Iowa.

*Application Number:* 04-03-C-00-CID.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$4,182,615.

*Earliest Charge Effective Date:* May 1, 2004.

*Estimated Charge Expiration Date:* July 1, 2006.

*Class of Air Carriers Not Required to Collect PFC's:* Part 135 air taxi/commercial operators.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Eastern Iowa Airport.

*Brief Description of Projects Approved for Collection and Use:*

Acquire two snow removal end loaders.

Rehabilitate runway 13/31.

Extend south end of runway 13/31.

Improve north end of runway 13/31 safety area and relocate road.

Extend north of runway 13/31 and construct taxiway F connection.

Improve east end of runway 9/27 safety area.

Reconstruct T-hangar taxiways and general aviation aprons.

Construct runway and taxiways overlay.

Construct cargo ramp expansion, phase I.

Construct terminal and cargo ramp expansion and rehabilitation, phase II.

Construct cargo apron.

Rehabilitate cargo apron, phase III.

Rehabilitate cargo apron, phase IV.

*Decision Date:* February 6, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Nicoletta S. Oliver, Central Region Airports Division, (816) 329-2642.

*Public Agency:* Jackson Hole Airport Board, Jackson, Wyoming.

*Application Number:* 04-09-C-00-JAC.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$1,814,693.

*Earliest Charge Effective Date:* November 1, 2004.

*Estimated Charge Expiration Date:* November 1, 2008.

*Class of Air Carriers Not Required to Collect PFC's:* None.

*Brief Description of Projects Approved for Collection and Use:*

Terminal building expansion.

Landside improvements.

Noise monitoring system and Part 150 update.

Runway threshold lighting.

Security improvements.

*Decision Date:* February 9, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Christopher Schaffer, Denver Airports District Office, (303) 342-1258.

*Public Agency:* County of Mercer, West Trenton, New Jersey.

*Application Number:* 04-02-C-00-TTN.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$1,061,436.

*Earliest Charge Effective Date:* May 1, 2004.

*Estimated Charge Expiration Date:* May 1, 2011.

*Class of Air Carriers Not Required to Collect PFC's:* Nonscheduled/on-demand air carriers filing FAA Form 1800-31.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Trenton-Mercer Airport.

*Brief Description of Projects Approved for Collection and Use:*

Construct taxiway E—construction only.

Airport planning studies.

Acquire aircraft rescue and firefighting safety equipment.

• Install apron lighting.

Acquire airport snow sweeper.

Install airfield guidance signage.

Construct taxiway G.

Remove obstructions—runway 24 runway protection zone.

Improve terminal building.

Improve runway 6/24.  
 Rehabilitate taxiways A, C and a portion of D.  
 Rehabilitate runway 16/34.  
 Conduct environmental assessment.  
 Acquire aircraft rescue and firefighting vehicles.  
 Improve runway safety areas, phase I.  
 Security enhancements.  
 Design snow removal building, phase I.

PFC application services.

*Decision Date:* February 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Dan Vornea, New York Airports District Office, (516) 227-3812.

*Public Agency:* Indian Wells Valley Airport District, Inyokern, California.

*Application Number:* 04-04-C-00-IYK.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$3.00.

*Total PFC Revenue Approved in this Decision:* \$36,183.

*Earliest Charge Effective Date:* April 1, 2004.

*Estimated Charge Expiration Date:* October 1, 2004.

*Class of Air Carriers Not Required to Collect PFC's:* Nonscheduled/on-demand air carriers filing FAA Form 1800-31.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Inyokern Airport.

*Brief Description of Project Approved for Collection And Use:*

Install security gates and rehabilitate pavement.

*Decision Date:* February 12, 2004.

**FOR FURTHER INFORMATION CONTACT:** David Delshad, Western Pacific Region Airports Division, (310) 725-3627.

*Public Agency:* City of Springfield Airport Board, Springfield, Missouri.

*Application Number:* 03-04-C-00-SGF.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$1,847,000.

*Earliest Charge Expiration Date:* May 1, 2004.

*Estimated Charge Expiration Date:* August 1, 2005.

*Class of Air Carriers Not Required to Collect PFC's:* Nonscheduled Part 135 and air taxi operators.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class

accounts for less than 1 percent of the total annual enplanements at Springfield-Branson Regional Airport.

*Brief Description of Projects Approved for Collection and Use:*

Design midfield terminal.

Purchase and install loading bridge.

Modify existing loading bridges (four).

PFC consulting fees.

*Brief Description of Withdrawn Projects:*

Acquire land for midfield terminal.

*Determination:* This project was withdrawn by the public agency by letter dated December 3, 2003.

Construct snow removal equipment building.

Construct taxiway T.

*Determination:* These projects were withdrawn by the public agency by letter dated August 13, 2003.

*Decision Date:* February 18, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Lorna Sandridge, Central Region Airports Division, (816) 329-2641.

*Public Agency:* Golden Triangle Regional Airport Authority, Columbus, Mississippi.

*Application Number:* 04-03-C-00-GTR.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$285,555.

*Earliest Charge Effective Date:* August 1, 2005.

*Estimated Charge Expiration Date:* October 1, 2007.

*Class of Air Carriers Not Required to Collect PFC's:* None.

*Brief Description of Projects Approved for Collection and Use:*

Construction of air traffic control tower.

Master plan/noise compatibility study.

Handicapped lift device.

Runway overlay, grooving, and marking.

Taxiway seal coat.

Reconstruction of general aviation ramp.

*Decision Date:* February 23, 2004.

**FOR FURTHER INFORMATION CONTACT:**

David Shumate, Jackson Airports District Office, (601) 664-9882.

*Public Agency:* Niagara Frontier Transportation Authority, Buffalo, New York.

*Application Number:* 04-05-C-00-BUF.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$3.00.

*Total PFC Revenue Approved in this Decision:* \$7,045,262.

*Earliest Charge Effective Date:* May 1, 2009.

*Estimated Charge Expiration Date:* April 1, 2010.

*Class of Air Carriers Not Required to Collect PFC's:* Air taxi/commercial operators filing FAA Form 1800-31.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Buffalo Niagara International Airport.

*Brief Description of Projects Approved for Collection and Use:*

Design and construction, extension of runway 14/32.

Design and construction, extension, widening and rehabilitation of taxiway D.

Design and construction, extension and rehabilitation of runway 5/23.

Design and construction, extension and rehabilitation of taxiway A.

Design and construction, overhead canopies for pedestrian walkways.

*Decision Date:* February 23, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Philip Brito, New York Airports District Office, (516) 227-3800.

*Public Agency:* County of Westchester, Mount Vernon, New York.

*Application Number:* 04-02-1-00-HPN.

*Application Type:* Impose a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$20,200,000.

*Earliest Charge Effective Date:* May 1, 2004.

*Estimated Charge Expiration Date:* October 1, 2014.

*Class of Air Carriers Not Required to Collect PFC's:* Nonscheduled/on-demand air carriers filing FAA Form 1800-31.

*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Westchester County Airport.

*Brief Description of Project Approved for Collection:* New deicing facilities.

*Decision Date:* February 25, 2004.

**FOR FURTHER INFORMATION CONTACT:** Dan Vornea, New York Airports District Office, (516) 227-3812.

*Public Agency:* Benedum Airport Authority, Clarksburg, West Virginia.

*Application Number:* 04-03-C-00-CKB.

*Application Type:* Impose and use a PFC.

*PFC Level:* \$4.50.

*Total PFC Revenue Approved in this Decision:* \$2,920,641.

*Earliest Charge Effective Date:* May 1, 2004.

*Estimated Charge Expiration Date:* May 1, 2054.  
*Class of Air Carriers Not Required to Collect PFC's:* None.  
*Brief Description of Projects Approved for Collection and Use:*  
 Terminal modifications.  
 Construct de-ice containment facility.  
 Construct run-up pad.  
 Install segmented circle/wind cone.  
 Runway extension (land acquisition).  
 Runway extension (construction).  
*Decision Date:* February 25, 2004.

**FOR FURTHER INFORMATION CONTACT:** Matthew DiGiulian, Beckley Airports District Office, (304) 252-6216.  
*Public Agency:* Metropolitan Nashville Airport Authority, Nashville, Tennessee.  
*Application Number:* 04-11-C-00-BNA.  
*Application Type:* Impose and use a PFC.  
*PFC Level:* \$3.00  
*Total PFC Revenue Approved in this Decision:* \$81,518,055.

*Earliest Charge Effective Date:* April 1, 2007.  
*Estimated Charge Expiration Date:* May 1, 2014.  
*Class of Air Carriers Not Required to Collect PFC's:* Part 135 air taxis.  
*Determination:* Approved. Based on information contained in the public agency's application, the FAA has determined that the approved class accounts for less than 1 percent of the total annual enplanements at Nashville International Airport.  
*Brief Description of Projects Approved for Collection and Use:*  
 Airfield construction.  
 Develop general aviation area south of Murfreesboro Road and east of runway 2C/20C.  
 Engineering study to develop land north of runway 13/31.  
 Relocate electrical vault on west side.  
 Storm water treatment facility engineering study and upgrade.  
 Widen taxiway fillets at taxiways L2, K2, T3, and Lima Kilo.

Runway 2C/20C extension (part B).  
 Noise mitigation.  
 Two elevators in terminal building.  
 Airfield pavement rehabilitation (phases 1, 2, 3, 4, and 5) and runway 2R/20L joint and crack repair.  
 Acquire aircraft rescue and firefighting equipment.  
 Acquire pavement sweeper.  
 Airfield re-signing.  
 Acquire snow removal equipment.  
*Brief Description of Disapproved Project:*  
 Terminal ambulance.  
*Determination:* The eligibility of emergency vehicles is limited to those vehicles required to meet Part 139 requirements. This vehicle is not a Part 136 requirement.  
*Decision Date:* February 26, 2004.  
**FOR FURTHER INFORMATION CONTACT:** Cynthia K. Wills, Memphis Airports District Office, (901) 322-8190.

**AMENDMENTS TO PFC APPROVALS**

Amendment No. city, state	Amendment approved date	Original approved net PFC revenue	Amended approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
92-01-C-05-MCO Orlando, FL .....	02/06/04	\$26,441,847	\$34,099,841	09/01/94	09/01/94
95-03-C-02-MCO Orlando, FL .....	02/06/04	\$21,527,408	\$18,637,986	04/01/96	11/01/95
02-05-C-03-BGM Binghamton, NY .....	02/24/04	\$4,567,319	\$4,567,151	03/01/05	03/01/05

Issued in Washington, DC on March 31, 2004.  
**JoAnn Horne,**  
*Manager, Financial Analysis and Passenger Facility Charge Branch.*  
 [FR Doc. 04-8371 Filed 4-12-04; 8:45 am]  
 BILLING CODE 4910-13-M

**DEPARTMENT OF TRANSPORTATION**  
**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA-2004-17048]

**Notice of Request for Comments on Renewing Approval for an Information Collection: OMB Control No. 2126-0014 (Transportation of Hazardous Materials, Highway Routing)**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice; request for comments.

**SUMMARY:** This notice announces that the FMCSA intends to request the Office of Management and Budget (OMB) to renew approval of the information collection described below. That information collection requires States and Indian tribes to identify designated/

restricted highway routes and restrictions or limitations affecting how motor carriers may transport certain hazardous materials on the highway. This notice is required by the Paperwork Reduction Act.

**DATES:** Please submit your comments by June 14, 2004.

**ADDRESSES:** Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590, or submit electronically at <http://dmses.dot.gov/submit>. Be sure to include the docket number appearing in the heading of this document on your comment. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you would like to be notified when your comment is received, you must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael Johnsen (202-366-4111), Hazardous Materials Division (MC-

ECH), Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4:00 p.m., EST., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:** *Title:* Transportation of Hazardous Materials; Highway Routing.

*OMB Control Number:* 2126-0014.  
*Background:* The data for the Transportation of Hazardous Materials; Highway Routing designations are collected under authority of 49 U.S.C. 5112 and 5125. That authority places responsibility on the Secretary of Transportation (Secretary) to specify and regulate standards for establishing, maintaining, and enforcing routing designations.

Under 49 CFR 397.73, the Administrator has the authority to request that each State and Indian tribe, through its routing agency, provide information identifying hazardous materials routing designations within their respective jurisdictions. That information is collected and consolidated by the FMCSA and published annually in whole, or as updates, in the **Federal Register**.

**Respondents:** The reporting burden is shared by the 50 States, the District of Columbia, Puerto Rico, American Samoa, Guam, Northern Marianas, and the Virgin Islands.

**Estimated Total Annual Burden:** The annual reporting burden is estimated to be 13 hours, calculated as follows: (53 respondents × 1 response × 15 minutes/60 minutes) = 13.25 hours, rounded to 13 hours.

**Frequency:** There is one response annually from approximately 53 respondents.

**Public Comments Invited:** Your comments are particularly invited on whether the collection of information is necessary for the FMCSA to meet its goal of reducing truck crashes, including whether the information is useful to this goal; the accuracy of the estimate of the burden of the information collection; ways to enhance the quality, utility and clarity of the information collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Electronic Access and Filing:** You may submit or retrieve comments online through the Docket Management System (DMS) at <http://dmses.dot.gov/submit>. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site. You may also download an electronic copy of this document from the DOT Docket Management System on the Internet at <http://dms.dot.gov/search.htm>. Please include the docket number appearing in the heading of this document.

**Authority:** The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended; and 49 CFR 1.73.

Issued: April 6, 2004.

**Annette M. Sandberg,**  
Administrator.

[FR Doc. 04-8320 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA-99-6480, FMCSA-2001-11426]

#### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of renewal of exemption; request for comments.

**SUMMARY:** This notice publishes the FMCSA decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 24 individuals. The FMCSA has statutory authority to exempt individuals from vision standards if the exemptions granted will not compromise safety. The agency has concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

**DATES:** This decision is effective April 23, 2004. Comments from interested persons should be submitted by May 13, 2004.

**ADDRESSES:** You may submit comments identified by DOT DMS Docket Numbers FMCSA-99-6480 and FMCSA-2001-11426 by any of the following methods:

- **Web site:** <http://dms.dot.gov>.

Follow the instructions for submitting comments on the DOT electronic docket site.

- **Fax:** 1-202-493-2251.

- **Mail:** Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-0001.

- **Hand Delivery:** Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

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

**Instructions:** All submissions must include the agency name and docket numbers for this notice. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of

this document. Note that all comments received will be posted without change to <http://dms.dot.gov>, including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

**Docket:** For access to the docket to read background documents or comments received, go to <http://dms.dot.gov> at any time or to 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 FURTHER INFORMATION CONTACT:** Ms. Sandra Zywokarte, Office of Bus and Truck Standards and Operations, (202) 366-2987, FMCSA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590-0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

**Public Participation:** The DMS is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help guidelines under the "help" section of the DMS web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

**Privacy Act:** 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 the Department of Transportation'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>.

#### Exemption Decision

Under 49 U.S.C. 31315 and 31316(e), the FMCSA may renew an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption." The procedures for requesting an exemption (including renewals) are set out in 49 CFR Part 381. This notice addresses 24 individuals who have requested renewal of their exemptions in a timely manner. The FMCSA has evaluated these 24



applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period. They are:

Louis N. Adams  
Guy M. Alloway  
Lyle H. Banser  
Lloyd J. Botsford  
Joseph E. Buck, Sr.  
Paul D. Gaither  
David L. Grajola  
Walter D. Hague, Jr.

Marshall L. Hood  
Edward W. Hosier  
Charles F. Koble  
Robert W. Lantis  
Lucio Leal  
Terry W. Lytle  
Earl R. Mark  
Richard W. Neyens

Anthony G. Parrish  
Bill L. Percy  
Robert H. Rogers  
Bobby C. Spencer  
Sammy D. Steinsultz  
Mark J. Stewing  
Frankie A. Wilborn  
Jeffrey L. Wuollett

These exemptions are extended subject to the following conditions: (1) That each individual have a physical exam every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retain a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for 2 years unless rescinded earlier by the FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31315 and 31136(e).

#### Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than 2 years from its approval date and may be renewed upon application for additional 2-year periods. In accordance with 49 U.S.C. 31315 and 31136(e), each of the 24 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (64 FR 68195, 65 FR 20251, 67 FR 17102, 67 FR 10471, 67 FR 19798). Each of these 24 applicants has requested timely renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the standard specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision

deficiencies over the past 2 years indicates each applicant continues to meet the vision exemption standards. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, the FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

#### Comments

The FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31315 and 31136(e). However, the FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by May 13, 2004.

In the past the FMCSA has received comments from Advocates for Highway and Auto Safety (Advocates) expressing continued opposition to the FMCSA's procedures for renewing exemptions from the vision requirement in 49 CFR 391.41(b)(10). Specifically, Advocates objects to the agency's extension of the exemptions without any opportunity for public comment prior to the decision to renew, and reliance on a summary statement of evidence to make its decision to extend the exemption of each driver.

The issues raised by Advocates were addressed at length in 66 FR 17994 (April 4, 2001). The FMCSA continues to find its exemption process appropriate to the statutory and regulatory requirements.

Issued on: April 8, 2004.

**Pamela M. Pelcovits,**

*Office Director, Policy, Plans, and Program Development.*

[FR Doc. 04-8319 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

#### Notice of Funds Availability and Request for Comment To Assist in the Development and Implementation of a Procedure for Fair Competitive Bidding by Amtrak and Non-Amtrak Operators of State-Supported Intercity Passenger Rail Routes

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice.

**SUMMARY:** Under this Notice, the FRA solicits comments from interested parties on how the Secretary of Transportation, working with affected States, could develop and implement a procedure for fair competitive bidding by Amtrak and non-Amtrak operators for State-supported intercity passenger rail routes. FRA also encourages interested States to submit a Statement of Interest in receiving a grant to support an initiative leading to a fair and open competitive selection of an operator to provide passenger rail service over a specific intercity route that receives or will receive State financial support. Services eligible for funding under programs administered by the Federal Transit Administration are not eligible for a grant under this notice. Responses to this notice are sought on or before May 28, 2004.

**DATES:** All submissions of Statements of Interest and comments must be received in FRA's offices by close of business Friday, May 28, 2004. The deadline for the submission of applications will be noted in the solicitation from FRA to prospective grantees as a result of the evaluation of the Statements of Interest.

**ADDRESSES:** Applicants must submit an original and six (6) copies to the Federal Railroad Administration at one of the following addresses:

Postal address (note correct zip code):  
Federal Railroad Administration,  
Attention: Alex Chavrid, Chief,  
Passenger Programs Division (RDV-11),

Mail Stop #20, 1120 Vermont Ave., NW., Washington, DC 20590.

FedEx/courier address (note correct zip code): Federal Railroad Administration, Attention: Alex Chavrid, Chief, Passenger Programs Division, (RDV-11), Room #773, 1120 Vermont Ave., NW., Washington, DC 20005.

Due to delays caused by enhanced screening of mail delivered via the US Postal Service, applicants are encouraged to use other means to assure timely receipt of materials.

**FOR FURTHER INFORMATION CONTACT:**

Mark Yachmetz, Associate Administrator for Railroad Development (RDV-1), Federal Railroad Administration, 1120 Vermont Avenue NW., Washington, DC 20590. Phone: (202) 493-6381; Fax: (202) 493-6330.

**SUPPLEMENTARY INFORMATION:** The demonstration will be supported with up to \$2,485,250 of Federal funds provided to FRA as part of the Transportation, Treasury, and Independent Agencies Appropriations Act, 2004 (included as Division F of the Consolidated Appropriations Act, 2004 (Public Law 108-199 (January 23, 2004))). FRA anticipates soliciting one or more grant applications and awarding one or more grants to eligible participants before September 30, 2004. The funds made available under this program will be available for activities related to developing and/or implementing a fair and open competitive process for selecting an operator of a State-supported intercity passenger rail route. FRA anticipates that no further public notice will be made with respect to selecting applicants for this demonstration.

*Purpose:* From the creation of Amtrak in 1971 until the enactment of the Amtrak Reform and Accountability Act (ARAA) in 1997, the National Railroad Passenger Corporation, better known as Amtrak, had the exclusive right to operate intercity passenger rail service over the routes where it provided service. ARAA eliminated Amtrak's monopoly as the exclusive intercity passenger rail service operator on these routes. Some have argued since enactment of ARAA that competition in the selection of intercity rail passenger service operators could result in improved service and/or lower costs. On June 22, 2002, Secretary of Transportation, Norman Y. Mineta, identified the five principles for intercity passenger rail reform advocated by the U.S. Department of Transportation. Included among these principles are: "Introduce carefully managed competition to provide higher

quality rail services at reasonable prices." Subsequently, on June 27, 2003, Secretary Mineta submitted to Congress proposed legislation: "The Rail Passenger Reform Investment Act" that would take this principle and make competitive selection of intercity passenger rail service operators by States the foundation for a new approach to providing intercity passenger rail service in the United States. Since the enactment of ARAA, some States have contemplated using competitive processes to select operators of intercity passenger rail service they deem important enough to support financially. However, to date there has not yet been a successful process through which a fair and open competition has resulted in the selection of an operator other than Amtrak. Section 151 of the General Provisions of the Transportation, Treasury, and Independent Agencies Appropriations Act, 2004 (included as Division F of the Consolidated Appropriations Act, 2004 (Public Law 108-199 (January 23, 2004))) provides as follows: "For the purpose of assisting State-supported intercity rail service, in order to demonstrate whether competition will provide higher quality rail passenger service at reasonable prices, the Secretary of Transportation, working with affected States, shall develop and implement a procedure for fair competitive bidding by Amtrak and non-Amtrak operators for State-supported routes: *Provided*, That in the event a State desires to select or selects a non-Amtrak operator for the route, the State may make an agreement with Amtrak to use facilities and equipment of, or have services provided by, Amtrak under terms agreed to by the State and Amtrak to enable the non-Amtrak operator to provide the State-supported service: *Provided further*, That if the parties cannot agree on terms, the Secretary shall, as a condition of receipt of Federal grant funds, order that the facilities and equipment be made available under reasonable terms and compensation: *Provided further*, That when prescribing reasonable compensation to Amtrak, the Secretary shall consider quality of service as a major factor when determining whether, and the extent to which, the amount of compensation shall be greater than the incremental costs of using the facilities and providing the services: *Provided further*, That the Secretary may reprogram up to \$2,500,000 from the Amtrak operating grant funds for costs associated with the implementation of the fair bid procedure and demonstration of competition under this

section." (Note: Section 168 of Division H of the Consolidated Appropriations Act, 2004, imposes an across-the-board rescission of 0.59 percent to all appropriations in the act, thereby reducing the appropriation that is available for costs associated with the implementation of the fair bid procedure and demonstration of competition to \$2,485,250.)

Section 151 provides the Secretary of Transportation with significant flexibility and latitude in establishing the referenced "fair bid procedure." The purpose of this notice is threefold. First, FRA seeks comment and recommendations on how such a "fair bid procedure" should be structured, what issues should be addressed in such a procedure, how they could be best addressed, how the available funds should best be used and whether the available funds are adequate for the intended purpose. Second, FRA seeks to identify the extent of interest among the States in competitively selecting operators of State-supported intercity rail passenger service. Finally, FRA wishes to identify the State or States that could implement or make the most progress toward implementing a "fair bid procedure" in the most timely manner with the available Federal funding.

*Authority:* The authority for the program can be found in Section 151 of the Transportation, Treasury, and Independent Agencies Appropriations Act, 2004 (included as Division F of the Consolidated Appropriations Act, 2004 (Public Law 108-199 (January 23, 2004))). The Secretary of Transportation's responsibilities under this program have been delegated to the Federal Railroad Administration.

*Funding:* The Transportation, Treasury, and Independent Agencies Appropriations Act, 2004, provides \$2,485,250 for this purpose. It is anticipated that the available funding could be used for one or more grants. If two grants are awarded, FRA may choose not to award the grants in equal amounts. Additional funding for this or related work may be available in subsequent fiscal years and may be awarded without further competition.

*Eligible Participants:* Any State that presently provides financial assistance for an intercity passenger rail service operated by Amtrak or any State or group of States that is willing to provide financial assistance for an intercity rail passenger service, the operator of which is selected through a fair bid procedure, is eligible to participate in this program. Comment and recommendations on how such a "fair bid procedure" should be structured, what issues should be

addressed in such a procedure, how they could be best addressed, how the available funds should best be used and whether the available funds are adequate for the intended purpose are solicited from eligible participants and any other interested party.

*Requirements for Statements of Interest:* The following points describe the minimum content that is required in Statements of Interest.

1. Describe the service to be subject to fair bid competition, including frequencies of service, schedules for operation, any unique aspects of the service sought by the State, endpoints and intermediate stops and connections to other intercity and commuter rail and transit services, and estimates of annual ridership, revenue and expenses during the period of operation covered by the fair bid competition.

2. Describe the analysis, if any, undertaken regarding the incorporation of this service into State and/or regional transportation plans.

3. Describe the experience or analysis, if any, undertaken by the State regarding competitive selection of passenger service providers, by any mode of intercity transportation, for commuter rail service or for local transit service.

4. Describe how the State or States envision their role and that of the selected operator in defining the key attributes of the service to be provided.

5. Describe the history, if any, of State and other non-Federal financial support for this service and the financial support the State and other non-Federal sources propose during the period of operation resulting from the fair bid competition, clearly indicating the estimated amount and sources for the required non-Federal funds required.

6. Identify the entity that would conduct the fair bid competition. To the extent this entity does not presently have legal authority to undertake such a competition, identify the process and schedule under which this authority would be provided.

7. Describe the route over which the service would be operated, including the owner of the rail infrastructure, the traffic types (including ownership of trains), volumes, and speeds presently involved in operation on the track segment(s) over which the service would operate.

8. Describe any communications between the State and the owner of the rail infrastructure over which the service would operate that addresses the issue of access for passenger service operated by an entity other than

Amtrak, including the terms and conditions under which this access would be provided.

9. Describe how the State or States would propose that a fair bid procedure to be implemented by the Secretary should address the issue of access to rail infrastructure.

10. Describe the equipment proposed for use in providing the service, its current ownership, current use and any commitment that the State might have for access to this equipment.

11. Describe how the State or States would propose that a fair bid procedure to be implemented by the Secretary should address the issue of access to rail passenger equipment.

12. Describe the provisions the State or States would make to address the liability of the operator selected under the fair bid competition, the owner of the rail infrastructure and others in the event of an accident.

13. Describe how the State or States would propose that a fair bid procedure to be implemented by the Secretary should address the issue of liability.

14. Describe any other issues that need to be addressed either by the Secretary or by the State or States to implement a fair bid competitive process for selection of an operator of an intercity passenger rail service.

*Format:* Statements of Interest or comments may not exceed twenty-five pages in length.

*Selection Criteria:* The following will be considered to be positive selection factors in evaluating Statements of Interest for this demonstration:

1. The contribution the proposed fair bid competitive selection will make to understanding the issues that must be addressed in competitive selection of intercity rail operators.

2. The timeliness of the initiation of the competitive bid process and initiation of the competitively bid service.

3. The ability of the State or States to adequately address the challenges facing a competitive selection of an operator of intercity passenger rail service.

4. Financial commitment from non-Federal sources.

5. Cost to the Federal Government.

6. Past and likely future State commitments to support the service in question.

7. Projected ridership, revenues, expenses and capital needs of the expected service.

8. Likely effects of the competitively bid service on other Amtrak services.

9. Length of the demonstration period and prospects for the service at the end of the demonstration period.

Issued in Washington, DC on April 7, 2004.

**Mark E. Yachmetz,**

*Associate Administrator for Railroad Development.*

[FR Doc. 04-8321 Filed 4-12-04; 8:45 am]

BILLING CODE 4910-06-P

## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

April 6, 2004.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Pub. L. 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

**DATES:** Written comments should be received on or before May 13, 2004 to be assured of consideration.

#### Internal Revenue Service (IRS)

*OMB Number:* 1545-0056.

*Form Number:* IRS Forms 1023 and 872-C.

*Type of Review:* Extension.

*Title:*

Form 1023: Application for Recognition of Exemption Under section 501(c)(3) of the Internal Revenue Code; and

Form 872-C: Consent Fixing Period of Limitation upon Assessment of Tax Under section 4940 of the Internal Revenue Code.

*Description:* Form 1023 is filed by applicants seeking Federal income tax exemption as organizations described in section 501(c)(3). IRS uses the information to determine if the applicant is exempt and whether the applicant is a private foundation. Form 872-C extends the statute of limitations for assessing tax under section 4940.

*Respondents:* Not-for-profit institutions.

*Estimated Number of Respondents/Recordkeepers:* 29,409.

*Estimated Burden Hours Respondent/Recordkeeper:*

Form	Recordkeeping	Learning about the law or the form	Preparing and sending the form to the IRS
1023 Parts I to IV .....	55 hr., 43 min .....	5 hr., 00 min .....	8 hr., 32 min.
1023 Schedule A .....	7 hr., 10 min .....	00 min .....	7 min.
1023 Schedule B .....	4 hr., 46 min .....	30 min .....	36 min.
1023 Schedule C .....	5 hr., 1 min .....	35 min .....	42 min.
1023 Schedule D .....	4 hr., 4 min .....	42 min .....	47 min.
1023 Schedule E .....	9 hr., 19 min .....	1 hr., 5 min .....	1 hr., 17 min.
1023 Schedule F .....	2 hr., 37 min .....	2 hr., 52 min .....	3 hr., 3 min.
1023 Schedule G .....	2 hr., 37 min .....	00 min .....	2 min.
1023 Schedule H .....	1 hr., 54 min .....	42 min .....	45 min.
1023 Schedule I .....	3 hr., 35 min .....	00 min .....	3 min.
872-C .....	1 hr., 25 min .....	24 min .....	25 min.

*Frequency of response:* On occasion.  
*Estimated Total Reporting/Recordkeeping Burden:* 2,069,267 hours.  
*OMB Number:* 1545-0704.  
*Form Number:* IRS Form 5471 and related Schedules.  
*Type of Review:* Revision.  
*Title:* Information Return of U.S. Persons with Respect to Certain Foreign Corporations.

*Description:* Form 5471 and related schedules are used by U.S. persons that have an interest in a foreign corporation. The form is used to report income from the foreign corporation. The form and schedules are used to satisfy the reporting requirements of sections 6035, 6038 and 6046 and the regulations thereunder pertaining to the

involvement of U.S. persons with certain foreign corporations.  
*Respondents:* Business or other for-profit, Individuals or households.  
*Estimated Number of Respondents/Recordkeepers:* 43,000.  
*Estimated Burden Hours Respondent/Recordkeeper:*

Form	Recordkeeping	Learning about the law or the form	Preparing and sending the form to the IRS
5471 .....	82 hr., 45 min .....	16 hr., 14 min .....	24 hr., 17 min.
Schedule J (Form 5471) .....	3 hr., 49 min .....	1 hr., 29 min .....	1 hr., 37 min.
Schedule M (Form 5471) .....	26 hr., 33 min .....	6 min .....	32 min.
Schedule N (Form 5471) .....	8 hr., 22 min .....	2 hr., 28 min .....	2 hr., 43 min.
Schedule O (Form 5471) .....	10 hr., 45 min .....	24 min .....	35 min.

*Frequency of response:* Annually.  
*Estimated Total Reporting/Recordkeeping Burden:* 6,700,035 hours.  
*OMB Number:* 1545-0720.  
*Form Number:* IRS Forms 8038, 8038-G, and 8038-GC.  
*Type of Review:* Revision.  
*Title:* Form 8038: Information Return for Tax-Exempt Private Activity Bond Issues;

Form 8038-G: Information Return for Tax-Exempt Governmental Obligation; and  
 Form 8038-GC: Information Return for Small Tax-Exempt Governmental Bond Issues, Leases, and Installment Sales  
*Description:* Forms 8038, 8038-G, and 8038-GC collect the information that IRS is required to collect by Code section 149(e). IRS uses the information

to assure that tax-exempt bonds are issued consistent with the rules of Internal Revenue Code (IRC) sections 141-149.  
*Respondents:* State, local or tribal government, not-for-profit institutions  
*Estimated Number of Respondents/Recordkeepers:* 3,816.  
*Estimated Burden Hours Respondent/Recordkeeper:*

Form	Learning about the law or the form	Preparing the form	Copying, assembling, and sending the form to the IRS
8038 .....	10 hr., 35 min .....	12 hr., 27 min .....	16 min.
8038-G .....	2 hr., 52 min .....	3 hr., 15 min .....	00 min.
8038-GC .....	2 hr., 22 min .....	2 hr., 34 min .....	00 min.

*Frequency of response:* Quarterly, Annually, Other (8038-GC at least once every 5 years).  
*Estimated Total Reporting/Recordkeeping Burden:* 293,900 hours.  
*OMB Number:* 1545-0908.  
*Form Number:* IRS Forms 8282 and 8283.  
*Type of Review:* Revision.

*Title:* Form 8282: Donee Information Return (Sale, Exchange or Other Disposition of Donated Property); and Form 8283: Noncash Charitable Contributions.  
*Description:* Internal Revenue Code section 170(a)(1) and regulation section 1.170A-13(c) require donors of property valued over \$5,000 to file certain information with their tax return in order to receive the charitable

contribution deduction. Form 8283 is used to report the required information. Code section 6050L requires donee organizations to file an information return with the IRS if they dispose of the property received within two years. Form 8282 is used for this purpose.  
*Respondents:* Individuals or households, Business or other for-profit.  
*Estimated Number of Respondents/Recordkeepers:* 4,718,000.

*Estimated Burden Hours Respondent/ Recordkeeper:*

Recordkeeping .....	3 hr., 35 min.
Learning about the law or the form.	12 min.
Preparing and sending the form to the IRS.	15 min.

*Frequency of response:* Annually.  
*Estimated Total Reporting/ Recordkeeping Burden:* 9,485,220 hours.  
*OMB Number:* 1545-1603.  
*Regulation Project Number:* REG-104691-97 Final.

*Type of Review:* Extension.  
*Title:* Electronic Tip Report.  
*Description:* The regulations provide rules authorizing employers to establish electronic systems for use by their tipped employees in reporting tips to their employer. The information will be used by employers to determine the

amount of income tax and FICA tax to withhold from the tipped employee's wages.

*Respondents:* Business or other for-profit, Individuals or households.  
*Estimated Number of Respondents/ Recordkeepers:* 300,000.  
*Estimated Burden Hours Respondent/ Recordkeeper:* 2 hours  
*Frequency of response:* On occasion.  
*Estimated Total Reporting/ Recordkeeping Burden:* 600,000 hours.  
*OMB Number:* 1545-1668.  
*Form Number:* IRS Form 8865 and Schedules.

*Type of Review:* Extension.  
*Title:* Return of U.S. Persons With Respect to Certain Foreign Partnerships.  
*Description:* The Taxpayer Relief Act of 1997 significantly modified the information reporting requirements with respect to foreign partnerships. The Act made the following three changes: (1)

Expanded section 6038B to require U.S. persons transferring property to foreign partnerships in certain transactions to report those transfers; (2) expanded section 6038 to require certain U.S. Partners of controlled foreign partnerships to report information about the partnerships; and (3) modified the reporting required under section 6046A with respect to acquisitions and dispositions of foreign partnership interests. Form 8865 is used by U.S. persons to fulfill their reporting obligations under sections 6038B, 6038, and 6046A.

*Respondents:* Business or other for-profit, Individuals or households, Not-for-profit institutions.  
*Estimated Number of Respondents/ Recordkeepers:* 5,000.  
*Estimated Burden Hours Respondent/ Recordkeeper:*

Form	Recordkeeping	Learning about the law or the form	Preparing, copying, assembling and sending the form to the IRS
8865 .....	98 hr., 55 min .....	22 hr., 38 min .....	36 hr., 22 min.
Schedule K-1 (Form 8865) .....	31 hr., 4 min .....	10 hr., 3 min .....	18 hr., 10 min.
Schedule O (Form 8865) .....	13 hr., 9 min .....	2 hr., 22 min .....	2 hr., 42 min.
Schedule P (Form 8865) .....	5 hr., 15 min .....	30 min .....	36 min.

*Frequency of response:* Annually.  
*Estimated Total Reporting/ Recordkeeping Burden:* 458,510 hours.

*OMB Number:* 1545-1733.  
*Form Number:* IRS Form 720-CS.  
*Type of Review:* Extension.  
*Title:* Carrier Summary Report.  
*Description:* Representatives of the motor fuel industry, state governments, and the Federal government are working to ensure compliance with excise taxes on motor fuels. This joint effort has resulted in a system to track the movement of all products to and from terminals. Form 720-CS is an information return that will be used by carriers to report their monthly deliveries and receipts of products to and from terminals.

*Respondents:* Business or other for-profit.  
*Estimated Number of Respondents/ Recordkeepers:* 475.  
*Estimated Burden Hours Respondent/ Recordkeeper:*

Recordkeeping .....	14 hr., 21 min.
Learning about the law or the form.	30 min.
Preparing and sending the form to the IRS.	45 min.

*Frequency of response:* Monthly.  
*Estimated Total Reporting/ Recordkeeping Burden:* 183,027 hours.  
*OMB Number:* 1545-1734.

*Form Number:* IRS Form 720-TO.  
*Type of Review:* Extension.  
*Title:* Terminal Operator Report.

*Description:* Representatives of the motor fuel industry, state governments, and the Federal government are working to ensure compliance with excise taxes on motor fuels. This joint effort has resulted in a system to track the movement of all products to and from terminals. Form 720-TO is an information return that will be used by terminal operators to report their monthly receipts and disbursements of products.

*Respondents:* Business or other for-profit.  
*Estimated Number of Respondents/ Recordkeepers:* 1,500.  
*Estimated Burden Hours Respondent/ Recordkeeper:*

Recordkeeping .....	19 hr., 21 min.
Learning about the law or the form.	30 min.
Preparing and sending the form to the IRS.	49 min.

*Frequency of response:* Monthly.  
*Estimated Total Reporting/ Recordkeeping Burden:* 2,347,020 hours.  
*OMB Number:* 1545-1735.  
*Revenue Procedure Number:* Revenue Procedure 2001-20.  
*Type of Review:* Extension.

*Title:* Voluntary Compliance on Alien Withholding Program ("VCAP").

*Description:* The revenue procedure will improve voluntary compliance of colleges and universities in connection with their obligations to report, withhold and pay taxes due on compensation paid to foreign students and scholars (nonresident aliens). The revenue procedure provides an optional opportunity for colleges and universities which have not fully complied with their tax obligations concerning nonresident aliens to self-audit and come into compliance with applicable reporting and payment requirements.

*Respondents:* Not-for-profit institutions, State, local or tribal government.  
*Estimated Number of Respondents/ Recordkeepers:* 495.  
*Estimated Burden Hours Respondent/ Recordkeeper:* 700 hours.

*Frequency of response:* On occasion.  
*Estimated Total Reporting/ Recordkeeping Burden:* 346,500 hours.  
*OMB Number:* 1545-1862.  
*Form Number:* IRS Form 8316.  
*Type of Review:* Extension.

*Title:* Information Regarding Request for Refund of Social Security Tax Erroneously Withheld on Wages Received by a Nonresident alien on an F, J, or M Type Visa.



*Description:* Form 8316 is requested from nonresident alien taxpayers claiming a refund of Social Security tax erroneously withheld on wages received.

*Respondents:* Individuals or households.

*Estimated Number of Respondents/Recordkeepers:* 22,000.

*Estimated Burden Hours Respondent/Recordkeeper:* 15 minutes.

*Frequency of response:* On occasion.

*Estimated Total Reporting/*

*Recordkeeping Burden:* 5,500 hours.

*Clearance Officer:* Glenn P. Kirkland, (202) 622-3428, Internal Revenue Service, Room 6411-03, 1111 Constitution Avenue, NW., Washington, DC 20224.

*OMB Reviewer:* Joseph F. Lackey, Jr., (202) 395-7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**Lois K. Holland,**

*Treasury PRA Clearance Officer.*

[FR Doc. 04-8261 Filed 4-12-04; 8:45 am]

BILLING CODE 4830-01-P

## DEPARTMENT OF THE TREASURY

### Office of the Secretary

#### List of Countries Requiring Cooperation With an International Boycott

In order to comply with the mandate of section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which may require participation in, or cooperation with, an

international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Bahrain,  
Kuwait,  
Lebanon,  
Libya,  
Oman,  
Qatar,  
Saudi Arabia,  
Syria,  
United Arab Emirates, and  
Yemen, Republic of.

Dated: April 7, 2004.

**Barbara Angus,**

*International Tax Counsel, (Tax Policy).*

[FR Doc. 04-8262 Filed 4-12-04; 8:45 am]

BILLING CODE 4810-25-M

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### Open Meeting of the Joint Committee of the Taxpayer Advocacy Panel

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice.

**SUMMARY:** An open meeting of the Joint Committee of the Taxpayer Advocacy Panel will be conducted. The Taxpayer Advocacy Panel is reviewing public comment, ideas, and suggestions on

improving customer service at the Internal Revenue Service brought forward by the Area and Issue Committees.

**DATES:** The meeting will be held Friday, May 7, 2004, 8 a.m. to 5:30 p.m., and Saturday, May 8, 2004, 8 a.m. to 12:30 p.m. central daylight time.

**FOR FURTHER INFORMATION CONTACT:** Barbara Toy at 1-888-912-1227, or 414-297-1611.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Joint Committee of the Taxpayer Advocacy Panel (TAP) will be held Friday, May 7, 2004, 8 a.m. to 5:30 p.m., and Saturday, May 8, 2004, 8 a.m. to noon, central daylight time at the Embassy Suites Hotel Chicago Downtown, 600 North State Street, Chicago, IL 60610. If you would like to have the Joint Committee of TAP consider a written statement, please call 1-888-912-1227 or 414-297-1611, or write Barbara Toy, TAP Office, MS-1006-MIL, 310 West Wisconsin Avenue, Milwaukee, WI 53203-2221, or fax to 414-297-1623, or you can contact us at [www.improveirs.org](http://www.improveirs.org).

The agenda will include the following: Monthly committee summary report, discussion of issues brought to the joint committee, office reports, and discussion of next meeting.

Dated: March 7, 2004.

**Bernard Coston,**

*Director, Taxpayer Advocacy Panel.*

[FR Doc. 04-8379 Filed 4-12-04; 8:45 am]

BILLING CODE 4830-01-P

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## Corrections

Federal Register

Vol. 69, No. 71

Tuesday, April 13, 2004

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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.

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**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39****[Docket No. 2003-NM-47-AD; Amendment 39-13566; AD 2004-07-22]****RIN 2120-AA64****Airworthiness Directives; Boeing Model 747 Series Airplanes***Correction*

In rule document 04-7449 beginning on page 18250, in the issue of

Wednesday, April 7, 2004 make the following correction:

**§ 39.13 [Corrected]**

On page 18254, in the third column, in § 39.13, under the heading **Initial Inspection**, in the first line, paragraph "(a)" should read "(d)".

[FR Doc. C4-7449 Filed 4-12-04; 8:45 am]

BILLING CODE 1505-01-D



# Federal Register

Tuesday,  
April 13, 2004

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## Part II

### Department of the Interior

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Fish and Wildlife Service

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50 CFR Part 17

Endangered and Threatened Wildlife and  
Plants; Proposed Designation of Critical  
Habitat for the California Red-legged Frog  
(*Rana aurora draytonii*); Proposed Rule

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

RIN-1018-AJ16

**Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the California Red-legged Frog (*Rana aurora draytonii*)**

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the California red-legged frog (*Rana aurora draytonii*) pursuant to the Endangered Species Act of 1973, as amended (Act). A total of approximately 1,674,582 hectares (4,138,064 acres) in Alameda, Butte, Contra Costa, El Dorado, Fresno, Kern, Los Angeles, Marin, Mariposa, Merced, Monterey, Napa, Plumas, Riverside, San Benito, San Diego, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, Santa Cruz, Solano, Sonoma, Stanislaus, Tehama, Tuolumne, and Ventura Counties, California, is proposed for designation as critical habitat.

This proposed designation of critical habitat for the California red-legged frog is being published in accordance with the November 6, 2002, consent decree that ordered us to publish a proposal by March 2004. In light of this deadline, we have based this proposal solely on the configuration of our previously published final designation of critical habitat for the California red-legged frog (66 FR 14626, March 13, 2001). We hereby solicit data and comments from the public on all aspects of this proposal, including data on economic and other impacts of the designation.

We may revise this proposal prior to final designation to incorporate or address new information received during public comment periods or otherwise available to us.

**DATES:** We will accept comments until June 14, 2004. Public hearing requests must be received by May 28, 2004.

**ADDRESSES:** If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Suite W. 2605, Sacramento, California 95825.

2. You may hand-deliver written comments and information to our

Sacramento Fish and Wildlife Office, at the above address, or fax your comments to 916/414-6712.

3. You may send your comments by electronic mail (e-mail) to [fw1crlf@r1.fws.gov](mailto:fw1crlf@r1.fws.gov). For directions on how to submit electronic filing of comments, see the "Public Comments Solicited" section below. In the event that our Internet connection is not functional, please submit comments by the alternate methods mentioned above.

All comments and materials received, as well as supporting documentation used in preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** For general information, and for information about Alameda, Butte, Contra Costa, El Dorado, Fresno, Kern, Marin, Mariposa, Merced, Napa, Plumas, San Joaquin, San Mateo, Santa Clara, Solano, Sonoma, Stanislaus, Tehama, and Tuolumne Counties, contact Wayne White, Field Supervisor, Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Suite W. 2605, Sacramento, California 95825 (telephone 916/414-6600; facsimile 916/414-6712).

For information about Monterey, Los Angeles, San Benito, San Luis Obispo, Santa Barbara, Santa Cruz, and Ventura Counties, contact Diane Noda, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2394 Portola Road, Suite B, Ventura, California 93003 (telephone 805/644-1766; facsimile 805/644-3958).

For information about areas in the San Gabriel Mountains of Los Angeles County or Riverside and San Diego Counties, contact Jim Bartel, Field Supervisor, Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008 (telephone 760/431-9440; facsimile 760/431-9624).

**SUPPLEMENTARY INFORMATION:****Public Comments Solicited**

It is our intent that any final action resulting from this proposal will be as accurate as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. On the basis of public comment, during the development of the final rule we may find that areas proposed are not essential, appropriate for exclusion under section 4(b)(2), or not appropriate for exclusion, in which

case they would be removed from or made part of the final designation. We particularly seek comments concerning:

(1) The reasons why any areas should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of designation will outweigh any threats to the species resulting from the designation;

(2) Specific information on the amount and distribution of California red-legged frog and its habitat, and which habitat or habitat components are essential to the conservation of this species and why;

(3) Whether the primary constituent elements for the California red-legged frog as defined in this proposal are biologically and scientifically accurate, specifically,

(a) Whether aquatic habitat used for breeding must have a minimum deep water depth of 0.5 meters (m) (20 inches (in));

(b) Whether aquatic components must consist of two or more breeding sites located within 2 kilometers (km) (1.25 miles (mi)) of each other;

(c) Should the primary constituent elements be more descriptive of the variations in habitat preference throughout the range of the subspecies;

(4) Whether the two recently discovered populations of California red-legged frogs in Youngs Creek, in Calaveras County, and in artificial ponds in Nevada County are essential to the conservation of the subspecies and should be included in designated critical habitat;

(5) Land use designations and current or planned activities in or adjacent to the areas proposed and their possible impacts on proposed critical habitat;

(6) Any foreseeable economic or other potential impacts resulting from the proposed designation, in particular, any impacts on small entities;

(7) Some of the lands we have identified as essential for the conservation of the California red-legged frog are not being proposed as critical habitat. We specifically solicit comment on the inclusion or exclusion of such areas and:

(a) Whether these areas are essential;

(b) Whether these areas warrant exclusion; and

(c) The basis for not designating these areas as critical habitat (section 3(5)(A) or section 4(b)(2) of the Act);

(8) With specific reference to the recent amendments to sections 4(a)(3) and 4(b)(2) of the Act, we request information from the Department of Defense to assist the Secretary of the Interior in excluding critical habitat on lands administered by or under the

control of the Department of Defense based on the benefit of an Integrated Natural Resources Management Plan (INRMP) to the conservation of the species; and information regarding impacts to national security associated with proposed designation of critical habitat; and

(9) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods (see ADDRESSES section). Please submit electronic comments in ASCII file format and avoid the use of special characters or any form of encryption. Please also include "Attn: RIN 1018-AJ16" in your e-mail subject header and your name and return address in the body of your message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly by calling our Sacramento Fish and Wildlife Office at phone number 916/414-6600. Please note that the e-mail address [fw1crlf@r1.fws.gov](mailto:fw1crlf@r1.fws.gov) will be closed out at the termination of the public comment period. In the event that our Internet connection is not functional, please submit comments by the alternate methods mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home addresses from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

## Preamble

### *Designation of Critical Habitat Provides Little Additional Protection to Species*

In 30 years of implementing the Act, the Service has found that the designation of statutory critical habitat provides little additional protection to most listed species, while consuming significant amounts of conservation resources. The Service's present system for designating critical habitat is driven by litigation rather than biology, limits our ability to fully evaluate the science involved, consumes enormous agency resources, and imposes huge social and economic costs. The Service believes that additional agency discretion would allow our focus to return to those actions that provide the greatest benefit to the species most in need of protection.

### *Role of Critical Habitat in Actual Practice of Administering and Implementing the Act*

While attention to and protection of habitat is paramount to successful conservation actions, we have consistently found that, in most circumstances, the designation of critical habitat is of little additional value for most listed species, yet it consumes large amounts of conservation resources. Sidle (1987) stated, "Because the ESA [Act] can protect species with and without critical habitat designation, critical habitat designation may be redundant to the other consultation requirements of section 7."

Currently, only 445 or 36 percent of the 1244 listed species in the U.S. under the jurisdiction of the Service have designated critical habitat (Service 2004). We address the habitat needs of all 1244 listed species through conservation mechanisms such as listing, section 7 consultations, the Section 4 recovery planning process, the Section 9 protective prohibitions of unauthorized take, Section 6 funding to the States, and the Section 10 incidental take permit process. The Service believes that it is these measures that may make the difference between extinction and survival for many species.

### *Procedural and Resource Difficulties in Designating Critical Habitat*

We have been inundated with lawsuits regarding critical habitat designation, and we face a growing number of lawsuits challenging critical habitat determinations once they are made. These lawsuits have subjected the Service to an ever-increasing series of court orders and court-approved settlement agreements, compliance with

which now consumes nearly the entire listing program budget. This leaves the Service with little ability to prioritize its activities to direct scarce listing resources to the listing program actions with the most biologically urgent species conservation needs.

The consequence of the critical habitat litigation activity is that limited listing funds are used to defend active lawsuits and to comply with the growing number of adverse court orders. As a result, the Service's own to proposals to undertake conservation actions based on biological priorities are significantly delayed.

The accelerated schedules of court-ordered designations have left the Service with almost no ability to provide for additional public participation beyond those minimally required by the Administrative Procedure Act (APA), the Act, and the Service's implementing regulations, or to take additional time for review of comments and information to ensure the rule has addressed all the pertinent issues before making decisions on listing and critical habitat proposals, due to the risks associated with noncompliance with judicially imposed deadlines. This in turn fosters a second round of litigation in which those who will suffer adverse impacts from these decisions challenge them. The cycle of litigation appears endless, is very expensive, and in the final analysis provides little additional protection to listed species.

The costs resulting from the designation include legal costs, the cost of preparation and publication of the designation, the analysis of the economic effects and the cost of requesting and responding to public comment, and in some cases the costs of compliance with National Environmental Policy Act (NEPA); all are part of the cost of critical habitat designation. These costs result in minimal benefits to the species that are not already afforded by the protections of the Act enumerated earlier, and they directly reduce the funds available for direct and tangible conservation actions.

## Background

### *Species Description*

The California red-legged frog (*Rana aurora draytonii*) is the largest native frog in the western United States. It is endemic to California and Baja California, Mexico. It is typically found from sea level to elevations of approximately 1,500 meters (m) (5,000 feet (ft)). The California red-legged frog ranges in body length from 40 to 130 millimeters (mm) (1.6 to 5.1 in), with



adult females attaining a significantly longer body length than males (138 mm (5.4 in) versus 116 mm (4.6 in)) (Hayes and Miyamoto 1984). The posterior abdomen and hind legs of adults vary in color, but are often red or salmon pink; the back is characterized by small black flecks and larger irregular dark blotches with indistinct outlines on a brown, gray, olive, or reddish-brown background. Dorsal spots usually have light centers (Stebbins 1985), and the dorsolateral folds (folds along the sides of the frog) are prominent. Larvae range from 14 to 80 mm (0.6 to 3.1 in) in length, and the background color of the body is dark brown or olive with darker spots (Storer 1925). A line of very small, indistinct gold-colored spots are thought to become the dorsolateral fold. The California red-legged frog is one of two subspecies of the red-legged frog (*R. aurora*). For a detailed description of the two subspecies, see the Recovery Plan for the California Red-legged Frog (Service 2002) and references identified within the plan.

#### Life History

Male California red-legged frogs appear at breeding sites 2 to 4 weeks before females (Storer 1925). A pair in amplexus (breeding position) moves to an oviposition site (the location where eggs are laid), and the eggs are fertilized while being attached to a brace. Braces include emergent vegetation such as bulrushes (*Scirpus* sp.), cattails (*Typha* sp.), or roots and twigs, although breeding has been documented in ponds without emergent vegetation (Steven Bobzien *in litt.* 2001). Each mass contains about 2,000 to 5,000 individual eggs measuring approximately 2.0 to 2.8 mm (0.08 to 0.11 in) in diameter. Eggs hatch in 6 to 14 days depending on water temperatures (Jennings *et al.*, 1992). Larvae typically metamorphose between July and September 3.5 to 7 months after eggs are laid (Storer 1925; Wright and Wright 1949). However, several researchers have recently observed larvae to overwinter in Contra Costa, Marin, Santa Clara, and San Luis Obispo Counties (Bobzien *et al.* 2000), and possibly in Ventura County (R. Smith, Los Angeles Zoo, *in litt.* 2001), with new metamorphs being observed in March and April.

Of the various life stages, larvae probably experience the highest mortality rates. Survival rate from hatching to metamorphosis (the process of changing from a tadpole to a frog) has been estimated as less than 1 percent (Jennings *et al.* 1992), 1.9 percent (Cook 1997), or less than 5 percent (Lawler *et al.* 1999) for California red-legged frog tadpoles co-occurring with bullfrog

tadpoles, and 30 to 40 percent for California red-legged frog tadpoles occurring without bullfrogs (Lawler *et al.* 1999). Sexual maturity can be attained at 2 years of age by males and 3 years of age by females (Jennings and Hayes 1985), with adults living 8 to 10 years (Jennings, U.S. Geological Survey (USGS), Biological Resources Division (BRD), pers. comm. 2000). However, the average life span is probably much lower (Scott, USGS, BRD, pers. comm. 2000).

#### Geographic Range

The historic range of the California red-legged frog extended along the coast from the vicinity of Point Reyes National Seashore, Marin County, California, and inland from the vicinity of Redding, Shasta County, California, southward to northwestern Baja California, Mexico (Jennings and Hayes 1985; Hayes and Krempels 1986). California red-legged frogs have been documented in 46 counties in California, but now remain in only 248 streams or drainages in 26 counties; the subspecies has lost approximately 70 percent of its former range (61 FR 25813, May 23, 1996). California red-legged frogs are still locally abundant within portions of the San Francisco Bay area (including Marin County) and the central coast. Within the remaining distribution of the subspecies, only isolated populations have been documented in the Sierra Nevada, northern Coast, and northern Transverse ranges. The subspecies was previously believed to be extirpated (exterminated) from most of its range in the southern Transverse and Peninsular Ranges, but two additional populations have recently been discovered. The species is still present in Baja California, Mexico (California Natural Diversity Data Base (CNDDB) 1998; Service, *in litt.* 2003).

#### Threats

The California red-legged frog was listed as a threatened subspecies on May 23, 1996 (61 FR 25813). Habitat loss and alteration, overexploitation, and introduction of exotic predators were significant factors in the subspecies' decline in the early-to-mid-1900s. Reservoir construction, expansion of introduced predators, management of grazing in riparian areas resulting in loss of stream bank habitat and plunge pools, and prolonged drought fragmented and eliminated many of the Sierra Nevada foothill populations. Only a few drainages currently support California red-legged frogs in the Sierra Nevada foothills, compared to more than 60 historical records. In Northern California, few California red-legged

frog populations occupy naturally occurring wetland environments. As natural wetlands and streams were converted for agriculture, flood control, and urban development, California red-legged frogs colonized small artificial impoundments created by cattle ranchers for the purpose of providing water for their cattle. Without these impoundments, the range of California red-legged frogs would be limited further in this region.

Several researchers have attributed the decline and extirpation of California red-legged frogs to the introduction of bullfrogs (*Rana catesbeiana*) and predatory fishes (Hayes and Jennings 1986; Moyle 1973). This decline has been attributed to both predation and competition. Twedt (1993) observed the predation of juvenile northern red-legged frogs (*R. aurora aurora*) and suggested that bullfrogs may prey on subadult red-legged frogs. This is supported by Cook (Sonoma County Water Agency, *in litt.* 2000) and David Cook and M. Jennings (*in litt.* 2000), who documented bull frog predation of both tadpoles and juvenile California red-legged frogs, as well as a large adult, by bullfrogs. In addition, bullfrogs may have a competitive advantage over red-legged frogs. Bullfrogs are larger, have more generalized food habits (Bury and Whelan 1984), and have an extended breeding season (Storer 1933) during which an individual female produces as many as 20,000 eggs (Emlen 1977). Further, bullfrog larvae are unpalatable to predatory fish (Kruse and Francis 1977). Bullfrogs also interfere with red-legged frog reproduction. Both California and northern red-legged frogs have been observed in amplexus with both male and female bullfrogs (Twedt 1993; Service files).

California red-legged frogs are currently threatened by human activities, many of which operate concurrently and cumulatively with each other and with natural disturbances (e.g., droughts and floods). Current factors associated with declining populations of the frog include degradation and loss of habitat through urbanization, mining, improper management of grazing, recreation, invasion of nonnative plants, impoundments, water diversions, degraded water quality, and introduced predators. These factors have resulted in the isolation and fragmentation of habitats within many watersheds, often precluding dispersal between subpopulations and jeopardizing the viability of metapopulations (broadly defined as multiple subpopulations that occasionally exchange individuals through dispersal and are capable of

colonizing or rescuing habitat patches when the local subpopulations have been extirpated). The fragmentation of existing habitat, and the continued colonization of existing habitat by nonnative species, may represent the most significant current threats to California red-legged frogs.

Numerous studies have demonstrated the impacts of fragmentation on other anuran (frog and toad) species. Urban populations of common frogs (*Rana temporaria*) were more genetically distinct than rural populations (Hitchins and Beebee 1997). Based on genetic analysis, Reh and Seitz (1990) found that highways effectively isolated *R. temporaria* populations. Kuhn (1987, in Reh and Seitz 1990) estimated that 24 to 40 cars per hour killed 50 percent of common toad (*Bufo bufo*) individuals migrating across a road, while Heine (1987, in Reh and Seitz 1990) found that 26 cars per hour could reduce the survival rate of toads crossing roads to zero. In addition, Fahrig *et al.* (1995) found a significant negative correlation between traffic density and the density of anuran populations. Thus, heavily traveled roads are an important human-caused landscape component, hindering amphibian movement through vehicle strikes and thereby fragmenting amphibian populations.

In addition to the fragmentation of habitat, activities that occur on upland habitats can have both direct and indirect significant deleterious impacts on California red-legged frogs. For example, amphibian species-richness (number of species in an area) is related to land use in the watersheds of Puget Sound, Washington (Richter and Azous 1995, 1997); species-richness was significantly lower in watersheds where more than 40 percent of the land area was developed. This was attributed to increases in the total water level fluctuations within wetlands (*e.g.*, both increases in the number of fluctuations of water levels within the wetland and increases in the magnitude of fluctuations). Specifically, urbanization leads to higher peak flows and volumes, resulting in increases in the magnitude, frequency, and duration of wetland hydroperiods and stream levels (Reinalt and Taylor 1997). Urbanization within the range of the California red-legged frog often results in similar effects on wetlands.

Urbanization results in additional water runoff sources into wetlands and stream courses associated with irrigation and home use activities, especially during the summer months. This often drastically alters the hydroperiod and converts intermittent streams and seasonal wetlands to

perennial aquatic habitat. Such alteration allows nonnative species such as bullfrogs and nonnative warm water fish species to invade the habitat and further adversely affect California red-legged frog populations. California red-legged frogs are rarely found in areas where a large majority of the watershed has been developed (H.T. Harvey and Associates 1997, Service files). This is further supported by Schueler (1994), who summarized research examining macroinvertebrate and fish diversity. Those results illustrated the difficulty of maintaining predevelopment stream quality when watershed development exceeds 10–15 percent impervious cover. For example, Klein (1979, in Schueler 1994) found that macroinvertebrate diversity consistently became poor when watershed imperviousness exceeded 10 to 15 percent; this has been supported by Schueler and Galli (1992 in Schueler 1994) and Shaver *et al.* (1994, in Schueler 1994). This loss of diversity has also been observed in fish (Klein 1979; Limburg and Schmidt 1990, both in Schueler 1994).

In addition to the modification of hydroperiod, impacts within the watershed can also affect water and habitat quality. As watersheds are developed, the area of impervious surface increases, resulting in an increase of sediments containing organic matter, pesticides and fertilizers, heavy metals, hydrocarbons, and other debris entering streams and wetlands (U.S. Environmental Protection Agency (EPA) 1993). Skinner *et al.* (1999) found developed watersheds had greater concentrations of toxic effluents than less developed areas with more open space. The decrease in water quality can have profound impacts on native amphibians and other wetland vertebrates. Richter and Azous (1997) observed that wetlands adjacent to undeveloped upland areas were more likely to have richer populations of native amphibians. Mensing *et al.* (1998) found that amphibian abundance was negatively influenced by land use at small scales (*e.g.*, within 0.5 to 1.0 km (0.30 to 0.60 mi).

Habitat fragmentation, wetland conversions, and hydrological alterations cumulatively result in changes in wetland species composition, including amphibian composition. Amphibian declines can be attributed to increasing numbers of nonnative competitors and predators capable of thriving in disturbed conditions (Harris 1998). Onorato *et al.* (1998) found native fish species were sensitive to anthropogenic disturbances

and were becoming less abundant within the study area. They also found introduced generalists able to tolerate lower quality habitat and to replace native fish species within the system. This scenario has been demonstrated in Santa Clara Valley, California, where the loss of California red-legged frog populations was attributed in part to the invasion of bullfrogs into urbanized areas (H.T. Harvey and Associates 1997).

#### Climate

California red-legged frogs are adapted to survive in a Mediterranean climate where habitat quality varies spatially and temporally. Due to this variability, population sizes can vary widely from year to year. During favorable years, California red-legged frogs can experience extremely high rates of reproduction and produce large numbers of dispersing young, resulting in an increase in the number of occupied sites. In contrast, frogs may temporarily disappear from an area during periods of extended drought. Therefore, it is important for the long-term survival and recovery of the species to protect those sites that appear to be unoccupied, but can be recolonized by dispersing individuals from nearby subpopulations (Semlitsch 2000).

#### Habitat

California red-legged frogs use a variety of habitat types, including various aquatic, riparian, and upland habitats. They include, but are not limited to, ephemeral ponds, intermittent streams, seasonal wetlands, springs, seeps, permanent ponds, perennial creeks, manmade aquatic features, marshes, dune ponds, lagoons, riparian corridors, blackberry (*Rubus* sp.) thickets, nonnative annual grasslands, and oak savannas. Among the variety of habitats where California red-legged frogs have been found, the only common factor is association with a permanent water source. Apparently, California red-legged frogs can use virtually any aquatic system, provided a permanent water source, ideally free of nonnative predators, is nearby. Permanent water sources can include, but are not limited to, ponds, perennial creeks (or permanent plunge pools within intermittent creeks), seeps, and natural and artificial springs. California red-legged frogs may complete their entire life cycle in a particular area (*i.e.*, a pond that is suitable for all life stages) or utilize multiple habitat types. These variable life-history characteristics enable California red-legged frogs to change habitat use in response to

varying conditions. During a period of abundant rainfall, the entire landscape may become suitable habitat. Conversely, habitat use may be drastically confined during periods of prolonged drought.

Populations of California red-legged frogs are most likely to persist where multiple breeding areas are within an assemblage of habitats used for dispersal (N. Scott and G. Rathbun in litt. USGS, BRD, 1998), a trait typical of many frog and toad species (Laan and Verboom 1990; Reh and Seitz 1990; Mann et al. 1991; Sjogren-Gulve 1994; Griffiths 1997; Marsh et al. 1999). Breeding sites have been documented in a variety of aquatic habitats. Larvae, juveniles, and adult frogs have been observed inhabiting streams, creeks, ponds, marshes, sag ponds, deep pools, and backwaters within streams and creeks, dune ponds, lagoons, estuaries, and artificial impoundments, such as stock ponds. Furthermore, breeding has been documented in these habitat types irrespective of vegetation cover. Frogs successfully breed in artificial ponds with little or no emergent vegetation (S. Bobzien in litt. 2000), and have been observed to successfully breed and inhabit stream reaches that are not cloaked in riparian vegetation (Bobzien et al. 2000). The importance of riparian vegetation for this subspecies is not well understood. It is believed that riparian plant communities provide good foraging habitat due to the moisture and camouflage that occur within the community, as well as providing areas for dispersal and supporting pools and backwater aquatic areas for breeding. However, other factors are more likely to influence the suitability of aquatic breeding sites, such as the general lack of introduced aquatic predators.

California red-legged frogs often disperse from their breeding habitat to utilize various aquatic, riparian, and upland estivation habitats in the summer; however, it is also common for individuals to remain in the breeding area on a year-round basis. Frogs use a number of habitat features, including ponds, streams, marshes, boulders or rocks, organic debris such as downed trees or logs, industrial debris, and agricultural features such as drains, watering troughs, or spring boxes. When riparian habitat is present, frogs spend considerable time resting and feeding in the vegetation (G. Rathbun in litt. 2000). When riparian habitat is absent, frogs spend considerable time resting and feeding under rocks and ledges, both in and out of water (Trish Tatarian, Sonoma State University, Sonoma County in litt. 2000). California red-legged frogs can also use small mammal

burrows and moist leaf litter (Jennings and Hayes 1994). Stream channels with portions narrower and deeper than 46 centimeters (cm) (18 in) may also provide habitat (61 FR 25813). This type of dispersal and habitat use is not observed in all California red-legged frogs, however, and is likely dependent on the year-to-year variations in climate and habitat suitability and varying requirements of each life stage.

#### Dispersal

At any time of the year, adult California red-legged frogs may move from breeding sites. They can be encountered living within streams at distances exceeding 2.9 km (1.8 mi) from the breeding site and have been found farther than 100 m (328 ft) from water in adjacent dense riparian vegetation. The California red-legged frog has been observed inhabiting riparian areas for up to 77 days (J. Bulger et al., USGS, BRD, in litt. 2000), but typically remains within 60 m (200 ft) of water. During periods of wet weather, starting with the first rains of fall, some individuals may make overland excursions through upland habitats. Most of these overland movements occur at night. Evidence from marked adult frogs on the San Simeon coast of San Luis Obispo County, California, suggests that frog movements of about 1.6 km (1 mi), over upland habitats, are possible over the course of a wet season (N. Scott and G. Rathbun, in litt. 1998). Frogs will make long-distance, straight-line, point-to-point movements rather than using corridors for moving between habitats (N. Scott and G. Rathbun, in litt. 1998). Dispersing adult frogs in northern Santa Cruz County traveled distances from 0.4 km (0.25 mi) to more than 3.2 km (2 mi) without apparent regard to topography, vegetation type, or riparian corridors (J. Bulger, in litt. 2000). Many newly metamorphosed juveniles tend to disperse short distances initially from July through September, and then move farther away from the breeding habitat during warm rain events (Monk 1997a; M. Jennings in litt. 2000; N. Scott in litt. 2000; Brian Mori in litt. 2000). Bobzien et al. (2000) observed juveniles inhabiting a wide variety of habitats while adults primarily inhabited deep pools; and they postulated that juveniles might segregate themselves away from adults to escape predation and competition.

The dispersal capabilities of juveniles have not been studied, but are likely dependent upon rainfall and moisture levels during and immediately following dispersal events and on habitat availability and environmental

variability. There is anecdotal evidence that juvenile red-legged frogs disperse at least 1 km (0.6 mi) away from breeding habitat. These data are the result of consulting biologists conducting surveys for California tiger salamanders (*Ambystoma californiense*) in eastern Alameda (Monk and Associates 1997a and 1997b) and Santa Clara Counties (B. Mori, in litt. 2000). In both locations, newly metamorphosed California red-legged frogs were found dispersing away from breeding habitat during rain events. The ability of juveniles and adults to disperse is important for the long-term survival and recovery of the subspecies because the dispersing individuals can recolonize areas subjected to localized extirpation.

The manner in which nondispersing California red-legged frogs use upland habitats is not well understood. The length of time California red-legged frogs spend in upland habitats, patterns of use, and whether juveniles, subadults, and adults use uplands differently are under study. Preliminary data from San Simeon and Pico creeks in central California indicated that the number of days when California red-legged frogs were found more than 2.0 m (7 ft) from water ranged from 0 to 56 days (G. Rathbun, in litt. 2000), while the majority of California red-legged frogs observed in eastern Contra Costa County spent the entire wet season within streamside habitat (T. Tatarian, in litt. 2000). However, several frogs have been documented moving away from the streamside habitat for varying periods (T. Tatarian, pers. comm. 2001).

The healthiest California red-legged frog populations persist as a collection of subpopulations that exchange genetic information through individual dispersal events. These populations persist and flourish where suitable breeding and nonbreeding habitats are interspersed throughout the landscape and are interconnected by unfragmented dispersal habitat. Where this habitat mosaic exists, local extirpations may be counterbalanced by the colonization of new habitat or recolonization of unoccupied areas of suitable habitat. Studies on other frogs and toads have demonstrated that the probability of a habitat being occupied is positively correlated with the distance to the nearest currently occupied habitat patch (Laan and Verboom 1990; Mann et al. 1991; Marsh et al. 1999). Isolated patches far removed from occupied patches eventually became extirpated (Sjogren-Gulve 1994). In addition to distance between habitat patches, the fragmentation of dispersal routes can also result in the isolation of subpopulations. Studies from other

anuran species have shown that fragmentation has resulted in problems associated with inbreeding (Reh and Seitz 1990; Hitchings and Beebe 1997) and an increase in unoccupied suitable habitat, and can ultimately result in extinction (Sjogren-Gulve 1994).

The long-term probability of the survival and recovery of California red-legged frogs is dependent upon the protection of existing breeding habitat, the movements of individuals between aquatic patches, and the ability to recolonize newly created or vacated habitats. Recolonization, which is vital to the recovery of this subspecies, is dependent upon landscape characteristics including the distance between patches, the number and severity of barriers between patches, and the presence of interconnecting elements (e.g., habitat where frogs can rehydrate), and upon the dispersal capability of California red-legged frogs (Laan and Verboom 1990).

Since the publication of our last designation of critical habitat for the California red-legged frog on March 13, 2001 (66 FR 14626), two new populations of the subspecies have been documented. However, due to limited access to these populations since they occur on private property and the limited information we have concerning their status, we have not been able to make a determination at this time as to whether they are essential to the conservation of the subspecies. We specifically seek information concerning these two new populations to assist us in making that determination. If, upon receipt of additional data and further analysis, we determine these populations to be essential to the conservation of the subspecies, it would be our intention to include them in final critical habitat.

The first population was discovered on private property in the South Fork Yuba River watershed in Nevada County, California, in 2002. This presence of this population was subsequently confirmed by Sacramento Fish and Wildlife staff in 2003. During the site visit, California red-legged frog tadpoles were observed suggesting the presence of a breeding population. Further, during this site visit, there was no specific evidence visible of invasive or predatory species on site. The California red-legged frogs on this site occur in artificial ponds, but they are not active stock ponds. Because this population is located on private land, we have not had the opportunity to study it. Consequently, we are not able to make any specific conclusions regarding the status of this population of the subspecies at this locale.

A second population of California red-legged frogs was discovered on private land in Youngs Creek, Calaveras County, California, in 2003. The population was subsequently confirmed, but due to limited access, we have not been able to determine the extent of this population. Youngs Creek is a tributary of Cosgove Creek, a tributary to Calaveras River; however, during the site visits, there was no specific evidence visible of invasive or predatory species bullfrogs are known to occur in ponds on adjacent property.

#### Previous Federal Action

On February 2, 1994, we published a proposal to list the frog as an endangered species (59 FR 4888). Based on information provided during the public comment period, we subsequently published a final rule listing the California red-legged frog as threatened on May 23, 1996 (61 FR 25813). At the time of the final listing, we determined that designating critical habitat was not prudent due to the potential increased degree of threat from the publication of specific localities. This specific information would make the species more vulnerable to vandalism and also to collection for market consumption. Consequently, we did not designate critical habitat for the subspecies.

On March 24, 1999, the Earthjustice Legal Defense Fund, on behalf of the Jumping Frog Research Institute, the Southwest Center for Biological Diversity, and the Center for Sierra Nevada Conservation, filed a lawsuit in the Northern District of California on our failure to designate critical habitat for the California red-legged frog.

On December 15, 1999, the court ordered us to make a prudency determination by August 31, 2000, and issue a final rule by December 29, 2001. On January 18, 2000, the court clarified an error in the December 15, 1999, order stating that the Service shall issue a final rule by December 29, 2000. On August 22, 2000, we submitted a declaration requesting an extension of the court order to March 1, 2001, citing the need to extend the comment period. On September 11, 2000, we published a proposed rule to designate approximately 2,175,000 ha (5,373,650 ac) as critical habitat for the California red-legged frog (65 FR 54891) in California. The comment period was open until October 11, 2000. During this comment period, four public hearings were held in Ventura (September 19, 2000), San Luis Obispo (September 21, 2000), Dublin (September 26, 2000), and Sacramento (September 28, 2000). On December 21, 2000, we published a

notice (65 FR 80409) announcing the reopening of the comment period on the proposal to designate critical habitat for the California red-legged frog and a notice of availability of the draft economic analysis on the proposed determination. The comment period was reopened until January 22, 2001. A final rule designating critical habitat for the California red-legged frog was signed on March 1, 2001, and published in the *Federal Register* on March 13, 2001 (66 FR 14626).

On June 8, 2001, the Home Builders Association of Northern California, California Chamber of Commerce, California Building Industry Association, California Alliance for Jobs, and the Building Industry Legal Defense Fund filed a lawsuit in the U.S. District Court for the District of Columbia challenging the Service's designation of critical habitat for the California red-legged frog. *Home Builders Ass'n of Northern California, et al. v. Norton, et al.*, Civ. No. 01-1291 (R/L) (D. D.C.). On November 6, 2002, the court entered a consent decree remanding the designation to the Service to conduct an economic analysis in accordance with the Tenth Circuit's decision in *New Mexico Cattle Growers Ass'n v. U.S. Fish and Wildlife Service*, 248 F.3d 1277 (10th Cir. 2001). The consent decree vacated the critical habitat designation for the California red-legged frog with the exception of Units 5 and 31, Units not known to be occupied by the frog, and ordered the Service to promulgate a proposed revised designation by March 2004, and a final revised rule by November 2005. This proposed rule is published in accordance with the November 6, 2002, consent decree.

#### Critical Habitat

Section 3(5)(A) of the Act defines critical habitat as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" means the use of all methods and procedures that are necessary to bring an endangered or a threatened species to the point at which listing under the Act is no longer necessary.

The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve,



preserve, or other conservation area. It does not allow government or public access to private lands. Under section 7 of the Act, Federal agencies must consult with us on activities they undertake, fund, or permit that may affect critical habitat and lead to its destruction or adverse modification. However, the Act prohibits unauthorized take of listed species and requires consultation for activities that may affect them, including habitat alterations, regardless of whether critical habitat has been designated. We have found that the designation of critical habitat provides little additional protection to most listed species.

To be included in a critical habitat designation, habitat must be either a specific area within the geographic area occupied by the species on which are found those physical or biological features essential to the conservation of the species (primary constituent elements, as defined at 50 CFR 424.12(b)) and which may require special management considerations or protections, or be specific areas outside of the geographic area occupied by the species which are determined to be essential to the conservation of the species. Section 3(5)(C) of the Act states that not all areas that can be occupied by a species should be designated as critical habitat unless the Secretary determines that all such areas are essential to the conservation of the species. Our regulations (50 CFR 424.12(e)) also state that, "The Secretary shall designate as critical habitat areas outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species." Regulations at 50 CFR 424.02(j) define special management considerations or protection to mean any methods or procedures useful in protecting the physical and biological features of the environment for the conservation of listed species. When we designate critical habitat, we may not have the information necessary to identify all areas that are essential for the conservation of the species. Nevertheless, we are required to designate those areas we consider to be essential, using the best information available to us. Accordingly, we do not designate critical habitat in areas outside the geographic area occupied by the species unless the best available scientific and commercial data demonstrate that unoccupied areas are essential for the conservation needs of the species.

Section 4(b)(2) of the Act requires that we take into consideration the

economic, national security, and any other relevant impact, of specifying any particular area as critical habitat. We may exclude areas from critical habitat designation when the benefits of exclusion outweigh the benefits of including the areas within critical habitat, provided the exclusion will not result in extinction of the species.

Our Policy on Information Standards Under the Endangered Species Act, published in the *Federal Register* on July 1, 1994 (59 FR 34271) and our U.S. Fish and Wildlife Service Information Quality Guidelines (2002) provide criteria, establish procedures, and provide guidance to ensure that our decisions represent the best scientific and commercial data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge.

Section 4 of the Act requires that we designate critical habitat on the basis of what we know at the time of designation. Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery.

Areas that support populations of a listed species, but are outside the designation of critical habitat for it, will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as determined on the basis of the best available information at the time of the action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of

designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

#### Methods

In identifying areas that are essential to conserve the California red-legged frog, we used the best scientific and commercial data available. These included data from research and survey observations published in peer-reviewed articles, recovery criteria and strategy outlined in the Recovery Plan (Service 2002), regional Geographic Information System (GIS) watershed and species coverages, data compiled in the California Natural Diversity Database (CNDDB), data and analysis used to develop regional Habitat Conservation Plans (HCPs), and data collected from reports submitted by biologists holding section 10(a)(1)(A) recovery permits. In the development of this proposal, we also took into consideration any information provided to us during the public comment periods on our previous proposed critical habitat designation (65 FR 54891, September 11, 2000) and draft economic analysis of our proposed critical habitat (65 FR 80409, December 21, 2000).

#### Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to designate as critical habitat, we are required to consider those physical and biological features (primary constituent elements) that are essential to the conservation of the species, and that may require special management considerations and protection. These include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected protection from disturbance or are representative of the historic geographical and ecological distributions of a species.

Due to the complex life history and dispersal capabilities of the California red-legged frog, and the dynamic nature of the environments in which they are found, the primary constituent elements described below are found throughout the watersheds that are being designated as critical habitat. Special management, such as habitat rehabilitation efforts (e.g., removal of nonnative predators),



may be necessary throughout the area being proposed for designation. Critical habitat for California red-legged frogs will provide for breeding and nonbreeding habitat and for dispersal between these habitats, as well as allowing for expansion of frog populations, which is essential to the conservation of the subspecies.

Critical habitat includes: (a) Essential aquatic habitat; (b) associated uplands; and (c) dispersal habitat connecting essential aquatic habitat.

#### Breeding and Foraging Habitat

Aquatic habitat is essential for providing space, food, and cover, necessary to sustain all life stages of California red-legged frogs. It consists of virtually all low-gradient fresh water bodies, including natural and man-made (e.g., stock) ponds, backwaters within streams and creeks, marshes, lagoons, and dune ponds, except for deep lacustrine water habitat (e.g., deep lakes and reservoirs 20 ha (50 ac) or larger in size) inhabited by nonnative predators. The subspecies requires a permanent water source to ensure that aquatic habitat is available year round. Permanent water sources can include, but are not limited to, ponds, perennial creeks (or permanent plunge pools within intermittent creeks), seeps, and springs. Aquatic habitat used for breeding must have a minimum deep water depth of 0.5 m (20 in) and maintain water during the entire tadpole rearing season (at least March through July). During periods of drought, or less-than-average rainfall, these breeding sites may not hold water long enough for individuals to complete metamorphosis, but these sites would still be considered essential breeding habitat in wetter years. Ponds that support a small population of California red-legged frogs, but are not surrounded by suitable upland habitat, or are cut off from other breeding ponds or permanent water sources by impassable dispersal barriers, do not have the primary constituent elements for California red-legged frog critical habitat.

To be a primary constituent element for California red-legged frog critical habitat, the aquatic components must consist of two or more breeding sites located within 2 km (1.25 mi) of each other; at least one of the breeding sites must also be a permanent water source. Also, the aquatic component can consist of two or more seasonal breeding sites with a permanent nonbreeding water source located within 2 km (1.25 mi) of each breeding site. California red-legged frogs have been documented to travel 3.6 km (2.25 mi) in a virtual straight-line migration from nonbreeding to breeding

habitats (J. Bulger, in litt. 2000). We believe that this is likely the upward limit of dispersal capability and that the 2-km (1.25-mi) dispersal element will ensure that connectivity between breeding habitats will be maintained within areas designated as critical habitat. In addition, breeding sites must be connected by essential dispersal habitat, described below.

#### Associated Upland Habitat For Forage, Shelter, Water Quality Maintenance

Associated upland and riparian habitat is essential to maintain California red-legged frog populations associated with essential aquatic habitat. The associated uplands and riparian habitat provide food and shelter sites for California red-legged frogs and assist in maintaining the integrity of aquatic sites by protecting them from disturbance and supporting the normal functions of the aquatic habitat. The palustrine or emergent aquatic habitat is often characterized by presence of cattail (*Typha* spp.), bulrush (*Scirpus* spp.), and other persistent emergent vegetation that allows for shelter, forage, and attachment of egg masses, while the associated adjacent upland habitat often contains blackberry (*Rubus* sp.) and other upland perennial species that provide for shelter from predatory species and forage habitat (Service 2002).

Key conditions include the timing, duration, and extent of water moving within the system, filtering capacity, and maintaining the habitat to favor California red-legged frogs and discourage the colonization of nonnative species such as bullfrogs. Essential upland habitat consists of all upland areas within 90 m (300 ft) of the edge of the ordinary high-water mark, or no further than the watershed boundary. This is based, in part, on the work of J. Bulger *et al.* (in litt. 2000), who found that frogs were capable of inhabiting upland habitats within 60 m (200 feet) of aquatic habitat for continuous durations exceeding 20 days, and G. Rathbun (in litt. 2000), who observed frogs inhabiting riparian habitat for durations exceeding 30 days.

#### Dispersal Habitat

Essential dispersal habitat provides connectivity among California red-legged frog breeding habitat (and associated upland) patches. While frogs can pass many obstacles, and do not require a particular type of habitat for dispersal, the habitat connecting essential breeding locations and other aquatic habitat must be free of barriers (e.g., a physical or biological feature that prevents frogs from dispersing beyond

the feature) and at least 90 m (300 ft) wide. Essential dispersal habitat consists of all upland and wetland habitat free of barriers that connects two or more patches of essential breeding habitat within 2 km (1.25 mi) of one another. Dispersal barriers include heavily traveled roads (an average of 30 cars per hour from 10 p.m. to 4 a.m.) that possess no bridges or culverts; moderate to high density urban or industrial developments; and large reservoirs over 20 ha (50 ac) in size. Agricultural lands such as row crops, orchards, vineyards, and pastures do not constitute barriers to California red-legged frog dispersal.

In summary, the primary constituent elements for the California red-legged frog consist of three components:

- (1) Aquatic habitat with a permanent water source with pools (*i.e.*, water bodies) having a minimum depth of 0.5 m (20 in) for breeding and which can maintain water during the entire tadpole rearing season;
- (2) Upland areas up to 90 m (300 ft) from the water's edge associated with the above aquatic habitat that will provide for shelter, forage, maintenance of the water quality of the aquatic habitat, and dispersal; and
- (3) Upland barrier-free dispersal habitat that is at least 90 m (300 ft) in width that connect at least two (or more) suitable breeding locations defined by the aquatic habitat above, all within 2 km (1.25 miles) of one another.

#### Criteria Used To Identify Critical Habitat

We considered several criteria in the selection and proposal of specific boundaries for California red-legged frog critical habitat. These criteria, which follow the recovery strategy outlined in the final Recovery Plan (Service 2002), focused on designating units (1) Throughout the geographic and elevational range of the subspecies; (2) that would result in protecting populations that are geographically distributed in a manner that allows for the continued existence of viable and essential metapopulations despite fluctuations in the status of subpopulations; and (3) that possess large continuous blocks of occupied habitat, representing source populations and/or unique ecological characteristics, or areas where the re-establishment of California red-legged frogs is essential to the recovery of the subspecies (Service 2002). We first determined the occupancy status of areas. Areas were considered to possess extant populations if California red-legged frogs have been documented in that area since 1985. We then selected areas that

are inhabited by populations (source populations) that are capable of maintaining their current population levels and capable of providing individuals to recruit into subpopulations found in adjacent areas. We also selected several areas that may lack source populations, but which have other unique ecological significance, with the goal of maintaining the full range of the genetic variability and evolutionary adaptation in the subspecies. These include areas on the periphery of the current range and elsewhere that represent the historic distribution of the subspecies, and areas that provide connectivity among source populations or between source populations and unoccupied extirpated areas. Of the approximate 1,674,582 ha (4,140,440 ac) that are proposed for designation as critical habitat for the California red-legged frog, an estimated 81,020 ha (200,212 ac) are considered unoccupied habitat (Units 5 and 31). All of this unoccupied habitat occurs on Federal lands, and was identified in the core areas essential for California red-legged frog recovery in our final Recovery Plan (Service 2002). Both unoccupied and occupied areas not included in this designation can still be targets for recovery actions, including reestablishing populations.

The critical habitat units were delineated by first creating data layers in a geographic information system (GIS) format of all of the core areas as proposed in the final Recovery Plan (Service 2002). We then used the California Watershed Map (CALWATER version 2.2), a coverage developed by California Department of Water Resources (DWR), to identify watersheds containing core areas and delineate their boundaries in a 1:24,000 format. CALWATER is a set of watershed boundaries meeting standardized delineation criteria, consisting of six levels of increasing specificity, with the primary purpose of assigning a single, unique code to a specific watershed polygon (e.g., a planning watershed). CALWATER delineates the boundaries of planning watersheds 1,200 to 4,000 ha (3,000 to 10,000 ac) in size. We used these planning watersheds as the minimum mapping unit to delineate critical habitat units because watersheds represent functional, hydrologic management units that allow for efficient evaluation of factors that affect the quality of aquatic habitat and, thus, are extremely relevant to amphibian populations. The use of planning watersheds also allowed us to delineate critical habitat that protects habitat

quality, breeding and nonbreeding habitat, and dispersal habitat in a manner consistent with the overall goal of protecting and sustaining metapopulations.

We selected all of the planning watersheds that intersected areas of high California red-legged frog abundance, areas essential to maintain connectivity, and/or areas of unique ecological significance as identified by the core areas from the final Recovery Plan (Service 2002). In areas where planning watersheds were large and/or watersheds were significantly altered hydrologically, we used alternative structural, political, or topographic boundaries (e.g., roads, county boundaries, elevation contour lines) as critical habitat boundaries because in these areas the benefits of using planning watersheds were limited.

Using the planning watersheds as the minimum mapping unit of this critical habitat designation would not allow us to avoid towns, other developed areas, or other areas where the primary constituent elements are not found. To address this shortcoming, we overlaid the planning watersheds with a 100-m Universal Transverse Mercator (UTM) North American Datum of 1983 (NAD 83) grid. Using information from recent digital aerial photography, we then removed NAD 83 grid cells that did not contain the primary constituent elements. Although the data available to us were not sufficiently detailed to definitively map the primary constituent elements by grid cell, this approach did allow us to remove significant urban and other developed areas, including some agricultural lands, from the final designation.

We could not depend solely on federally owned lands for critical habitat designation as these lands are limited in geographic location, size, and habitat quality within the current range of the California red-legged frog. In addition to the federally owned lands, we are designating critical habitat on non-Federal public lands and privately owned lands, including land owned by the California Department of Parks and Recreation, the California Department of Fish and Game, DWR, and the University of California, as well as regional and local park lands and water district lands. All non-Federal lands designated as critical habitat meet the definition of critical habitat under section 3 of the Act in that they are within the geographical area occupied by the subspecies, are essential to the conservation of the subspecies, and may require special management considerations or protection.

We are also proposing to designate areas that are not currently known to be occupied by the subspecies, but which are essential for its conservation. We included one area in Tuolumne County in the Sierra Nevada and one in the Tujunga watershed in Los Angeles County in the Peninsular Range of southern California. These areas, within the historic range of the subspecies with some occurrences documented as recently as the mid-1980s, are strong candidate areas for re-establishment due to preliminary positive discussions with Federal agencies and adjacent landowners, are composed entirely of large blocks of Federal land, and are identified in the final Recovery Plan (Service 2002) as important reestablishment areas essential to the recovery of the California red-legged frog. These areas also provide important connectivity among currently occupied areas. In order for future reestablishment to be successful, special management in these areas is needed, including habitat restoration and the removal of nonnative species, such as predators. However, the primary constituent elements for California red-legged frogs are present in these areas.

Without reestablishment in the Sierra Nevada and Southern California, it is probable that California red-legged frogs will be extirpated from these areas, greatly reducing the likelihood of eventual recovery of the species. As a result, we have determined that reestablishment of California red-legged frog populations in these currently unoccupied areas is essential to the conservation of the species. Since the listing of California red-legged frogs as a threatened species in 1996, no progress has been made improving habitat for this species within these unoccupied areas. Because California red-legged frogs have been extirpated from these areas, Federal agencies have determined their actions will not adversely affect California red-legged frogs and have further declined to use their authority under section 7(a)(1) to help recover the California red-legged frogs in the Sierra Nevada and southern Transverse and Peninsular Ranges. Therefore, given the lack of protection for these areas, it is important to ensure that special management actions are implemented in unoccupied lands within the Sierra Nevada by designating them as critical habitat.

#### *Special Management Considerations or Protections*

As we undertake the process of designating critical habitat for a species, we first evaluate lands defined by those physical and biological features

essential to the conservation of the species for inclusion in the designation pursuant to section 3(5)(A) of the Act. Secondly, we then evaluate lands defined by those features to assess whether they may require special management considerations or protections. As discussed throughout this proposed rule, our previous final designation of critical habitat for the California red-legged frog (66 FR 14626, March 13, 2001) and in our final recovery plan for the species (Service 2002), the frog and its habitat are threatened by a multitude of factors including by not limited to: degradation and loss of habitat through urbanization, mining, improper management of grazing, recreation, invasion of nonnative plants, impoundments, water diversions, degraded water quality, and introduced predators, and previous overexploitation. While many of these threats operate concurrently and cumulatively with each other and with natural disturbances (e.g., droughts and floods), the fragmentation of existing habitat, and the continued colonization of existing habitat by nonnative species, may represent the most significant current threats to California red-legged frogs. As such we believe that each area proposed for designation as critical habitat may require some level of management and/or protection to address the current and future threats to the California red-legged frog and habitat essential to its conservation to ensure the overall recovery of the subspecies.

#### *Relationship to Section 4(a)(3) of the Act*

The Sikes Act Improvements Act of 1997 (Sikes Act) requires each military installation that includes land and water suitable for the conservation and management of natural resources to complete, by November 17, 2001, an Integrated Natural Resources Management Plan (INRMP). An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found there. Each INRMP includes an assessment of the ecological needs on the installation, including needs to provide for the conservation of listed species; a statement of goals and priorities; a detailed description of management actions to be implemented to provide for these ecological needs; and a monitoring and adaptive management plan. We consult with the military on the development and implementation of INRMPs for installations with listed species.

The 2004 National Defense Authorization Act (Pub. L. 108-136,

November 2003), Section 318 Military Readiness and Conservation of Protected Species makes the following amendment to section 4(a)(3) of the Act:

The Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan [INRMP] prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

We believe that bases that have completed and approved INRMPs that address the needs of the species generally do not meet the definition of critical habitat as those bases require no additional special management or protection. Further, the statutory amendment to section 4(a)(3) the Act provides guidance on the relationship of INRMPs to critical habitat. Therefore, lands essential to the conservation of a species that are owned or managed by DOD and covered by INRMPs are excluded from critical habitat designations if they meet the following three criteria: (1) A current INRMP must be complete and provide a conservation benefit to the species; (2) the plan must provide assurances that the conservation management strategies will be implemented; and (3) the plan must provide assurances that the conservation management strategies will be effective, by providing for periodic monitoring and revisions as necessary. If all of these criteria are met, then the lands covered under the plan would be excluded from a designation of critical habitat for the species.

Vandenberg Air Force Base completed an INRMP in 1997 prior to the passage and implementation of the Sikes Act Improvements Act of 1997. While we did not specifically participate in its development, this older plan does provide conservation measures for the California red-legged frog, as well as for the management of important wetland habitats across the base. The INRMP provides management direction on conserving listed and imperiled species and their habitats on the base. Known frog sites are protected from disturbance from human activities and grazing through measures appropriate to the given situation. Vandenberg's INRMP specifies monitoring of California red-legged frog populations on the base, and periodic surveys to provide continuous evaluation of the subspecies' status at known and new sites identified on the base. In addition, Vandenberg actively consults with us on all actions that may affect California red-legged frogs on the

base, and has implemented conservation measures as recommended. Therefore, we have determined that Vandenberg Air Force Base that the INRMP as drafted and implemented provides a conservation benefit to the California red-legged frog. As such, the lands essential to the conservation of the California red-legged frog on Vandenberg Air Force Base have been excluded from this proposed designation of critical habitat for the subspecies.

The Camp Parks U.S. Army Reserve Training Area completed an INRMP in 2003 and a biological opinion was issued in July of 2003. The INRMP does provide conservation measures for the California red-legged frog and provides management direction on conserving listed and imperiled species and their habitats on the base. In addition, Camp Parks actively consults with us on all actions that may affect California red-legged frogs on the base, and has implemented conservation measures as recommended. Therefore, we have determined that the INRMP as drafted and implemented provides a conservation benefit to the California red-legged frog. As such, the lands essential to the conservation of the California red-legged frog on Camp Parks have been excluded from this proposed designation of critical habitat for the subspecies. Camp Parks has worked with us and developed an Endangered Species Management Plan (ESMP) as an appendix to their INRMP. The ESMP was drafted specifically for California red-legged frogs and includes nonnative predator control and other conservation measures that would benefit the frog. Camp Parks has already implemented several portions of the ESMP and had done so even prior to the final approval of the INRMP.

#### *Relationship to Section 4(b)(2) of the Act*

Section 4(b)(2) of the Act states that critical habitat shall be designated, and revised, on the basis of the best available scientific data available after taking into consideration the economic impact, the effect on national security, and any other relevant impact, of specifying any particular area as critical habitat. An area may be excluded from critical habitat if it is determined, following an analysis, that the benefits of such exclusion outweigh the benefits of specifying a particular area as critical habitat, unless the failure to designate such area as critical habitat will result in the extinction of the species. Consequently, we may exclude an area from designated critical habitat based on economic impacts, the effect on national

security, or other relevant impacts such as preservation of conservation partnerships, if we determine the benefits of excluding an area from critical habitat outweigh the benefits of including the area in critical habitat, provided the action of excluding the area will not result in the extinction of the species.

In our critical habitat designations, we have used both the provisions outlined in section 4(b)(2) of the Act to evaluate those specific areas that are proposed for designation as critical habitat and those areas which are subsequently finalized (*i.e.*, designated). We have applied the provisions of these sections of the Act to lands essential to the conservation of the subject species to evaluate and either exclude them from final critical habitat or not include them in proposed critical habitat. Lands which we have either excluded from or not included in critical habitat based on those provisions include those covered by: (1) Legally operative HCPs that cover the species, and provide assurances that the conservation measures for the species will be implemented and effective; (2) draft HCPs that cover the species, have undergone public review and comment, and provide assurances that the conservation measures for the species will be implemented and effective (*i.e.*, pending HCPs); (3) Tribal conservation plans that cover the species and provide assurances that the conservation measures for the species will be implemented and effective; (4) State conservation plans that provide assurances that the conservation measures for the species will be implemented and effective; (5) Fish and Wildlife Service Comprehensive Conservation Plans that provide assurances that the conservation measures for the species will be implemented and effective.

#### *Exclusions of Military Lands Pursuant to Section 4(b)(2) of the Act*

Although Camp San Luis Obispo (CSLO) completed their INRMP in November 2001, they are now updating it to include an additional species, and we are in process of evaluating it to determine if it adequately covers and provides a conservation benefit to the California red-legged frog. CSLO contains habitat essential to the conservation of the California red-legged frog. The proposed critical habitat encompasses more than 90 percent of CSLO. Subsection 4(b)(2) of the Act allows us to exclude areas from critical habitat designation where the benefits of exclusion outweigh the benefits of designation, provided the exclusion will not result in the extinction of the

species, in this case, the California red-legged frog.

#### (1) Benefits of Inclusion

The principal benefit of any designated critical habitat is that activities in such habitat that may affect critical habitat require consultation under section 7 of the Act. Such consultation would ensure that adequate protection is provided to avoid adverse modification of critical habitat. In the absence of designated critical habitat, this consultation will not look specifically at the issue of adverse modification of critical habitat; however, it will look at the very similar concept of jeopardy to the listed species. Our experience is that, under most circumstances, consultations under the jeopardy standard will reach the same result as consultations under the adverse modification standard. Implementing regulations (50 CFR Part 402) define "jeopardize the continued existence of" and "destruction or adverse modification of" in virtually identical terms. Jeopardize the continued existence of means to engage in an action "that reasonably would be expected \* \* \* to reduce appreciably the likelihood of both the survival and recovery of a listed species." Destruction or adverse modification means an Alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species." Common to both definitions is an appreciable detrimental effect on both survival and recovery of a listed species, in the case of critical habitat by reducing the value of the habitat so designated. Thus, actions satisfying the standard for adverse modification are nearly always found to also jeopardize the species concerned, and the existence of a critical habitat designation does not materially affect the outcome of consultation. Additional measures to protect the habitat from adverse modification are not likely to be required.

We have determined that the benefits of designating critical habitat on CSLO are small. The primary benefit of designation is the prohibition on destruction or adverse modification of critical habitat under section 7 of the Act. However, all frog habitat on CSLO is occupied, and we believe that section 7 consultation on any proposed action on these bases that would result in an adverse modification conclusion would also result in a jeopardy conclusion. As noted above, we expect that, when completed and adopted, the updated INRMPs will provide equal or greater protection to California red-legged frog

habitat on the bases than a critical habitat designation.

#### (2) Benefits of Exclusion

CSLO is a training facilities managed by the California Army Reserve National Guard (CA ARNG) and the U.S. Army (Army), respectively. Their mission is to provide a major training area for National Guard and U.S. Army Reserve troops for overseas deployment, and to protect public safety during emergency disasters. During the public comment period for the proposal for the previous designation of critical habitat for the California red-legged frog, CSLO concluded that the designation, if it were to become final, would seriously limit their ability to conduct their critical training activities. They conclude that a final designation that includes these installations would likely result in delays in training and closure of areas to allow for reinitiation of section 7 consultation on critical habitat. They asserted that the designation of critical habitat for the California red-legged frog on their facilities will have a detrimental effect on the ability of the CA ARNG and Army to meet their training mission and potentially affect national security.

Even though the lands on these bases currently meet the definition of critical habitat for the California red-legged frog, we have determined that it is appropriate to exclude CSLO from this critical habitat designation under section 4(b)(2) of the Act in the interest of national security. The primary benefit of excluding CSLO is to ensure that their mission-critical military training activities can continue without interruption while the INRMPs are being completed. CSLO is in the process of updating their draft INRMP. We fully expect that, once the INRMP is completed and approved, areas of the base included in the proposed critical habitat designation will no longer meet the definition of critical habitat, as they will require no additional special management or protection.

Training activities are ongoing, and the CA ARNG and Army believe that by implementing specific conservation measures, their training activities are not likely to adversely affect California red-legged frogs on the bases, ensuring compliance with section 7(d) of the Act. In particular, CSLO considers all permanent and intermittent waterways and riparian areas to be sensitive habitat and provides buffers. Sections of Chorro Creek, and several ponds, springs, and reservoirs have been fenced to exclude military training activities and cattle grazing. Although avoiding these areas constrains training activities to some



degree, the effectiveness of their overall mission is not compromised. Camp Parks has also identified essential California red-legged frog habitat and has designated these areas as sensitive habitat areas. Further, Camp Parks is currently implementing measures to promote the conservation of California red-legged frogs by implementing control of non-native predators.

The proposed critical habitat designation included about 90 percent of CSLO. If these areas are included in the final designation of critical habitat for the California red-legged frog, the CA ARNG and U.S. Army would be compelled by their interpretation of the Act to significantly curtail necessary training within the area designated as critical habitat, to the detriment of mission-critical training capability and potentially national security, until the reinitiation of consultation is concluded. As a result, this would greatly restrict use of the installation, severely limiting CSLO's utility as training sites.

#### *Benefits of Exclusion Outweigh the Benefits of Inclusion*

Through the development of this proposal, we have identified lands that we believe to be essential to the conservation of the California red-legged frog. We have considered these lands in relation to lands owned and managed by DOD that are used for mission-critical training. Based on our analysis above and our analysis and treatment of these lands in our previous designation of critical habitat for the California red-legged frog, we have determined that the benefits of excluding these lands from critical habitat pursuant to the potential effects on national security as allowed under section 4(b)(2) of the Act outweigh the potential benefits of including these lands in the proposed designation. Further, we have determined that excluding the bases will not result in the extinction of the red-legged frog, as numerous frog core areas remain within the final critical habitat designation and sections 7(a)(2) and 9 of the Act still apply to the activities affecting red-legged frogs on CSLO.

Should additional information become available that changes our analysis of the benefits of excluding any of these areas compared to the benefits of including them in the critical habitat designation, we may revise this final designation accordingly. Maps delineating essential habitat for the California red-legged frog, overlaid with "mission-critical" training areas on CSLO, are available for public review and comment at the Sacramento Fish

and Wildlife Office (see ADDRESSES section) or on the Internet at <http://sacramento.fws.gov/es/documents>. These maps are provided to allow the public the opportunity to adequately comment on these exclusions.

#### *Relationship of Critical Habitat to the San Joaquin County Multi-Species/Open Space Habitat Conservation Plan (San Joaquin County MSHCP)*

The San Joaquin County MSHCP was developed and a finalized EIR/EIS completed in November 2000. A non-jeopardy biological opinion was issued on the plan in May 2001. Participants in this HCP include seven cities and the County of San Joaquin. The San Joaquin MSHCP encompasses all of San Joaquin County except for federally-owned lands at the Lawrence Livermore Laboratory and some areas encompassing projects not covered by the San Joaquin County MSHCP (Tracy Hills, The American River Water Resources Investigation Project, Folsom South Canal Connection of the East Bay Municipal Utility District Supplemental Water Supply Program, and the South County Surface Water Supply Project). The San Joaquin County MSHCP is also a subregional plan under the State's NCCP and was developed in cooperation with the California Department of Fish and Game. Approximately 100,841 ac (40,808 ha) of covered species habitat are proposed for conservation.

We are proposing to exclude a portion of Unit 15 from proposed critical habitat for the California red-legged frog pursuant to section 4(b)(2) of the Act because it is within the planning area boundary for the San Joaquin County MSHCP. Our analysis for excluding portions of Unit 15 from proposed critical habitat is outlined below. The San Joaquin County Multi-Species Conservation Plan (SJMSCP) identifies the California red-legged frog as a covered species and has identified areas where growth and development are expected to occur (build-out areas). Only one percent of the area considered habitat for the California red-legged frog would be affected by development activities.

#### *Benefits of Inclusion*

As stated previously, the benefits of designating critical habitat on lands within the boundaries of approved HCPs are small. Where HCPs are in place that include coverage for the California red-legged frog, the HCPs and their IAs include management measures and protections designed to protect, restore, monitor, manage, and enhance the habitat to benefit the conservation of

the species. The San Joaquin County MSHCP seeks to accomplish these goals for the California red-legged frog through the implementation of specific conservation objectives. The principal benefit of designating critical habitat is that federally authorized or funded activities that may affect a species' critical habitat would require consultation with us under section 7 of the Act. In the case of the San Joaquin County MSHCP, we must evaluate the impact of the plan on the species for which the participants are seeking incidental take permits, pursuant to section 7 of the Act.

#### *Benefits of Exclusion*

The benefits of excluding lands within HCPs from critical habitat designation include relieving landowners, communities, and counties of any additional regulatory burden that might be imposed by critical habitat. Many HCPs, particularly large regional HCPs, take many years to develop and, upon completion, become regional conservation plans that are consistent with the recovery objectives for listed species that are covered within the plan area. Additionally, many of these HCPs provide conservation benefits to unlisted sensitive species. Imposing an additional regulatory review after an HCP is completed solely as a result of the designation of critical habitat may undermine conservation efforts and partnerships in many areas. In fact, it could result in the loss of species' benefits if participants abandon the voluntary HCP process because it may result in additional regulations requiring more of the participants than other parties who have not voluntarily participated in species conservation. Designation of critical habitat within the boundaries of approved HCPs could be viewed as a disincentive to those entities currently developing HCPs or contemplating them in the future.

A related benefit of excluding lands within HCPs from critical habitat designation is the unhindered, continued ability to seek new partnerships with future HCP participants including States, counties, local jurisdictions, conservation organizations, and private landowners, which together can implement conservation actions that we would be unable to accomplish otherwise. If lands within HCP plan areas are designated as critical habitat, it would likely have a negative effect on our ability to establish new partnerships to develop HCPs, particularly large, regional HCPs that involve numerous participants and address landscape-level conservation of species and habitats. By preemptively



excluding these lands, we preserve our current partnerships and encourage additional conservation actions in the future.

Furthermore, an HCP or NCCP/HCP application must itself be consulted upon. While this consultation will not look specifically at the issue of adverse modification to critical habitat, unless critical habitat has already been designated within the proposed plan area, it will determine if the HCP jeopardizes the species in the plan area. The jeopardy analysis is similar to the analysis of adverse modification to critical habitat. In addition, Federal actions not covered by the HCP in areas occupied by listed species would still require consultation under section 7 of the Act. HCP and NCCP/HCPs typically provide for greater conservation benefits to a covered species than section 7 consultations because HCPs and NCCP/HCPs assure the long-term protection and management of a covered species and its habitat, and funding for such management through the standards found in the 5 Point Policy for HCPs (64 FR 35242) and the HCP "No Surprises" regulation (63 FR 8859). Such assurances are typically not provided by section 7 consultations, which, in contrast to HCPs, often do not commit the project proponent to long-term special management or protections. Thus, a consultation typically does not accord the lands it covers the extensive benefits a HCP or NCCP/HCP provides. The development and implementation of HCPs or NCCP/HCPs provide other important conservation benefits, including the development of biological information to guide the conservation efforts and assist in species conservation, and the creation of innovative solutions to conserve species while allowing for development.

#### *Benefits of Exclusion Outweigh the Benefits of Inclusion*

We have reviewed and evaluated HCPs and NCCP/HCPs currently approved and implemented within the areas being proposed as critical habitat for the California red-legged frog. Based on this evaluation, we find that the benefits of exclusion of the lands essential to the conservation of the California red-legged frog in the planning area for the San Joaquin County MSHCP outweigh the benefits of proposing portions of Unit 15 as critical habitat.

The exclusion of these lands from critical habitat will help preserve the partnerships that we have developed with the local jurisdiction and project proponent in the development of the HCP and NCCP/HCP. The educational

benefits of critical habitat, including informing the public of areas that are essential for the long-term survival and conservation of the species are still accomplished from material provided on our website and through public notice and comment procedures required to establish an HCP or NCCP/HCP. The public has also been informed through the public participation that occurs in the development of many regional HCPs or NCCP/HCPs. For these reasons, we believe that proposing critical habitat has little benefit in areas covered by HCPs, provided that the HCP or NCCP/HCP specifically and adequately covers the species for which critical habitat is being proposed. We do not believe that this exclusion would result in the extinction of the species.

Should additional information become available that changes our analysis of the benefits of excluding any of these areas compared to the benefits of including them in the critical habitat designation, we may revise this final designation accordingly. Maps delineating essential habitat for the California red-legged frog, overlaid with the planning area for the San Joaquin County MSHCP, are available for public review and comment at the Sacramento Fish and Wildlife Office (*see ADDRESSES* section) or on the Internet at <http://sacramento.fws.gov>. These maps are provided to allow the public the opportunity to adequately comment on these exclusions.

#### *Relationship of Critical Habitat to the Draft Western Riverside Multiple Species Habitat Conservation Plan (MSHCP)*

The Draft Western Riverside Multiple Species Habitat Conservation Plan (MSHCP) has been in development for several years. Participants in this HCP include 14 cities; the County of Riverside, including the Riverside County Flood Control and Water Conservation Agency, Riverside County Transportation Commission, Riverside County Parks and Open Space District, and Riverside County Waste Department; the California Department of Parks and Recreation; and the California Department of Transportation. The Western Riverside MSHCP is also being proposed as a subregional plan under the State's NCCP and is being developed in cooperation with the California Department of Fish and Game. Within the 1.26 million-acre (510,000 ha) planning area of the MSHCP, approximately 153,000 ac (62,000 ha) of diverse habitats are proposed for conservation. The proposed conservation of 153,000 ac (62,000 ha) will complement other

existing natural and open space areas that are already conserved through other means (e.g., State Parks, Forest Service, and County Park Lands).

The County of Riverside and the participating jurisdictions have signaled their sustained support for the Western Riverside MSHCP as evidenced by the November 5, 2002, passage of a local bond measure to fund the acquisition of land in support of the MSHCP. On November 14, 2002, a Notice of Availability of a Draft Environmental Impact Report (EIS/EIR) and Receipt of and Application for an Incidental Take Permit was published in the **Federal Register**. Public comment on these documents was accepted until January 14, 2003. Subsequently, on June 17, 2003, the County of Riverside Board of Supervisors voted unanimously to support the completion of the Western Riverside MSHCP.

The Western Riverside MSHCP indicates that conservation actions within their planning area will be implemented such that the long-term conservation of the Riverside fairy shrimp will be addressed. Although the MSHCP is not yet completed and implemented, significant progress has been achieved in the development of this HCP, including the preparation of the EIS/EIR, the solicitation of public review and comment, and the initiation of a consultation with us on the issuance of incidental take permits for those species identified for coverage within the draft plan.

We are excluding a portion of Unit 30 from proposed critical habitat for the California red-legged frog pursuant to section 4(b)(2) of the Act because it is within the planning area boundary for the proposed Western Riverside MSHCP. Our analysis for excluding the portion of Unit 30 within the planning area boundary for the Western Riverside MSHCP from proposed critical habitat is outlined below.

#### *Benefits of Inclusion*

As stated previously, the benefits of designating critical habitat on lands within the boundaries of approved HCPs are small. Where HCPs are in place that include coverage for the California red-legged frog, the HCPs and their IAs include management measures and protections designed to protect, restore, monitor, manage, and enhance the habitat to benefit the conservation of the species. The Western Riverside MSHCP seeks to accomplish these goals for the California red-legged frog through the implementation of specific conservation objectives. The principal benefit of designating critical habitat is that federally authorized or funded

activities that may affect a species' critical habitat would require consultation with us under section 7 of the Act. In the case of the proposed Western Riverside MSHCP, we must evaluate the impact of the plan on the species for which the participants are seeking incidental take permits, pursuant to section 7 of the Act.

#### Benefits of Exclusion

The benefits of excluding lands within HCPs from critical habitat designation include relieving landowners, communities, and counties of any additional regulatory burden that might be imposed by critical habitat. Many HCPs, particularly large regional HCPs take many years to develop and, upon completion, become regional conservation plans that are consistent with the recovery objectives for listed species that are covered within the plan area. Additionally, many of these HCPs provide conservation benefits to unlisted, sensitive species. Imposing an additional regulatory review after an HCP is completed solely as a result of the designation of critical habitat may undermine conservation efforts and partnerships in many areas. In fact, it could result in the loss of species' benefits if participants abandon the voluntary HCP process because it may result in additional regulations requiring more of them than other parties who have not voluntarily participated in species conservation. Designation of critical habitat within the boundaries of approved HCPs could be viewed as a disincentive to those entities currently developing HCPs or contemplating them in the future.

A related benefit of excluding lands within HCPs from critical habitat designation is the unhindered, continued ability to seek new partnerships with future HCP participants including states, counties, local jurisdictions, conservation organizations, and private landowners, which together can implement conservation actions that we would be unable to accomplish otherwise. If lands within HCP plan areas are designated as critical habitat, it would likely have a negative effect on our ability to establish new partnerships to develop HCPs, particularly large, regional HCPs that involve numerous participants and address landscape-level conservation of species and habitats. By preemptively excluding these lands, we preserve our current partnerships and encourage additional conservation actions in the future.

Furthermore, an HCP or NCCP/HCP application must itself be consulted upon. While this consultation will not

look specifically at the issue of adverse modification to critical habitat, unless critical habitat has already been designated within the proposed plan area, it will determine if the HCP jeopardizes the species in the plan area. The jeopardy analysis is similar to the analysis of adverse modification to critical habitat. In addition, Federal actions not covered by the HCP in areas occupied by listed species would still require consultation under section 7 of the Act. HCP and NCCP/HCPs typically provide for greater conservation benefits to a covered species than section 7 consultations because HCPs and NCCP/HCPs assure the long-term protection and management of a covered species and its habitat, and funding for such management through the standards found in the 5 Point Policy for HCPs (64 FR 35242) and the HCP "No Surprises" regulation (63 FR 8859). Such assurances are typically not provided by section 7 consultations that, in contrast to HCPs, often do not commit the project proponent to long-term special management or protections. Thus, a consultation typically does not accord the lands it covers the extensive benefits a HCP or NCCP/HCP provides. The development and implementation of HCPs or NCCP/HCPs provide other important conservation benefits, including the development of biological information to guide the conservation efforts and assist in species conservation, and the creation of innovative solutions to conserve species while allowing for development.

#### *Benefits of Exclusion Outweigh the Benefits of Inclusion*

We have reviewed and evaluated HCPs and NCCP/HCPs currently approved and implemented within the areas being proposed as critical habitat for the California red-legged frog. Based on this evaluation, we find that the benefits of exclusion the lands essential to the conservation of the California red-legged frog in the planning area for the proposed and pending Western Riverside MSHCP outweigh the benefits of proposing portions of Unit 30 as critical habitat.

The exclusion of these lands from critical habitat will help preserve the partnerships that we have developed with the local jurisdiction and project proponent in the development of the HCP and NCCP/HCP. The educational benefits of critical habitat, including informing the public of areas that are essential for the long-term survival and conservation of the species is still accomplished from material provided on our website and through public notice and comment procedures

required to establish a HCP or NCCP/HCP. The public has also been informed through the public participation that occurs in the development of many regional HCPs or NCCP/HCPs. For these reasons, we believe that proposing critical habitat has little benefit in areas covered by HCPs, provided that the HCP or NCCP/HCP specifically and adequately covers the species for which critical habitat is being proposed. We do not believe that this exclusion would result in the extinction of the species.

In the event that the Western Riverside MSHCP is not found to benefit the California red-legged frog and the coverage for this species is not granted, we will include the areas essential to the conservation of the California red-legged frog in Unit 30 in the final designation of Critical Habitat.

Maps delineating essential habitat for the California red-legged frog, overlaid with the planning area for the Western Riverside MSHCP are available for public review and comment at the Sacramento Fish and Wildlife Office (see ADDRESSES section) or on the Internet at <http://sacramento.fws.gov/es/documents>. These maps are provided to allow the public the opportunity to adequately comment on these exclusions.

#### *Critical Habitat Designation*

The areas we are proposing as critical habitat currently provide all of those habitat components necessary to meet the primary biological needs of the California red-legged frog, as described in the final Recovery Plan (Service 2002), and defined by the primary constituent elements. We did not include all areas currently occupied by California red-legged frogs, only areas possessing large populations, representing unique ecological characteristics, or representing historic geographic area where California red-legged frogs can be re-established.

In selecting areas of critical habitat, we made an effort to avoid developed areas, such as towns and other similar lands that are not likely to contribute to California red-legged frog conservation. However, the minimum mapping unit that we used to approximate our delineation of critical habitat for California red-legged frogs did not allow us to exclude all developed areas such as roads and rural developed areas or other lands. Existing features and structures within the boundaries of the mapped units, such as buildings, roads, aqueducts, railroads, other paved areas, lawns, and other urban landscaped areas, and uplands removed from essential aquatic and dispersal habitat, are not likely to contain the primary

constituent elements essential for the conservation of the California red-legged frog. Therefore, Federal actions limited to these areas would not trigger a section 7 consultation, unless they affect the species and/or primary constituent elements in adjacent critical habitat.

Table 1 shows the approximate area of proposed critical habitat by county and

land ownership. Proposed critical habitat for the California red-legged frog includes approximately 1,674,582 ha (4,140,440 ac) in Alameda, Butte, Contra Costa, El Dorado, Fresno, Kern, Los Angeles, Marin, Mariposa, Merced, Monterey, Napa, Plumas, Riverside, San Benito, San Diego, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara,

Santa Clara, Santa Cruz, Solano, Sonoma, Stanislaus, Tehama, Tuolumne, and Ventura Counties, California. These total numbers also include the specific areas excluded as discussed above. A brief description of each proposed critical habitat unit is given below.

TABLE 1.—APPROXIMATE AREA ENCOMPASSING PROPOSED CRITICAL HABITAT IN HECTARES (HA) (ACRES (AC)) BY COUNTY AND LAND OWNERSHIP

County	Federal land	Local/state land	Private land	Total
Plumas	22,904 ha (56,598 ac)	NA	2,458 ha (6,074 ac)	25,362 ha (62,672 ac)
Butte	15,115 ha (37,350 ac)	135 ha (335 ac)	6,305 ha (15,582 ac)	21,555 ha (53,267 ac)
El Dorado	8,624 ha (21,312 ac)	10 ha (26 ac)	15,456 ha (38,193 ac)	24,090 ha (59,531 ac)
Tuolumne	49,054 ha (121,216 ac)	NA	NA	49,054 ha (121,216 ac)
Mariposa	1,262 ha (3,120 ac)	NA	NA	1,262 ha (3,120 ac)
Tehama	2,727 ha (6,740 ac)	NA	12,771 ha (31,560 ac)	15,498 ha (38,300 ac)
Napa	2,151 ha (5,317 ac)	758 ha (1,874 ac)	20,056 ha (49,562 ac)	22,965 ha (56,753 ac)
Sonoma	NA	819 ha (2,025 ac)	7,154 ha (17,678 ac)	7,973 ha (19,703 ac)
Solano	826 ha (2,042 ac)	67 ha (168 ac)	9,765 ha (24,130 ac)	10,658 ha (26,340 ac)
Marin	30,247 ha (74,742 ac)	4,846 ha (11,976 ac)	45,649 ha (112,802 ac)	80,742 ha (199,520 ac)
Alameda	337 ha (833 ac)	1,853 ha (4,581 ac)	95,404 ha (235,750 ac)	97,594 ha (241,164 ac)
Contra Costa	47 ha (117 ac)	7,618 ha (18,826 ac)	47,676 ha (117,810 ac)	55,341 ha (136,753 ac)
Santa Clara	2,298 ha (5,678 ac)	15,563 ha (38,459 ac)	69,941 ha (172,828 ac)	87,802 ha (216,966 ac)
San Joaquin	NA	38 ha (96 ac)	11,386 ha (28,136 ac)	11,424 ha (28,232 ac)
Stanislaus	27 ha (67 ac)	10,809 ha (26,711 ac)	5,824 ha (14,392 ac)	16,660 ha (41,170 ac)
Merced	1,010 ha (2,496 ac)	2,627 ha (6,493 ac)	66,880 ha (165,266 ac)	70,517 ha (174,255 ac)
Fresno	6,807 ha (16,822 ac)	NA	3,058 ha (7,557 ac)	9,865 ha (24,379 ac)
San Benito	11,826 ha (29,224)	NA	102,340 ha (252,888)	114,166 ha (282,112 ac)
San Mateo	418 ha (1,033 ac)	9,785 ha (24,180 ac)	67,711 ha (167,319)	77,914 ha (192,532 ac)
Santa Cruz	137 ha (340 ac)	10,059 ha (24,858 ac)	32,773 ha (80,985 ac)	42,969 ha (106,183 ac)
Monterey	18,604 ha (45,972 ac)	1,487 ha (3,675 ac)	135,419 ha (334,629 ac)	155,510 ha (384,276 ac)
San Luis Obispo	11,010 ha (27,208 ac)	2,050 ha (5,068 ac)	203,916 ha (503,889 ac)	216,976 ha (536,165 ac)
Kern	473 ha (1,171 ac)	NA	12,148 ha (30,021 ac)	12,621 ha (31,192 ac)
Santa Barbara	79,365 ha (196,117 ac)	1,134 ha (2,804 ac)	123,083 ha (304,147 ac)	203,582 ha (503,068 ac)
Ventura	104,547 ha (258,343 ac)	NA	6,458 ha (15,959 ac)	111,005 ha (274,302 ac)
Los Angeles	76,927 ha (190,091 ac)	4,961 ha (12,261 ac)	26,269 ha (64,914 ac)	108,157 ha (267,266 ac)
Riverside	11,829 ha (29,232 ac)	NA	6,784 ha (16,764 ac)	18,613 ha (45,996 ac)
San Diego	4,296 ha (10,616 ac)	NA	410 ha (1,015 ac)	4,706 ha (11,631 ac)
Total	463,438 ha (1,145,211 ac)	74,949 ha (185,229 ac)	1,147,070 ha (2,834,503 ac)	1,674,582 ha (4,138,064 ac)

**Unit 1. North Fork Feather Unit**

Unit 1 consists of drainages found within the North Fork Feather River drainage. The unit encompasses approximately 46,917 ha (115,939 ac). The North Fork Feather unit is the northeasternmost of the critical habitat units. This unit is located in Plumas and Butte Counties. Approximately 81 percent of the unit consists of Federal lands managed by Plumas and Lassen National Forests, and the majority of the remaining area is privately owned. California red-legged frogs have been documented in the French Creek watershed in Butte County. This population represents one of only three existing populations in the Sierra Nevada. This unit is in need of special management, including the eradication of exotic predators in suitable breeding habitat adjacent to documented breeding habitats. Other necessary management may include re-establishment of red-legged frogs within the area; however, natural recolonization is likely to occur if nonnative predators are removed.

**Unit 2**

Unit 2 is an artifact of the previous proposed designation of critical habitat for the California red-legged frog. There is no Unit 2 in this current proposal.

**Unit 3. Weber Creek/Cosumnes Unit**

Unit 3 consists of drainages in the Weber Creek and North Fork Cosumnes River watersheds in El Dorado County. The unit encompasses approximately 24,090 ha (59,531 ac), of which 36 percent is within the El Dorado National Forest and 64 percent is privately owned. California red-legged frogs have been documented in the Weber Creek watershed. This population represents one of only three existing populations in the Sierra Nevada. This unit requires special management, including the eradication of exotic predators in suitable breeding habitat adjacent to documented breeding habitats. Other necessary management may include re-establishment of red-legged frogs within the area; however, natural recolonization is likely to occur if nonnative predators are removed.

**Unit 4**

Unit 4 is an artifact of the previous proposed designation of critical habitat for the California red-legged frog. There is no Unit 4 in this current proposal.

**Unit 5. Yosemite Unit**

Unit 5 consists of drainages found in the tributaries of the Tuolumne River and Jordan Creek, a tributary to the Merced River, in Tuolumne and

Mariposa Counties. The unit encompasses approximately 50,316 ha (124,336 ac), of which 100 percent is managed by Stanislaus National Forest or the National Park Service (NPS). Historically, California red-legged frogs were found in several locations in Unit 5 and in adjacent areas, including two historical occurrences from 1984. Although this unit currently is considered unoccupied, it contains all of the constituent elements and is in need of special management practices that include the eradication of nonnative predators in suitable breeding habitat. This area is a candidate for reestablishment, and is within a core recovery area as defined in the draft Recovery Plan and considered essential to the conservation of California red-legged frogs in the Sierra Nevada.

**Unit 6. Headwaters of Cottonwood Creek Unit**

Unit 6 consists of drainages found within the headwaters of Cottonwood and Red Bank Creeks in Tehama County. The unit encompasses approximately 15,498 ha (38,300 ac), of which approximately 18 percent is within the boundaries of the Mendocino National Forest; the majority of the remaining 82 percent is privately owned. Unit 6 is occupied by a population known from CNDDDB (2000) records. No additional sightings have been reported from the area. This area contains all of the constituent elements and is essential in that it represents the northernmost population of California red-legged frogs within the Coast Range. This area has not been adequately surveyed and additional populations may be present. This population may be used as a source population to provide natural reestablishment in the northern portion of the Coast Range.

**Unit 7. Cleary Preserve Unit**

Unit 7 consists of drainages found within the watersheds that form the tributaries to Pope Creek in Napa County. The unit encompasses approximately 13,793 ha (34,087 ac), of which approximately 88 percent is privately owned; the remaining 12 percent is managed by Federal or State agencies. Unit 7 represents one of the few documented occurrences of California red-legged frogs in this area (McGinnis 2001) and represents an important link between populations in Marin County and populations on the east side of the Coast Range.

**Unit 8. Annadel State Park Preserve Unit**

Unit 8 consists of the Upper Sonoma Creek watershed found partially within

Annadel State Park in Sonoma County. The unit encompasses approximately 2,559 ha (6,326 ac), of which approximately 76 percent is privately owned and 24 percent is managed by the California Department of Parks and Recreation (CDPR). Unit 8 is occupied by one known core population of California red-legged frogs (Cook 1997). This area represents a source population with potential linkage to the Sears Point unit as well as units to the west.

**Unit 9. Stebbins Cold Canyon Preserve Unit**

Unit 9 consists of drainages found within and adjacent to Stebbins Cold Canyon Preserve and the Quail Ridge Wilderness Preserve in Napa and Solano Counties. The unit is comprised of watersheds that form Capell Creek, including Wragg Canyon, Markley Canyon, Steel Canyon, and Wild Horse Canyon watersheds. The unit encompasses approximately 8,589 ha (21,227 ac), of which approximately 75 percent is privately owned and 25 percent is managed by the University of California Natural Reserve System, the Quail Ridge Wilderness Conservancy, and the Bureau of Land Management (BLM). Unit 9 represents one of the historic occurrences of California red-legged frogs in this area, and represents an important link between populations in Marin County and populations on the east side of the Coast Range.

**Unit 10. Sears Point Unit**

Unit 10 consists of Stage Gulch and Lower Petaluma River watersheds, tributaries to the Petaluma River. This unit is located in and adjacent to Sears Point in Sonoma and Marin Counties and encompasses approximately 4,358 ha (10,771 ac), all of which is privately owned. Unit 10 is occupied by several subpopulations. Essential breeding habitat is dispersed throughout the unit, and has been documented in several ponds and streams. This unit provides linkages to the units to the north, east, and west.

**Unit 11. American Canyon Unit**

Unit 11 consists of watersheds within and adjacent to American Canyon Creek and Sulphur Springs Creek in Napa and Solano Counties. Watersheds within this unit include Fagan Creek, a tributary to the Napa River, the Jameson Canyon watershed, and the Sky Valley and Pine Lake watersheds that flow into Lake Herman. The unit encompasses approximately 11,240 ha (27,779 ac), of which 99 percent is privately owned. Unit 11 is occupied by several subpopulations.



**Unit 12. Point Reyes Unit**

Unit 12 consists of watersheds within and adjacent to Bolinas Lagoon, Point Reyes, and Tomales Bay in Marin and Sonoma Counties. This unit encompasses approximately 81,168 ha (200,572 ac); 44 percent is managed by the NPS, CDFG, and the Marin Municipal Water District, and 56 percent is privately owned. Unit 12 is occupied with several populations known primarily through research by G. Fellers, BRD (Service files). Essential breeding habitat is dispersed throughout the unit. This unit contains one of the largest known populations of California red-legged frogs.

**Unit 13. Tiburon Peninsula Unit**

Unit 13 consists of the Belvedere Lagoon watershed within and adjacent to the Tiburon Peninsula in Marin County. The unit encompasses approximately 628 ha (1,554 ac), all of which is privately owned. Unit 12 is occupied by one known breeding population known from CNDDB (2000) records.

**Unit 14. San Mateo/Northern Santa Cruz Unit**

Unit 14 consists of coastal watersheds within San Mateo County and northern Santa Cruz County that drain into the Pacific Ocean. The unit encompasses approximately 96,296 ha (237,955 ac), of which 83 percent is privately owned; the remaining 17 percent is primarily managed by the San Francisco Public Utilities Commission (SFPUC) and CDFG. Unit 14 is occupied by several core subpopulations known from various sources including formal consultations with the U.S. Army Corps of Engineers (Corps) (Service files). Essential breeding habitat is dispersed throughout the unit; populations have been documented in ponds and wetlands throughout Unit 14. This area contains numerous areas with large populations including Pescadero Marsh, and watersheds to the south.

**Unit 15. East Bay/Diablo Range Unit**

Unit 15 consists of watersheds within Contra Costa, Alameda, San Joaquin, Santa Clara, Stanislaus, San Benito, Merced, and Fresno Counties. The unit encompasses approximately 426,480 ha (1,053,850 ac), of which 87 percent is privately owned; the remaining 13 percent is managed, in part, by East Bay Regional Park District (EBRPD), East Bay Municipal Utilities District (EBMUD), Contra Costa Water District (CCWD), U.S. Bureau of Reclamation (BOR), U.S. Department of Energy (DOE), CDFG, SFPUC, CDFG, Santa Clara Valley Water District, and DWR. Unit 15 is occupied

with several large core subpopulations, including the population within CCWD and EBRPD lands, and essential breeding habitat is located throughout the unit.

**Unit 16. Pajaro River Unit**

Unit 16 consists of portions of two watersheds that are part of the Pajaro River Drainage, the Flint Hills watershed in San Benito County, and the Santa Clara Valley watershed in Santa Clara and San Benito Counties. The unit encompasses approximately 19,524 ha (48,247 ac) and is all privately owned. Unit 16 is occupied and is an essential unit in providing connectivity from the outer coast plain and ranges to the inner Coast Ranges.

**Unit 17. Elkhorn Slough/Salinas River Unit**

Unit 17 consists of coastal drainages of southern Santa Cruz and northern Monterey Counties. The unit is located in Santa Cruz, Monterey, and San Benito Counties. The unit encompasses approximately 66,799 ha (165,067 ac), of which 93 percent is privately owned; CDFG and the Elkhorn Slough National Estuarine Research Reserve manage the remaining 7 percent. Unit 17 is occupied and provides connectivity from the coastal plain and outer coast ranges to the inner coast ranges. The unit represents a unique ecological set in that it is a large estuary/freshwater slough system not typically found on the California coast.

**Unit 18. Carmel River Unit**

Unit 18 consists of drainages comprising the Carmel River watershed in Monterey County. This unit encompasses approximately 62,976 ha (155,620 ac), of which approximately 26 percent is managed by the Los Padres National Forest and CDFG, while the remaining 74 percent is privately owned. Unit 18 is occupied, and populations of California red-legged frogs are found throughout the drainage from the headwaters to the coast. This unit provides connectivity from the Elkhorn Slough unit to the more southern coastal units.

**Unit 19. The Pinnacles Unit**

Unit 19 consists of two watersheds, Gloria Lake and George Hansen Canyon, in San Benito and Monterey Counties. This unit encompasses approximately 11,051 ha (27,309 ac), of which 57 percent is managed by the NPS and BLM; the remaining 43 percent is privately owned. Unit 19 is occupied and is representative of the inner coast range. The unit provides connectivity between the Pajaro River and other

populations to the north and populations in southern Monterey County and northern San Luis Obispo County.

**Unit 20. Estrella River/Cholame Creek Unit**

Unit 20 consists of the drainages comprising the Cholame Creek, Estrella River, and the Saw Tooth Ridge watersheds in Monterey, San Luis Obispo, and Kern Counties. The unit encompasses approximately 159,576 ha (394,325 ac), of which 99 percent is privately owned and the remaining 1 percent is federally managed. Unit 20 is occupied by a large population. The unit contains areas in a unique ecological setting of springs, wetlands and vernal pools in a very dry ecological setting. This unit also provides connectivity between inner and outer Coast Ranges and into the Transverse Ranges.

**Unit 21. San Simeon Unit/Morro Bay Unit**

Unit 21 consists of the coastal watersheds of San Luis Obispo County from Arroyo de la Cruz south to Los Osos Creek. The unit encompasses approximately 84,757 ha (209,445 ac), of which 94 percent is privately owned; the remaining 6 percent is managed by CDFG and Federal agencies. Unit 21 is occupied and contains several core populations of California red-legged frogs. This unit also supports a unique ecological setting, representative of the central coastal oak savannah grassland. This unit also provides connectivity from the outer Coast Range in Monterey County into the Transverse Ranges in San Luis Obispo and Santa Barbara Counties.

**Unit 22. Lopez Lake/Arroyo Grande Creek Unit**

Unit 22 consists of the watersheds of Arroyo Grande Creek and its tributaries in San Luis Obispo County. The unit encompasses approximately 34,500 ha (85,254 ac), of which 79 percent is privately owned and Los Padres National Forest and BLM manage the remaining 21 percent. Unit 22 is occupied and provides habitat connectivity from the San Simeon Unit-Morro Bay Unit down into the Sisquoc River Unit and Transverse Range.

**Unit 23. Coastal Dunes Unit**

Unit 23 consists of coastal watersheds comprising the coastal dune ponds from Arroyo Grande south to San Antonio Creek in San Luis Obispo and Santa Barbara Counties. The unit encompasses approximately 21,358 ha (52,782 ac), of which 3 percent is managed by Federal,



State, and local municipalities (primarily Service and CDPR), with the remaining 97 percent in private ownership. Unit 23 is occupied and represents a core population occupying a unique coastal dune system. This unit also provides connectivity between the Lopez Lake/Arroyo Grande Creek Unit down into the Santa Ynez River Unit.

#### **Unit 24. Santa Ynez River Unit**

Unit 24 consists of watersheds forming the Santa Ynez River in Santa Barbara County. The unit encompasses approximately 98,744 ha (244,004 ac), of which approximately 60 percent is privately owned; the BOR and Los Padres National Forest manage the remaining 40 percent. Unit 24 is occupied and contains core populations. Frogs are found on the Santa Ynez River from the headwaters to the estuary. The headwaters provide connectivity to the Sisquoc River Unit and the Matilija/Sespe/Piru Creek Unit. This unit provides essential connectivity from coastal dune systems, up the Santa Ynez River to the headwaters of the Transverse Range.

#### **Unit 25. Sisquoc River Unit**

Unit 25 consists of watersheds forming the drainages of the Sisquoc River in Santa Barbara County. These include the Cherokee Spring, Ernest Blanco Spring, Horse Canyon, La Brea Creek, Manzano Creek, Peach Tree Spring, and the Lower Sisquoc River watersheds. The unit encompasses approximately 49,284 ha (121,785 ac), of which 39 percent is privately owned, and 61 percent is managed by the Los Padres National Forest. Unit 25 is occupied. This unit represents a core population that provides connectivity from Lopez Lake/Arroyo Grande Creek Unit into the westernmost portion of the Transverse Ranges. It is also the only undammed river included as critical habitat in this region; for this reason, the threats of nonnative fish are minimal.

#### **Unit 26. Coastal Santa Barbara Unit**

Unit 26 consists of coastal tributaries including the Bear Creek watershed, east to and including the Ellwood Canyon watershed in Santa Barbara County. The unit encompasses approximately 39,977 ha (98,791 ac), of which 23 percent is managed by the Los Padres National Forest and the CDPR; the remaining 77 percent is privately owned. Unit 26 is occupied by numerous small populations. It contains a unique ecological setting; numerous and relatively small watersheds along a south-facing coastal terrace drain directly into the Pacific Ocean. This type of habitat is not found elsewhere in

California. Populations in this unit may play an important role in stabilizing populations in tributaries to the Santa Ynez River, which is affected by agriculture, water management, and non-native species.

#### **Unit 27. Matilija/Sespe/Piru Creek Unit**

This unit consists of watersheds that comprise portions of the Matilija, Sespe, and Piru Creek drainages in Santa Barbara, Ventura, and Los Angeles Counties. The unit encompasses approximately 126,955 ha (313,716 ac), of which 96 percent is managed by the Los Padres National Forest and 4 percent is privately owned. Unit 27 is occupied and provides connectivity across the Transverse Ranges from the Santa Ynez River Unit to the San Francisquito-Amargosa Creek Unit. The Sespe Creek area, which includes portions of the Sespe Wilderness and provides the primary east-west connectivity, currently supports large numbers of bullfrogs and predatory fish and is in need of special management.

#### **Unit 28. San Francisquito-Amargosa Creek Unit**

This unit consists of San Francisquito and Amargosa Creeks and the intervening drainages in Los Angeles County, including all or parts of the Lancaster, Rock Creek, Acton, Bouquet Eastern, Mint Canyon, and Sierra Pelona watersheds. The unit encompasses approximately 42,851 ha (105,890 ac), of which 80 percent is primarily managed by the Angeles National Forest; the remaining 20 percent is privately owned. Unit 28 is occupied, supporting a substantial core population and may be a source population for units to the south and west. This unit also supports the only known population occupying a drainage flowing into the Mojave Desert.

#### **Unit 29. Malibu Coastal Unit**

This unit consists of the upper coastal watersheds in the Santa Monica Mountains of Ventura and Los Angeles Counties that drain into the Pacific Ocean near Malibu, including the West Las Virgenes Canyon, Lindero Canyon, Sherwood, Triunfo Canyon, East Las Virgenes Canyon, and Monte Nido watersheds. The unit encompasses approximately 21,235 ha (52,475 ac), of which approximately 67 percent is privately owned and 33 percent is managed in part by the NPS, CDPR, and local municipalities. Unit 29 contains one occupied drainage; California red-legged frogs have likely persisted in this drainage because of its isolation from the nonnative predators that are prevalent in most drainages in this

recovery unit. Unit 29 contains all of the constituent elements, in addition it supports a habitat mosaic of coastal sage scrub, coast live oak woodlands, and grasslands that is substantially different from habitat contained in other units.

#### **Unit 30. Santa Rosa Plateau/Santa Ana Mountains Unit**

This unit consists of portions of the watersheds comprising the Santa Rosa Plateau and the Santa Ana Mountains in Riverside and San Diego Counties, including De Luz Creek, Murrieta, and San Mateo Canyon watersheds. The unit encompasses approximately 23,319 ha (57,627 ac), of which approximately 69 percent is managed by the U.S. Forest Service (Forest Service), and approximately 31 percent is privately owned (a portion of which is owned by The Nature Conservancy).

The unit includes habitat essential to the conservation of the California red-legged frog, and is within a core recovery area, as defined in the draft Recovery Plan. This unit contains a small, genetically unique population on The Nature Conservancy's Santa Rosa Plateau Ecological Reserve (Reserve). This unit is the focal point of recovery efforts essential for the conservation of the California red-legged frog and its genetic diversity in southern California. The Reserve and adjacent watershed lands contain riparian habitat with the primary constituent elements essential to the maintenance of the California red-legged frog population and the re-establishment of the subspecies in southern California. A recovery program is currently being implemented on the Reserve that includes habitat restoration, nonnative species/predator removal, and augmentation of the red-legged frog population. Preliminary discussions have been initiated with the Cleveland National Forest concerning re-establishment of California red-legged frogs in the San Mateo watershed. Additionally, The Nature Conservancy has acquired lands between the current Reserve and Cleveland National Forest, and intends to acquire additional lands in this corridor to add to the Reserve. Habitat restoration, and nonnative predator management activities are being conducted in these areas, and these lands are being evaluated for possible red-legged frog re-establishment.

#### **Unit 31. Tujunga Unit**

This unit consists of portions of the Tujunga watersheds in Los Angeles County. It encompasses approximately 29,744 ha (73,500 ac), of which 100 percent is managed by the Angeles National Forest. This unit contains

habitat essential to the conservation of California red-legged frogs in southern California and is within a core recovery area as defined in the draft Recovery Plan. Red-legged frogs are not known to currently occupy this unit, but numerous populations have been historically documented within the boundaries of the unit and adjacent Forest Service lands. This unit is a focal point for reestablishment of the California red-legged frog in southern California. Preliminary discussions have been initiated with the Angeles National Forest concerning the re-establishment project, in addition to nonnative species management and habitat restoration.

#### Effect of Critical Habitat Designation

##### Section 7 Consultation

The regulatory effects of a critical habitat designation under the Act are triggered through the provisions of section 7, which applies only to activities conducted, authorized, or funded by a Federal agency (Federal actions). Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Individuals, organizations, States, local governments, and other non-Federal entities are not affected by the designation of critical habitat unless their actions occur on Federal lands, require Federal authorization, or involve Federal funding.

Section 7(a)(2) of the Act requires Federal agencies, including us, to insure that their actions are not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. This requirement is met through section 7 consultation under the Act. Our regulations define "jeopardize the continued existence" as to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species (50 CFR 402.02). "Destruction or adverse modification of designated critical habitat" is defined as a direct or indirect alteration that appreciably diminishes the value of the critical habitat for both the survival and recovery of the species (50 CFR 402.02). Such alterations include, but are not limited to, adverse changes to the physical or biological features, *i.e.*, the primary constituent elements, that were the basis for determining the habitat to be critical. However, in a March 15, 2001, decision of the United States Court of Appeals for

the Fifth Circuit (*Sierra Club v. U.S. Fish and Wildlife Service et al.*, 245 F.3d 434), the Court found our definition of destruction or adverse modification to be invalid. In response to this decision, we are reviewing the regulatory definition of adverse modification in relation to the conservation of the species.

Section 7(a)(4) requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist the agency in eliminating conflicts that may be caused by the proposed action. The conservation recommendations in a conference report are advisory.

We may issue a formal conference report, if requested by the Federal action agency. Formal conference reports include an opinion that is prepared according to 50 CFR 402.14, as if critical habitat were designated. We may adopt the formal conference report as the biological opinion when critical habitat is designated, if no substantial new information or changes in the action alter the content of the opinion (*see* 50 CFR 402.10(d)).

If a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Through this consultation, the action agency would ensure that the permitted actions do not destroy or adversely modify critical habitat.

If we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we would also provide reasonable and prudent alternatives to the project, if any are identifiable. Reasonable and prudent alternatives are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Service's Regional Director believes would avoid the destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to

extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation or conference with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

Federal activities that may affect the California red-legged frog, occupied habitat, or its critical habitat will require consultation under section 7. Activities on private, State, county, or lands under local jurisdictions requiring a permit from a Federal agency, such as Federal Highway Administration or Federal Emergency Management Act funding, or a permit from the Corps under section 404 of the Clean Water Act, will continue to be subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat, and actions on non-Federal lands that are not federally funded, authorized, or permitted do not require section 7 consultation.

Section 4(b)(8) of the Act requires us to evaluate briefly and describe, in any proposed or final regulation that designates critical habitat, those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. We note that such activities may also jeopardize the continued existence of the species.

Activities that, when carried out, funded, or authorized by a Federal agency may directly or indirectly destroy or adversely modify critical habitat for California red-legged frog include, but are not limited to:

(1) Sale, exchange, or lease of lands managed by the BLM, BOR, Department of Defense (DOD), DOE, NPS, or Forest Service;

(2) Regulation of activities affecting waters of the United States by the Army Corps under section 404 of the Clean Water Act, with the exception of maintenance activities on ponds located on private lands for the express purposes of maintaining the area to water stock;

(3) Regulation of water flows, water delivery, damming, diversion, and

channelization by the BOR and the Corps or other water transfers, diversion, or impoundment, groundwater pumping, irrigation activity that causes barriers or deterrents to dispersal, inundates or drains habitat, or significantly converts habitat;

(4) Regulation of grazing, recreation, mining, or logging by the BLM, BOR, DOD, or NPS;

(5) Funding and implementation of disaster relief projects by the FEMA and the Natural Resource Conservation Service's Emergency Watershed Program, including erosion control, flood control, streambank repair to reduce the risk of loss of property;

(6) Funding and regulation of new road construction or road improvements by the FHA;

(7) Funding of construction or development activities by the Department of Housing and Urban Development or other agencies that destroy, fragment, or degrade suitable habitat;

(8) Clearing of vegetation and hydrological modifications by the DOE or other agencies; and

(9) Promulgation of air and water quality standards under the Clean Air Act and the Clean Water Act and the clean up of toxic waste and superfund sites under the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act by the EPA.

With the exception of the two unoccupied units, all lands proposed for designation as critical habitat are within the geographic range of the California red-legged frog and are occupied by the subspecies, and/or are likely to be used by the subspecies, whether for foraging, breeding, growth of larvae and juveniles, intra-specific communication, dispersal, migration, genetic exchange and sheltering. Federal agencies already consult with us on activities in areas currently occupied by the subspecies, or if the subspecies may be affected by the action, to ensure that their actions do not jeopardize the continued existence of the subspecies. Furthermore, in unoccupied habitat, we are only proposing to designate federally managed land as critical habitat. Thus, we do not anticipate substantial additional regulatory protection will result from the proposed critical habitat designation.

If you have questions regarding whether specific activities may constitute adverse modification of critical habitat in California, contact the Field Supervisor, Sacramento Fish and Wildlife Office (see **ADDRESSES** section). Requests for copies of the regulations on

listed plants and wildlife and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Branch of Endangered Species, 911 N.E. 11th Ave, Portland, OR 97232 (telephone 503/231-2063; facsimile 503/231-6243).

#### Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial data available, and to consider the economic, national security, and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species.

An analysis of the economic impacts of proposing critical habitat for California red-legged frog is being prepared. We will announce the availability of the draft economic analysis as soon as it is completed, at which time we will seek public review and comment. When published, copies of the draft economic analysis will be available by contacting the Sacramento Fish and Wildlife Office directly (see **ADDRESSES** section) or available for downloading from the Internet at <http://sacramento.fws.gov/es/documents>.

#### Peer Review

In accordance with our joint policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of this review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite the selected peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the public comment periods on this proposed rule during the preparation of a final rulemaking. Accordingly, the decision may differ from this proposal.

#### Public Hearings

The Act provides for one or more public hearings on this proposal, if

requested. Requests for public hearings must be made in writing 45 days following the publication of the proposal in the **Federal Register**. We will schedule public hearings on this proposal, if any are requested, and will announce the dates, times and locations of those hearings in the **Federal Register** and local newspapers at least 15 days prior to the first hearing.

#### Clarity of the Rule

Executive Order 12866 requires each agency to write regulations and notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical jargon that interferes with the clarity? (3) Does the format of the proposed rule (groupings and order of the sections, use of headings, paragraphing, and so forth) aid or reduce its clarity? (4) Is the description of the notice in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? What else could we do to make this proposed rule easier to understand?

Send a copy of any comments on how we could make this proposed rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You may e-mail your comments to this address: [Exsec@ios.doi.gov](mailto:Exsec@ios.doi.gov).

#### Required Determinations

##### *Regulatory Planning and Review*

In accordance with Executive Order 12866, this document is a significant rule in that it may raise novel legal and policy issues, but it is not anticipated to have an annual effect on the economy of \$100 million or more or affect the economy in a material way. As such, the Office of Management and Budget (OMB) has reviewed this rule. The Service is preparing a draft economic analysis of this proposed action. The Service will use this analysis to meet the requirement of section 4(b)(2) of the Act to determine the economic consequences of designating the specific areas as critical habitat and excluding any area from critical habitat if it is determined that the benefits of such exclusion outweigh the benefits of specifying such areas as part of the critical habitat, unless failure to designate such area as critical habitat will lead to the extinction of the California red-legged frog. This analysis will also be used to determine

compliance with Executive Order 12866, Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act, and Executive Order 12630.

This analysis will be made available for public review and comment. Copies may be obtained from the Sacramento Fish and Wildlife Office's Internet Web site at <http://sacramento.fws.gov/es/documents>, or by contacting the Sacramento Fish and Wildlife Office directly (see ADDRESSES section)

*Regulatory Flexibility Act (5 U.S.C. 601 et seq.)*

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities.

The SBREFA amended the Regulatory Flexibility Act (RFA) to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. However, the SBREFA does not explicitly define "substantial number" or "significant economic impact." Consequently, to assess whether a "substantial number" of small entities are affected by this proposed designation, the following analysis considers the relative number of small entities likely to be impacted in an area. The SBREFA also amended the RFA to require a certification statement.

According to the Small Business Administration (SBA), small entities include small organizations, such as independent nonprofit organizations, and small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents, as well as small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than \$5 million in annual sales, general and heavy construction businesses with less than \$27.5 million in annual business, special trade contractors doing less than

\$11.5 million in annual business, and agricultural businesses with annual sales less than \$750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this proposed rule as well as types of project modifications that may result. In general, the term significant economic impact is meant to apply to a typical small business firm's business operations.

To determine if this proposed rule would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities (*e.g.*, housing development, oil and gas production, timber harvesting etc.). We considered each industry individually to determine if certification is appropriate. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement; some kinds of activities are unlikely to have any Federal involvement and so will not be affected by the designation of critical habitat. Designation of critical habitat only affects activities conducted, funded, permitted or authorized by Federal agencies; non-Federal activities are not affected by the designation.

If this critical habitat designation is made final, Federal agencies must consult with us if their activities may affect designated critical habitat. Consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process. In areas where occupancy by California red-legged frog is unknown, the designation of critical habitat could trigger additional review of Federal agencies pursuant to section 7 of the Act and may result in additional requirements on Federal activities to avoid destruction or adverse modification of critical habitat. There are two units (Unit 5 and Unit 31) in this proposed designation that are currently not known to be occupied by the California red-legged frog. These units occur entirely on Federal lands or are managed by Federal agencies, the Stanislaus National Forest and the NPS (Unit 5) and Angeles National Forest (Unit 31).

During the development of our last designation of critical habitat for the California red-legged frog, we conducted an economic analysis of our proposed designation (65 FR 54892, September 11, 2000) and made it available to the public for review on December 21, 2000 (65 FR 80409). Because the scope of this analysis was the proposed critical habitat, it evaluated the potential

economic impacts of the proposed regulation to approximately 2,175,000 ha (5,373,650 ac), a significantly larger area than was designated as final critical habitat for the California red-legged frog. In that analysis we additionally evaluated the potential effect of the proposed regulation on small entities. We determined in that analysis that small business in the construction, development, mining, ranching and timber industries could potentially be affected by proposed regulation if the designation leads to significant project modifications or delays associated with those activities. The results of the analysis further suggested that if the areas proposed as critical habitat were designated, it appeared unlikely that the designation would lead to a significant increased number of consultations and project modifications (*i.e.*, significant additional regulatory and/or economic burden) because the majority of the area designated is considered occupied by the species. As such, this rule is not expected to result in any significant regulatory restrictions in addition to those currently in existence.

Many of the activities sponsored by Federal agencies within critical habitat areas are carried out by small entities (as defined by the Regulatory Flexibility Act) through contract, grant, permit, or other Federal authorization. As discussed above, these actions are already currently required to comply with the protections of the Act, and the designation of critical habitat is not anticipated to have any additional effects on these activities. The analysis did, however, recognize that to the extent that these industries constitute small business entities, there may be some costs resulting from the regulation. However, we did not believe that these costs would reach the threshold for being considered significant economic impacts to a substantial number of small business entities.

In the development of our final designation of critical habitat, we significantly modified our proposal such that only 1,674,582 ha (4,140,440 ac) were designated, a reduction of approximately 22 percent or 488,580 ha (1,206,330 ac) from the proposal. Of the approximate 1,674,582 ha (4,140,440 ac) that were finalized and which are currently being proposed for designation as critical habitat for the California red-legged frog, an estimated 5 percent or 81,020 ha (200,212 ac) is considered unoccupied habitat (Units 5 and 31). Because the scope of the final designation and this new proposed designation is significantly less than that originally proposed in 2000 and analyzed, we believe that it is unlikely



that this proposal, if finalized, would result in a significant economic impact on a substantial number of small entities. We will further analyze this when we conduct our analysis of the potential economic effects of this new proposed designation of critical habitat for the California red-legged frog.

Therefore, based on the analysis conducted for our previous designation, we are certifying that this proposed designation of critical habitat is not expected to have a significant adverse impact on a substantial number of small entities, and an initial regulatory flexibility analysis is not required.

This assessment of economic effect may be modified prior to publication of a final rule, based on a review of the draft economic analysis currently being prepared pursuant to section 4(b)(2) of the Act, Executive Order 12866, and public comments received during the public comment period. This analysis is for the purposes of compliance with the Regulatory Flexibility Act and does not reflect our position on the type of economic analysis required by *New Mexico Cattle Growers Assn. v. U.S. Fish & Wildlife Service* 248 F. 3d 1277 (10th Cir. 2001).

#### *Executive Order 13211*

On May 18, 2001, the President issued an Executive Order 13211 (E.O. 13211) on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This proposed rule is considered by OMB to be a significant regulatory action under E.O. 12866 in that it may raise novel legal and policy issues. However, we do not anticipate that the proposed designation of critical habitat for the California red-legged frog will significantly affect energy supplies, distribution, or use. Therefore, we do not believe that this action is a significant action and no Statement of Energy Effects is required. We will further examine any potential effect in our economic analysis of this proposal.

#### *Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)*

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.):

(a) This rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat.

However, as discussed above, these actions are currently subject to equivalent restrictions through the listing protections of the subspecies, and no further restrictions are anticipated.

(b) This rule will not produce a Federal mandate of \$100 million or greater in any year, that is, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments.

#### *Takings*

In accordance with Executive Order 12630, this rule is not anticipated to have significant takings implications. A takings implication assessment is not required. As discussed above, the designation of critical habitat affects only Federal actions. The rule will not increase or decrease the current restrictions on private property concerning take of the California red-legged frog. Due to current public knowledge of the subspecies' protections, the prohibition against take of the subspecies both within and outside of the designated areas, and the fact that critical habitat provides no substantial incremental restrictions in areas occupied by the California red-legged frog, we do not anticipate that property values will be affected by the critical habitat designation. While real estate market values may temporarily decline following designation, due to the perception that critical habitat designation may impose additional regulatory burdens on land use, we expect any such impacts to be short term. Additionally, critical habitat designation does not preclude development of HCPs and issuances of incidental take permits. Owners of areas that are included in proposed critical habitat will continue to have the opportunity to utilize their property in ways consistent with the survival of the California red-legged frog.

#### *Federalism*

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from and coordinated development of this critical habitat proposal with appropriate State resource agencies in California. The impact of the proposed designation on State and local governments and their activities is not believed to be significant. We will examine this more fully in our economic analysis of the

proposal. The designation may have some benefit to these governments in that the areas essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the survival of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning, rather than forcing/necessitating them to wait for case-by-case section 7 consultations to occur.

#### *Civil Justice Reform*

In accordance with Executive Order 12988, the Department of the Interior's Office of the Solicitor has determined that this proposed rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are proposing to designate critical habitat in accordance with the provisions of the Endangered Species Act. The rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of the California red-legged frog.

#### *Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)*

This proposed rule does not contain any information collection requirements that require OMB approval under the Paperwork Reduction Act. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB Control Number.

#### *National Environmental Policy Act*

We have determined that we do not need to prepare an Environmental Assessment or an Environmental Impact Statement as defined by the National Environmental Policy Act of 1969, in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

#### *Government-to-Government Relationship With Tribes*

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951); Executive Order 13175 (November 9, 2000; 65 FR 67249) and DOI's manual at 512 DM 2, we readily acknowledge our



responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis.

We are not aware of any Tribal lands essential for the conservation of the California red-legged frog within the areas proposed for designation as critical habitat. Therefore, this proposal does not contain any Tribal lands or lands that we have identified as impacting Tribal trust resources.

**Relationship With Mexico**

We are not aware of any existing national-level regulatory mechanism in Mexico that would protect the California red-legged frog or its habitat. Although new legislation for wildlife is pending in Mexico, and Mexico has laws that could provide protection for rare species, there are enforcement challenges. Even if specific protections were available and enforceable in Mexico, the portion of the California red-legged frog's range in Mexico alone, in isolation, would not be adequate to ensure the long-term conservation of the subspecies.

**References Cited**

A complete list of all references cited in this final rule is available upon request from the Sacramento Fish and Wildlife Office (see ADDRESSES section).

**Authors**

The primary authors of this notice are Douglas Krofta of the Arlington Fish and Wildlife Office and staff from the Carlsbad, Ventura, and Sacramento Fish

and Wildlife Offices (see ADDRESSES section).

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Proposed Regulation Promulgation**

For the reasons outlined in the preamble, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

**PART 17—[AMENDED]**

1. The authority citation for part 17 continues to read as follows:

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.95(d) by revising the introductory text of the critical habitat designation for the California red-legged frog (*Rana aurora draytonii*) to read as follows:

**§ 17.95 Critical habitat—fish and wildlife.**

\* \* \* \* \*

(d) *Amphibians.*  
\* \* \* \* \*

**CALIFORNIA RED-LEGGED FROG (*Rana aurora draytonii*)**

1. Critical habitat units are depicted for Alameda, Butte, Contra Costa, El Dorado, Fresno, Kern, Los Angeles, Marin, Mariposa, Merced, Monterey, Napa, Plumas, Riverside, San Benito, San Diego, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara, Santa Clara, Santa Cruz, Solano, Sonoma,

Stanislaus, Tehama, Tuolumne, and Ventura Counties, California, on the maps below.

2. Within these areas, the primary constituent elements for the California red-legged frog consist of three components:

(a) Aquatic habitat with a permanent water source with pools (i.e., water bodies) having a minimum depth of 0.5 m (20 in) for breeding and which can maintain water during the entire tadpole rearing season;

(b) Upland areas up to 90 m (300 ft) from the water's edge associated with the above aquatic habitat that will provide for shelter, forage, maintenance of the water quality of the aquatic habitat, and dispersal; and

(c) Upland barrier-free dispersal habitat that is at least 90 m (300 ft) in width that connects two or more suitable breeding locations defined by the aquatic habitat above, all within 2 km (1.25 mi) of one another.

3. Existing features and structures within the boundaries of the mapped units, such as buildings, roads, aqueducts, railroads, other paved areas, lawns, and other urban landscaped areas, and uplands removed from essential aquatic and dispersal habitat, will not contain one or more of the primary constituent elements and, therefore, would not trigger a section 7 consultation, unless they affect the species and/or primary constituent elements in adjacent critical habitat.

4. Map 1, Index map of critical habitat units for California Red-Legged Frog, follows:

\* \* \* \* \*

Dated: March 30, 2004.

**Paul Hoffman,**

*Acting Assistant Secretary of Fish and Wildlife and Parks.*

[FR Doc. 04–7693 Filed 4–12–04; 8:45 am]

**BILLING CODE 4310–55–P**



# Federal Register

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Tuesday,  
April 13, 2004

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Part III

## Department of Health and Human Services

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Substance Abuse and Mental Health  
Services Administration

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Mandatory Guidelines and Proposed  
Revisions to Mandatory Guidelines for  
Federal Workplace Drug Testing  
Programs; Notices

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Mandatory Guidelines for Federal Workplace Drug Testing Programs

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Revised mandatory guidelines.

**SUMMARY:** The Department of Health and Human Services ("HHS" or "Department") is establishing standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These standards ensure that specimen validity testing (SVT) and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

**DATES:** *Effective Date:* November 1, 2004.

*Comment Date:* Submit comments on or before June 14, 2004.

**ADDRESSES:** You may submit comments, identified by (insert docket number and/or RIN number), by any of the following methods:

- E-mail: [wvogl@samhsa.gov](mailto:wvogl@samhsa.gov). Include docket number and/or RIN number in the subject line of the message.
- Fax: 301-443-3031.
- Mail: 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.
- Hand Delivery/Courier: 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

**Instructions:** All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be available for public review at 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Walter F. Vogl, Ph.D., Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, telephone (301) 443-6014, fax (301) 443-3031, or e-mail: [wvogl@samhsa.gov](mailto:wvogl@samhsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) establish the scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies, under

authority of section 503 of Pub. L. 100-71, 5 U.S.C. 7301 note, and E. O. No. 12564. The Mandatory Guidelines were first published in the *Federal Register* on April 11, 1988 (53 FR 11979), and revised on June 9, 1994 (59 FR 29908), and on November 13, 1998 (63 FR 63483).

The Department is revising the Mandatory Guidelines here concerning the determination of the validity of urine specimens. In another document published along with this revision, the Department is proposing to revise the Mandatory Guidelines again to add alternative specimens, instrumented initial test facilities, and point of collection testing.

The alternative specimen proposal will be subject to a 90-day comment period after which the Department will consider the comments received and issue a final revision. Until the final revision on alternative specimens is issued, the Mandatory Guidelines as contained in this revision govern.

This revision becomes effective 180 days after the date of publication so that laboratories have an opportunity to purchase and become familiar with testing equipment to be used in assessing the validity of a urine specimen.

The revision of the Guidelines is subject to further comment only on the creatinine criterion that is part of the requirement to report a urine specimen as substituted because the Department has based this criterion on information received after the comment period closed on October 22, 2001.

##### II. Summary of the Proposed Revised Mandatory Guidelines

On August 21, 2001, HHS published a notice in the *Federal Register* (66 FR 43876), proposing that the Mandatory Guidelines be revised to include standards for determining the validity of urine specimens collected by Federal agencies under the Federal Workplace Drug Testing Program. These proposed revisions to the Mandatory Guidelines establish the analytical standards for determining the validity of urine specimens in order to ensure that SVT and reporting procedures are uniformly applied to all Federal agency urine specimens. Set forth below is a description of the major provisions of the proposed revision of the Mandatory Guidelines, including, among other things, definitions for certain terms associated with SVT, a discussion of the specific SVT requirements and how validity testing results should be reported, clarification of the qualifications and responsibilities of a Medical Review Officer (MRO), how a

donor may challenge the accuracy of a validity testing result, and an expansion of the existing performance testing program and laboratory inspection program.

##### *Provisions of the Proposed Revisions to the Mandatory Guidelines*

###### 1. Definitions

The proposed revisions added definitions specifically associated with specimen validity testing. These include the definitions for adulterated specimen, confirmatory validity test, dilute specimen, initial validity test, invalid result, non-negative specimen, oxidizing adulterant, and substituted specimen.

###### 2. SVT Requirement

The proposed revisions require each Federal agency to have specimen validity tests conducted on all urine specimens collected under the Mandatory Guidelines.

###### 3. Split Specimen Testing

The proposed revisions grant the donor the right to request that a split (Bottle B) specimen be tested to confirm an adulteration or substitution result that was reported by the primary laboratory on the primary (Bottle A) specimen.

###### 4. SVT Reporting Criteria

The proposed revisions add a new section, entitled "Validity Testing," to the Mandatory Guidelines. The new section requires a laboratory to conduct validity testing and establishes the criteria that must be used by a laboratory to report a specimen as adulterated, substituted, invalid, or dilute.

###### 5. Cutoff Levels

The proposed revisions establish a pH cutoff for reporting a specimen as adulterated and establish a creatinine cutoff and a specific gravity cutoff for reporting a specimen as substituted. The creatinine concentration cutoff is proposed to be less than 5 mg/dL. The specific gravity cutoff is proposed to be less than 1.002. The pH cutoff is proposed to be less than 3.

###### 6. Retesting

The proposed revisions require a second laboratory to conduct validity tests when it is unable to reconfirm the drug or drug metabolite that was originally reported positive in a single specimen or primary (Bottle A) specimen. The proposed revisions also add criteria for retesting a specimen for adulterants and substitution.

### 7. Quality Control

The proposed revisions establish specific quality control criteria and other procedural and test requirements for performing each individual validity test.

### 8. MRO Qualifications and Duties

The proposed revisions clarify the qualifications and responsibilities of the MRO and expand the MRO's duties to review adulteration, substitution, and invalid test results reported by a laboratory.

### 9. Donor's Right To Challenge Results

The proposed revisions provide that a donor has the same right to challenge the accuracy of a positive, adulterated, or substituted result reported for a single specimen collection as for a split specimen collection.

### 10. HHS Notification of Results

The proposed revisions state that an MRO will notify the designated regulatory office that is responsible for the laboratory certification program when a second laboratory fails to reconfirm a positive, adulterated, or substituted result reported by a first laboratory.

### 11. Performance Testing and Laboratory Inspection Programs

The proposed revisions expand the performance testing program and the laboratory inspection program. The performance testing program will include performance testing samples to challenge each certified laboratory's ability to correctly perform validity tests. The inspection program will include inspecting and evaluating the SVT procedures used by the laboratories in a manner similar to that for all other laboratory operations.

### III. Summary of Public Comments and HHS's Response

The August 21, 2001, Federal Register notice proposing revisions to the Mandatory Guidelines set forth a 60-day public comment period, ending on October 22, 2001. During the public comment period, the terrorist strikes of September 11 occurred, which have demanded a new focus and resolve from our government and citizens, that continue undiminished to date. Initially, there was concern that the public comment period would need to be extended, or that some comments might be delayed due to temporary disruptions in the delivery of documents. In light of the national emergency, the Department determined that public comments would be considered, even if they were received

a few days after the formal ending date. That proved to be unnecessary. The Department received 23 public comments by October 22nd on the proposed changes from Federal agencies, individuals, organizations, laboratories, and companies that were then made available for public view on our Internet Web site ([www.drugfreeworkplace.gov](http://www.drugfreeworkplace.gov)). All written comments were reviewed and taken into consideration in the preparation of the revised Mandatory Guidelines. Set forth below is an overview of the various comments and recommendations received and the Department's responses to those concerns. Similar comments are considered together.

Over the past several years, there has been an increasing number of chemical adulterants marketed on the Internet and in counter-culture, pro-drug use magazines. These adulterants are advertised as able to prevent laboratories from detecting drugs or metabolites in physiological specimens (e.g., urine, hair, oral fluid) that are collected as part of a drug testing program. These products are often toxic or corrosive and are sold to be added to a specimen in order to mask the presence of any drugs or metabolites. Examples of adulterants include various nitrites (Klear, Whizzies), pyridinium chlorochromate (Urine Luck, LL481, Sweet Pee's Spoiler), surfactant (Mary Jane SuperClean 13), and acid (Amber-13, THC-Free). As of this time, approximately 400 different products (although many contain the same adulterant) are available for adulterating urine specimens.

Even more blatant are recent increases in openly marketed promises to conceal current illicit drug use by substituting a "clean" urine specimen for the drug-user's "dirty" one. Some products actually advertise a prosthetic device in a range of skin tones complete with waistband, fluid reservoir, thermocouple heating device, and externally formulated and color-dyed solution marketed as synthetic urine. These devices and systems are targeted for use by individuals who want to conceal their illicit drug use by using such a system to suborn a drug test.

The final requirements that make up the revisions to the Mandatory Guidelines are based on seven years of experience with SVT. These revisions are the collective product of a broad community of medical, forensic, research, and production laboratory testing experts who have contributed their knowledge, determination, and problem-solving skills to address those who would cheat on a drug test.

In reviewing different specimen validity test procedures and methods, the Department learned from mistakes made by participants. The Department corrected these mistakes as they occurred, including making corrections or canceling test results in cases where laboratory inspectors, contractor staff, and Federal program staff were not certain about the ability of a laboratory forensically to defend a test result in court. This approach is a practice the Department will continue.

The Department has established these final requirements for SVT to produce the most accurate, reliable, and correctly interpreted test results. In a national system that has reduced the number of detected adulterated and substituted specimens to the current levels of about three one-hundredths of one percent of all federally mandated workplace tests performed in the past year, some may ask if it is worth the effort to prevent this very small number of individuals from masking their personal use of illicit drugs. The answer is yes. The purpose of the entire program has been to prevent and deter the use of illicit drugs in the Federal workplace. It has been vitally important to always project a sure and certain standard that Federal employees will be held personally accountable regarding employment selection or even job retention should they choose to use illicit drugs.

The Department intends to decrease or remove opportunities to subvert a workplace drug test through these revisions to the Mandatory Guidelines and will seek to hold all individuals accountable for their choices.

#### 1. Mandatory SVT (Paragraph 2.1(a)(4))

The Department specifically requested comments from Federal agencies and employees covered by E.O. 12564 and Pub. L. 100-71 regarding the proposal to require SVT as part of their drug testing programs. Only one Federal agency submitted a comment on this issue. The comment submitted concurred with the proposal to make SVT mandatory on urine specimens collected by all Federal agencies. Because there were no comments submitted by Federal agencies or Federal employees opposed to the proposal, the Department believes it is appropriate to require each Federal agency to make SVT a required part of its workplace drug testing program.

#### 2. Donor Right To Request a Retest of an Adulterated or Substituted Specimen (Sections 2.2(h) and 2.6(e))

One commenter suggested that the proposed requirement for the donor to request a retest on a single specimen or

a test of a split specimen within 72 hours after being notified by the MRO that his or her specimen was reported positive, adulterated, or substituted was insufficient. The 72-hour rule has been in the Guidelines since 1994 and the Department is not aware of any occasion in which the donor was unable to request a test of a split specimen within this time frame. Additionally, MROs have the discretion to extend the 72-hour time frame when necessary. The proposed revision to this section of the Mandatory Guidelines simply expands the donor's ability to request a retest when a specimen is identified as adulterated or substituted. The donor shall be allowed the same ability to request through the MRO a retest of a single specimen that is reported either drug positive, adulterated, or substituted. In cases where a split specimen was collected consistent with agency policy, the donor shall be allowed the same ability to request through the MRO a retest of the split (Bottle B) specimen when the primary specimen is reported either drug positive, adulterated, or substituted. Based on our experience, the Department continues to believe that 72 hours is a sufficient period of time for a donor to request a retest on a single specimen or a test of the split specimen after being notified by the MRO that his or her specimen was reported positive, adulterated, or substituted.

The same commenter also suggested that a Federal agency should have the authority to direct a retest of a single specimen or the test of a split specimen at any time. The Department believes that limiting the ability to request a retest to the donor ensures that each donor is offered the same chance to dispute the reported test results. However, the Guidelines do not preclude a judge from issuing a court order to retest a specimen, an administrative law judge from ordering a retest of a specimen, or a Federal agency from retesting a specimen as part of a legal or administrative proceeding to defend a test result when the donor elected not to request a retest of a specimen reported positive, adulterated, or substituted. A new paragraph 2.6(e)(4) has been included to ensure that a Federal agency may conduct a retest under this limited situation.

### 3. SVT (Section 2.4(g))

One commenter suggested that it is unnecessary for all laboratories to have the capability to identify and quantitate oxidizing adulterants and recommended establishing a list of laboratories that would specialize in adulteration testing. The Department does not agree with this

recommendation. The Department believes that all laboratories must have the capability and actually test all specimens for one or more oxidizing adulterants. This is especially critical for those specimens where a drug test result or other evidence indicates that a specimen may be adulterated. Otherwise, many specimens adulterated with oxidants may simply be reported as negative. This action is consistent with the Federal Workplace Drug Testing Program goal of ensuring an accurate and reliable result on every specimen tested, whether the result is positive or negative for drugs, adulterated, substituted, or invalid.

One commenter suggested there is no value in determining the pH for every specimen because the number of specimens reported with a pH that is too low or too high is extremely low. The Department believes that the elimination of this requirement would allow the use of adulterants that alter the pH causing it to be out of the normal physiological range, and hence interfere with obtaining a valid drug test or adulterant result. Therefore, as was proposed, the revisions to the Mandatory Guidelines shall require that a laboratory determine the pH for every specimen tested.

One commenter suggested the requirement that a laboratory must test a specimen for oxidizing adulterants did not clearly state that the test(s) was to be performed on each specimen. The Department agrees that the statement of the requirement in the proposed revisions was unclear. As a result, paragraph 2.4(g)(4) has been revised to indicate that one or more validity tests for oxidizing adulterants must be performed on each specimen.

One commenter recommended either to define abnormal color or odor or to delete any reference to abnormal physical characteristics as a condition to perform additional validity tests. The Department believes there are physical characteristics that can be used to identify specimens that may require some additional validity tests. However, definitions cannot be developed to specifically describe all the possible abnormal characteristics that may be observed by laboratory personnel. In response to this comment, the parenthetical reference to color, odor, or excessive foaming has been deleted in the Mandatory Guidelines to avoid limiting the possible characteristics that may be used to trigger additional validity tests. Because of the large number of adulterants being marketed to mask the presence of or remove drugs or metabolites from a specimen, the Department fully intends for color, odor,

and excessive foaming, among others, to remain as abnormal physical characteristics that can be evaluated at a laboratory and prompt additional testing as specified in paragraph 2.4(g)(5). However, a laboratory may choose not to test the specimen if the laboratory believes that testing the specimen may damage its instruments. For example, a specimen that is gelatinous may possibly clog the tubing used in an immunoassay analyzer, thereby shutting down the instrument and requiring extensive maintenance. In such a case, the laboratory may assume that the urine specimen is not a valid urine specimen and must report an invalid result to the MRO. This invalid result is then used by the MRO to direct the agency to have the donor immediately submit another urine specimen using a direct observed collection. See section 2.6(c).

One commenter stated that insufficient data exists to support the proposed requirement that a specimen be reported as an "invalid result" if validity testing performed on the specimen shows creatinine concentration and specific gravity results that are considered to be inconsistent with normal human physiology. The Department believes that the conditions given for creatinine concentration and specific gravity results that are inconsistent with normal range values indicate possible tampering with the specimen. The requirement to report these inconsistent values as "invalid results" ensures the collection of another specimen to determine if the donor did provide a valid specimen or, in fact, did tamper with the first specimen collected.

With regard to the proposal to establish the lower specific gravity cutoff as less than 1.002 for the substitution criteria, the Department has reconsidered this proposal and is establishing the specific gravity cutoff as less than or equal to 1.0010. Note that this cutoff is stated to four decimal places. This will retain the specific gravity cutoff that the laboratories have been using since HHS issued guidance for all laboratories in determining the validity of a specimen (Division of Workplace Programs Memorandum dated September 28, 1998, Subject: Guidance for Reporting Specimen Validity Test Results, Program Document #35). At the time the Program Guidance was issued and the proposed changes to the Mandatory Guidelines were published in August 2001, the refractometers that were in use read the values to three decimal places (*i.e.*, 1.001). Since the time that the Department published the proposed



cutoff of less than 1.002, a new series of electronic refractometers have been made available that measure specific gravity to four decimal places. The use of a refractometer that measures specific gravity to four decimal places allows a laboratory to report and display specific gravity values that are within one ten-thousandth from the cutoff rather than being essentially a "yes" or "no" answer (that is, 1.000 or 1.001 for a "yes" answer, 1.002 for a "no" answer when using a three decimal place refractometer). Therefore, the Department directs that all laboratories must use refractometers that report and display specific gravity to four decimal places. These instruments also have electronic and hard copy reporting peripheral device capability and thus allow machine generated documentation, which recent administrative and legal proceedings have advocated.

After the close of the public comment period, and prior to the publication of a final notice in the *Federal Register* that would have established the criteria used to report a specimen as substituted, the Department became aware of supplemental information from a Congressionally-mandated study by the Department of Transportation (DOT) Federal Aviation Administration (FAA) indicating that the Department's treatment of substitution should be reconsidered. The information was presented at a conference sponsored by the FAA in Tampa, Florida, on February 4-6, 2003, that brought together toxicologists, nephrologists and other physicians, MROs, technical experts in various fields, and HHS and DOT officials. Attendees at the conference generally agreed that it would be appropriate to lower the creatinine criterion that is part of the requirement to report a urine specimen as substituted. This information lead DOT to publish an interim final rule in the *Federal Register* (68 FR 31624) on May 28, 2003, that changed the way MROs were expected to interpret substitution results reported by the laboratories.

This supplemental information strongly suggested that if the Department adopted the proposed cutoffs as written, in rare, but very real circumstances, it might be possible to misidentify an individual as providing a substituted specimen, when in fact the specimen was actually produced by the individual. To date, to the best of our knowledge, there have not been any Federal employees who have raised a challenge to the specific creatinine decision point of less than or equal to 5 mg/dL and specific gravity less than or equal to 1.001 or greater than or equal

to 1.020 as defining a "substituted specimen." After careful consideration of the supplemental information, the Department believes that it is appropriate to propose lowering the creatinine decision point to identify a substituted specimen to less than 2 mg/dL and specific gravity to less than or equal to 1.0010 or greater than or equal to 1.0200. With regard to the proposal in August 2001 to establish the lower specific gravity cutoff as less than 1.002 for the substitution criteria, the Department has reconsidered this proposal and is requiring to establish the specific gravity cutoff as less than or equal to 1.0010. Note that this cutoff is now stated to four decimal places. This will retain the specific gravity cutoff that the laboratories have been using since HHS issued guidance for all laboratories in determining the validity of a specimen (Division of Workplace Programs memorandum dated September 28, 1998, Subject: Guidance for Reporting Specimen Validity Test Results, Program Document #35). At the time the Program Guidance was issued and the proposed changes to the Mandatory Guidelines were published in August 2001, the refractometers that were in use read the values to three decimal places (i.e., 1.001). Since the time that the Department published the proposed cutoff of less than 1.002, a new series of electronic refractometers have been made available that measure specific gravity to four decimal places. Therefore, the Department is requiring that all laboratories must use refractometers that report and display specific gravity to four decimal places. These instruments also have electronic and hard copy reporting peripheral device capability and thus allow machine generated documentation, which recent administrative and legal proceedings have advocated.

#### 4. Reporting Results (Section 2.4(h))

Three commenters expressed concern that the same test could be used for both the initial and confirmatory validity tests. The commenters believe that the initial validity test should use a different analytical methodology than the confirmatory validity test before a specimen can be reported adulterated or substituted. The Department agrees with the commenters' recommendation that initial and confirmatory validity tests use a different analytical methodology and has revised the reporting policy for adulterants to require that two different methods are used before a specimen can be reported as adulterated. If a laboratory uses the same test (e.g., the same colorimetric test) for both the initial test and the confirmatory test, the

laboratory may only report an "invalid result" for a specimen rather than an adulterated result. Paragraph 2.4(h)(4) clearly describes the combination of methods that a laboratory must use to report a specimen as adulterated for a specific adulterant. The only exceptions to this requirement pertain to the tests used to measure the creatinine concentration, specific gravity, and pH.

To report a specimen as adulterated because the pH is too low or too high, a pH meter may be used for both the initial and confirmatory pH tests because it is considered a reference method by the scientific community, is a highly reliable instrument, and gives extremely accurate results when properly calibrated. Further, pH values represent a logarithmic scale and therefore represent very large differences between each pH unit. Based on this assessment, using a pH meter for both the initial and confirmatory pH tests is scientifically and forensically valid.

The Department believes it is scientifically acceptable to use the same creatinine test for both the initial and confirmatory creatinine tests and to use refractometry to measure specific gravity for both the initial and confirmatory specific gravity tests. For creatinine, the most accepted method to determine the creatinine concentration is the Jaffe' or modified Jaffe' colorimetric procedure. In addition, any endogenous substance that may interfere with the creatinine colorimetric test is going to produce a reading such that the creatinine concentration will appear to be higher rather than lower than the true creatinine concentration. In other words, interfering compounds will increase the creatinine concentration, raising it above 2 mg/dL, and therefore the specimen will not meet the criteria to report it as substituted. As of this time, the Department does not know of any endogenous interfering substance that will lower the apparent reading on the colorimetric creatinine test. Therefore, the Department believes it is acceptable to use the same colorimetric creatinine test for both the initial and confirmatory tests.

With regard to using refractometry for both specific gravity tests, a refractometer, like a pH meter, is considered a reference instrument and its results are scientifically acceptable. Therefore, the Department believes it is acceptable to use refractometry for both specific gravity tests. Moreover, the combination of specific gravity and creatinine serves as two tests employing different scientific principles.

A valid scientific identification is based on the use of two methods used on two separate aliquots obtained from the original urine specimen. The nature of the analytical method is based on the chemical composition of the substance to be tested. Further, the combination of techniques is a function of both the expected prevalence of the substance to be tested and the nature of the analytical technique. This may be illustrated by the following examples:

(1) For drugs, drugs are tested by immunoassay on the first aliquot. Each immunoassay test has variable specificity for a particular drug class. The gas chromatography/mass spectrometry (GC/MS) confirmatory drug test is specific for a particular drug or metabolite. The presence of drugs is not expected in a urine specimen. While the number of drugs to be identified in a urine specimen is limited to those specified by these Guidelines, the number of drugs to be excluded comprises a long list.

(2) For creatinine, creatinine is tested by colorimetric assays using the same assay in each of two aliquots. The presence of creatinine in urine is expected. Its concentration is normally expected to be relatively high and it is among a very small number of waste products found in urine.

(3) For alcohol, although not part of the Federal workplace drug testing program, a breath sample is initially tested on an approved device and, if positive, a confirmatory test is conducted using the same approved device on a second breath sample. The most common of the breath devices utilizes a fuel cell in which the alcohol is consumed resulting in a proportional electronic response. Alcohol is a volatile substance and although not expected to be present in the breath, is among a very short list of possible substances. The concentration of alcohol, when present in the body, is relatively very high.

The three examples constitute valid scientific and forensic identification although there is variation in the analytical parameters and expected prevalence of the substances in biological specimens. Program Documents 35 and 37 issued by HHS in 1998 and 1999 established the framework for reporting a specimen as substituted and adulterated. This framework included an analysis on two aliquots with various qualitative and quantitative procedures. Each laboratory had the flexibility to develop the specific testing requirements, to validate the methods used, and to establish quality control procedures using good laboratory practices. This generally stated scientific approach has been

recommended since the inception of this program.

Our on-going review of specimen validity test results and inspection of laboratories has shown analysis to date to be competent and reasonable and to have met satisfactory scientific criteria. Results of these specimen validity tests have also been introduced and effectively been supported in legal proceedings. The Department conducted a special review of SVT in all certified laboratories. This included analysis for adulterants where the same test was used on two different aliquots of the donor's specimen. Based on program experience and availability and development of refined analytical procedures, the Department is establishing specific requirements for analytical procedures to identify the common adulterants. See section 2.4(h).

One commenter recommended reporting any specimen with a nitrite concentration between 200 mcg/mL and 500 mcg/mL as an "invalid result." The Department agrees with this recommendation and has changed the Guidelines at paragraph 2.4(h)(7)(iii) to include a nitrite range as one of the conditions upon which a specimen must be reported as an "invalid result." Although a 500 mcg/mL nitrite concentration is established as the concentration at or above which a specimen is reported adulterated for nitrite, clinical evidence (*see* Urry, F.M. *et al.*, Nitrite Adulteration of Workplace Urine Drug Testing Specimens. 1. Sources and Associated Concentrations of Nitrite in Urine and Distinction Between Natural Sources and Adulteration, "Journal of Analytical Toxicology" 22: 89-95 (1998)) indicates that any nitrite concentration above 129 mcg/mL is not physiologically possible and is, therefore, an abnormal concentration. The Department also notes that since Program Documents 35 and 37 were issued in 1998 and 1999 and the proposed Changes to the Mandatory Guidelines were published in August 2001, some adulterant products now contain lower amounts of nitrite mixed with other oxidant compounds in an effort to avoid detection.

#### 5. Retesting a Specimen for Adulterants (Section 2.4(k))

One commenter suggested deleting any reference to limit of quantitation (LOQ) when a second laboratory is retesting a specimen for any adulterant other than when retesting for pH or to reconfirm the presence of nitrite. The commenter suggested that the retesting should use the limit of detection (LOD) as is used when retesting a specimen for

a drug positive to ensure consistency between the retesting policy for drugs and the policy for retesting adulterants. The Department agrees with the recommendation and has specified using the LOD to reconfirm the presence of an adulterant except when retesting for pH and nitrite. However, the retesting for an adulterant requires the second laboratory to use its confirmatory test for the adulterant that was reported present in the single or Bottle A specimen by the first laboratory. For example, reconfirming a pH that was too low or too high requires the second laboratory to test an aliquot of a single specimen or the split (Bottle B) specimen using its confirmatory pH meter test. Another example, reconfirming the presence of chromium (VI) requires the second laboratory to test an aliquot of a single specimen or the split (Bottle B) specimen using its confirmatory test to determine the presence of chromium (VI) above the LOD. The second laboratory cannot use its initial colorimetric test to reconfirm the presence of chromium (VI).

#### 6. Quality Control Requirements for Validity Tests (Section 2.5(d))

One commenter suggested that the Mandatory Guidelines should specify what the reference method is for each type of validity test. The Department believes that the methods being used for the various validity tests, with the exception of the pH meter, do not meet the classical definition of a reference method (*i.e.*, a method to which other tests are compared). The Department views it as more important that the performance characteristics of the method used for each type of validity test can be documented by the laboratory prior to using the method, as is the case for the drug tests used by the laboratories. Establishing the performance characteristics of a method prior to its use ensures that the method can provide accurate measurements on donor specimens which are verified by simultaneously obtaining results for quality control samples. If the quality control samples results indicate a possible error, then all specimens associated with those quality control samples must be retested until the quality control sample results satisfy the acceptance criteria established by the laboratory.

One commenter suggested that the proposed number of calibrators and controls is excessive for some of the validity tests. The Department believes that the proposed quality control requirements for the validity tests are appropriate and are similar to those required for the initial and confirmatory

drug tests. Since the results of validity tests can lead to the same personnel actions that may occur as if the specimen was reported positive for a drug, it is essential that every effort is made to ensure the accuracy and reliability of every validity test result.

#### 7. Requirements for Measuring Creatinine Concentration (Section 2.5(e))

One commenter suggested that requiring calibrators at 5 mg/dL and 20 mg/dL for a creatinine test requires an unnecessary re-validation of the test and that a control in the normal range (greater than 20 mg/dL) is useful. The Department proposed using calibrators at 5 mg/dL and 20 mg/dL because most creatinine tests are calibrated at 100 mg/dL. Since the decision points for our workplace drug testing program are so much lower than used for most clinical laboratory testing, it is essential that the method be validated and calibrated at 2 mg/dL to ensure the highest degree of accuracy and confidence around the decision point used to determine a substituted specimen. With regard to including a control in the normal range, the commenter overlooked the fact that a control in the normal range was included in the requirements for the initial creatinine test. Given an initial creatinine test result at less than the 2 mg/dL cutoff concentration, there is no need to run another control in the normal range for the confirmatory test. However, controls are needed above and below 2 mg/dL to ensure the highest degree of accuracy and confidence around the cutoff.

#### 8. Requirements for Measuring Specific Gravity (Section 2.5(f))

One commenter stated that the requirement for four quality control samples when determining specific gravity is excessive. The commenter suggested simply including one calibrator at each decision point and one control in the normal range. The Department believes that a decision point must be bracketed whenever possible to ensure the accuracy of a test result rather than using the approach recommended by the commenter. Since the time the proposed policy was published, the Department has re-evaluated the control requirements for measuring specific gravity. The Department believes that each initial and confirmatory specific gravity test should have a calibrator and controls covering the entire range rather than selecting controls based on whether the specimen is being evaluated against the lower decision point (*i.e.*, less than or equal to 1.0010) or the higher decision

point (*i.e.*, greater than or equal to 1.0200). Therefore, the Department has combined the controls that are required when conducting either the initial or confirmatory specific gravity tests regardless of which decision point is applicable.

#### 9. Requirements for Measuring pH (Section 2.5(g))

One commenter suggested that, when determining pH levels, a control in the normal range should also be included. The Department agrees with this suggestion and is requiring that either a calibrator or control in the normal range be included in each test batch when conducting either the initial or confirmatory pH test.

One commenter noted that the controls proposed for a colorimetric pH test are inconsistent with the controls required for a pH meter test. The Department believes that this inconsistency cannot be eliminated due to the differences in the way colorimetric pH tests and pH meters are calibrated.

Section 2.5(g) has been revised to require the use of three controls when using a pH screening test (*i.e.*, pH paper, dipsticks, or colorimetric tests that have a narrow dynamic range and do not support the pH cutoffs) to determine if the pH of a specimen is too low or too high. This section also specifies the calibrators and controls that must be used if an initial colorimetric pH test or initial pH meter test is conducted without having used a screening test to determine if the pH of a specimen may be too low or too high. Additionally, the Department believes that when a pH screening test is used and the pH of the specimen is possibly too low or too high, the initial and confirmatory pH meter tests may use calibrators and controls that are focused on either the lower or upper decision point, as appropriate. This is a reasonable approach because pH meter tests are manual rather than automated. However, an exception exists when a colorimetric pH test is used as the initial pH test whether a screening pH test was or was not conducted. The Department believes that most laboratories will use an initial colorimetric pH test to test all specimens received, rather than using screening tests, because it is an automated procedure and would be efficient and cost effective compared to using pH screening tests or a "manual" pH meter test. To avoid having to repeat the colorimetric pH test with focused calibrators and controls only for those specimens that may have a pH that is too low or too high, the entire pH range

should be covered with appropriate calibrators and controls.

#### 10. Requirements for Performing Oxidizing Adulterant Tests (Section 2.5(h))

Several commenters expressed concern with the proposed requirements for performing oxidizing adulterant tests. There was a general request for more specific information and a concern that these oxidizing tests fail to meet appropriate scientific standards. The Department agrees that the proposed requirement for performing oxidizing adulterants was unclear. Therefore, the Department has revised the requirements described in section 2.5(h). The Department expects each laboratory to test each specimen for one or more oxidizing adulterants. This can be accomplished by either using a single test that responds to several oxidizing adulterants (*e.g.*, a general oxidant colorimetric test for the initial test for oxidizing adulterants) or one or more initial tests that identify specific oxidizing adulterants (*e.g.*, an initial nitrite colorimetric test, an initial chromium (VI) colorimetric test). Additionally, the Department is permitting the general oxidant colorimetric test to be used with different calibrators or controls to possibly detect different adulterants. For example, the general oxidant colorimetric test can be used to detect nitrite using a calibrator or control with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or to detect chromium (VI) using a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff. Since individuals attempting to subvert the drug testing program may use a number of different oxidizing adulterants, the testing requirement for oxidizing adulterants is intentionally drafted broadly to permit the flexibility needed to combat such tampering with the testing process. Although these oxidizing adulterant tests are new, the Department expects the laboratories to validate each oxidizing adulterant test before it is used to test donor specimens and to apply the specified quality control requirements to ensure the proper performance of each test on donor specimens.

#### 11. Requirements for Performing "Other" Adulterant Tests (Section 2.5(j))

One commenter suggested that the proposed requirement for the performance of "other" validity tests for adulterants did not permit the flexibility necessary to ensure that as new adulterants are identified, the Mandatory Guidelines would permit

laboratories to test for these new adulterants. The Department agrees with that comment and has revised paragraph 2.5(j)(3) to ensure that newly identified adulterants not included in paragraphs 2.5(j)(1) or (2) or in any other section of the Mandatory Guidelines can be tested for by a laboratory.

One commenter asked if a specimen containing glutaraldehyde could be reported as adulterated based on using the confirmatory test procedure on two separate aliquots. The revision to the Mandatory Guidelines requires that a specimen can only be reported adulterated for glutaraldehyde if the initial and confirmatory glutaraldehyde tests use different methodologies. For glutaraldehyde, the characteristic response on immunoassay drug tests is very well established and may serve as the initial test for determining the presence of glutaraldehyde or by performing a separate initial aldehyde test. The confirmatory test for glutaraldehyde traditionally has been gas chromatography/mass spectrometry.

#### 12. MRO Qualifications and Review of Results (Section 2.6)

One commenter recommended that the Mandatory Guidelines be revised to require an MRO to complete formal training and pass an examination, as required in the DOT Procedures for Transportation Workplace Drug and Alcohol Testing Program (49 CFR Part 40). The Department recognizes that other changes to the Mandatory Guidelines may be needed; however, our intent in the solicitation of comment was to focus only on proposing changes associated with mandating validity testing on specimens collected under the Mandatory Guidelines.

One commenter expressed concern that an MRO may direct a laboratory to send a specimen to another laboratory before determining that the second laboratory has the capability to perform any additional tests. The Department agrees that an MRO should always contact a laboratory to determine its capability before having a specimen transferred for additional validity testing. This policy applies especially to paragraph 2.6(c)(2) when Laboratory A reports an invalid result and the laboratory and MRO agree that further testing may be useful in an attempt to be able to report a positive, adulterated, or substituted result.

#### 13. Laboratory Result Not Reconfirmed by a Second Laboratory (Section 2.6(g))

One commenter interpreted the proposed requirement that the MRO notify the designated HHS regulatory office when a second laboratory was

unable to reconfirm the result reported by the original laboratory testing the specimen as meaning that the MRO is not receiving the same notification. The agency's designated representative always receives all results reported by an MRO. This requirement is intended to ensure that the HHS regulatory office is notified of such reports to permit the initiation of an investigation to determine if an error was made by either laboratory.

#### 14. Additional Changes Related to the New SVT Requirements

In addition to the changes discussed above, the Department is revising other sections of the Mandatory Guidelines that are directly affected by the new SVT requirements.

In section 1.2, the original definitions for an "initial test" and a "confirmatory test" are being changed to read "initial drug test" and "confirmatory drug test," respectively, to prevent any confusion with the new definitions for "initial validity test" and "confirmatory validity test." The Department is adding the word "drug" throughout the Mandatory Guidelines when referring to initial drug tests and confirmatory drug tests.

Under section 2.2(f)(4), the collector must direct the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into his or her pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a refusal to cooperate in the testing process. The Department believes this requirement is necessary because of the ease with which a donor can conceal a small amount of an adulterant and the availability of numerous adulterants on the Internet and in drug culture magazines. This change also ensures consistency with the collection procedure specified in the DOT drug testing regulations (49 CFR Part 40). The Department believes that every effort must be made to prevent a donor from bringing something to the collection site that could be used to adulterate a specimen and, thereby, preventing it from being properly tested for drugs.

Section 2.4(h)(2) was revised to ensure that each specimen is subject to validity testing to determine that it is a valid urine specimen before a negative result is reported.

Section 2.2(h)(8) was deleted because it only deals with the testing of a split (Bottle B) specimen that failed to

reconfirm a positive drug result reported for Bottle A.

In section 2.4(h), the Department included all the reporting requirements to report a specimen adulterated, substituted, diluted, or as an invalid result in paragraphs (4), (5), (6), and (7).

A new section 2.4(h)(12) was included to require a laboratory to report on the Federal CCF and/or computer-generated electronic report the actual numerical value (e.g., concentration) associated with an adulterated specimen (when applicable) and the confirmatory creatinine concentration and the confirmatory specific gravity for a substituted specimen. The Department believes that this requirement will eliminate the need for an MRO to generate a separate written request, thereby reducing the paperwork associated with each adulterated and substituted specimen.

Section 2.4(h)(15) was revised to require each laboratory to provide a statistical summary report every six months rather than monthly to a Federal agency. The format for the report was also changed to include the provision for information on adulterated, substituted, and invalid specimens. The Department believes reducing the frequency of the report to a semi-annual basis is cost effective and avoids requiring laboratories to report a summary for several specimens as opposed to a more reasonable number that would be tested over a six-month period of time. Both of these changes are consistent with the requirements in the DOT drug testing regulations (49 CFR Part 40).

In sections 2.4(i) and 3.9, the requirement to retain positive specimens in long-term storage is expanded to include specimens reported as adulterated, substituted, and invalid. Because administrative and/or legal actions may be taken that relate to specimens with these results, it is imperative that they be retained frozen and available for possible future retesting.

In section 2.4(j), the retesting policy for drugs has been expanded. If a second laboratory fails to reconfirm the presence of a drug when retesting a single specimen or testing a split (Bottle B) specimen, the second laboratory is required to conduct validity tests in an attempt to determine a reason for failing to reconfirm the presence of the drug or metabolite.

Sections 2.5(k)(1) and (3) have been revised to require that an agency blind sample program includes samples that are adulterated or substituted along with negative samples and drug positive samples. This requirement ensures that



a laboratory's procedures are challenged with samples that are adulterated or substituted.

Section 2.6, where appropriate, has been revised to describe how an MRO is expected to review adulterated, substituted, and invalid results as well as drug positive results.

Sections 2.6(g)(1) through (16) give specific requirements on how an MRO reports a result to a Federal agency when Laboratory B fails to reconfirm the test result reported by Laboratory A. The Department believes these requirements are necessary to ensure uniformity among MROs when a failed to reconfirm occurs.

Section 2.6(h) has been revised to describe how an MRO shall report a final test result to a Federal agency.

Section 3.4 has been revised to ensure that each laboratory has the capability to test for the five required classes of drugs as well as to conduct validity tests as specified in these Mandatory Guidelines.

Section 3.5 has been revised to clarify that all drug and validity tests are to be conducted by a certified laboratory at the same facility.

Sections 3.17, 3.18, and 3.19 have been revised to clearly distinguish between performance testing (PT) samples that contain drugs and PT samples that will challenge a laboratory's specimen validity tests. In the proposed changes to the Mandatory Guidelines, a revision was proposed to section 3.2 to indicate that laboratories would be challenged with specimen validity samples in the PT program and inspections would include reviewing validity testing procedures. The Department believes the specific performance requirements for the samples challenging a laboratory's specimen validity tests are comparable to the requirements for the performance testing with samples containing drugs or metabolites.

#### 15. Other Changes

The Department is making several technical changes and/or clarifications to other sections of the Mandatory Guidelines. Several of these changes reflect policies or procedures that have been previously implemented. The Department believes it is appropriate to include these changes in this revision of the Guidelines.

The term "collection site person" is being replaced with the term "collector" throughout the Mandatory Guidelines. The Department is making this change because the use of the term "collector" has become the most common way to refer to the individual involved with collecting a specimen from a donor.

The term "specimen chain of custody form" is being replaced with the term "Federal drug testing custody and control form" (or "Federal CCF") throughout the Mandatory Guidelines. This is the official name given to the form approved by the Office of Management and Budget (OMB) to collect a urine specimen from a Federal employee.

The definition for "chain of custody" has been revised to clarify that it refers to a "process" that is used to track the handling and storage of specimens rather than "procedures" and deleted the sentences that reference the OMB form because the Federal CCF is defined separately.

Section 2.2(g) was revised because the current Federal CCF does not allow a collector to transfer the custody of a specimen to another individual prior to releasing the specimen to an express carrier or courier for shipment to a laboratory. In addition, the first sentence requiring the collector to maintain the specimen bottle within sight is redundant with the requirement in paragraph 2.2(f)(17) as revised and was deleted.

Section 2.4(b)(2) was revised to clearly describe the types of errors that may occasionally occur on a Federal CCF and/or specimen bottle label/seal that are considered to be fatal flaws. These errors require a laboratory to stop the testing process and to report the result as rejected for testing. Paragraph 2.4(b)(3) was added to describe two types of correctable flaws that, if not corrected, would also require the laboratory to report a specimen as rejected for testing. Provisions similar to these were originally implemented by Program Document #9 (October 10, 1991). The Department believes including these provisions in the Guidelines will ensure uniform treatment by laboratories when these types of errors occur. The provisions are also consistent with those contained in the DOT drug testing regulations (49 CFR Part 40).

Section 2.4(f)(1) was revised to allow a laboratory to report a quantitative drug test result three different ways. The Department believes that a laboratory should have the option to report a quantitative result as either "exceeds the linear range of the test," "greater than or equal to (specify the upper limit of linearity)," or as an accurate quantitative result obtained by diluting an aliquot of the specimen before conducting the confirmatory drug test.

Section 2.4(h)(13) and (14) were revised to describe the different ways results can be transmitted from a laboratory to an MRO. A laboratory

always completes the test result section on the Federal CCF; however, a copy of the Federal CCF may or may not be sent to the MRO depending on whether the test result is negative or non-negative. For a negative result, an electronic report is sufficient. The Department believes the reporting requirements in these two sections will reduce the paperwork burden and is consistent with the intended use of the five-part Federal CCF.

A new section 2.4(h)(11) was included to require a laboratory to report to an MRO a quantitative value for morphine or codeine that is greater than or equal to 15,000 ng/mL. Section 2.6(d) was also revised regarding the policy that an MRO must follow when verifying a donor specimen as positive for morphine or codeine when the concentration is at or above 15,000 ng/mL. The Department believes that a morphine or codeine concentration at or above 15,000 ng/mL is high enough to prevent falsely accusing an individual of opiate abuse who may have only eaten poppy seeds or falsely accusing an individual who does not exhibit any clinical evidence of opiate abuse and does not provide a legitimate medical explanation. These revisions are also consistent with the laboratory reporting and MRO verification policies in DOT 49 CFR Part 40.

Section 2.4(h)(14) was revised to clarify that a laboratory may report all test results by faxing a completed copy of the Federal CCF, sending a completed copy of the Federal CCF by courier or mail, electronically transmitting a legible image or copy of the completed Federal CCF, and/or may forward a computer-generated electronic report. The Department believes that revising this paragraph clarifies the point that sending a computer-generated electronic report does not prohibit a laboratory from also sending a completed Federal CCF by one of the other ways described. The section also requires that a copy of the completed Federal CCF must be transmitted by one of the ways described for a non-negative result (*i.e.*, a computer-generated electronic report is not sufficient, by itself, when a laboratory reports a non-negative result to the MRO).

Sections 2.5(b) and (c) were revised to modify the general quality control requirements for the initial drug and confirmatory drug tests. The current Guidelines require including "positive control(s) fortified with drug or metabolite" and "at least one positive control with the drug or metabolite at or near the threshold (cutoff)." These two requirements can actually be satisfied using a single control, which was not



the intent of the requirements. The use of the original phrase "at or near the threshold (cutoff)" is too vague and allows different interpretations. The Department believes the revised requirements will ensure consistency by stating that each initial drug test batch shall include a control targeted at 25 percent above the cutoff and a control targeted at 75 percent of the cutoff. The revised requirements in these two sections have been described in other NLCP program documents for several years and placing them in the Mandatory Guidelines eliminates possible misinterpretation.

A new section 2.5(c)(4) was added to require a laboratory to include in each confirmatory drug test batch at least one calibrator or control at or below 40 percent of the cutoff. Prior Department policy required a laboratory to include such a calibrator or control only when the confirmatory drug test batch contained an aliquot of a single specimen or a split (Bottle B) specimen received from a different laboratory for confirmatory drug testing. The Department believes including a calibrator or control at or below 40 percent of the cutoff in each confirmatory drug test batch is appropriate to ensure that the laboratory documents the accuracy of the confirmatory drug test below the cutoff for each confirmatory drug test whether it contains or does not contain such a specimen received from a different laboratory. This has been clarified in other program documents and ensures that a uniform policy exists in all laboratories.

Section 3.20 has been revised to provide that the number of inspectors on an inspection team can be two or more rather than the three previously specified for any inspection. In practice, the number of inspectors on an inspection team has varied depending on the size of the laboratory. This change was implemented several years ago because the consolidation and growth of several laboratories caused a significant increase in their workloads, and these increases made it difficult for inspectors to review a sufficient number of non-negative test results in the time allotted. By changing the number of inspectors for different sized laboratories, the percentage of non-negative test results reviewed by the inspection teams remains somewhat comparable between the different sized laboratories. Currently, there are several very small laboratories, and using two inspectors is clearly sufficient to conduct a thorough review of the laboratory's procedures and test results. Conversely, several very large

laboratories have workloads that require more inspectors to conduct a thorough review of both their procedures and test results. The Department believes this change is fair, equitable, and cost effective for all the laboratories.

Other appropriate minor editorial changes are being made for clarity and consistency.

#### 16. List of Adulterants

In accordance with the **Federal Register** notice (66 FR 43876) dated August 21, 2001, the Department will begin including a list of known adulterants in the monthly **Federal Register** notice that lists the laboratories that meet minimum standards to engage in urine drug testing for Federal agencies. The list will be revised as new adulterants are identified.

#### Executive Order 12866: Economic Impact

In accordance with Executive Order 12866, the agency has submitted the Guidelines for review by the Office of Management and Budget. However, because the Mandatory Guidelines will not have an annual impact of \$100 million or more, and will not have a material adverse effect on the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, they are not subject to the detailed analysis requirements of Section 6(a)(3)(C) of Executive Order 12866.

#### Paperwork Reduction Act of 1995

These guidelines contain information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Title:** Mandatory Guidelines for Federal Workplace Drug Testing Programs.

**Description:** The Mandatory Guidelines for Federal Workplace Drug Testing Programs establish the scientific and technical guidelines for Federal Workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of section 503 of Public Law 100-71, 5 U.S.C. 7301 and Executive Order 12564. These

revisions to the Mandatory Guidelines do not change the information collection requirements in them.

The Mandatory Guidelines establish the standards for a National Laboratory Certification Program (NLCP), which include requirements for a laboratory to become certified and to maintain certification. Prior to the initial certification process, each interested laboratory is required to submit an application to the NLCP contractor for review and evaluation.

Certified laboratories are inspected every six months. Prior to each maintenance inspection, the laboratory receives and completes a copy of Sections B and C of the NLCP inspection checklist. The information submitted by the laboratory allows the members of the inspection team to become familiar with a laboratory's procedures before arriving at the laboratory to conduct the inspection, thereby facilitating the completion of the inspection.

The Mandatory Guidelines require certified laboratories to maintain information concerning quality assurance and quality control, security and chain of custody, documentation, to report test results in accordance with the specifications, and to participate in a performance testing and inspection program. In addition, there are procedures that are used to review the suspension or proposed revocation of a certified laboratory.

The Mandatory Guidelines also require using an OMB-approved Federal custody and control form (CCF) to document the integrity and security of a urine specimen from the time it is collected until received by the laboratory.

**Description of Respondents:** Individuals or Households; Business or other for-profit; Not-for profit institutions.

**Response burden estimate:** We estimate the total annual response burden imposed by the Mandatory Guidelines to be 1,786,839 hours. This is comprised as follows: (1) A laboratory is estimated to require an average of 3 hours to complete the NLCP Application form. An average of 3 laboratories apply each year, resulting in an annual estimate of 9 hours of response burden. (2) Sections B and C of the NLCP Inspection Checklist, which average 3 hours to complete, must be completed in advance of each of the 2 annual inspections. Based on 50 certified laboratories undergoing 2 maintenance inspections each year, the annual estimated response burden for the NLCP Inspection Checklist is 300 hours. (3) Recordkeeping, reporting and

disclosure burden for each laboratory is estimated at 250 hours per laboratory per year, for an annual total of 12,500 hours for 50 laboratories. This estimate includes the following:

Section	Topic
<b>Recordkeeping</b>	
2.3(a)(4)*	Responsible person at laboratory documents in-service training of personnel.
2.3(a)(5)* and 2.4(q)(1)*	Maintain manual of all procedures used and dates they were in effect.
2.3(a)(6)* and 2.5(a)*	Documentation of quality assurance program.
2.3(f)*	Specifies contents of laboratory personnel files.
2.4(a)(1)*	Requires documentation of laboratory visitor access.
2.4(a)(2)* and (b)(4)*	Requires use of laboratory chain of custody form by personnel conducting tests.
2.4(h)(17)*	Requires specimen records to be maintained for two years.
2.4(p)*	Requires two year retention of documentation of all aspects of testing process.
2.5(k)(6)	Requires documenting retesting when false positive error occurs on blind performance testing sample.
<b>Reporting</b>	
2.2(c), 2.2(f)(8) and 2.2(f)(14)	Require use of Federal CCF by collector and specify things to note on it.
2.4(h); 3.17(f)	Specifies reporting of test results from laboratory to Medical Review Officer (MRO); specifies same reporting method for performance testing samples.
2.4(h)(15)	Specifies contents of periodic laboratory summary statistical report to Federal agency.
2.6(h)(1)	Specifies MRO reporting of final test results to Federal agency using Federal CCF.
3.17(f)	Specifies laboratory reporting of performance test samples.
4.4 and 4.5(a)	Specify contents of laboratory request for official review of suspension/proposed revocation of certification.
4.6	Requires appellant notification to reviewing official at end of abeyance period.
4.7(a)	Specifies contents of appellant review submission.
4.9(a) and (c)	Specify contents of appellant expedited review file.
<b>Disclosure</b>	
3.4	Requires laboratories to notify non-regulated private-sector employers/clients when testing specimens not under Guidelines.

**Note:** Activities designated by an \* are considered to be usual and customary business practices for such laboratories and no additional burden is considered to be imposed by these requirements.

(4) There are an estimated 7,096,000 Federal CCFs completed each year, with an average response burden of 5 minutes for the donor, 4 minutes for the collector, 3 minutes for the laboratory, and 3 minutes for the Medical Review Officer. This results in 1,419,200 hours of burden.

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to: SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The information collection provisions in the Mandatory Guidelines have been approved under OMB control number 0930-0158. This approval expires July 31, 2006. 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.

**Charles G. Curie,**  
*Administrator, SAMHSA.*

Dated: April 2, 2004.  
**Tommy G. Thompson,**  
*Secretary.*

The Mandatory Guidelines as revised are hereby adopted in accordance with section 503 of Public Law 100-71 and Executive Order 12564. For the public's convenience, the full version of the Mandatory Guidelines as revised is provided. It includes the new validity testing requirements as well as the changes to the opiate cutoff concentrations that became effective on December 1, 1998 (63 FR 63483).

**Mandatory Guidelines for Federal Workplace Drug Testing Programs**

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**Authority:** E.O. 12564 and sec. 503 of Pub. L. 100-71.

### Subpart A—General

#### Section 1.1—Applicability

(a) These mandatory guidelines apply to:

- (1) Executive Agencies as defined in 5 U.S.C. 105;
- (2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));
- (3) And any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(b) Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(c) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(d) These Guidelines do not apply to drug testing conducted under legal authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.<sup>1</sup> (e)

<sup>1</sup> Although HHS has no authority to regulate the transportation industry, the Department of

Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

(f) Agencies shall purchase drug testing services only from laboratories certified by HHS or an HHS-recognized certification program in accordance with these Guidelines.

#### Section 1.2 Definitions

For purposes of these Guidelines, the following definitions are adopted:

**Aliquot.** A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

**Adulterated Specimen.** A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

**Calibrator.** A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

**Certifying Scientist.** An individual with at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience shall also

Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines \* \* \*". See, e.g., 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation that its federally regulated employers use only HHS certified laboratories in the testing of employees, 49 CFR 40.39, and incorporates the scientific and technical aspects of the guidelines in its regulations. The DOT-regulated industry should refer to the DOT regulations at 49 CFR Part 40.

include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to test systems being out of control-limits or detecting aberrant test or quality control results.

**Chain of Custody.** Refers to the process used to document the handling and storage of a specimen.

**Collection Site.** A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

**Collector.** A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collector shall have successfully completed training to carry out this function.

**Confirmatory Drug Test.** A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

**Confirmatory Validity Test.** A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

**Control.** A sample used to monitor the status of an analysis to maintain its performance within desired limits.

**Dilute Specimen.** A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

**Donor.** The individual from whom a urine specimen is collected.

**Federal Drug Testing Custody and Control Form (Federal CCF).** The OMB-approved form used to document the handling and transfer of a specimen from the time of collection until receipt by the laboratory and used by the certifying scientist to certify the laboratory results.

**Initial Drug Test (also known as Screening Test).** An immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

**Initial Validity Test.** The first test used to determine if a urine specimen is adulterated, dilute, or substituted.

**Invalid Result.** Refers to the result reported by a laboratory for a urine

specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

**Laboratory Chain of Custody Form.** The form(s) used by the testing laboratory to document the handling and security of the specimen and all aliquots of the specimens during testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who handled the specimens or aliquots and the date and purpose of the access.

**Limit of Detection.** The lowest concentration at which an analyte can be reliably shown to be present under defined conditions.

**Limit of Quantitation.** The lowest concentration at which an analyte can be reliably shown to be present and quantified under defined conditions.

**Medical Review Officer (MRO).** A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's test result together with his or her medical history and any other relevant biomedical information.

**Non-Negative Specimen.** A urine specimen that is reported as adulterated, substituted, positive (for a drug or drug metabolite), or invalid.

**Oxidizing Adulterant.** A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine, halogens, peroxidase, and peroxide.

**Quality Control Sample.** A sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative urine samples, and blind samples are collectively referred to as "quality control samples" and each as a "sample."

**Reason to Believe.** Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of Executive Order 12564.

**Sample.** A representative portion of a urine specimen or quality control sample used for testing.

**Secretary.** The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

**Specimen.** The portion of urine that is collected from a donor.

**Standard.** A reference material of known purity or a solution containing a reference material at a known concentration.

**Substituted Specimen.** A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

### Section 1.3 Future Revisions

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the **Federal Register**.

## Subpart B—Scientific and Technical Requirements

### Section 2.1 The Drugs

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

- (1) Federal agency applicant and random drug testing programs shall, at a minimum, test urine specimens for marijuana and cocaine;
- (2) Federal agency applicant and random drug testing programs may also test urine specimens for opiates, amphetamines, and phencyclidine;
- (3) When conducting reasonable suspicion, post accident, or unsafe practice testing, a Federal agency may have a urine specimen tested for any drug listed in Schedule I or II of the CSA; and
- (4) Federal agency drug testing programs shall have validity tests performed on urine specimens, as provided under section 2.4(g).

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency

testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines shall not be used for any other analysis or test unless authorized by an agency's drug-free workplace program.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

### Section 2.2 Specimen Collection Procedures

(a) **Designation of Collection Site.** An agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) **Security.** A collection site must be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for collecting specimens shall be secured during the time a specimen is collected.

(c) **Chain of Custody.** A Federal CCF shall be properly completed by a collector for each urine specimen collected for a Federal agency to document the collection of the specimen and the transfer of the specimen to the laboratory for testing.

(d) **Access to Authorized Personnel Only.** No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) **Privacy.** The procedure for collecting a urine specimen shall allow individual privacy unless there is reason to believe that a particular donor may alter or substitute the specimen to be provided.

(f) **Integrity and Identity of Specimen.** The collector shall take the following minimum precautions to ensure that a urine specimen is correctly documented as being provided by a specific donor and that the donor has not adulterated, substituted, or diluted the specimen:

- (1) To deter the dilution of a specimen at the collection site, a toilet bluing

agent shall be placed in a toilet tank wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When a donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor, the coordinator of the drug testing program, or any other agency official who can positively identify the donor. If the donor's identity cannot be established, the collector shall not proceed with the collection.

(3) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the donor's urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet. The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into the pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, a direct observation collection procedure is used. If the item appears to be inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure.

(5) The donor shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the donor shall remain in the presence of the collector and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate the specimen.

(7) The collector shall give the donor a clean specimen bottle or specimen collection container. The donor may

provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collector shall note any unusual behavior or appearance on the Federal CCF.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A person of the same gender as the donor shall accompany the donor into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collector shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collector shall instruct the donor not to flush the toilet until the specimen is delivered to the collector. After the collector has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collector in completing the chain of custody procedures.

(10) Upon receiving the specimen from the donor, the collector shall determine the volume of urine in the specimen bottle/container.

(i) If the volume is at least 30 milliliters (mL), the collector will proceed with step (11) below.

(ii) If the volume is less than 30 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen shall be collected. The donor may be given a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces). If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collector shall contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 30 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen shall be collected using the procedure specified in step (13) below.

(11) After the specimen has been provided and submitted to the collector, the donor shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collector shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate

the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of the specimen is outside the range of 32°–38°C/90°–100°F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available. A donor may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collector shall also inspect the specimen to determine if this is any sign indicating that the specimen may not be a valid urine specimen. Any unusual finding shall be noted on the Federal CCF.

(15) A specimen suspected of not being a valid urine specimen shall be forwarded to the laboratory for testing.

(16) When there is any reason to believe that a donor may have altered or substituted the specimen, another specimen shall be obtained as soon as possible under the direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available.

(17) Both the donor and the collector shall keep the specimen bottle/container in view at all times prior to its being sealed and labeled. If the specimen is transferred from a specimen collection container to a specimen bottle, the collector shall request the donor to observe the transfer of the specimen and the placement of the tamper-evident label/seal on the bottle.

(18) The collector and the donor shall be present at the same time during procedures outlined in paragraphs (19) to (22) of this section.

(19) The collector shall place the tamper-evident label/seal on the specimen bottle. The collector shall record the date of the collection on the tamper-evident label/seal.

(20) The donor shall initial the tamper-evident label/seal on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collector shall ensure that all the information required on the Federal CCF is provided.



(22) The donor shall be asked to read and sign a statement on the Federal CCF certifying that the specimen identified as having been collected from him or her is in fact the specimen he or she provided.

(23) Based on a reason to believe that the donor may alter or substitute the specimen to be provided, a higher level supervisor shall review and concur in advance with any decision by a collector to obtain a specimen under direct observation. The person directly observing the specimen collection shall be of the same gender. The agency shall select the observer if there is no collector of the same gender available.

(24) The collector shall sign the Federal CCF.

(25) The urine specimen and Federal CCF are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and Federal CCF be under the control of the collector. If the collector leaves the collection site momentarily, the urine specimen and Federal CCF shall be taken with him or her or shall be secured. After the collector returns to the collection site, the custody process will continue. If the collector is leaving for an extended period of time, the specimen and Federal CCF shall be packaged for shipment to the laboratory before he or she leaves the collection site.

(g) *Collection Control.* If the specimen and Federal CCF are not immediately prepared for transfer to the laboratory, they shall be appropriately safeguarded until the specimen and Federal CCF are prepared for transfer to the laboratory.

(h) *Split Specimens.* An agency may, but is not required to, use a split specimen method of collection. If the urine specimen is split into two specimen bottles (hereinafter referred to as Bottle A and Bottle B) the following procedure shall be used:

(1) The donor shall urinate into either a specimen bottle or specimen collection container. The collector, in the presence of the donor, after determining specimen temperature, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B or, if Bottle A was used to collect the specimen, pours an appropriate amount into Bottle B. A minimum of 45 mL of urine is required when using a split specimen procedure, i.e., 30 mL for Bottle A and 15 mL for Bottle B.

(2) The Bottle A specimen, containing a minimum of 30 mL of urine, is to be

used for the drug test. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(3) A minimum of 15 mL of urine shall be poured into the second specimen bottle (Bottle B).

(4) All requirements of this part shall be followed with respect to Bottle A and Bottle B, including the requirements that a copy of the Federal CCF accompany the two bottles processed under split sample procedures.

(5) The collector shall send the split specimens (Bottle A and Bottle B) at the same time to the laboratory that will be testing the Bottle A specimen.

(6) If the test of the primary (Bottle A) specimen is verified positive, adulterated, or substituted by the MRO, the MRO shall report the result to the agency. Only the donor may request through the MRO that the split (Bottle B) specimen be tested by a second certified laboratory to reconfirm the positive, adulterated, or substituted result reported by the primary laboratory. The MRO shall honor the request if it is made within 72 hours after informing the donor that a positive, adulterated, or substituted result was being reported to the agency. The second laboratory shall test the split specimen in accordance with the requirements in section 2.4 pertaining to retesting for drugs, adulterants, or substitution.

(7) Any action taken by a Federal agency as a result of an MRO verified positive, adulterated, or substituted test result (e.g., removing a donor from performing a safety-sensitive function) may proceed whether Bottle B is or is not tested.

(i) *Transportation to Laboratory.* A collector shall arrange to ship the collected specimens to the certified laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. The collector shall ensure that the Federal CCF is enclosed within the container sealed for shipment to the drug testing laboratory. Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the Federal CCFs, there is no requirement that such personnel document chain of custody for the package during transit.

### Section 2.3 Laboratory Personnel

#### (a) Day-to-Day Management.

(1) The laboratory shall have a responsible person (RP) to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multi-speciality laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for laboratory personnel, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible person whenever procedures are first placed into use or

changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in paragraph 2.4(q)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that specimen results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(b) *Certifying Test Results.* The certified laboratory shall have one or more certifying scientists, as defined in section 1.2, who review all pertinent data and quality control results to attest to the validity of the laboratory's test results. A laboratory may designate certifying scientists that only certify results that are reported negative and certifying scientists that certify results that are reported both negative and non-negative.

(c) *Day-to-Day Operations and Supervision of Analysts.* The laboratory's urine drug testing facility shall have an individual(s) to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other Personnel.* Other technical and nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Each laboratory personnel file shall include, at a minimum, a resume, any professional certification or license, a job description, and documentation to show that the individual has been properly trained to perform his or her job.

#### Section 2.4 Laboratory Analysis Procedures

##### (a) *Security and Chain of Custody.*

(1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary or emergency personnel (e.g., firefighters and medical rescue teams), all authorized visitors and maintenance and service personnel shall be escorted at all times. The laboratory shall maintain a record that documents the dates, time of entry and exit, escort and purpose of entry of authorized visitors, maintenance personnel, and service personnel accessing secured areas.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on a laboratory chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete appropriate entries on the laboratory chain of custody forms for those specimens or aliquots as they are received.

##### (b) *Receiving.*

(1) After opening a shipping package and gaining access to a specimen and its accompanying Federal CCF, an accessioner shall compare the

information on the specimen bottle label/seal to the information on the accompanying Federal CCF.

(2) The following discrepancies are considered to be fatal flaws and the laboratory must stop the testing process and reject the specimen for testing and indicate the reason for rejecting the specimen on the Federal CCF:

(i) The specimen ID number on the specimen bottle label/seal does not match the ID number on the Federal CCF or the ID number is missing either on the Federal CCF or on the specimen bottle label/seal;

(ii) The specimen bottle label/seal is broken or shows evidence of tampering on the specimen bottle from a single specimen collection or on the primary (Bottle A) specimen from a split specimen collection (and the split specimen cannot be designated as the primary (Bottle A) specimen);

(iii) The collector's printed name and signature are omitted on the Federal CCF; or

(iv) There is an insufficient amount of urine for analysis in the specimen bottle from a single specimen collection or in the primary (Bottle A) specimen from a split specimen collection (unless the split specimen can be designated as the primary (Bottle A) specimen).

(3) The following discrepancies are considered to be correctable flaws:

(i) If a collector failed to sign the Federal CCF, the laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the laboratory may report the test result for the specimen. If the laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(ii) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If the laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

(4) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and laboratory chain of custody forms shall be used by laboratory personnel conducting initial and confirmatory

tests while the original specimen bottles and Federal CCFs remain in secure storage.

(c) *Short-Term Refrigerated Storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. A certified laboratory must have the capability to ensure proper storage conditions in the event of a prolonged power failure.

(d) *Specimen Processing.* A laboratory will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly. Every batch shall satisfy the quality control requirements in section 2.5.

(e) *Initial Drug Test.* (1) The initial drug test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

#### INITIAL DRUG TEST LEVEL

	(ng/mL)
Marijuana metabolites .....	50
Cocaine metabolites .....	300
Opiate metabolites .....	2,000
Phencyclidine .....	25
Amphetamines .....	1,000

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed initial drug test methods, testing levels, and proposed performance test program.

(3) A negative specimen shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be a valid specimen.

(4) Multiple initial drug tests (also known as rescreening) for the same drug or drug class may be performed provided that all tests meet all Guideline cutoffs and quality control requirements (see section 2.5(b)). Examples: a test is performed by immunoassay technique "A" for all drugs using the HHS cutoff levels, but presumptive positive amphetamines are forwarded for immunoassay technique "B" to eliminate any possible

presumptive positives due to structural analogues; a valid analytical result cannot be obtained using immunoassay technique "A" and immunoassay technique "B" is used in an attempt to obtain a valid analytical result.

#### (f) *Confirmatory Drug Test.*

(1) A specimen identified as positive on an initial drug test shall be confirmed for the class(es) of drugs screened positive on the initial drug test using gas chromatography/mass spectrometry (GC/MS) at the cutoff values listed in this paragraph. Each confirmatory drug test shall provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear range of the standard curve, the certified laboratory may record the result as "exceeds the linear range of the test" or as "greater than or equal to (insert the value for the upper limit of the linear range)," or may dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

#### CONFIRMATORY DRUG TEST LEVEL

	(ng/mL)
Marijuana metabolite <sup>1</sup> .....	15
Cocaine metabolite <sup>2</sup> .....	150
Opiates	
Morphine .....	2,000
Codeine .....	2,000
6-Acetylmorphine <sup>3</sup> .....	10
Phencyclidine .....	25
Amphetamines	
Amphetamine .....	500
Methamphetamine <sup>4</sup> .....	500

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid.

<sup>2</sup> Benzoylcegonine.

<sup>3</sup> Test for 6-AM when the morphine concentration is greater than or equal to 2,000 ng/mL.

<sup>4</sup> Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/mL.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed confirmatory test methods, testing levels, and proposed performance test program.

(3) A specimen that tests negative on confirmatory drug tests shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be a valid specimen.

(g) *Validity Testing.* A certified laboratory shall:

- (1) Determine the creatinine concentration on every specimen;
- (2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;
- (3) Determine the pH on every specimen;
- (4) Perform one or more validity tests for oxidizing adulterants on every specimen; and
- (5) Perform additional validity tests when the following conditions are observed:

- (i) Abnormal physical characteristics;
- (ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or
- (iii) Possible unidentified interfering substance or adulterant.

The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (i), (ii), and (iii) of this section.

#### (h) *Reporting Results.*

(1) The laboratory shall report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen by the laboratory using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified as correct by a certifying scientist.

(2) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each specimen validity test result indicates that the specimen is a valid urine specimen.

(3) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(4) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported adulterated when:

(i) The pH is less than 3 or greater than or equal to 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(ii) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-

wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(iii) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(iv) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration greater than or equal to the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(v) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(vi) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration greater than or equal to the LOD of the analysis on the second aliquot;

(vii) The presence of a surfactant is verified by using a surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial

test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(viii) The presence of any other adulterant not specified in 4(iii) through 4(vii) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(5) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(6) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(7) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported as an invalid result when:

(i) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(ii) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(iii) The nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/mL nitrite using a general

oxidant colorimetric test for both the initial test and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(iv) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff greater than or equal to 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(v) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff greater than or equal to the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(vi) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(vii) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff, a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is greater than or equal to the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(viii) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(ix) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(x) Interference with the GC/MS drug confirmation assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(xi) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(xii) If the physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different,



the test result for Bottle A is one of the reasons stated in (i) through (xi) of this section and/or was screened negative for drugs.

(8) The laboratory shall reject a specimen for testing when a fatal flaw occurs as described in paragraph 2.4(b)(2) or when a correctable flaw as described in paragraph 2.4(b)(3) is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(9) The laboratory must report all non-negative test results for a specimen. For example, a specimen can be positive for a specific drug and adulterated.

(10) For a specimen that is tested positive for a drug, the laboratory shall report the specimen as positive and specify the drug for which the specimen is positive. The concentration of the drug shall be provided to the MRO only when the MRO requests such information. The MRO's request may either be a general request covering all such results or be on a case by case basis. When the concentration of an analyte exceeds the linear range of the standard curve, the laboratory may report to the MRO that the quantitative value "exceeds the linear range of the test," that the quantitative value is "greater than or equal to (insert the value for the upper limit of the linear range)," or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen. The MRO shall not disclose the concentration of the drug to the agency.

(11) The laboratory shall provide quantitative values for confirmed opiate results for morphine or codeine that are greater than or equal to 15,000 ng/mL, even if the MRO has not requested quantitative values for the test result.

(12) For a specimen that is found to be adulterated or substituted, the laboratory shall report the specimen as adulterated or substituted and shall provide the numerical values that support the adulterated (when applicable) or substituted result. For a specimen that has an invalid result for one of the reasons stated in paragraphs 2.4(h)(7)(iv) to (xii), the laboratory shall contact the MRO and both will decide if testing by another certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the laboratory then reports the invalid result to the MRO.

(13) The laboratory may transmit results to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner

designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(14) For all test results, a laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

(15) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a semi-annual statistical summary report of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. In order to avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory must not send a summary report if the agency has fewer than five specimen test results in a six-month period. When that situation occurs, the laboratory must send the agency a report indicating that not enough specimens were tested to permit providing a summary report. The summary report shall include test results that are reported within the six-month period. Normally, the summary report is sent within 14 calendar days after the end of the six-month period covered by the report. The summary report shall contain the following information:

- Reporting Period: (inclusive dates)  
Laboratory Name and Address  
Federal Agency Name
- (i) Specimen Results Reported (total number)
    - By Type of Test
      - (a) Pre-employment (number)
      - (b) Post-Accident (number)
      - (c) Random (number)
      - (d) Reasonable Suspicion/Cause (number)
      - (e) Return-to-Duty (number)
      - (f) Follow-up (number)
      - (g) Type of Test Not Noted on CCF (number)
  - (ii) Specimens Reported
    - (a) Negative (number)
    - (b) Negative and Dilute (number)
  - (iii) Specimens Reported as Rejected for Testing (total number)
    - By Reason
      - (a) Fatal flaw (number)
      - (b) Uncorrected Flaw (number)
  - (iv) Specimens Reported as Positive (total number)
    - By Drug

- (a) Marijuana Metabolite (number)
- (b) Cocaine Metabolite (number)
- (c) Opiates (number)
  - (1) Codeine (number)
  - (2) Morphine (number)
- (3) 6-AM (number)
- (d) Phencyclidine (number)
- (e) Amphetamines (number)
  - (1) Amphetamine (number)
  - (2) Methamphetamine (number)
- (v) Adulterated (number)
- (vi) Substituted (number)
- (vii) Invalid Result (number)

(16) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by HHS or any Federal agency for which the laboratory is performing drug testing services.

(17) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(i) *Long-Term Storage.* Long-term frozen storage ( $-20^{\circ}\text{C}$  or less) ensures that positive, adulterated, substituted, and invalid urine specimens will be available for any necessary retest. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens reported positive, adulterated, substituted, or invalid. Within this 1-year period, an agency may request the laboratory to retain the specimen for an additional period of time. If no such request is received from the agency, the laboratory may discard the specimen at the end of this 1-year period.

(j) *Retesting a Specimen for Drugs.*

(1) A second laboratory shall use its confirmatory drug test when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen for the drug or drug metabolite that was reported positive in the single specimen or the primary (Bottle A) specimen by the first laboratory.

(2) Because some drugs or drug metabolites may deteriorate during storage, the retest of an aliquot of a single specimen or the test of a split (Bottle B) specimen is not subject to a specific drug cutoff requirement, but must provide data sufficient to confirm the presence of the drug or metabolite.

(3) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory shall attempt to determine the reason for not reconfirming the presence of the drug or drug metabolite by conducting specimen validity tests. The second laboratory shall conduct the same



specimen validity tests it would conduct on a single specimen or a primary (Bottle A) specimen. The second laboratory reports all test results to the MRO.

(k) *Retesting a Specimen for Adulterants.*

(1) A second laboratory shall use the required confirmatory validity test specified in paragraph 2.4(h)(4) and the same confirmatory criterion specified in paragraph 2.4(h)(4) to reconfirm an adulterant result when retesting an aliquot from a single specimen collection or when testing a split (Bottle B) specimen.

(2) The second laboratory may only retest an aliquot from a single specimen collection or test a split (Bottle B) specimen for the adulterant reported by the first laboratory.

(l) *Retesting a Specimen for Substitution.*

(1) A second laboratory shall use its confirmatory creatinine test and confirmatory specific gravity test, when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen, to reconfirm that the creatinine concentration was less than 2 mg/dL and the specific gravity was less than or equal to 1.0010 or greater than or equal to 1.0200.

(2) The second laboratory may only retest an aliquot from a single specimen collection or test a split (Bottle B) specimen to reconfirm the substituted result reported by the first laboratory.

(m) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the Secretary.

(n) *Laboratory Facilities.*

(1) Laboratory facilities shall comply with applicable provisions of any State licensor requirements.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and performing the validity tests specified in these Guidelines.

(o) *Inspections.* The Secretary, a Federal agency, or any organization performing laboratory certification on behalf of the Secretary may inspect the laboratory at any time. Federal agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the award of a contract the agency may carry out pre-award inspections and

evaluation of the procedural aspects of the laboratory's drug testing operation.

(p) *Documentation.* The drug testing laboratories shall maintain and make documents of all aspects of the testing process available for at least 2 years. This 2-year period may be extended upon written notification by HHS or by any Federal agency for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; Federal CCFs and laboratory chain of custody forms; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain method validation data and any documents for any specimen under legal challenge for an indefinite period.

(q) *Additional Requirements for Certified Laboratories.*

(1) Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, corrective actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) Laboratory calibrators and controls shall be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers. The calibrators and controls shall be properly labeled as to content and concentration. The standards (e.g., pure reference materials, stock standard solutions, purchased standards) shall be labeled with the following dates: when received (if applicable); when prepared or opened; when placed in service; and expiration date.

(3) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically

thereafter. There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) A laboratory shall make available a qualified individual to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on a non-negative result reported by the laboratory.

(6) The laboratory shall not enter into any relationship with an agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an agency use a specific MRO.

*Section 2.5 Quality Assurance and Quality Control*

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (e.g., accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), specificity) shall be documented for each test as appropriate. Validation of procedures shall document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Laboratory Quality Control Requirements for Initial Drug Tests.*

Each analytical run of specimens to be screened shall include:

(1) Sample(s) certified to contain no drug (i.e., negative urine samples);

(2) At least one control fortified with drug or metabolite targeted at 25 percent above the cutoff;

(3) At least one control fortified with drug or metabolite targeted at 75 percent of the cutoff;

(4) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known calibrators, those values will be used to calculate sample data;

(5) A minimum of 10 percent of the total specimens and quality control samples in each analytical run shall be quality control samples; and

(6) One percent of each run, with a minimum of at least one sample, shall be the laboratory's blind quality control samples to appear as routine specimens to the laboratory analysts.

(c) *Laboratory Quality Control Requirements for Confirmatory Drug Tests.*

Each analytical run of specimens to be confirmed shall include:

(1) Sample(s) certified to contain no drug (*i.e.*, negative urine samples);

(2) Positive calibrator(s) and control(s) fortified with drug or metabolite;

(3) At least one control with drug or metabolite targeted at 25 percent above the cutoff; and

(4) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(d) *Laboratory Quality Control Requirements for Specimen Validity Tests.*

(1) Each validity test result shall be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(2) Each analytical run of specimens for which an initial or confirmatory validity test is being performed shall include the appropriate calibrators and controls.

(e) *Requirements for performing creatinine tests.*

(1) The creatinine concentration shall be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test.

(2) The initial creatinine test shall have a calibrator at 2 mg/dL.

(3) The initial creatinine test shall have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) shall have a calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, and a control in the range of 3 mg/dL to 4 mg/dL.

(f) *Requirements for performing specific gravity tests.*

(1) The refractometer shall report and display the specific gravity to four decimal places. The refractometer shall be interfaced with a laboratory information management system (LIMS), computer, and/or generate a hard copy of the digital electronic display to document the numerical result.

(2) The initial and confirmatory specific gravity tests shall have a calibrator or control at 1.0000.

(3) The initial and confirmatory specific gravity tests shall have the following controls:

(i) One control targeted at 1.0020;

(ii) One control in the range of 1.0040 to 1.0180; and

(iii) One control greater than or equal to 1.0200 but not greater than 1.0250.

(g) *Requirements for performing pH tests.*

(1) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH validity test must be performed.

(2) pH screening tests shall have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use.

(3) An initial colorimetric pH test shall have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 11;

(iii) One control in the range of 2 to 2.8;

(iv) One control in the range 3.2 to 4;

(v) One control in the range of 4.5 to 9;

(vi) One control in the range of 10 to 10.8;

(vii) One control in the range of 11.2 to 12.

(4) An initial pH meter test, if a pH screening test is not used, shall have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 2 to 2.8;

(v) One control in the range 3.2 to 4;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12.

(5) An initial or confirmatory pH meter test, if a pH screening test is used,

shall have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 2 to 2.8; and

(iv) One control in the range 3.2 to 4.

(6) An initial or confirmatory pH meter test, if a pH screening test is used, shall have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(h) *Requirements for performing oxidizing adulterant tests.*

(1) The initial test shall include an appropriate calibrator at a cutoff specified in sections 2.4(h)(4) and (7) for the compound of interest, a control without the compound of interest (*i.e.*, a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration.

(2) A confirmatory test for a specific oxidizing adulterant shall use a different analytical method than that used for the initial test. Each confirmatory test batch shall include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(i) *Requirements for performing nitrite tests.* The initial and confirmatory nitrite tests shall have a calibrator at the cutoff concentration, a control without nitrite (*i.e.*, certified negative urine), one control in the range of 200 mcg/mL to 400 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

(j) *Requirements for performing "other" adulterant tests.*

(1) The initial and confirmatory tests for any "other" adulterant that may be identified in the future shall satisfy the requirements in section 2.5(d).

(2) The confirmatory test for "other" adulterants shall use a different analytical principle or chemical reaction than that used for the initial test.

(3) The initial and confirmatory tests for adulterants in this section shall include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(k) *Agency Blind Sample Program.*

(1) Agencies shall only use blind quality control samples that have been certified by the supplier to be negative (*i.e.*, certified by immunoassay and GC/MS to contain no drug), drug positive (*i.e.*, certified by immunoassay and GC/MS to contain a drug(s)/metabolite(s) between 1.5 and 2 times the initial drug test cutoff concentration), adulterated (*i.e.*, certified to be adulterated with a specific adulterant using an appropriate confirmatory validity test(s)), or substituted (*i.e.*, the creatinine concentration and specific gravity satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively). The supplier shall also provide the expiration date for each quality control sample to ensure that each quality control sample will give the expected result when it is submitted and correctly tested by a laboratory before the expiration date.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test samples to each laboratory it contracts with in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 200 blind samples) and thereafter a minimum of 3 percent blind samples (up to a maximum of 100 blind samples) submitted per quarter.

(3) Approximately 75 percent of the blind quality control samples shall be negative (*i.e.*, certified to contain no drug), approximately 15 percent shall be positive for one or more drugs, and approximately 10 percent shall be either adulterated or substituted. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The agency shall investigate any unsatisfactory blind performance test sample results and submit its findings to the Secretary. The Secretary shall continue the investigation to ensure that the laboratory has corrected the cause of the unsatisfactory performance test result. A report of the Secretary's investigative findings and the corrective action taken by the laboratory shall be sent to the agency contracting officer. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test sample and the error is determined to be an administrative error (clerical, sample mixup, *etc.*), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could

have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test sample and the error is determined to be a technical or methodological error, the laboratory shall submit all data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the Responsible Person. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. The Secretary has the option of revoking (section 3.13) or suspending (section 3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

#### Section 2.6 Reporting and Review of Results

##### (a) MRO Qualifications.

(1) An MRO shall be a licensed physician (Doctor of Medicine or Osteopathy).

(2) An MRO shall have knowledge about and clinical experience in controlled substance abuse disorders, detailed knowledge of alternative medical explanations for laboratory positive drug test results, knowledge about issues relating to adulterated and substituted specimens, and knowledge about possible medical causes for specimens that may be reported as having an invalid result.

(3) An MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest.

(b) MRO Review of Results. An essential part of the drug testing program is the final review of each test result reported by a laboratory. A positive drug test result does not automatically identify a donor as an illegal drug user nor does an

adulterated, substituted, or invalid test result automatically indicate that a donor has tampered with a specimen. The review of a non-negative test result shall be performed by the MRO before the result is transmitted to the agency's designated representative. Staff under the direct, personal supervision of the MRO may review and report a negative test result to the agency's designated representative.

##### (c) MRO Review of Positive, Adulterated, Substituted, or Invalid Test Results.

(1) Prior to making a final decision on a specimen that was reported positive, adulterated, substituted, or an invalid test result by the laboratory, the MRO shall interview the donor to determine if the donor has a valid medical explanation for the test result. This action could include a review of the donor's medical history and a review of any other biomedical factors. The MRO shall review medical records made available by the donor when a result could have resulted from taking a legally prescribed medication. After making a determination, the MRO reports the verified result to the agency's designated representative.

(2) When a laboratory reports an invalid result because of one of the reasons specified in paragraphs 2.4(h)(7)(iv) to (xii), the MRO and the laboratory shall determine if additional testing by another HHS-certified laboratory may be useful in resolving the reason for the invalid result and possibly being able to report a positive or adulterated result. If the MRO and the laboratory agree that no further testing would be useful, the MRO shall report the invalid result as "Test Cancelled—Invalid Result (specify reason for the invalid result)" to the agency and indicate one of the following actions:

(i) An immediate direct observed collection is not required because the explanation provided by the donor for the invalid result is acceptable with no further action required unless a negative test result is required (*i.e.*, pre-employment, return-to-duty, or follow-up test); or

(ii) An immediate direct observed collection is required because the explanation provided by the donor for the invalid result is not acceptable.

(d) Verification for Opiates; Review for Prescription Medication. Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test result—of illegal use of any opium, opiate, or opium derivative (*e.g.*, morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. This

requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (*i.e.*, the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is greater than or equal to 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(e) *Donor Request to MRO for Retest.*

(1) For a positive, adulterated, or substituted result reported on a single specimen or a primary (Bottle A) specimen, a donor may request through the MRO that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For a single specimen or primary (Bottle A) specimen reported as an invalid result, a donor may not request that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory.

(2) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a retest of an aliquot from the single specimen or to test the split (Bottle B) specimen.

(3) If the single specimen or split (Bottle B) specimen cannot be tested by a second laboratory (*e.g.*, insufficient volume, lost in transit, split (Bottle B) not available), the MRO shall direct the agency to immediately collect another specimen under direct observation.

(4) If a donor chooses not have an aliquot from the single specimen or the split (Bottle B) specimen tested by a second HHS-certified laboratory, a Federal agency may have a single or split specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

(f) *Result Consistent with Legal Drug Use.* If the MRO determines there is a legitimate medical explanation for the positive drug test result, he or she shall normally take no further action and report the test result as negative.

(g) *Laboratory Result Not Reconfirmed by a Second Laboratory.* After a second laboratory tests an aliquot of the single specimen or the split (Bottle B) specimen, the MRO shall take the following actions when the second laboratory reports the following results:

(1) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical

explanation for the adulteration result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test to the agency and indicates the adulterant that is present in the urine specimen. The MRO gives the donor 72 hours to request that Laboratory A retests the single or Bottle A specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(2) *Failed to reconfirm a single or all drug positive results and substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the single or Bottle A specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(3) *Failed to reconfirm a single or all drug positive results and not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the appropriate regulatory office.

(4) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and gives the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the appropriate regulatory office.

(5) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(6) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(7) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(8) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(9) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(10) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specify drug(s)). The MRO tells



the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(11) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s) and specify adulterant or substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(12) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s) and adulterated) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(13) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s) and specify adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(14) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result ((specify adulterant) and not substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(15) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (specify adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(16) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

(h) *Reporting Final Results.* The MRO shall report the final results of the tests in writing and in a manner designed to ensure confidentiality of the information. When reporting the result

for a single specimen or primary (Bottle A) specimen to the agency, the MRO shall report whether the specimen was negative, dilute, positive (specify drug), refusal to test (adulterated or substituted), or test cancelled (state reason). When reporting the result for a retest of an aliquot of a single specimen or the test of a split (Bottle B) specimen to the agency, the MRO shall report reconfirmed, failed to reconfirm (state reason), refusal to test (adulterated or substituted), or cancel both test results as described in section 2.6(g). The MRO shall not disclose any numerical values to the agency.

#### Section 2.7 Protection of Employee Records

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 522a. In addition, laboratory contracts shall require compliance with patient access and confidentiality provisions of sec. 503 of Public Law 100–71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover the agency's records of employee urinalysis results. The contract and the Privacy Act System of Records shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

#### Section 2.8 Individual Access to Test and Laboratory Certification Results

In accordance with sec. 503 of Public Law 100–71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

### Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

#### Section 3.1 Introduction

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory

conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

#### Section 3.2 Goals and Objectives of Certification

(a) *Uses of Urine Drug Testing.* Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs, drug metabolites, adulterants, or substituted specimens according to sections 2.4(e), 2.4(f), and 2.4(g) to protect the rights of the Federal employees being tested.

(b) *Need to Set Standards; Inspections.* The ability to accurately determine the presence or absence of specific drugs/metabolites or to accurately determine the validity of a urine specimen is critical to achieving the goals of the testing program and to protect the rights of the Federal employees being tested. Standards have been set which laboratories engaged in Federal employee urine drug testing shall meet to achieve the required accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. Applicant laboratories shall test three cycles of performance testing samples that challenge the laboratory's ability to correctly test for drugs and to correctly perform specimen validity tests. Applicant laboratories shall undergo an initial inspection and upon certification are also required to undergo a second inspection within 3 months after being certified. Certified laboratories are required to analyze quarterly performance testing samples that challenge the laboratories to correctly test for drugs and to correctly perform validity tests and are required to undergo periodic inspections.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a non-negative test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be



treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, proper documentation of all records, storage of non-negative specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

### Section 3.3 General Certification Requirements

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification under these standards.

### Section 3.4 Capability to Test for Five Classes of Drugs and to Conduct Validity Tests

To be certified, a laboratory must be capable of testing for marijuana, cocaine, opiates, amphetamines, and phencyclidine using the initial immunoassay and confirmatory GC/MS methods and conducting the specimen validity tests as specified in these Guidelines. The certification program will be limited to these five classes of drugs and specimen validity tests in accordance with the methods specified in these Guidelines (sections 2.4(e), (f), and (g)). The laboratory will be inspected and performance tested for these drugs and validity tests. Certified laboratories must clearly inform all non-regulated, private-sector employers/clients when their specimens are being tested using procedures that are different from those for which the laboratory is certified (*i.e.*, testing specimens not under the Guidelines).

### Section 3.5 Initial and Confirmatory Capability at Same Site

Certified laboratories shall have the capability to perform initial and confirmatory drug tests and initial and confirmatory validity tests at the same laboratory site.

### Section 3.6 Personnel

Laboratory personnel shall meet the requirements specified in section 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a

laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

### Section 3.7 Quality Assurance and Quality Control

Certified laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. As specified in these Guidelines, quality control procedures shall be designed, implemented, and reviewed to monitor testing.

### Section 3.8 Security and Chain of Custody

Laboratories shall meet the security and chain of custody requirements provided in section 2.4(a).

### Section 3.9 One-Year Storage for Positive, Adulterated, Substituted, and Invalid Specimens

All positive, adulterated, substituted, and invalid specimens shall be retained in accordance with the provisions of section 2.4(i) of these Guidelines.

### Section 3.10 Documentation

The laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in section 2.4(p).

### Section 3.11 Reports

The laboratory shall report test results in accordance with the specifications in section 2.4(h).

### Section 3.12 Certification

(a) *General.* The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified any laboratory that is certified by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of an HHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

- (1) The adequacy of the laboratory facilities;
- (2) The expertise and experience of the laboratory personnel;
- (3) The excellence of the laboratory's quality assurance/quality control program;
- (4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug or validity tests and reporting done by the laboratory.

(c) *Corrective Action by Certified Laboratories.* A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification. The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug and validity testing and reporting, to resolve problems related to drug and validity testing, and to enforce all standards set forth in these Guidelines. The Secretary shall have the authority to issue directives to any laboratory suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; order any laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through proficiency testing; order any laboratory to send aliquots of urine specimens to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; order the review of results for specimens tested under the Guidelines for private-sector employers/clients to the extent necessary to ensure the full reliability of drug and validity testing for Federal agencies; and order any other action necessary to address deficiencies in drug or validity testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

### Section 3.13 Revocation

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by an HHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of test results.

(b) *Factors to Consider.* The Secretary shall consider the following factors in determining whether revocation is necessary:

- (1) Unsatisfactory performance in analyzing and reporting the results of drug and validity tests; for example, a false positive error in reporting the results of an employee's drug test;
- (2) Unsatisfactory participation in performance evaluations or laboratory inspections;
- (3) A material violation of a certification standard or a contract term or other condition imposed on the

laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of results.

(c) *Period and Terms.* The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug and validity testing of Federal employees.

#### Section 3.14 Suspension

(a) *Criteria.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug and validity testing for Federal agencies. The Secretary may also accept suspension of certification by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Period and Terms.* The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug and validity testing of Federal employees.

#### Section 3.15 Notice

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by facsimile mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) *Opportunity for Informal Review.* The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart D contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) *HHS-Recognized Certification Program.* The Secretary's responsibility under this section may be carried out by an HHS-recognized certification program in accordance with these Guidelines.

(e) *Public Notice.* The Secretary will publish in the *Federal Register* the name, address, and telephone number of any laboratory that has its certification suspended or revoked under section 3.13 or section 3.14, respectively, and the name of any laboratory which has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart D.

#### Section 3.16 Recertification

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under section 3.13(a) or the reviewing official's decision under section 4.9(e) or 4.14(a), a laboratory which has had its certification revoked may reapply for certification as an applicant laboratory.

#### Section 3.17 Performance Testing (PT) Requirement for Certification

(a) *An Initial and Continuing Requirement.* The PT program is a part of the initial evaluation of a laboratory seeking certification (both PT and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) *Three Initial Cycles Required.* Successful participation in three PT cycles of testing shall be required before a laboratory is eligible to be considered for certification.

(c) *Four Cycles Per Year.* After certification, laboratories shall be challenged with at least 10 PT samples on a quarterly cycle.

(d) *Laboratory Procedures Identical for PT Samples and Routine Specimens.* All procedures associated with the handling and testing of the PT samples

by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine specimens, unless otherwise specified.

(e) *Agency PT Samples.* Any certified laboratory shall be subject to receiving and testing PT samples (see section 2.5(k)) submitted by a Federal agency. A certified laboratory is expected to correctly test and report each agency submitted PT sample (that is, report a negative sample as negative, a drug positive sample as positive, an adulterated sample as adulterated, or a substituted sample as substituted).

(f) *Reporting PT Sample Results.* The laboratory shall report results of PT program samples to the certifying organization in the same manner as specified in section 2.4(h) for routine specimens.

#### Section 3.18 PT Program Samples

(a) *Drug PT Samples.* Each PT cycle shall have samples that contain the drugs and drug metabolites listed in sections 2.4(e) and (f). For some samples, the composition will consist of the parent drug as well as metabolites. Also, more than one drug class may be included in one sample, but generally no more than two drugs will be present in any one sample. For any particular PT cycle, the samples in each set of samples going to the laboratories may vary but, within any annual period, all laboratories participating in the PT program will have analyzed the same total set of samples.

(b) *Composition of the Drug PT Samples.* PT program samples shall satisfy, but are not limited to, one of the following criteria:

(1) A drug or drug metabolite concentration will be at least 20 percent above the cutoff for either the initial drug test or the confirmatory drug test depending on which is to be evaluated;

(2) For retest samples, the drug or drug metabolite concentration may be as low as 40 percent of the cutoff;

(3) For routine samples, the drug or drug metabolite concentration may be below the cutoff for special purposes;

(4) A negative sample shall contain no target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff;

(5) Samples may be fortified with interfering substances.

(c) *Specimen Validity Testing PT Samples.* Each PT cycle shall contain samples that challenge a laboratory's ability to identify substituted and adulterated specimens. For any particular PT cycle, the samples in each set of samples going to the laboratories may vary but, within any annual period,

all laboratories participating in the PT program will have analyzed the same total set of specimen validity testing PT samples.

(d) *Composition of the Specimen Validity Testing PT Samples.* Specimen validity testing PT samples shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be less than 2.75 or greater than 11.25;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL;

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

### Section 3.19 Evaluation of PT Sample Results

#### (a) Initial Certification of Applicant Laboratories.

(1) An applicant laboratory shall not report any false positive drug test result on any PT sample during the initial certification process. A false positive drug result will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade of 90 percent for the three cycles of PT samples that challenge the laboratory's ability to conduct drug tests (*i.e.*, it must correctly identify and confirm 90 percent of the total drug challenges). A laboratory which achieves a score on any one cycle of the initial certification process such that it can no longer achieve a grade of 90 percent over three consecutive PT cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values over the three initial PT cycles that are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean (whichever range is larger) for at least 80 percent of the total drug challenges. Failure to satisfy this requirement for the total drug challenges will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative value on a drug challenge sample that differs by more than 50 percent from the calculated reference group mean. An applicant laboratory that obtains a quantitative value that differs by more than 50 percent on any drug challenge sample will result in disqualification.

(5) An applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least

50 percent of the challenges for each drug. An applicant laboratory that fails to successfully quantitate at least 50 percent of the challenges for each drug will result in disqualification.

(6) An applicant laboratory shall maintain an overall grade of 80 percent for the three cycles of PT samples that challenge the laboratory's ability to conduct specimen validity tests (*i.e.*, to correctly identify and confirm 80 percent of the total specimen validity testing challenges). An applicant laboratory that achieves a score on any one of the initial PT cycles such that it can no longer achieve a total grade of 80 percent over the three consecutive PT cycles for the specimen validity testing samples will result in disqualification.

(7) For quantitative specimen validity tests, an applicant laboratory shall obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean.

An applicant laboratory that achieves a score on any one initial PT cycle such that it cannot achieve a total grade of 80 percent over three consecutive PT cycles for the specimen validity testing samples will be disqualified.

(8) An applicant laboratory shall not obtain any quantitative value on a specimen validity testing sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  units for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means. An applicant laboratory that reports such an error for an initial certification PT sample will be disqualified.

(9) For qualitative specimen validity tests, an applicant laboratory shall correctly report at least 80 percent of the challenges for each qualitative specimen validity test over the three initial PT cycles. Failure to correctly report at least 80 percent for each qualitative specimen validity test will result in disqualification.

(10) An applicant laboratory shall not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the calculated group reference mean is within the acceptable pH range, or substituted when the calculated group means for both creatinine and specific gravity are within the acceptable range.

An applicant laboratory reporting any such error will be disqualified.

#### (b) Evaluation of Certified Laboratories.

(1) *Requirement for No False Positives.* A certified laboratory that reports a false positive drug result for a PT sample may be subject to suspension or revocation of its certification. The most serious false positive is by drug class, such as reporting THCA in a negative PT sample or reporting cocaine metabolite in a PT sample containing only opiates. An identification or reporting error within a class (*e.g.*, reporting codeine for morphine) is unacceptable, but is less serious than a misidentification of a class.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* Failure of a certified laboratory to maintain a grade of 90 percent over two consecutive PT cycles (*i.e.*, to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges) may result in suspension or revocation of the laboratory's certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges Within  $\pm 20$  Percent or  $\pm 2$  Standard Deviations.* Quantitative values reported by a certified laboratory over two consecutive PT cycles must be within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean (whichever is larger) for at least 80 percent of the total drug challenges. A certified laboratory that fails to achieve the 80 percent requirement may have its certification suspended or revoked.

(4) *Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean.* A certified laboratory shall not obtain any quantitative value on a drug challenge that differs by more than  $\pm 50$  percent from the calculated reference group mean. More than one error of this type for the same drug class over two consecutive PT cycles may result in suspension or revocation of the laboratory's certification.

(5) *Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug.* For each drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(3) and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) *No False Adulterated or Substituted Specimen Validity Testing Sample Result.* A certified laboratory shall not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the calculated group reference mean is within the acceptable

pH range, or substituted when the calculated group means for both creatinine and specific gravity are within the acceptable range. A certified laboratory that reports this type of error may have its certification suspended or revoked.

(7) *Requirement to Identify and Confirm 80 Percent of the Total Specimen Validity Testing Challenges.* A certified laboratory shall maintain an overall grade of 80 percent over two consecutive PT cycles that challenge the laboratory's ability to conduct specimen validity tests (i.e., to correctly identify and confirm 80 percent of the total specimen validity testing challenges). A certified laboratory that fails to maintain a grade of 80 percent over two consecutive PT cycles may have its certification suspended or revoked.

(8) *Requirement to Correctly Quantitate 80 Percent of the Total Challenges for Quantitative Specimen Validity Tests.* For quantitative specimen validity tests, a certified laboratory shall obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean.

A certified laboratory that fails to achieve 80 percent over two consecutive PT cycles may have its certification suspended or revoked.

(9) *Requirement to Report No More than One Quantitative Error for a Quantitative Specimen Validity Test.* A certified laboratory shall not obtain any quantitative value on a specimen validity testing sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  unit for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means. More than one error of this type for the same adulterant, for creatinine, for pH, or for specific gravity over two consecutive PT cycles may result in suspension or revocation of a laboratory's certification.

(10) *Requirement for Each Qualitative Specimen Validity Test.* For each qualitative specimen validity test, a certified laboratory shall correctly report at least 80 percent of the challenges for each qualitative specimen validity test over two consecutive PT cycles. A certified laboratory that fails to correctly report at least 80 percent of the

challenges may have its certification suspended or revoked.

(11) *Procedures When Requirements in Paragraphs (b)(1)—(b)(10) of this Section Are Not Met.* The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and to develop and submit a plan for implementing corrective actions to address the source of the error within 30 days. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) *Eighty Percent of Participating Laboratories Must Detect Drug or Specimen Validity Testing Challenge.* A laboratory's performance shall be evaluated for all drug and specimen validity testing challenges unless the overall response from participating laboratories indicates that less than 80 percent of them were able to correctly report the drug or specimen validity testing challenge.

(d) *Participation Required.* Failure to participate in a PT cycle or to participate satisfactorily may result in the suspension or revocation of a laboratory's certification.

#### Section 3.20 Inspections

(a) *Frequency.* Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of two or more qualified and trained inspectors shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall ability of the laboratory to satisfy the certification requirements specified in these Guidelines.

(b) *Inspectors.* The Secretary shall establish criteria for the selection of inspectors to ensure high quality, unbiased, and thorough inspections. The inspectors shall perform inspections consistent with the guidance in section 3.12(b).

(c) *Inspection Performance.* Inspectors shall assess the overall compliance of

the certified or applicant laboratory to these Guidelines. The laboratory's operation shall be consistent with good forensic laboratory practice and shall be in compliance with these Guidelines. It is the laboratory's responsibility to correct deficiencies identified during the inspection consistent with these Guidelines and with good forensic laboratory practice. In accordance with sections 3.13 and 3.14, deficiencies identified at inspections may be the basis for suspending or revoking a laboratory's certification.

#### Section 3.21 Results of Inadequate Performance

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in sections 3.13 and 3.14 of these Guidelines.

#### Section 3.22 Listing of Certified Laboratories

A **Federal Register** listing of laboratories certified by HHS will be updated and published periodically. Laboratories which are in the applicant stage of HHS certification are not to be considered as meeting the minimum requirements in these Guidelines. A laboratory is not certified until HHS has sent the laboratory an HHS letter of certification.

#### Subpart D—Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

##### Section 4.1 Applicability

These procedures apply when:

(a) The Secretary has notified a laboratory in writing that its certification to perform urine drug testing under these Mandatory Guidelines for Federal Workplace Drug Testing Programs has been suspended or that the Secretary proposes to revoke such certification.

(b) The laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

##### Section 4.2 Definitions

**Appellant.** Means the laboratory which has been notified of its suspension or proposed revocation of its certification to perform urine drug and/or validity testing and has requested an informal review thereof.

**Respondent.** Means the person or persons designated by the Secretary in implementing these Guidelines (currently the National Laboratory Certification Program is located in the



Division of Workplace Programs, Substance Abuse and Mental Health Services Administration).

**Reviewing Official.** Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

#### *Section 4.3 Limitation on Issues Subject to Review*

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of the Mandatory Guidelines shall not be subject to review under these procedures.

#### *Section 4.4 Specifying Who Represents the Parties*

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

#### *Section 4.5 The Request for Informal Review and the Reviewing Official's Response*

Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

#### *Section 4.6 Abeyance Agreement*

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while

the laboratory attempts to regain compliance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

#### *Section 4.7 Preparation of the Review File and Written Argument*

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) **Appellant's Documents and Brief.** Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) **Respondent's Documents and Brief.** Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform urine drug and/or validity testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or

proposed revocation (respondent's brief).

(c) **Reply Briefs.** Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) **Cooperative Efforts.** Whenever feasible, the parties should attempt to develop a joint review file.

(e) **Excessive Documentation.** The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

#### *Section 4.8 Opportunity for Oral Presentation*

(a) **Electing Oral Presentation.** If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) **Presiding Official.** The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) **Preliminary Conference.** The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) **Time and Place of Oral Presentation.** The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place



determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a

witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

*Section 4.9 Expedited Procedures for Review of Immediate Suspension*

(a) *Applicability.* When the Secretary notifies a laboratory in writing that its certification to perform urine drug and/or validity testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following: (1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically, and (2) a written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with section 4.8(c) and will conduct the oral presentation in accordance with the procedures of sections 4.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or

proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in section 4.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile or overnight mail.

*Section 4.10 Ex Parte Communications*

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

*Section 4.11 Transmission of Written Communications by Reviewing Official and Calculation of Deadlines*

Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing. In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

*Section 4.12 Authority and Responsibilities of Reviewing Official*

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in

accordance with the objectives of these procedures.

#### Section 4.13 Administrative Record

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

#### Section 4.14 Written Decision

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

#### Section 4.15 Court Review of Final Administrative Action; Exhaustion of Administrative Remedies

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under section 4.9(e) or 4.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. 04-7985 Filed 4-6-04; 12:39 pm]

BILLING CODE 4162-20-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of proposed revisions to mandatory guidelines.

**SUMMARY:** The Department of Health and Human Services ("HHS" or "Department") is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluid at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

**DATES:** Submit comments on or before July 12, 2004.

**ADDRESSES:** You may submit comments, identified by (insert docket number and/or RIN number), by any of the following methods:

- E-mail: [wvogl@samhsa.gov](mailto:wvogl@samhsa.gov). Include docket number and/or RIN number in the subject line of the message.
- Fax: 301-443-3031
- Mail: 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.
- Hand Delivery/Courier: 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

• Information Collection Requirements: Submit comments to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202-395-6974 (fax).  
*Instructions:* All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be available for public review at 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Walter F. Vogl, Ph.D., Drug Testing Section, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, 301-443-6014 (voice), 301-443-3031 (fax), [wvogl@samhsa.gov](mailto:wvogl@samhsa.gov) (e-mail).

## SUPPLEMENTARY INFORMATION:

### Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and have since been revised in the **Federal Register** on June 9, 1994 (59 FR 29908), and on September 30, 1997 (62 FR 51118). The Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of Pub. L. 100-71, 5 U.S.C. section 7301 note, and E.O. 12564.

In developing and organizing the proposed revisions to the Guidelines, there are a number of issues presented in this preamble, that include the rationale for the order and manner of presentation of what is proposed and why. These issues are first presented by general topic area, and later presented in summary, as they appear in the text of the proposed Guidelines.

### History of the HHS Certification Program for Federal Employee Drug Testing Programs, and Related Knowledge

Since the beginning of the program in 1988, many challenges have been overcome and lessons learned from the specific and rigorous HHS certification of laboratories to perform forensic workplace testing for job applicants and Executive Branch Federal employees.

The initial Guidelines were published for a 60-day public comment period, and were first published as a final notice in the **Federal Register** in April of 1988. Originally, it was believed that fewer than 10 laboratories would apply for HHS certification under the Guidelines to conduct Federal employee drug testing, and that the Department would not require even that many to test the urine specimens from all Federal agencies.

This situation changed very quickly when the Department of Transportation (DOT) published a final drug testing rule (54 FR 49854) in December 1989 for its regulated transportation industries. DOT required its regulated industries to use drug testing laboratories that were certified by HHS. This requirement began a close relationship between HHS and DOT. Additionally, the Nuclear Regulatory Commission (NRC) in its Fitness for Duty program contained in 10 CFR Part 26 requires its licensees to use drug testing laboratories certified by HHS.

As the Guidelines received both public and judicial support, the private sector chose to incorporate the requirement to use only a laboratory that has HHS certification under the Guidelines, for employee drug testing. Between July 1988 and early 1990, 50 laboratories had received HHS certification under the Guidelines, while another 100 laboratories were awaiting certification.

In developing the preamble for the proposed expansion and revision of the Guidelines, it has been very helpful to keep in sight important areas of consideration that have remained visible as the program matured over the ensuing fifteen years. These include, but are not limited to, custody and control that ensures donor specimen identity and integrity, specimen collection procedures, analytical testing methods, quality control and quality assurance, reporting results, the role of the medical review officer (MRO), and HHS certification issues that include testing site inspections and performance testing (PT) samples.

The Department has remained committed to maintaining the integrity of the entire Drug-Free Federal Workplace Program by identifying and using the most accurate, reliable drug testing technology available. To accomplish that goal, the Department collaborates with the DOT, NRC, Federal regulators, researchers, the testing industry, and both public and private sector employers on an on-going basis on scientific and program matters. As the number and types of commercial workplace drug testing products and testing options have increased over the past decade, the Department, through SAMHSA's Drug Testing Advisory Board (DTAB), has expressed increasing interest in assessing these new products and procedures for possible use in Federal agency employee testing programs.

Laboratory-based testing using automated screening tests at instrumented initial test facilities (IITFs) was proposed by the same group of individuals that developed the Guidelines as an area of interest immediately after the Guidelines were first published in 1988. At that time, the industries regulated by the NRC began using this approach as part of their Fitness for Duty programs to allow job applicants access to nuclear power plants. A study of 10 sites (including both NRC licensee and other private sector sites) was conducted where such an IITF was used. Point of collection test (POCT) devices were also being developed, but with non-instrumented, visually read end-points. By 1997, the

Department began, as discussed below, a dedicated assessment of drug testing using alternative specimens and drug testing technologies, including head hair, oral fluid (saliva), and sweat, for possible application in Federal workplace drug testing programs.

#### The Added Specimens—Major Change

The Department proposes to expand the kinds of specimens that may be tested under Federal agency workplace drug testing programs. The proposed addition of head hair, oral fluid, and sweat specimens are the result of a directed Department process that began with a 3-day scientific meeting of the DTAB held in April 1997 to discuss drug testing of alternative specimens and using new testing technologies as they apply to workplace drug testing programs. The entire meeting was open to the public. The first two days consisted of presentations on the principles and criteria of workplace drug testing program requirements and industry representatives discussing alternative specimens (hair, oral fluid, sweat as well as urine) and technologies (non-instrument based on-site tests). The presentations focused on the following areas for each specimen/technology: specimen collection and chain of custody, initial test reagents and procedures, confirmatory test procedures, internal quality control program, reporting test results, interpreting test results, and external quality assurance program. Industry coordinators selected the presenters for the alternative specimens and technologies to ensure a thoroughly unbiased review based on the science available. On the third day, the public was given an opportunity to make official statements or comments.

Following this meeting, the DTAB members continued reviewing the large amount of information presented at the meeting. Their efforts resulted in the identification of specific requirements necessary for the scientific, administrative, and procedural integrity of a comprehensive workplace drug testing program, which includes alternative specimens and technologies. They developed a chart summarizing workplace drug testing program requirements, reviewed the technical materials submitted to them, and identified the necessary workplace drug testing requirements for each alternative specimen/testing technology.

The DTAB has continued its evaluation of the information submitted by the industry representatives on alternative specimens and technologies since September 1997. The first working draft of the new Guidelines was

presented at the June 2000 DTAB meeting. The initial, work-in-progress draft Guidelines were placed on our web site and the public was invited to submit supplemental information and informal comments to help improve our knowledge base. Twenty-eight separate commenters submitted comments on the first working draft. The comments were summarized and presented at the next DTAB meeting held in September 2000. At the September 2000 DTAB meeting, the second working draft of the Guidelines was presented and, again, comments were requested from all interested parties. At the December 2000 DTAB meeting, the public comments submitted were used to prepare the third working draft of the Guidelines.

As the DTAB continued to work on the Guidelines, the Department initiated a voluntary pilot PT program. PT samples were developed and produced at government expense. The PT samples were sent to several laboratories for testing at the laboratories' own expense, using the procedures that they routinely use to test head hair, oral fluid, and sweat specimens. This pilot PT program began in April 2000 and was necessary for two reasons. First, it was necessary to determine if it was possible to prepare stable and accurate PT samples for the different types of specimens that would be needed as part of a laboratory certification program. Second, the results reported by the laboratories would indicate if the PT program could establish credibility, precision, accuracy, and reliability in drug testing with alternative specimens. Based on the information obtained from four rounds of PT samples, it appears that valid PT samples can be prepared, although some further refinement is needed, and that over time some laboratories testing alternative specimens have been able to achieve performance levels approaching those levels applied to urine testing laboratories. The criteria for laboratory-based hair, oral fluid, and sweat testing, and for POCT urine and oral fluid tests have been developed and proposed by the industry-lead working groups.

Although performance in the pilot PT program has been encouraging, with individual laboratory and group performance improving over time, there are still three serious concerns. First, the data from the pilot PT program to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to

detect varies by the type of specimen. That means that special awareness will be required to select the most appropriate type of specimen to be collected from a specific donor, when use of a specific drug is suspected. This public comment period is intended to provide an opportunity for all interested parties to review the testing criteria and associated specimen-specific procedures, to be sure that required performance is achievable and sustainable when implemented.

#### Alternative Specimens

The use of specimens other than urine in workplace drug testing programs have become a frequent topic in scientific meetings worldwide. This includes organizations such as the Society of Forensic Toxicologists, The International Association of Forensic Toxicologists, the Society of Hair Testing, and the American Academy of Forensic Sciences. The most frequently discussed specimens are hair, oral fluid, and sweat. Until recently it was considered too soon for the forensic community to apply these alternative specimens to workplace drug testing. Current scientific literature provides much of the information that was not previously available in peer reviewed literature. Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to suborning drug testing through adulteration, substitution, and dilution.

The preamble provides a list of scientific studies that were used in making the policy decisions. The Department asks whether commenters are aware of any other studies or data that would cast more light on the appropriateness of using any of the alternative specimens or on limitations on how the specimens should be used.

#### Hair

The Department is proposing that hair testing be included in the Federal Workplace Drug Testing Program. Hair testing increases the time period over which drug use can be detected as compared to urine, sweat, or oral fluid. Hair is easily collected, transported and stored, is less likely to transmit bio-organisms than urine or oral fluid, and is more difficult to adulterate than urine. As separation techniques and detection sensitivity and specificity have improved, scientists are now able to detect and quantify drugs and/or metabolites in hair at picogram levels. Like other drug testing specimens, drugs in hair are initially detected using an immunoassay technique and results are

confirmed with a more sophisticated technique, most frequently by gas chromatography/mass spectrometry (GC/MS). Tandem mass spectrometry (MS/MS) using GC or liquid chromatography (LC) separation has emerged in recent years as the testing method of choice in order to increase sensitivity and selectivity and to analyze polar compounds without derivitization.<sup>10,15,16</sup>

Hair consists of a hair follicle and hair shaft. At the base of the follicle (bulb) are highly vascularized matrix cells. As matrix cells in the dermis of the skin move outward during growth, they form layers of a hair shaft that include the outer protective cuticle, central cortex and inner medulla. Hair grows in three stages: about 85 percent of hair follicles are in active growth (anagen), while the others are in a transition phase (catagen) before the resting phase (telogen). At the vertex region of the scalp, the average growth rate of hair is about 0.4 millimeters per day or approximately 1 centimeter per month.<sup>1</sup> The Department is proposing to permit agencies as part of their Federal workplace program to test hair with lengths of about 1.5 inches long, representing a time period of 90 days, and to use these specimens for pre-employment, random, return-to-duty, or follow-up testing.

Analytes for the regulated drugs tested in hair are marijuana metabolite (delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA)), cocaine (parent drug and metabolites (benzoylecgonine, norcocaine, and cocaethylene)), phencyclidine (parent drug (PCP)), opiates (codeine, morphine, and heroin metabolite (6-acetylmorphine (6-AM))), and amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)).

Drugs and drug metabolites may be incorporated into hair by several different pathways.<sup>1,3-7</sup> As drugs and their metabolites travel through the body in blood, they passively diffuse from the bloodstream into the base of the hair follicle. Drugs and/or metabolites are embedded into the hair as bands during the growth process. The amount of drug in the hair band is proportional to the concentration in the blood when the hair was formed. The distance of the drug bands from the skin can estimate the time of drug use. Drugs and/or metabolites may also be incorporated into hair via secretions of the apocrine sweat glands and sebaceous glands, which are in close

contact with hair as it develops in and emerges from the skin. Sweat and sebum can deposit drugs and/or metabolites on the hair shaft that in turn are absorbed into the hair shaft during and after its formation. Sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion.

There are a number of factors that may influence the amount of drug incorporated into hair (e.g., drug dose, length of exposure, drug chemical structure, charge). Of particular concern are environmental contamination and the role of hair color.

Concern has been raised about environmental contamination where a person may claim, for example, that the drug is present because the individual was in a room where others were using marijuana or cocaine. While washing the hair sample may remove some of the contamination, ultimately we can differentiate environmental contamination from actual use because of the presence of the metabolite, which is not present when environmental contamination is the source of the drug.

The role of hair color is also a major concern. Melanin, which is responsible for pigmentation in hair, is produced in the hair bulb and incorporated into the cells that form the cortex and medulla during growth of the hair shaft. Melanin is a polyanionic polymer of two types: eumelanin and pheomelanin, the quantity of each determine hair color. Eumelanin concentration is highest in black hair and lowest in red hair while pheomelanin concentration is highest in red hair and lowest in black hair.<sup>2</sup> Melanin is absent in white hair.

Animal studies have shown that hair color influences drug incorporation with black hair containing the most and yellow (non-pigmented) hair the least.<sup>7</sup> In vitro studies in which black, brown, and blond hair from drug-free human subjects were placed in a solution of benzoylecgonine showed the highest concentration of the drug in black hair and the least in blond.<sup>8</sup> Although there have been a limited number of human clinical controlled studies, data show that higher concentrations of some drugs are found in dark hair when compared to blond or red hair (e.g., codeine<sup>2</sup>, cocaine<sup>9</sup>, amphetamine<sup>10</sup>). The limited population studies published in peer reviewed literature at this time do not indicate a significant association between hair color or race and drug analyte.<sup>11-13</sup> In one study, 1852 people that classified themselves as "black" or "white" showed no evidence of a group adversely affected by hair testing, compared to urine



testing, for cocaine and marijuana testing.<sup>11</sup> The examination of 500 positive hair samples for each of three drugs (cannabinoids, cocaine, and amphetamine) revealed little statistical evidence of selective binding of drugs to hair of a particular color.<sup>12</sup> Statistical examination of 2791 data points that include heroin and its metabolites, cocaine and its metabolites, MDMA and its analogs, and amphetamine and methamphetamine failed to detect a significant hair color effect.<sup>13</sup>

Despite these suspected limitations, the Department still proposes to go forward with incorporation of this new technology as an alternative to urine for Federal agencies who may find it useful in certain missions and tasks that only individual Federal agencies can identify. Though there continues to be some question about the effect of hair color on the amount of a drug or its metabolite present in hair, there is no question about the fact that the drug or metabolite is present. The purpose of the Federal Workplace Drug Testing Program is to ensure the safety of the workplace which it does in two ways. First, it identifies individuals in security or safety sensitive positions who have been using drugs, and second, it acts as a deterrent for people who might otherwise use drugs lest they be detected. Hair testing can improve the success of the program because it increases the time period over which drug use can be detected as compared to urine; it is easily collected, transported and stored; it is less likely to transmit bio-organisms than urine; and is more difficult to adulterate.

#### Oral Fluid

Testing methods for drugs in oral fluid have been developed in recent years and have been extensively used in some tested populations (e.g., therapeutic drug monitoring, risk assessment in the insurance industry, and non-Federal workplace testing).<sup>17-19</sup> Many studies support the use of oral fluid as a specimen for forensic drug testing.<sup>20,21</sup>

Oral fluid offers some advantages over other types of specimens.<sup>22</sup> Oral fluid is readily accessible and its collection is perceived as less invasive than a urine specimen collection. Oral fluid collections can easily be observed and, therefore, the specimen is less susceptible to adulteration or substitution by the donor. Drugs can be detected in oral fluids within one hour of use making oral fluids useful in detecting very recent drug use.<sup>27</sup>

Substitution can be identified by measuring an endogenous component (IgG) in the specimen. Although the

specimen volumes and amount of drug are lower in oral fluid than in urine specimens, current analytical methods (e.g., immunoassay, GC/MS, GC/MS/MS, LC/MS/MS) have the required sensitivity to be used for oral fluid specimen testing.<sup>23-26</sup>

As with the other relatively new test specimens for drugs of abuse testing, less is known about the pharmacokinetics and disposition of drugs into oral fluid as compared to urine.<sup>3,28-30</sup> Science shows that opiates, PCP, amphetamines and cocaine and most drugs including prescription medications enter oral fluid through passive diffusion of the drug from the blood stream into the oral fluid. However, the active component of marijuana (delta-9-tetrahydrocannabinol (THC)) does not diffuse into oral fluid.<sup>26,31,32</sup> The only way to detect marijuana use is through the presence of the parent drug (THC) in the oral fluid because the parent drug was present in the oral cavity. Unfortunately, further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination, i.e. the individual was present in a room when others smoked marijuana, for example.

In order to protect Federal workers from incorrect test results for marijuana, the Department proposes that a second biological specimen, a urine specimen, will need to be collected under the current Guidelines at the same time the oral fluid specimen is obtained, primarily for the purpose of testing for marijuana when the oral fluid specimen is positive for marijuana. The Department will revise the Guidelines when the science is available to differentiate between actual use and environmental contamination.

Analytes for the regulated drugs tested in oral fluid are marijuana (parent drug (THC)), cocaine (parent drug or metabolite benzoylecgonine), PCP (parent drug), opiates (codeine, morphine, and 6-AM), and amphetamines (amphetamine, methamphetamine, MDMA, MDA, MDEA).

The pH of oral fluid can affect incorporation of some drugs.<sup>33-35</sup> Salivary pH ranges from about 6.2 to 7.4. Increased saliva flow rate raises the pH up to a maximum of 8.0 due to higher bicarbonate levels. Oral fluid collection devices cause some stimulation of saliva flow. Studies have found that concentrations of drugs (e.g., cocaine and its metabolites) in non-stimulated oral fluid specimens were greater than the concentrations of specimens collected using other

methods.<sup>34</sup> Mechanical saliva stimulation (i.e., chewing gum) can also lower drug concentrations in oral fluid.<sup>33</sup> To avoid saliva stimulation some recommend spitting into a cup, but some donors may be opposed to spitting, especially when observed, and may experience dry mouth.

The Department finds that the collection difficulties associated with oral fluid collection procedures are not functionally different than other specimen collection difficulties currently encountered with urine. Therefore, despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because oral fluid testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

#### Sweat

The incorporation of drugs into sweat is poorly understood but possible mechanisms appear to be passive diffusion of drugs from blood into sweat gland and transdermal migration of drugs to the skin surface, where it is dissolved in sweat.<sup>3,36,37</sup> The time interval between drug consumption and detection in sweat depends on the nature of the particular drug or drug metabolite and the sensitivity of analytical method used.<sup>3,36,38</sup>

Sweat may be collected as liquid perspiration,<sup>38</sup> on sweat wipes,<sup>20,39</sup> or with a sweat patch.<sup>40-44</sup> Sweat collection is a non-invasive procedure<sup>37,38</sup> and privacy during collection does not appear to be a concern.<sup>38</sup> Commercially available sweat patches may be worn for an extended period of time, are waterproof, and are generally accepted by patients.<sup>39</sup> Currently, there are a limited number of commercially available collection devices,<sup>20,39</sup> only one of which is FDA-cleared. Attempts to remove or tamper with the FDA-cleared sweat patch are usually visible to personnel trained to remove them.<sup>3,37</sup> Sweat patch contamination issues continue to be a concern.<sup>3,39,45</sup> For example, one study suggests that sweat patches are susceptible to contamination by a drug that is on the skin before the sweat patch is applied and by absorption into the patch through the surface of the protecting membrane.<sup>39</sup> Other studies indicate that the polyurethane (outer) layer is impermeable to molecules larger than dimer water.<sup>45</sup> Based on that information, the Department believes that external absorption of any drugs through the outer layer is not possible under normal circumstances. With regard to contamination from a drug



present on the skin before applying the sweat patch, the Department proposes that the skin area be washed with soap and cool water or with a disposable towelette. Then the collector must thoroughly clean the skin area where the patches will be worn with alcohol wipes prior to application. However, the Department encourages researchers to conduct further research in this area.

The Department knows from direct experience both at the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration that some individuals may not be able to wear the sweat patch for the optimal period of time. Skin sensitivity and rash are factors that can only be known after the patch is applied for the first time.

The Department also knows from direct experience that if the patch is applied in a normally visible area of the body, such as the upper arm, that there could be a stigmatizing effect on the wearer.

Despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because sweat testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

Unlike urine, head hair, or oral fluid, the use of a sweat patch detects drug use that occurred shortly before the patch is applied and while the device remains applied to the skin.<sup>3,20,37,46</sup> The window of detection for the sweat patch is for as long as the patch remains on the skin and is a cumulative measure of drug ingestion.<sup>3,37</sup>

Unlike urine, primarily the parent drug is found in sweat; however, some drug metabolites may also be detected.<sup>3,20,36,37,47</sup> Some drugs and drug metabolites that have been detected in sweat are THC,<sup>51</sup> amphetamine, methamphetamine,<sup>20,48</sup> codeine, morphine, 6-AM, heroin,<sup>40,43,45,47,49,50</sup> PCP,<sup>72</sup> and cocaine, benzoylecgonine, ecgonine methylester.<sup>20,44,47,52</sup> Investigations to compare the detection of drugs in sweat to other specimens are ongoing.<sup>38-41,47,48,51,53,54</sup>

Analytes for the regulated drugs tested in sweat are marijuana (parent drug (THC)), cocaine (parent drug or metabolite benzoylecgonine), PCP (parent drug), opiates (codeine, morphine, and 6-AM), and amphetamines (amphetamine, methamphetamine, MDMA, MDA, and MDEA).

The amount of sweat excreted is variable for each person and between individuals and is dependent upon their daily activities, emotional state, and

environment.<sup>39</sup> The amount of sweat collected for testing is small and the drug concentration low. Therefore, the analytical procedures used for measurement of drugs and/or their metabolites in sweat must be very sensitive. Confirmation of drug analytes in sweat are routinely confirmed by GC/MS<sup>54</sup> and sometimes with LC/MS/MS.<sup>38</sup>

Currently, sweat testing is used in the private sector for monitoring drug use during substance abuse treatment<sup>37</sup> and is also used in the criminal justice system.<sup>17</sup> Sweat also appears to be well suited for return-to-duty and follow-up testing for workplace testing.<sup>3,20</sup>

#### The Added Types of Testing Options and Locations—Major Change

##### *Instrumented Initial Test Facility (IITF)*

The Department proposes to include IITF options in the Guidelines. An IITF is basically the screening part of a screening and confirmatory laboratory, but established in locations to potentially more quickly and economically meet special local testing needs. The Department has learned a great deal from the experience of the NRC, where such urine-based facilities were permitted beginning in 1990. These IITFs were intended to support the periodic large testing needs of nuclear-fueled electrical power generating facilities, whenever facility maintenance and fuel rod replacements were needed, at which time hundreds of maintenance workers needed to be allowed timely access into the secured areas of the nuclear power plant.

The numbers and fixed locations of IITFs make them more "like" laboratories. Presently there are fewer than 60 laboratories HHS-certified to perform workplace urine drug testing for Federal agencies. With the rigorous certification, performance testing, and inspection requirements proposed for the IITF, it is unlikely that the total number of laboratory and laboratory "like" facilities will increase very much, or even double to 120 in total. Thus, the IITF could be certified in much the same fashion as a laboratory with inspections and PT, with the focus exclusively on initial drug and validity testing.

The Department proposes that IITFs should: (1) Be at a permanent location, (2) meet program forensic standards, (3) participate in open and blind proficiency testing, (4) have a rigorous quality assurance program, (5) be subject to site inspections, (6) use instrumented immunoassay tests for drugs which meet FDA requirements for commercial distribution, (7) conduct

required specimen validity tests, (8) use HHS cutoffs, and (9) submit all non-negative specimens to a full service HHS-certified laboratory for required additional testing. In meeting these criteria, the IITF will meet Guideline requirements of the initial test section of an HHS-certified laboratory.

##### *POCT for Drugs*

POCT devices for drugs of abuse were first available in the early 1990s. POCTs include non-instrumented devices with visually read endpoints as well as semi-automated or automated instrumented testing devices with machine read endpoints. Drug tests conducted with these devices utilize competitive binding immunoassays, the same scientific principle as the initial tests conducted in certified laboratories.

The development and commercial availability of POCT products has evolved to include both urine and oral fluid specimens at this time, with more specimens likely to be added in the future. The Department has learned a great deal from collaboration with the National Institute on Drug Abuse, the Administrative Office of the U.S. Courts, the Federal Probation and Parole Office, and the Department of Defense (DoD) Armed Forces drug testing program office. Collectively, these collaborations and the results of actual product assessments<sup>58</sup> have provided the experience and knowledge to propose procedures in the Guidelines to more uniformly assess the on-going performance of these devices in Federal drug testing applications.

Non-instrumented POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories.<sup>55-58</sup> These tests were conducted on both spiked and donor specimens with and without drug analytes. Little difference in the performance of these devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedures for conducting and reading the tests.<sup>55,56</sup>

Non-instrumented POCTs for oral fluid have been characterized by only one group of independent investigators.<sup>59</sup> Their study was performed on spiked oral fluid at concentrations consistent with the proposed cutoffs. This study found device variability and difficulty in detecting cannabinoids, but suggests the rapid evolution of the technology should overcome current problems relating to targeted analyte and

manufacturer's cutoff and provide an assay consistent with proposed HHS cutoffs. The investigators felt that "there is every reason to be optimistic about the future for drug testing using oral fluid matrix."<sup>59</sup> Presently, there are no POCT devices that have received FDA clearance for drugs of abuse in hair or sweat.

POCTs could potentially be employed almost anywhere, with hundreds, if not thousands of testing sites possible. The value and utility of the POCT is that it provides quick, negative drug results and validity test results and has the added benefit of not requiring a fixed facility, expensive test equipment, and highly trained testing personnel; moreover, POCTs could be run in low numbers, infrequently, and at any given location, as needed. These factors make it very difficult, if not impossible to use a laboratory "like" inspection and quality assurance process. The use of highly trained laboratory personnel provides no specific or added value to any oversight process, beyond the actual testing of sample POCT devices. Further, the sheer potential number and diverse locations of sites where POCT devices might be used by choice, make large-scale, routine, or scheduled on-site inspections a logistic and budgeting nightmare.

In order to provide an equivalent program of on-going quality assurance for POCT devices, the Department proposes a certification process under which POCT device manufacturers would provide tests for evaluation to be placed on the list of SAMHSA-certified devices published by the Secretary. This would be followed by periodic additional testing as new lots of manufactured tests become available as well as PT sample requirements, training of POCT testers, and on-going quality assurance requirements. This is a complex area that will benefit from public comments now, and from lessons learned over time.

#### *Advantages of POCTs*

POCT products could potentially be employed almost anywhere. The value and utility of the FDA-cleared and SAMHSA-certified POCT is that it will provide quick, negative drug and specimen validity test results. Those specimens that test presumptively positive for drugs or indicate that additional specimen validity testing is necessary would then be referred for confirmatory testing.

POCT testing of urine is most suited for situations that require quick, negative drug and specimen validity test results such as in emergency/crisis management. It may be least suited for

pre-employment, return to duty and follow-up testing.

POCT testing of oral fluid is most suited for situations that require quick, negative results such as in emergency/crisis management. It is most suited for reasonable suspicion/cause and post-accident. It may be least suited for random testing. Oral fluid is not suited for return to duty, follow-up testing and pre-employment. In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

#### *POCT for Specimen Validity Testing*

Specimen validity POCT devices for the detection of substitution and the presence of adulterants have become more widely used in the past three years. Specimen validity POCTs include non-instrumented devices with visually read endpoints as well as semi-automated or automated instrumented testing devices with machine read endpoints. Specimen validity tests conducted with these devices utilize colorimetric assays, the same scientific principle as the initial tests conducted in certified laboratories.

Non-instrumented specimen validity POCT for urine testing have been subjected to evaluations by independent investigators and were able to detect abnormal urine specimens.<sup>60-62</sup> These tests were conducted on spiked specimens with drug analytes. Results from these preliminary studies are variable; however, they demonstrate the ability of the devices to detect adulterants and creatinine. This is why the Department will incorporate the evaluation of the accuracy and reliability of specimen validity testing as part of the POCT device evaluation process.

#### *Urine Specimen Validity Testing*

On August 21, 2001, HHS published a notice in the *Federal Register* (66 FR 43876), proposing that the Mandatory Guidelines be revised to include specific standards for determining the validity of urine specimens collected by Federal agencies under the Federal Workplace Drug Testing Program. The Department has issued a final revision with comments to the Mandatory Guidelines as they currently exist implementing the urine specimen validity testing requirements. These requirements have been incorporated in this revision.

#### **Manner of Presentation and the Use of Plain Language—Major Change**

Although the order of presentation in the proposed revisions to the Guidelines has been retained, the manner of presentation has been totally revised. This "improved" process has been based on the experience and very positive public feedback that other Federal agencies have had when they used a similar process. The goal of the HHS process was to revise the manner of presentation to use "plain language," and address complex issues by using simple questions to identify each specific topic. Unfortunately, these Guidelines are scientifically based and the answers are often complex.

Wherever possible, the questions and answers have been organized as a group for a specific specimen, testing option, or related topic. The Department understands that such organization may produce some repetition, for example when reading about head hair, oral fluid, or sweat, and seeing identical information presented for collection site, donor identification, or confidentiality, as repeated text. Because this change in format is significantly different than the current Guidelines, major changes from the current Guidelines will be noted in the discussion of each subpart.

#### **Organization of Draft Guidelines—No Major Change**

Within the text for the proposed revisions to the Guidelines, the order of presentation of topics follows the existing Guidelines, with expanded details to address the added specimens (head hair, oral fluid, sweat), testing options (ITF and POCT), and related issues. This seems to be the most appropriate way to permit those already familiar with the existing Guidelines to do a detailed comparison with what is being proposed. For those relatively few first-time readers of the Guidelines, they may wish to first review the current Guidelines so as to understand the current proposal. Where there are no changes to specific sections in the proposed revisions to the Guidelines, that has been stated in the preamble.

#### **HHS Contractor—No Major Change**

In accordance with current practice, the HHS contractor performs certain functions on behalf of the Department. These functions include maintaining a laboratory inspection program and a PT program that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results

submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Secretary regarding certification, continued certification, or suspension/revocation of laboratories' certification. It is important to note that while the contractor gathers and evaluates information provided to it by inspectors or laboratories, all final decisions regarding laboratory certification, suspension or revocation of certification status is retained within the Department.

In addition, the contractor has historically collected certain fees from the laboratories for services related to the certification process, specifically for laboratory application and inspection and PT activities for laboratories applying to become HHS-certified, and in the process of maintaining HHS-certification. All fees that are collected by the contractor are applied to its costs under the contract.

This same process, which has been used since the inception of the laboratory certification program, will also be used by the HHS contractor to collect similar fees from laboratories that seek, achieve, and continue HHS-certification for testing additional types of specimens (e.g., hair, oral fluid, sweat), and from IITFs that seek, achieve, and continue HHS-certification to test hair, oral fluid, sweat, or urine.

The Department also contributes funds to this contract for purposes not directly related to laboratory certification activities, such as evaluating the technologies and instruments and providing an assessment of their potential applicability to workplace drug testing programs.

#### Subpart A—Applicability

Sections 1.1, 1.2, 1.3, and 1.4 contain the same policies as described in the current Guidelines with regard to who is covered by the Guidelines, who is responsible for the development and implementation of the Guidelines, how a Federal agency requests a change from these Guidelines, and how these Guidelines are revised.

In section 1.5, where terms are defined, the Department proposes to add or revise several of the definitions contained in the Guidelines. These include, for example, new or revised definitions for adulterated specimen, certifying scientist, collector, confirmatory validity test, dilute specimen, failed to reconfirm, follow-up test, initial validity test, IITF, invalid result, non-negative specimen, oxidizing adulterant, POCT facility, post-accident test, pre-employment, random test,

reasonable suspicion/cause test, reconfirmed, rejected for testing, responsible person, responsible technician, return to duty test, specimen, split specimen, substituted specimen, and standard. Every effort has been made to define terms such that they would apply to each type of specimen collected, as appropriate.

Section 1.6 specifies what an agency is required to do to protect employee records. It is the same policy as described in the current Guidelines except it has been amended to include records at IITFs, POCT sites, specimen collection sites, and records produced and maintained by medical review officers.

#### Subpart B—Specimens—Major Change

In section 2.1, the Department proposes to expand the urine drug testing program for Federal agencies to permit testing head hair, oral fluid, and sweat specimens. The Department wants to make it very clear to agencies that there is no requirement that they use hair, saliva or sweat as part of their drug testing program, but rather that agencies may use those specimens. If they choose to use these alternative specimens then agencies are required to follow these Guidelines.

In section 2.2, in order to guide Federal agencies, the Department has added to the Guidelines a chart indicating in what circumstances each specimen can be collected.

#### Urine

Laboratory based urine testing has traditionally been used for pre-employment, random, reasonable suspicion/cause, post-accident, return-to-duty, and follow-up testing.

Drug ingestion for a 3–5 day interval preceding the specimen collection can usually be identified in urine. Based on the detection window, urine is most suited for random, return to duty and follow-up testing.

Because of the increasingly evident potential that Federal agency workplace urine-based drug testing has the potential for being seriously compromised by clandestine products and procedures intended to mask current drug use, especially when given sufficient time to obtain these products, urine drug testing may be least suited for pre-employment.

#### Oral Fluid

Drug detection times for the regulated analytes in oral fluid range from less than one to approximately 24 hours. Drugs may be detected in urine longer after drug use than in oral fluid. This makes oral fluid useful in detecting very

recent drug use. Based on the detection window, oral fluid is most suited for reasonable suspicion/cause and post-accident. It may be least suited for random testing if prior notice (greater than 24 hours) is given. Because of the short detection window, oral fluid is not suited for return to duty, and follow-up testing. In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

#### Hair

Hair is useful for detecting drug use for longer time intervals, *i.e.*, weeks (>7–10 days) to months. Based on the detection window, hair is most suited for pre-employment and random testing. The window of detection is much longer than that of urine. Hair may be used for return to duty and follow-up testing depending on the time of last known drug use. Hair is not suited for reasonable suspicion/cause and post-accident because it takes 7–10 days for drug or drug metabolites to appear in hair.

#### Sweat Patch

The window of detection for the sweat patch is for as long as the patch remains on the skin and is a cumulative measure of drug ingestion. The sweat patch may not be useful for pre-employment, random, reasonable suspicion/cause and post accident drug testing because it must be worn for days after its application. The sweat patch is best used for return to duty and follow-up testing.

The Department is specifically requesting public comment on the appropriateness of the reasons for defining and limiting the selection of specimens for the different types of testing proposed in this notice. Commenters are requested to submit supporting documentation if recommending that other reasons for testing would be appropriate for some of the types of specimens being collected.

In section 2.3, the Department proposes to prohibit routinely collecting more than one type of specimen from a donor at the same time except when an oral fluid specimen is collected. This restriction is appropriate because it prevents Federal agencies from expecting an individual to provide multiple specimens each time he or she is selected for a drug test and then attempting to compare results from different types of specimens. It is expected that different results would be obtained for the different types of specimens because the windows of

detection are different, as explained above. If a problem occurs during the collection of one type of specimen (e.g., shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen.

In section 2.4, the Department proposes to establish the requirement for all specimens to be collected as split specimens, and in section 2.5 to establish a minimum quantity that must be collected for each type of specimen. For hair, 100 mg of head hair was the quantity recommended by the hair testing industry. For oral fluid, the Department is proposing that 2 mL be collected in a collection tube rather than allowing oral fluid to be collected directly into a collection device that does not provide an accurate measurement of the volume of oral fluid collected. This approach allows establishing specific cutoffs for oral fluid testing. For sweat, since the "sweat patch" is the only FDA-cleared device currently available, the quantity of sweat collected is determined by the length of time the patch is worn. Requiring that the patch be worn at least 3 days but no more than 7 days ensures that a sufficient amount of sweat is collected that could possibly contain a measurable amount of drugs or drug metabolites. For urine, the Department is proposing to eliminate the single specimen collection procedure and to require each Federal agency to use the split specimen collection procedure. The 45 mL requirement ensures that each Federal employee is offered the same opportunity to have the split specimen tested by a second laboratory.

#### **Subpart C—Drug and Validity Tests—Major Change**

Section 3.1 contains the same policy that is in the current Guidelines regarding which tests must be performed on a specimen. A Federal agency is required to test each specimen for marijuana and cocaine, and is authorized to also test for opiates, amphetamines, and phencyclidine. The Department realizes that most Federal agencies already test for all five drug classes authorized by the existing Guidelines, but has not made this a mandatory requirement. The Department will continue to rely on the individual agencies and departments to determine their testing needs above the minimum. The one new requirement is that each Federal agency is required to ensure that each specimen is tested to determine if it is a valid specimen.

The policy in section 3.2 remains unchanged. Any Federal agency that

wishes to routinely test its specimens for any drug not included in the Guidelines must obtain approval from the Department before expanding its program. A specimen may be tested for any drug listed in Schedule I or II of the Controlled Substances Act when there is reasonable suspicion/cause to believe that a donor may have used a drug not included in these Guidelines. When reasonable suspicion/cause exists to test for another drug, the Department is proposing that a Federal agency must document the possibility that the use of another drug exists, attach the documentation to the original Federal drug testing custody and control form (Federal CCF), and ensure that the HHS-certified laboratory has the capability to test for the additional drug. The HHS-certified laboratory is expected to validate the test methods for this additional drug and to use the same quality control criteria that are used for the other drug analyses described in the Guidelines. The Department believes this proposed policy is sufficient to ensure that this testing for an additional drug would be forensically and scientifically supportable.

Section 3.3 restates the policy in the current Guidelines that specimens may not be used for any unauthorized purposes.

Sections 3.4, 3.5, 3.6, and 3.7 list the proposed cutoff concentrations for each type of specimen collected. As previously stated in this preamble, the Department is proposing to adopt the cutoff concentrations that were recommended by the industry working groups. Based on the results from the PT testing program, it appears that some industry proposed cutoff concentrations for the alternative specimens are currently set at what appears to be approaching a limit of quantitation that reflect the analytical capabilities of one or two laboratories to detect extremely low drug concentrations. The Department believes that each laboratory testing a specific type of specimen for a particular drug must be able to accurately determine the concentration for a drug or drug metabolite that is less than the cutoff concentration, as well as concentrations equal to or greater than the cutoff. The Department is specifically requesting comments on the appropriateness of these cutoff concentrations and the ability of laboratories to meet this requirement.

Since the late 1980's, a number of recommendations have been made that additional drugs be considered for inclusion in workplace drug testing. Over the past decade, MDMA and its analogues have become increasingly

prevalent in the workplace. The 2002 National Survey on Drug Use and Health (NSDUH) (available on the Internet at <http://www.samhsa.gov/oas/nhsda.htm>)<sup>63</sup> indicates that the estimated number of people using ecstasy, the generic name for MDMA, within the past year and within the month before the survey was taken, exceeded that found for heroin, crack cocaine, LSD, and PCP. This is further supported by Drug Abuse Warning Network (DAWN) data<sup>64</sup> which finds that MDMA was on the list of the top 10 drugs mentioned in emergency room visits, just below methamphetamine and was one of the top ten of drugs seized and sent to Federal, State and municipal crime laboratories, as noted in the National Forensic Laboratory Information System (NFLIS) 2002 Annual Report.<sup>65</sup> In 2000, the prevalence of MDMA found in active duty Army personnel exceeded that of methamphetamine.<sup>66</sup> Thus, Federal agencies may elect to test for additional drugs including MDMA, under section 3.2(a) of the Mandatory Guidelines.

The Department is specifically interested in obtaining information on the ability of the various immunoassay test kits to detect MDMA, within the amphetamine class of drugs. The Department is aware that DoD drug tests members of the uniformed services for MDMA using an additional initial test focused on that drug. Based on this experience from DoD, if drug testing is proposed at the cutoffs in this document, the Department believes that the only sensitive and specific manner to perform the initial test for methamphetamine, amphetamine, and MDMA is to use two separate initial tests, one for methamphetamine and amphetamine and a second initial test for MDMA. Recommendations on using a single amphetamine test kit or the need to use separate test kits are requested.

The Department periodically reviews the cutoff for all drugs authorized for workplace drug testing and revises those cutoffs as necessary to maximize the deterrent effect of the program. As a result of this review, the initial test cutoff for marijuana was lowered in 1994 and both the initial test and confirmatory test cutoff for opiates was raised in 1998. These changes were instituted after review of the science supporting the change, the technical capabilities of the certified laboratories and the effect of the change on the deterrent intent of workplace drug testing.

The Department proposes to lower the cutoff concentration for cocaine and amphetamine analytes. Reductions in



initial and confirmatory cutoffs for most drugs in urine will increase the time period in which those drugs will be found.<sup>67</sup> The proposed lower cutoffs will produce an increase in the number of urine specimens that are identified as containing cocaine metabolites and amphetamines.<sup>68-70</sup> The cutoff reductions proposed in this revision are estimated to identify 10–20 percent more urine specimens containing cocaine metabolites<sup>68,69</sup> and 5–24 percent more urine specimens containing amphetamines.<sup>70</sup> Data provided by currently certified laboratories are consistent with these estimates and will increase the deterrent effect of the program and allow early identification of substance use by individuals. The lowering of these cutoffs should not result in increased claims of passive exposure.<sup>71</sup>

The capability of HHS-certified laboratories to respond to these changes has been evaluated. Since the beginning of this program, laboratories certified by HHS have exhibited significantly less quantitative variability when analyzing PT samples than applicant laboratories. Evaluations of their performance since 1990 have also shown that the quantitative variability of the certified laboratory population has continued to decrease for all drugs. Evaluations of performance for the testing of cocaine and amphetamines have found that certified laboratories have demonstrated the precision and accuracy necessary for the proposed cutoff revisions. Certified laboratories demonstrated their ability to meet current Guideline requirements through the testing of quarterly PT samples containing amphetamine, methamphetamine, and benzoylecgonine. Documentation of their capabilities with method validations has demonstrated the precision and accuracy of the method down to 40 percent of the current cutoffs. In addition, laboratories have been challenged quarterly with PT samples which contained drug concentrations at 40 percent of the current cutoff and higher.

For urine, the Department proposes to lower the initial test cutoff concentration for cocaine metabolites from 300 ng/mL to 150 ng/mL with a corresponding decrease of the confirmatory test cutoff concentration from 150 ng/mL to 100 ng/mL. Additionally, the initial test cutoff concentration for amphetamines would be decreased from 1000 ng/mL to 500 ng/mL and the confirmatory test cutoff concentration decreased from 500 ng/mL to 250 ng/mL. The Department continues to require the presence of amphetamine at a concentration below

cutoff in order to report a specimen positive for methamphetamine. This "methamphetamine reporting rule" is retained because of concerns and experience that extremely high concentrations of pseudoephedrine and/or ephedrine in a urine specimen can still lead to inappropriate reporting of a methamphetamine positive result when in fact there is no methamphetamine present at a concentration above the cutoff. Additionally, this requirement to confirm the presence of amphetamine at a concentration below the cutoff is included for reporting a hair, oral fluid, or sweat patch methamphetamine positive result. The confirmatory testing for amphetamines would be expanded to test for MDMA, MDA, and MDEA. The Department believes that the certified laboratories have the capability to accurately test urine specimens using these revised cutoff concentrations. Additionally, the revised cutoff concentrations will increase the windows of detection for these drugs, thereby, increasing the number of specimens that may be reported positive.

In sections 3.8, 3.9, and 3.10, the Department is proposing which validity tests must be conducted on head hair, oral fluids and sweat patches. In section 3.11, the Department then reiterates which validity tests must be conducted on a urine specimen. The Department believes these policies are necessary to identify those individuals who are attempting to suborn a drug test. There are many products marketed on the Internet and in highly publicized market-focused publications that offer different approaches to suborn drug tests. At this time, many products are focused on defeating the well-established, mature urine drug testing program. The Department believes as alternative specimens become increasingly used, attempts to suborn alternative specimen drug tests will increase. The Department also recognizes that validity testing proposed for alternative specimens is not as robust as for urine, but is confident that this testing will be refined over time.

In sections 3.12, 3.13, 3.14, and 3.15, the Department reiterates the criteria that a laboratory will use to report a urine specimen as adulterated and proposes the criteria that a laboratory will use to report a head hair, oral fluid, and sweat patch, respectively, as adulterated.

Section 3.16 describes the proposed requirements to report an oral fluid specimen as substituted. The Department also reiterates the current requirements with regard to a urine specimen being reported as substituted.

Section 3.18 reiterates the criteria to report a urine specimen as dilute.

Sections 3.19, 3.20, 3.21, and 3.22 reiterate the criteria that will be used to report a urine specimen as an invalid result and propose the criteria that will be used to report a head hair, oral fluid, and sweat patch, respectively, as an invalid result. The Department believes these proposed criteria for each type of specimen collected are appropriate to ensure that each specimen is a valid specimen.

#### **Subpart D—Collectors—Major Change**

In section 4.1, the Department is proposing to expand the requirements for donor confidentiality for collectors.

Section 4.2 describes what specific training requirements individuals are required to have before they may serve as a collector.

Section 4.3 proposes that another person, such as another employee of the organization or company responsible for providing collection site services, must provide the training for an individual to become a collector and specifies the qualifications for this individual to be a trainer.

In section 4.4, the Department proposes what an organization must do before it allows an individual to serve as a collector. The Department believes these proposed expanded requirements are necessary to ensure that a collector knows the entire collection procedure, how to interact with the donor, how to maintain chain of custody, how to complete the Federal CCF, and how to transfer the specimen for testing.

#### **Subpart E—Collection Sites**

The collection site requirements in this subpart are essentially the same as those described in the current Guidelines, with variations for specimen collection that would vary around privacy issues required for the collection of a urine specimen, that would not be required for head hair, oral fluid, or sweat specimens, based on the experience and input from participating industry-led working groups for each type of specimen.

In sections 5.5, 5.6, 5.7, and 5.8, the Department is proposing specific privacy requirements when collecting head hair, oral fluid, sweat patch, and urine specimens, respectively. The privacy requirements for urine are the same as those described in the current Guidelines.

For hair, the Department proposes that head hair is the only type of hair to collect for a hair sample. The Department believes this is appropriate because collecting hair only from the



head is the least invasive area to collect a hair sample and affords the donor the most privacy. If head hair is not available, the Department believes it is more appropriate to conduct a drug test using a different specimen rather than attempting to collect hair from another body site.

For sweat, the Department proposes that the sweat patch may only be applied to the donor's upper arm, or back. The primary site for a sweat patch is the upper arm; however, applying a patch to a donor's chest or back is reasonable if the donor prefers to use these alternative sites to conceal the fact that they are wearing a sweat patch.

For oral fluid, the Department proposes that the donor provide an oral fluid specimen directly into an appropriate container. This approach will ensure that a minimum amount of oral fluid is collected and can then be split for on-site testing or sent to a laboratory for both initial and confirmatory testing.

For each type of specimen collected, the collector and the donor are the only individuals present while the specimen is being collected, except when a direct observed collection is used to collect a urine specimen and the observer is present with the donor.

#### **Subpart F—Federal Drug Testing Custody and Control Forms**

The requirement to collect a Federal agency specimen using an OMB-approved form is the same as in the current Guidelines. An OMB-approved Federal CCF must be used for each type of specimen collected. The form for each type of specimen will be developed with the assistance of each industry working group and Federal agencies and approval will be requested from OMB and comment sought from the public prior to these Guidelines being implemented. The Department seeks comments on whether it would be preferable, and practical, to have a single Federal CCF that could be used for all the various specimens, rather than a multiplicity of forms. The Department also seeks comment on whether it would be useful to add a requirement that employees and others could not alter the Federal CCF in any way, e.g., could not write comments on it.

#### **Subpart G—Collection Device**

Section 7.1 describes what is considered to be the collection device that is used to collect each type of specimen.

In section 7.2, the Department describes the proposed policy on which devices may be used to collect a

specimen. If the FDA has cleared a collection device, it has been determined that the device does not affect the specimen collected. If the FDA has not cleared a collection device, the Federal agency must only use a collection device that does not affect the specimen collected. This requirement arises from incidents in the past where specimen containers themselves, or liners in the lids of specimen containers were found to absorb drugs present in a urine specimen. This means that the actual drug concentration in the specimen was reduced simply by its presence in that particular type of specimen container. Since the Department is proposing drug testing using alternative specimens and technologies, it is reasonable to believe that new and different specimen collection devices will be used to collect Federal employee drug test specimens. The Department requests specific comments on this requirement.

#### **Subpart H—Specimen Collection Procedure—Major Change**

In section 8.1, the Department is proposing to establish the basic requirements that would apply to collecting any type of specimen. This includes a requirement for the collector to provide identification to the donor if the donor asks, explain the basic collection procedures to the donor, request that the donor read the instructions on the back of the Federal CCF, and answer any reasonable and appropriate questions the donor may have regarding the collection procedure.

In sections 8.2, 8.3, 8.4, and 8.5, the Department is proposing the collection procedure to be used to collect each type of specimen. The collection procedure for urine is essentially the same as that described in the current Guidelines. The major change is that a split specimen collection would be required for all specimen collections, including urine.

In section 8.6, the Department is proposing to require that a Federal agency conduct an annual inspection of each collection site that is used for its workplace drug testing program. If several Federal agencies are using the same collection site, then only one Federal agency is required to conduct an inspection. The Department believes this requirement will ensure that collectors and collection sites satisfy all the collection requirements in these Guidelines for each type of specimen collected. For the Department to directly carry out this responsibility for a Federal agency, the Department would incur substantial financial and administrative costs. However, to the

extent that Federal agencies lack the clinical or technical expertise required to fulfill their requirements under this proposal, they are free to enter into Economy Act transfers with the Department.

#### **Subpart I—HHS Certification of Laboratories and IITFs—Major Change**

Section 9.1 reaffirms the goals and objectives of the certification program that are the same as those described in the current Guidelines.

Section 9.2 describes who has the authority to certify laboratories or IITFs to conduct testing for Federal agencies. This is the same policy as in the current Guidelines.

Section 9.3 describes the process that a laboratory or IITF must follow to become certified to conduct testing for a Federal agency. The Department believes that including a description of the certification process will be extremely helpful to those laboratories or IITFs that are interested in applying for certification. It is also important to understand that a laboratory or IITF needs to be certified for each sample type it wants to test (e.g., hair, oral fluid, sweat, urine) since the testing procedures are different for each.

Section 9.5 describes the specifications for the PT samples. The requirements in this section are the same as in the current Guidelines.

Sections 9.6, 9.7, 9.8, and 9.9 describe the proposed PT requirements for an applicant laboratory to conduct testing for each type of specimen. The performance testing requirements for the urine testing program are the same as those in the current Guidelines and the Department is proposing that similar requirements apply to the other types of specimens.

Sections 9.10, 9.11, 9.12, and 9.13 describe the proposed PT requirements that apply to a certified laboratory for each type of specimen. The PT requirements for the urine testing program are the same as those in the current Guidelines and the Department is proposing that similar requirements apply to the other types of specimens.

Sections 9.14, 9.15, 9.16, and 9.17 describe the proposed PT requirements for an applicant IITF to become certified for each type of specimen tested. The Department is including requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as to that portion of a laboratory which performs initial testing.

Sections 9.18, 9.19, 9.20, and 9.21 describe the proposed PT requirements

for an HHS-certified IITF to remain certified to test each type of specimen.

Section 9.22 describes the inspection requirements for an applicant laboratory or IITF to become certified. As noted above, the Department is including requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as to that portion of a laboratory which performs initial testing.

Section 9.23 describes the inspection requirements for an HHS-certified laboratory or IITF to remain certified. The Department proposes to change the requirement that a certified laboratory or IITF be inspected by a team of three inspectors to a requirement that a certified laboratory or IITF be inspected by at least one inspector. The number of inspectors used for maintenance inspections would vary depending on the size of the laboratory. The Department believes that one trained inspector may be sufficient to conduct a thorough inspection of extremely small laboratories.

In section 9.24, the Department is proposing the requirements for an individual to serve as an inspector for the HHS-certification program. The proposed requirements have been used for the past several years and are being incorporated into the Guidelines. An individual may serve as an inspector for the Secretary if he or she has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K for a laboratory, or as a responsible technician as described in subpart M, has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary, submits a resume and documentation of qualifications to HHS, attends approved training, and submits an acceptable inspection report and performs acceptably as a trainee inspector on an inspection.

Section 9.25 describes what happens when an applicant laboratory or IITF fails to satisfy the PT requirements or the inspection requirements. The consequences are the same as currently apply to laboratories in the current Guidelines.

Sections 9.27, 9.28, and 9.29 apply the same requirements that are in the current Guidelines regarding the factors used to revoke the certification of a laboratory or an IITF, directing a laboratory or IITF to immediately suspend testing, and the issuance of a

notice regarding these actions. It is possible for a laboratory or IITF to lose certification for one sample type while retaining certification to test another type. This is because the kinds of testing procedures used to test one type of sample can be very different from procedures and equipment used to test another sample type.

Section 9.31 restates the policy in the current Guidelines that a list of HHS-certified laboratories and IITFs will be published monthly in the **Federal Register**. The list will also indicate the types of specimens for which each laboratory or IITF is certified to test.

#### **Subpart J—Blind Samples Submitted by an Agency**

Section 10.1 continues to require the supplier of a blind sample to ensure that the contents have been validated and are stable until the expiration date. Additionally, the Department proposes that drug positive blind samples must have concentrations sufficiently above the cutoff concentrations used to give a positive result. This requirement ensures that sample degradation will not affect the blind sample and the laboratory will always report a positive result. The Department also proposes that blind samples for the urine testing program contain adulterants or satisfy substitution criteria to challenge a laboratory's capability to identify adulterated or substituted specimens. The specific requirement for urine specimens is based on the donor privacy issue associated with providing a urine specimen, where direct observation is not used, and the potential exists for an adulterant to be added to the collected specimen before it is turned over to the collector. There are no similar donor privacy issues associated with the collection of head hair, oral fluid, or sweat.

The Department seeks comment on whether the proposed reduction of the blind sample rate to one percent will be sufficient to achieve the objectives of sending blind samples to laboratories especially with respect to the newer specimens with which laboratories, collectors and others are less familiar at this time.

In section 10.2, the Department is proposing to reduce the 20 percent requirement for blind samples, for each type of specimen to be tested (*i.e.*, urine, head hair, oral fluid, or sweat) to 3 percent during the initial 90-day period of a new Federal agency program because the 20 percent requirement is excessive and redundant. Since the beginning of the urine testing program, there has never been any evidence to suggest that each Federal agency needs

to challenge each laboratory with 20 percent blind samples to determine if a laboratory is making either administrative or technical errors in the testing of specimens.

In section 10.3, the Department is proposing how a blind sample is to be submitted to a laboratory. This section provides more detail on how to complete the Federal CCF and ensure proper submission of the blind samples to the laboratory or IITF.

In section 10.4, the Department is proposing the procedure to be used to investigate errors associated with blind samples. This proposed procedure provides direction and detail on how to evaluate information on what led to an inconsistent result.

#### **Subpart K—Laboratory—Major Change**

This subpart has basically the same requirements that are contained in the current Guidelines with the following changes.

Section 11.4 describes a new policy for when the responsible person (RP) leaves a certified laboratory. As stated in the current Guidelines, the RP assumes professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facility. The Department believes it is essential to ensure that drug testing is routinely performed under the direction and supervision of an individual with such qualifications. In this section, the Department proposes requirements to ensure this takes place. Additionally, the Secretary will begin the process of suspension or revocation in accordance with the Guidelines if the RP leaves and no RP is approved within 180 days. This requirement is essential to protect the interests of the United States and its employees to ensure that an HHS-certified laboratory has an individual that can fully attest to the forensic and scientific supportability of the laboratory's testing program.

Section 11.9 requires that a laboratory must be HHS-certified separately for each type of specimen that it wants to test for a Federal agency. The separate certification is necessary because of the differences among urine, head hair, oral fluid, and sweat specimens in all phases of collection, testing, reporting and ongoing inspection and performance testing. An HHS certification for a laboratory performing urine tests would provide no quality assurance about that laboratory performing testing on other specimens.

In section 11.15, the Department proposes to allow the use of additional analytical procedures for the confirmatory drug tests. For some of the types of specimens, the confirmatory

drug tests may be performed by LC/MS, GC/MS/MS, and LC/MS/MS in addition to the GC/MS that has been traditionally used to test urine specimens. The Department believes these additional confirmatory methods are scientifically valid, based on on-going reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied these newer instruments and technologies. These additional confirmatory methods are the methods and instruments that have been identified by the industry-led working groups that must be used to successfully detect and report the cutoff concentrations proposed in subpart C.

In sections 11.18, 11.19, 11.20, and 11.21, the Department is proposing to use the same analytical and quality control requirements for conducting validity tests for each type of specimen collected. The Department has intentionally proposed to use the same requirements for each type of specimen based on the established requirements for a urine specimen; however, information may become available during the public comment period to suggest that the requirements for each type of specimen should be different.

In sections 11.22, 11.23, 11.24, and 11.25, the Department reiterates the specific analytical requirements to conduct each validity test for a urine specimen and proposes the specific analytical requirements to conduct each validity test for head hair, oral fluid, and sweat patch specimen collected. The Department believes these requirements will ensure that the validity test results reported by a laboratory are scientifically supportable.

Sections 11.26, 11.27, 11.28, and 11.29 describe in detail how a certified laboratory is required to report test results to MROs for each type of specimen collected. These sections include the details of urine specimen validity testing, and also propose that laboratories report drug and/or metabolite concentrations to the MROs on all specimens reported as positive. The Department understands that the data exist, and can be reported electronically as part of the normal workflow, and no longer pose a barrier or significant burden to laboratories. In fact, the Department believes that requiring MROs to request concentrations by exception would create an extra burden to the MRO and the laboratory, and slow the reporting of the final test result by the MRO to the Federal agency. The Department encourages public comment on the appropriateness of this proposed requirement.

In section 11.33, the Department has revised the summary report that a laboratory must provide to a Federal agency to include validity test results. Additionally, the frequency of the report has been significantly reduced from monthly to semiannually. The Department believes that a semiannual report is sufficient to track the effectiveness of an agency's program.

In section 11.34, the Department is proposing a more detailed description of what information a donor is entitled to receive upon request through the MRO and the Federal agency. The Department believes access to the proposed information is appropriate and sufficient.

Section 11.35 describes the information a certified laboratory must provide to its private sector clients when it is using procedures to test its specimens that are different than those used to test Federal agency specimens.

#### **Subpart L—Point of Collection Test (POCT)—Major Change**

Employees of Federal agencies are in some cases located in remote areas of the country if they are serving with the Department of Interior, or overseas if they are serving with the Department of State. They are often in locations with few employees as is often the case when they are serving on American Indian reservations or in embassies in small foreign countries. It is often unrealistic to expect that a drug testing program in such places would operate in the same fashion as one that serves employees in the Washington, DC, area. It is in these circumstances and in cases where it is critical to receive an immediate test result that POCT tests play an important role.

Yet a POCT offers a particular challenge to the Federal drug testing program because the device that is used to produce a negative test result is really equivalent to a laboratory test to which the normal laboratory procedures and requirements cannot readily apply. Thus, while the sections of the Guidelines related to specimens, collection procedures, collections sites, chain of custody, drug and validity testing and others do apply, it is necessary to establish requirements particular to POCTs. In addition, it presents logistical problems on how to ensure compliance with the requirements of these Guidelines and thus ensure the integrity of the program when any one agency choosing to use POCT may have many remote sites all over the United States and in many cases all over the world.

To address the logistical problem, the Department considered several options

including establishing a new organization to oversee compliance, to do inspections, and to maintain the PT requirements. As we did so, however, logistical challenges developed that could not be readily overcome.

Instead, the Department is adopting a principle that if a Federal agency chooses to use POCTs, then it accepts some of the same responsibilities for ensuring compliance within their agency as the Department currently maintains for the laboratory-based Federal drug testing program. The specifics of these requirements are addressed below.

Section 12.2 establishes criteria for the Secretary to certify a POCT for use in the Federal drug testing program. The device must be FDA-cleared for the purposes of detecting drugs of abuse and it must be determined by the Secretary that it effectively determines the presence or absence of drugs and the validity of a specimen, either as an integral function of the POCT device or as a set of compatible devices or procedures. The second standard is applied because FDA's premarket notification clearance process ensures that a device is substantially equivalent to a legally marketed device, but does not ensure that the device will satisfy minimum performance requirements that are necessary for its use in the Federal drug testing program.

Section 12.4 identifies the two types of POCTs currently available, both of which could be considered for Secretarial certification: non-instrumented devices where end results are determined visually or instrumented devices where results are obtained by instrumental evaluation.

Section 12.5 provides manufacturers a list of what they must provide the Secretary in order to have their device or devices included on the list of SAMHSA-certified devices. Among the requirements, the manufacturer must provide 100 POCT devices and related testing procedures so that the Secretary may analyze the devices for effectiveness when testing for drugs and specimen validity.

Section 12.7 indicates that to remain on the list of SAMHSA-certified devices, the manufacturer must agree to provide to the Secretary any design changes or alterations that have been made to the device so that the Secretary may determine if additional testing is necessary to ensure effectiveness and 50 POCTs as outlined so that the Secretary can ensure the continued quality of the device.

Section 12.8 is critical to the use of POCTs within the Federal drug testing program. This section lays out the

responsibilities of the Federal agency in order for it to use POCT.

If a Federal agency chooses to use POCT, then it must use only POCTs that are on the list of SAMHSA-certified devices, ensure that only trained testers are used and provide them with a standard operating procedures manual, ensure that the requirements of the regulation are fulfilled, accomplish the inspection of the POCT test sites, accomplish proficiency testing, maintain records on the trainers as well as inspections, investigate failures, make available all Federal agency records for the POCT-related activities for periodic inspection by the Secretary, and other responsibilities. For the Department to directly carry out this responsibility for the Federal agency, the Department would incur substantial administrative and financial costs. However, to the extent that Federal agencies lack the clinical or technical expertise required to fulfill their requirements under this proposal, they are free to enter into Economy Act transfers within the Department.

With regard to performance testing, the Federal agency will provide sets of HHS-contractor prepared PT samples periodically to the POCT testing sites to ensure reliability and integrity of the system. The results of the proficiency tests will be forwarded to the Federal agency. Where errors have occurred the Federal agency must act to investigate the cause of the error and determine whether it was an error in procedure or a failure of the device. If the error was a procedural one, the Federal agency must assess the reason for error and take corrective action to ensure compliance with the Guidelines in the future.

If the error is with the device, the Federal agency must immediately notify the Secretary who may suspend the use of the device within the agency. The Department, after considering the information, may suspend the use of the device throughout the Federal drug testing program by informing the agencies through the **Federal Register** and notifying the manufacturer of the problem. The manufacturer then has 30 days to provide information for the Secretary's consideration at which time the Secretary will decide what action needs to be taken. Additionally, the Secretary will notify the FDA of any error with a device so that the FDA can evaluate whether an action under the Food, Drug, and Cosmetic Act is necessary.

The Secretary is also authorized to remove a device from the list of SAMHSA-certified devices in the absence of a suspension. A manufacturer may resubmit the device

for approval but in so doing must provide a statement to the Secretary describing what has been done to address the problem that led to the device's removal.

To further ensure the integrity of the system, the Guidelines require that one of every 10 negative samples must be sent to an HHS-certified laboratory for confirmation. The results of this process will be given to the Federal agency.

To date, POCT tests have only been developed for oral fluid and urine. If, in the future, POCTs are developed for hair and/or sweat and the POCTs are cleared by the FDA, the Department will review the devices to evaluate, among other things, whether they use the cutoff identified by these Guidelines, what their performance is around that cutoff, and whether the observed lot to lot variability is appropriate for the program's needs. Section 12.11 identifies the responsibility of the Secretary to inspect a Federal agency using POCT. These responsibilities include, but are not limited to, conducting a semiannual inspection of each Federal agency that uses POCT. These inspections will include a review of the Federal agency's records, standard operating procedure manual, POCT tester training records, POCT device quarterly PT results, and POCT quality assurance data maintained by each POCT tester and site.

Section 12.16 presents the requirements that a POCT tester must meet. It should be kept in mind that the individual is not just a collector but in some capacity functions as a technician in so far as the individual must perform the POCT test, determine specimen validity, perform analysis on periodic PT challenges, interpret and document test results, and when required, forward the specimens with non-negative test results to an HHS-certified laboratory for confirmatory testing. Thus the training and experience requirements reflect this additional responsibility.

To ensure that the process is carried out appropriately the Department has in section 12.18 outlined how a POCT should be conducted step by step. These procedures should be part of the Federal agency standard operating procedure manual. Again the process pays special attention to the integrity of the test results and the specimen, chain of custody, collection procedures, recordkeeping, and reporting.

The Guidelines for a POCT mirror the provision in subparts K and M in that they discuss how a negative result should be reported as well as what must happen to a specimen with non-negative results. The Guidelines further discuss reporting requirements, what

information is available to the donor, and what type of relationship is prohibited between a manufacturer of a POCT device or a POCT site operation and a Medical Review Officer. Also, what type of relationship can exist between a manufacturer of a POCT device or a POCT site operation and an HHS-certified laboratory is discussed.

#### **Subpart M—Instrumented Initial Test Facility (IITF)—Major Change**

In this subpart, the Department proposes the requirements for a new type of facility. It is being called an instrumented initial test facility (IITF). An IITF is essentially a laboratory that only conducts initial tests for drugs and validity tests. The facility is at a permanent location and uses instrumented initial tests. An IITF must satisfy most of the same requirements as if it were the section of a laboratory that performs only initial drug and validity testing and was located in an HHS-certified laboratory. An IITF is certified under the same provisions as a laboratory as indicated above in subpart I. One significant difference is that the IITF is managed by a responsible technician (RT) whose qualifications are described in section 13.6, and differ slightly from those of a responsible person as required for laboratories.

An IITF may be certified to test head hair, oral fluid, sweat, and/or urine specimens as stated in section 13.2. It is also important to understand that an IITF needs to be certified for each sample type it wants to test (e.g., hair, oral fluid, sweat, urine), since the testing procedures are different for each.

An IITF must test specimens using the same drug cutoff concentrations as used for the initial tests conducted by the HHS-certified laboratories as stated in section 13.3. The Department is including these requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as that portion of laboratory.

Section 13.8 describes a new policy for when the responsible technician (RT) leaves a certified laboratory. The RT assumes professional, organizational, educational, and administrative responsibility for the IITF drug testing. The Department believes it is essential to ensure that drug testing is routinely performed under the direction and supervision of an individual with such qualifications. In this section, the Department proposes requirements to ensure this takes place. Additionally, the Secretary will begin the process of suspension or revocation in accordance with the Guidelines if the



RT leaves and no RT is approved within 180 days. This requirement is essential to protect the interests of the United States and its employees to ensure that an HHS-certified IITF has an individual that can fully attest to the forensic and scientific supportability of the IITF testing program.

The Department proposes in section 13.16 that an IITF be required to retain records for a period of 2 years, which is the same period required for laboratories.

The Department proposes in section 13.17 that an IITF submit a semiannual report on the numbers of specimens tested for Federal agencies, again the same requirement as for laboratories.

In section 13.18, the Department proposes what information would be available to a donor from an IITF, again the same requirement as for laboratories.

In sections 13.19 and 13.20, the Department proposes to prohibit and permit the same types of relationships between the IITF and the MRO as between the laboratory and the MRO.

The Department proposes in section 13.21 that an IITF report a negative result to an MRO within 3 working days of receipt of the specimen and that negative results may be reported electronically. Reporting a negative result electronically is the same requirement as for a specimen that is determined to be negative on an initial test conducted by a certified laboratory.

In section 13.22, the Department proposes how a specimen that is presumptive drug positive, adulterated, substituted, or invalid must be shipped to an HHS-certified laboratory for confirmatory testing.

#### **Subpart N—Medical Review Officer (MRO)—Major Change**

In Section 14.1, the Department establishes who may serve as an MRO, including the requirement that the individual successfully complete an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary. This section also establishes the requirements for nationally recognized entities that seek approval by the Secretary to certify MROs or for subspecialty boards for physicians performing a review of Federal employee drug test results to submit their qualifications and sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in

the **Federal Register** of those entities and boards that have been approved.

In section 14.2, the Department is proposing the specific training requirements before a physician may serve as an MRO for Federal agencies. This training should occur before the physician takes the required examination.

In section 14.3, the Department proposes that an individual who works under the direct supervision of an MRO may conduct the review and report of a negative result. However, the MRO must review 5 percent of the negative results reported by staff to ensure that the staff are properly performing the review process.

In sections 14.4, 14.5, 14.6, and 14.7, the Department proposes the procedure an MRO must follow to review the results reported for each type of specimen. For specimens reported as invalid by the laboratory, the Department proposes to allow the MRO to direct the agency to have another specimen collected. The Department requests comments on whether the same type of specimen or one of the other types of specimens should be collected when this occurs.

Section 14.8 describes how the donor may request the testing of a split specimen.

Section 14.9 describes how the MRO reports a primary specimen test result to a Federal agency.

Section 14.10 describes the relationship that is prohibited between an MRO and a laboratory, POCT tester, or IITF.

#### **Subpart O—Split Specimen Tests—Major Change**

Section 15.1 amends the current Guidelines by giving the donor the right to have a split specimen tested when a primary specimen was reported substituted or adulterated. This section also proposes to give a Federal agency the option to have a split specimen tested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result if a donor chooses not have the split specimen tested.

In section 15.2, the Department is proposing the policy on how a second laboratory tests each type of split specimen when the primary specimen was reported positive for a drug(s).

In sections 15.3, 15.4, 15.5, and 15.6, the Department is proposing the policies on how a second laboratory will test each type of split specimen when the primary specimen was reported adulterated. Similarly, sections 15.7 and 15.8 describe the proposed policies on how a second laboratory will test a split

oral fluid or urine specimen when the primary specimen was reported substituted. It should be noted that a head hair or sweat patch sample cannot be reported as substituted.

In sections 15.10, 15.11, 15.12, and 15.13, the Department is proposing the actions an MRO must take after receiving the split specimen result from the second laboratory for each type of specimen.

Section 15.14 describes how an MRO reports the split specimen result to a Federal agency. It is the same procedure that is used to report the result on the primary specimen.

In section 15.15, the Department proposes to require that the certified laboratory retain a split specimen for the same length of time that the primary specimen is retained.

#### **Subpart P—Criteria for Rejecting a Specimen for Testing—Major Change**

The Department proposes to include this subpart to describe how laboratories, IITFs, or MROs are to handle errors or discrepancies that arise with the use of the Federal CCF. They were not contained in the current Guidelines; however, most of the policies were previously established in guidance documents. The Department believes there is a need to establish specific guidance on how a laboratory, IITF, or MRO must handle discrepancies. Since the forms used to transfer the custody of a specimen from the collector to the POCT tester have not yet been developed, the Department cannot propose a specific list of possible errors or discrepancies that would need to be corrected and included in this section. The Department, however, fully expects to include this list when the final Guidelines are developed.

In section 16.1, the Department proposes those discrepancies that are considered to be fatal flaws, that is, the laboratory or IITF must not test a specimen when one of the fatal flaws occurs. The Department is specifically requesting comments on any additional fatal flaws that may apply to the collection of head hair, sweat, and oral fluid or fatal flaws that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

Section 16.2 identifies only two errors that the Department believes must be corrected (recovered) by obtaining a memorandum for record (MFR) from the collector before the laboratory or IITF can report a test result to the MRO. The Department is specifically requesting comments on any additional correctable errors that may apply to the collection of head hair, sweat, and oral fluid or



correctable errors that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

Section 16.3 describes the types of omissions and discrepancies that occasionally occur on the Federal CCF. When an omission or discrepancy occurs that is considered to be insignificant, the laboratory or IITF may proceed with testing the specimen and reporting a result without taking any action to recover or correct the error, omission, or discrepancy. Although each of these errors, omissions, or discrepancies are considered insignificant, the Department believes that requiring collectors to be trained and certified will significantly reduce the occurrence of such errors, omissions, or discrepancies. However, when a collector, laboratory, or IITF makes an error, omission, or discrepancy more than once a month, the Department is proposing that the MRO contacts the collector, laboratory, or IITF and directs the collector or laboratory to take immediate action to prevent the recurrence of the error, omission, or discrepancy. The Department is requesting specific comments on the proposal to have the MRO track these types of problems as well as identifying other insignificant omissions or discrepancies that have not been included for the Federal CCF. Public comments are requested for possible omissions or discrepancies that may occur when completing a Federal CCF to document collecting head hair, sweat, and oral fluid specimens or insignificant types of discrepancies that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

In section 16.4, the Department proposes to identify those discrepancies that must be corrected before an MRO can report a test to the Federal agency. If one of these errors occurs and it is not corrected by obtaining an MFR from the collector, IITF, or laboratory, the MRO is required to cancel the test. The Department is requesting specific comments on any other errors that must be corrected before the MRO can report a test result or discrepancies that may occur and must be corrected when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

#### **Subpart Q—Laboratory/IITF Suspension/Revocation Procedures**

In this subpart, the Department is retaining the procedures that were described in the current Guidelines to suspend or revoke the HHS-certification

of laboratories and simply expanding them to include IITFs.

#### **Electronic Technology Applications**

The Department is aware that there has been a great deal of discussion in recent years concerning the application of electronic technology to the operation of drug testing programs. Electronic signatures on documents, electronic storage and transmission of records, and appropriate security precautions for confidential information are all issues of substantial interest as applied to Federal testing programs. The Department seeks comment on the extent to which this discussion should be reflected in the new version of the guidelines, and on whether specific provisions concerning electronic technology applications to Federal drug testing programs should be included.

#### **Impact of These Guidelines on Government Regulated Industries**

The Department is well aware that these proposed changes to the Guidelines may impact the DOT and NRC regulated industries depending on their decisions to incorporate the final Guidelines into their programs under their own authorities.

#### **Issues of Special Interest**

The Department requests public comment on all aspects of this notice. However, the Department is providing the following list of issues or areas for which specific comments are requested.

In the preamble discussion on alternative specimen issues, there are conflicting studies that hair color affects the amount of drug deposited into the hair. In other words, some studies purport that a drug user with dark hair is more likely to test positive because a drug is more likely to be deposited in black hair as compared to blond hair while other studies refute these findings. The Department is requesting specific comments on this hair color bias issue as it applies to the testing of individuals in a workplace environment.

With regard to testing oral fluid specimens for marijuana, there is scientific evidence that the parent marijuana compound (THC) in oral fluid is not from plasma, but is residual THC present either from smoking a marijuana cigarette or from oral contamination. To ensure that a THC result on an oral fluid specimen is from active exposure, the Department is proposing to always collect a urine specimen with an oral fluid specimen that would be available if the oral fluid specimen was positive for THC. The Department is requesting comments on this proposed policy.

Again with regard to oral fluids, the preamble mentions a possibility of an individual having a "dry mouth." The Department would appreciate any comments on whether the Department should adopt a specific procedure for "dry mouth" as it has for "shy bladder" under urine.

With regard to proper cleansing of the skin prior to the application of a sweat patch, the Department is requesting comment on the proposal that the skin area be washed with soap and cool water or with a disposable towelette followed by a thorough cleaning of the skin area where the patches will be worn with alcohol wipes.

The Department defines in section 1.5 both "confirmatory validity test" and "confirmatory drug test." The confirmatory validity test means putting a different aliquot of the specimen through the same analytical method. A confirmatory drug test involves a second analytical procedure performed on a different aliquot. The Department requests comments on whether the utilization of these procedures is sufficient.

In section 2.2, the Department is proposing to limit the use of alternative specimens for only those reasons listed. The Department is requesting comments on the appropriateness of the reasons listed and supporting documentation if recommending changes.

In section 2.5, the Department requires that a sweat patch should be worn at least three days and no more than 7 days. While the Department believes that this is an adequate time period, the Department seeks comments and additional science on whether the permitted time period should be longer or shorter, and what time frame should be used in specific circumstances.

Sections 3.4, 3.5, 3.6, and 3.7 list the proposed cutoff concentrations for each type of specimen collected. The Department is specifically requesting comments on the appropriateness of these proposed cutoffs and the changes in the cutoffs for urine. Additionally, the Department is interested in obtaining information on the ability of the various immunoassay test kits to detect MDMA within the amphetamine class of drugs.

In section 7.2, the Department is requiring a Federal agency to only use a collection device that does not affect the specimen collected. The Department is requesting specific comments on this requirement.

In section 11.13, the Department establishes criteria for laboratories validating an initial drug test. These criteria are significantly different from those that are currently in the

Guidelines and thus the Department specifically seeks comments on this change.

In sections 11.18, 11.19, 11.20, and 11.21, the Department is proposing to use the same analytical and quality control requirements for conducting validity tests for each type of specimen collected. The Department is requesting specific comments on this proposed policy.

Sections 11.26, 11.27, 11.28, and 11.29 propose to allow a laboratory to report quantitative values for non-negative specimens rather than waiting for the MRO to request the information. The Department is requesting comments on this change in reporting test results.

In sections 14.4, 14.5, 14.6, and 14.7, the Department is proposing to allow the MRO to direct the agency to have another specimen collected when an invalid test result is reported. The Department is requesting comments on whether the same type of specimen or another type of specimen should be collected.

In sections 16.1, 16.2, and 16.3, the Department is requesting specific comments on any additional fatal flaws, correctable errors, omissions or discrepancies that may apply to the collection of head hair, sweat, and oral fluid or that may occur when the collector transfers a specimen to a point of collection test (POCT) tester. Additionally, the Department is requesting comments on the requirement that MROs track these types of problems.

In section 16.4, the Department is requesting specific comment on any other errors that must be corrected before an MRO can report a test.

#### References

- Nakahara Y. (1999). Hair analysis for abused and therapeutic drugs. *J Chromatogr B Biomed Sci Appl*, 733:161.
- Rollins D.E., Wilkins D.G., Krueger G.G., Augsburg M.P., Mizuno A., O'Neal C., Borges C.R., and Slawson M.H. (2003). The effect of hair color on the incorporation of cocaine into human hair. *J Anal Toxicol*, 27:545.
- Huestis M.A. and Cone E.J. (1998). Alternative Testing Matrices, in *Drug Abuse Handbook*, edited by S.B. Karch, CRC Press, Boca Raton, FL.
- Kidwell D.A. and Blank D.L. (1996). Environmental Exposure—The Stumbling Block of Hair Testing, in *Drug Testing in Hair*, edited by P. Kintz, CRC Press, Boca Raton, FL.
- Cone E.J. and Joseph R.E. (1996). The Potential for Bias in Hair Testing for Drugs of Abuse, in *Drug Testing in Hair*, edited by P. Kintz, CRC Press, Boca Raton, FL.
- Henderson G.L. (1993). Mechanisms of drug incorporation into hair. *Forensic Sci Int*, 63:19.
- Rollins D.E., Wilkins D.G., Gygi S.P., Slawson M.H., and Nagasawa P.R. (1997). Testing for drugs of abuse in hair—Experimental observations and indications for future research. *Forensic Sci Review*, 9:24.
- Reid R.W., O'Connor F.L., and Crayton J.W. (1994). The in vitro differential binding of benzoylecgonine to pigmented human hair samples. *J Toxicol Clin Toxicol*, 32:405.
- Henderson G.L., Harkley M.R., Zhou C., Jones R.T., and Jacob P. (1998). Incorporation of isotopically labeled cocaine into human hair: race as a factor. *J Anal Toxicol*, 22:156.
- Borges C.R., Wilkins D.G., and Rollins D.E. (2001). Amphetamine and N-acetylamphetamine incorporation into hair: an investigation of the potential role of drug basicity in hair color bias. *J Anal Toxicol*, 25:221.
- Hoffman B.H. (1999). Analysis of race effects on drug-test results. *J Occup Environ Med*, 41:612.
- Kelly R.C., Mieczkowski T., Sweeney S.A., and Bourland J.A. (2000). Hair analysis for drugs of abuse. Hair color and race differentials or systematic differences in drug preferences? *Forensic Sci Int*, 107:63.
- Mieczkowski T. and Newel R. (2000). Statistical examination of hair color as a potential biasing factor in hair analysis. *Forensic Sci Int*, 107:13.
- Slawson M.H., Wilkins D.G., and Rollins D.E. (1998). The incorporation of drug into hair: relationship of hair color and melanin concentration to phencyclidine incorporation. *J Anal Toxicol*, 22:406.
- Uhl M. (1997). Determination of drugs in hair using GC/MS/MS. *Forensic Sci Int*, 84:281.
- Pichini S., Pacifici R., Altieri I., Pellegrini M., and Zuccaro P. (1999). Determination of opiates and cocaine in hair as trimethylsilyl derivatives using gas chromatography—tandem mass spectrometry. *J Anal Toxicol*, 23:343.
- Cone E.J. (2001). Legal, workplace, and treatment drug testing with alternative biological matrices on a global scale. *Forensic Sci Int*, 121:7.
- Yacoubian G.S., Wish E.D., and Perez D.M. (2001). A comparison of saliva testing to urinalysis in an arrestee population. *J of Psychoactive Drugs*, 33:289.
- Wish E.D. and Yacoubian G.S. (2002). A comparison of the Intercept® oral specimen collection device to laboratory urinalysis among Baltimore city arrestees. *Federal Probation*, 66:27.
- Caplan Y.H. and Goldberger B.A. (2001). Alternative specimens for workplace drug testing. *J Anal Toxicol*, 25:396.
- Cone E.J., Presley L., Lehrer M., Seiter W., Smith M., Kardos K.W., Fritch D., Salamone S., Niedbala R.S. (2002). Oral fluid testing for drugs of abuse: positive prevalence rates by Intercept™ immunoassay screening and GC-MS-MS confirmation and suggested cutoff concentrations. *J Anal Toxicol*, 26:541.
- Kidwell D.A., Holland J.C., and Athanaselis S. (1998). Testing for drugs of abuse in saliva and sweat. *J Chromatogr*, 713:111.
- Barnes A.J., Kim I., Schepers R., Moolchan E.T., Wilson L., Cooper G., Reid C., Hand C., and Huestis M.A. (2003). Sensitivity, specificity, and efficiency in detecting opiates in oral fluid with the Cozart® Opiate Microplate EIA and GC-MS following controlled cocaine administration. *J Anal Toxicol*, 27:402.
- Kim I., Barnes A.J., Schepers R., Moolchan E.T., Wilson L., Cooper G., Reid C., Hand C., Huestis M.A. (2003). Sensitivity and specificity of the Cozart microplate EIA cocaine oral fluid at proposed screening and confirmation cutoffs. *Clin Chem*, 49:9.
- Dams R., Huestis M.A., Lambert W.E., and Murphy C.M. (2003). Matrix effect in bioanalysis of illicit drugs with LC-MS/MS: influence of ionization type, sample preparation and biofluid. *J Am Soc Mass Spectrom*, 14:1290.
- Niedbala R.S., Kardos K.W., Fritch D.F., Kardos S., Fries T., and Waga J. (2001). Detection of marijuana use by oral fluid and urine analysis following single-dose administration of smoked and oral marijuana. *J Anal Toxicol*, 25:289.
- Cone E.J. (1997). New Developments in Biological Measures of Drug Prevalence. In: L. Harrison and A. Hughes (Eds.) *The Validity of Self-Reporting Drug Use: Improving the Accuracy of Survey Estimates*. NIDA Res Monogr 167:108.
- Schramm W., Smith R.H., Craig P.A., and Kidwell D.A. (1992). Drugs of abuse in saliva: a review. *J Anal Toxicol*, 16:1.
- Hödl K.M., de Boer, D., Zuidema, J., and Maes. R.A.A. (1995). Saliva as an analytical tool in toxicology. *Int J Drug Testing*, 1:1.
- Jenkins A.J., Oyler J.M., and Cone E.J. (1995). Comparison of heroin and cocaine concentrations in saliva with concentrations in blood and plasma. *J Anal Toxicol*, 19:359.
- Hawks R.L. (1982). The constituents of cannabis and the disposition and metabolism of cannabinoids. In Hawks R.L. (Ed): *The Analysis of Cannabinoids in Biological Fluids*, NIDA Research Monograph Series 42; U.S. Government Printing Office; Washington, DC; p. 125.
- Samyn N., Verstraete A., van Haeren C., and Kintz P. (1999). Analysis of drugs of abuse in saliva. *Forensic Sci Rev*, 11:1.
- Mucklow J.C., Bending M.R., Kahn G.C., Dollery C.T. (1978). Drug concentration in saliva. *Clin Pharmacol Ther*, 5:563.
- Cone E.J. (1993). Saliva testing for drugs of abuse. *Ann NY Acad Sci*, 694:91.
- Wolff F., Farrell M., Marsden J., Monteiro M.G., Ali R., Welch S., and Strang J. (1999). A review of biological indicators of illicit drug use, practical considerations and clinical usefulness. *Addiction*, 94:1279.
- Skopp G. and Pötsch L. (1999). Perspiration versus saliva—basic aspects concerning their use in roadside drug testing. *Int J Legal Med*, 112:213.
- Cone E.J. and Preston K.L. (1999). Drug testing in support of drug-abuse treatment programs. *AACC Therapeutic Drug Monitoring And Toxicology Education Article* 175:184.
- Crouch D.J., Cook R.F., Trudeau J.V., Dove D.C., Robinson J.J., Webster H.L., and Fatah A.A. (2001). The detection of drugs of abuse in liquid perspiration. *Technical Note, J Anal Toxicol*, 1:625.
- Kidwell D.A., Kidwell J.D., Shinohara F., Harper C., Roarty K., Bernadt K.,

- McCaulley R.A., and Smith F.P. (2003). Comparison of daily urine, sweat, and skin swabs among cocaine users. *Forensic Sci Int*, 133:63.
40. Kintz P., Brenneisen R., Brundeli P., and Mangin P. (1997). Sweat testing for heroin and metabolites in a heroin maintenance program. *Cl Chem*, 43:736.
41. Levitsky J.A., Bowerman D.L., Jenkins W.W., Johnson D.G., Levitsky J.S., and Karch S.B. (2001). Comparison of urine to sweat patch results in court ordered testing. *Forensic Sci Int*, 122:65.
42. Skopp G., Potsch L., Eser H.P., and Moller M.R. (1996). Preliminary practical findings on drug monitoring by a transcutaneous collection device. *J Forensic Sci*, 41:933.
43. Huestis M.A., Cone E.J., Wong C.J., Umbricht A., and Preston K.L. (2000). Monitoring opiate use in substance abuse treatment patients with sweat and urine drug testing. *J Anal Toxicol*, 24:509.
44. Warren M., Fortner N., Fogerson R., and Sutliff J. (1996). Detection of cocaine and its metabolites using the PharmChek™ sweat patch. Presentation Society of Forensic Toxicologists.
45. Fogerson R., Schoendorfer D., Fay J., and Spiehler V. (1997). Qualitative detection of opiates in sweat by EIA and GC-MS. *J Anal Toxicol*, 21:451.
46. Spiehler V., Fay J., Fogerson R., Schoendorfer D., and Niedbala R.S. (1996). Enzyme immunoassay validation for qualitative detection of cocaine in sweat. *Cl Chem*, 42:34.
47. Preston L.P., Huestis M.A., Wong C.J., Umbricht A., and Goldberger B.A. (1999). Monitoring cocaine use in substance-abuse-treatment patients with sweat and urine testing. *J Anal Toxicol*, 23:313.
48. Suzuki S., Inoue T., Hori H., and Inayama S. (1989). Analysis of methamphetamine in hair, nail, sweat, and saliva by mass fragmentography. *J Anal Toxicol*, 13:176.
49. Kintz P., Tracqui A., Mangin P., and Edel Y. (1996). Sweat testing in opioid users with a sweat patch. *J Anal Toxicol*, 20:393.
50. Fay J., Fogerson R., Schoendorfer D., Niedbala R.S., and Spiehler V. (1996). Detection of methamphetamine in sweat by EIA and GC-MS. *J Anal Toxicol*, 20:398.
51. Kintz P., Cirimele V., and Ludes B. (2000). Detection of cannabis in oral fluid (saliva) and forehead wipes (sweat) from impaired drivers. *J Anal Toxicol*, 24:557.
52. Fogerson R. and Sutliff J. (1995). Testing for cocaine and opiate use with the PharmChek™ Sweat Patch. presentation Society of Forensic Toxicologists.
53. Sampyn N., DeBoeck G., and Verstrate A.G. (2002). The use of oral fluid and sweat wipes for the detection of drugs of abuse in drivers. *J Forensic Sci*, 47:1380.
54. Samyn N., De Boeck G., Wood M., Lamaaras C.T.J., DeWaard S., Brookhuis K.A., Verstraete A.G., and Riedel W.J. (2002). Plasma, oral fluid and sweat wipe ecstasy concentrations in controlled and real life conditions. *Forensic Sci Int*, 128:90.
55. Crouch D.J., Hersch R.K., Cook R.F., Frank J.F., and Walsh J.M. (2002). A field evaluation of five on-site drug-testing devices. *J Anal Toxicol*, 26:493.
56. Kadehjian L.J. (2001). Performance of five non-instrumented urine drug-testing devices with challenging near-cutoff specimens. *J Anal Toxicol*, 25:670.
57. Peace M.R., Tarnai L.D., Poklis A. (2002). Performance evaluation of four on-site drug-testing devices for detection of drugs of abuse in urine. *J Anal Toxicol*, 24:589.
58. SAMHSA study entitled "On-site Testing: An Evaluation of Non-Instrumented Drug Test Devices," dated January 29, 1999, available on the Internet at <http://www.workplace.samhsa.gov/ResourceCenter/r409.htm>.
59. Walsh J.M., Flegel R., Crouch D.J., Cangianelli L., Baudys J. (2003). An evaluation of rapid point-of-collection oral fluid drug-testing devices. *J Anal Toxicol*, 27:429.
60. Peace M.R. and Tarnai L.D. (2002). Performance evaluation of three on-site adulterant detection devices for urine specimens. *J Anal Toxicol*, 26:464.
61. Wong B., Nguyen P., Wong R., and Tse H. (2002). Adulterants: Its detection and effects on urine drug screens. Abstract: Society of Forensic Toxicologists 2002 Meeting.
62. Wong R. (2002). The effect of adulterants on urine screen for drugs of abuse: Detection by an on-site dipstick device. *Am Clin Lab*, 21:37.
63. Report entitled "2002 National Survey on Drug Use and Health (National Household Survey on Drug Abuse)," available on the Internet at <http://www.samhsa.gov/oas/nhsda.htm>.
64. Report entitled "Emergency Department Trends From DAWN: Final Estimates 1995-2002," available on the Internet at <http://dawninfo.samhsa.gov>.
65. Report entitled "Year 2002 Annual Report National Forensic Laboratory Information System (NFLIS)."
66. Bruins M.R., Okano C.K., Lyons T.P., and Lukey B.J. (2002). Drug-positive rates for the army from fiscal years 1991 to 2000 and for the National Guard from fiscal years 1997 to 2000. *Mil Med*, 167:379.
67. Jones R.T. (1997). Pharmacokinetics of cocaine considerations when assessing cocaine use by urinalysis. NIDA Research Monograph, 175:221.
68. Wingert W.W. (1997). Lowering cutoffs for initial and confirmation testing for cocaine and marijuana: large scale study of effects on the rates of drug-positive results. *Clin Chem*, 43:100.
69. Cone E.J., Sampson-Cone A.H., Darwin W.D., Huestis M.A., and Oyler J.M. (2003). Urine testing for cocaine abuse: Metabolic and excretion patterns following different routes of administration and methods for detection of false negative results. *J Anal Toxicol*, 27:386.
70. Oyler J.M., Cone E.J., Joseph R.E. Jr, Moolchan E.T., and Huestis M.A. (2002). Duration of detectable methamphetamine and amphetamine excretion in urine after controlled oral administration of methamphetamine to humans. *Clin Chem*, 48:1703.
71. Cone A.J., Yousefnejad D., Hillsgrove M.J., Holicky B., and Darwin W.D. (1995). Passive inhalation of cocaine. *J Anal Toxicol*, 19:399.
72. Fay J.F., and Niedbala, S. (1995). Sweat eluate analysis for phencyclidine by STC Diagnostics PCP Micro-Plate EIA and GC/MS. Presentation Society of Forensic Toxicologists.

### Executive Order 12866: Economic Impact

In accordance with Executive Order 12866, the agency has submitted the Guidelines for review by the Office of Management and Budget. However, because the Mandatory Guidelines will not have an annual impact of \$100 million or more, and will not have a material adverse effect on the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, they are not subject to the detailed analysis requirements of section 6(a)(3)(C) of Executive Order 12866.

### Paperwork Reduction Act of 1995

These proposed revised Mandatory Guidelines contain information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Title:** Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

**Description:** The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100-71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine testing are approved under OMB control number 0930-0158. Since 1988 several products have appeared on the market making it easier for individuals to adulterate the urine sample. The proposed changes to the Guidelines address this concern. Also, scientific advances in the use of head hair, sweat,

and oral fluid in detecting drugs have made it possible for these specimens to be used in Federal programs with the same level of confidence that has been applied to the use of urine. The proposed changes establish when these alternative specimens may be used, the procedures that must be used in collecting a sample, and the certification process for approving a laboratory to test these alternative specimens.

In an effort to shorten the time for negative results to be reported to the Federal agency, the proposed changes also establish criteria for an IITF that will only perform initial tests and not confirmatory tests, and POCTs or on-site testing kits, as well as POCT testers.

*Description of Respondents:* Individuals or households; Businesses or other for-profit; Not-for-profit institutions.

*The burden estimates in the tables below are based on the following number of respondents:* 38,000 donors who apply for employment in testing designated positions, 100 collectors, 50 urine testing laboratories, 10 hair testing laboratories, 10 oral fluid testing laboratories, 2 sweat testing laboratories, 25 IITFs, 30 POCT manufacturers, 50 POCT testers, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/re-sponse	Total hours
9.3(c), 9.4(a) and (b)	Laboratory or IITF 9.4(a) and (b) required to submit application for certification .....	50	1	3	150
9.24(b)(3)	Materials to submit to become an HHS inspector .....	200	1	2	400
11.4(a)	Laboratory submits qualifications of alternate RP to HHS .....	50	.1	2	100
11.4(d)	Laboratory submit information to HHS on new RP .....	25	1	2	50
11.32(a)	Specifications for laboratory semi-annual statistical report of test results to each Federal agency .....	72	5	0.5	180
12.5	Specifies what a POCT manufacturer must submit to HHS to be approved .....	30	1	1	30
12.7(a)	Specifies what a POCT manufacturer must submit to HHS to remain on approved list .....	30	1	0.5	15
12.14(b)	Requirements for POCT manufacturer statement of action to overcome problems that cause a device to be removed from the approved list .....	1	1	3	3
13.8(a)	Information an IITF must submit to HHS for an RT .....	25	1	2	50
13.8(d)	Information an IITF must submit to HHS for a new RT candidate .....	25	1	2	50
13.17(a)	Specifies contents of IITF semi-annual statistical report to Federal agencies served .....	25	5	0.5	63
13.22(d)	Specifies how IITF reports test results for specimen that is presumptive drug positive, adulterated, substituted or invalid .....	25	100	0.05 (3 min)	125
15.14	Specifies that MRO must report all verified split specimen test results to the Federal agency .....	100	5	0.05 (3 min)	25
17.1(b); 17.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification .....	1	1	3	3
17.4	Specifies information appellant provides in first written submission when laboratory or IITF suspension/revocation is proposed .....	1	1	0.5	0.5
17.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period .....	1	1	0.5	0.5
17.7(a)	Specifies contents of appellant submission for review .....	1	1	50	50
17.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation .....	1	1	3	3
17.9(c)	Specifies contents of review file and briefs .....	1	1	50	50
Total	.....	456	.....	.....	1,358

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or appearance on the Federal CCF (sections

8.5(a)(8) and (14)); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); and MRO notifies the Federal agency and HHS when an error occurs on a blind sample (section 10.4(c)). SAMHSA has not

calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/re-sponse	Total hours
4.4(c)	Collector is given name and phone of Federal agency point of contact .....	100	1	0.05 (3 min)	5
11.33(b)	Information on drug test that laboratory must provide to donor through MRO .....	50	10	3	1,500

## ESTIMATE OF ANNUAL DISCLOSURE BURDEN—Continued

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
12.24	Information related to drug test that POCT tester must provide to donor through MRO .....	50	10	1	500
13.18	Information related to drug test that IITF must provide to donor through MRO .....	25	10	2	500
14.8(b)	MRO must inform donor of right to request split specimen test when non-negative result is reported .....	100	5	3	1,500
Total	.....	325	.....	.....	4,005

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (section 8.1(b) and (d)); and a laboratory must tell private sector clients when the

laboratory is not testing their specimen under the Guidelines (section 11.35). SAMHSA believes having the collector explain the collection procedure to the donor and to answer any questions is a standard business practice and not a disclosure burden. With regard to requiring a laboratory to inform a private sector client that its specimens

are not being tested under the Guidelines, this is also a standard business practice and not considered an additional burden because it ensures that a private sector client is not being misled into believing that its specimens are being tested under the Guidelines.

## ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
8.2–8.5	Collector completes Federal CCF for each type of specimen collected .....	100	380	0.07 (4 min)	2,660
11.8(a)	Laboratory completes Federal CCF upon receipt of specimen and before reporting result .....	50	760	0.05 (3 min)	1,900
12.18(c)	POCT tester completes Federal CCF for primary specimen and documents chain of custody .....	50	100	0.05 (3 min)	250
13.12(a)	IITF completes Federal CCF upon receipt of specimen and before reporting result .....	25	1520	0.05 (3 min)	1,900
14.3(a)(4)	MRO completes the Federal CCF before reporting the result .....	100	380	0.05 (3 min)	1,900
15.1(b)	Donor must request the split to be tested in writing .....	300	1	0.05 (3 min)	15
Total	.....	625	.....	.....	8,625

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (section 4.3(a)) and that the documentation be maintained in the collector's training file (section 4.4(b)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (sections 8.5(a)(8) and (14)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection

procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K and M describe a number of recordkeeping requirements for laboratories and instrumented initial test facilities (IITFs) associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.*, sections 11.1(a), 11.1(d), 11.2(b), 11.2(c), 11.2(d), 11.7(c), 11.8(b), 11.8(c), 11.8(e), 11.13(b), 11.14(c), 11.16, 11.17(c), 11.17(d), 11.31(a), 13.4(a), 13.4(d), 13.5, 13.7(b), 13.7(c), 13.7(d), 13.10(c), 13.11(c), 13.12(b), 13.12(c), 13.12(e), 13.13, and 13.16(a)). These recordkeeping requirements are necessary for any laboratory or IITF to conduct forensic drug testing and to ensure the scientific

supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis. This same opinion applies to the recordkeeping requirements for POCT testers in section 12.23, for IITFs in section 13.16(a), and for MROs in section 14.3(a)(5).

Thus the total annual response burden associated with the testing of these alternative specimens by the new laboratories and Instrumented Initial Test Facilities (IITFs) and Point of Collection Test sites is estimated to be 13,888 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,089 hours currently approved by OMB under control number 0930-0158 for urine testing under the existing Mandatory Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed revised Mandatory Guidelines to OMB for its review.



Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the *Federal Register*. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB. (address above).

**Charles G. Curie,**  
Administrator, SAMHSA.

Dated: April 2, 2004.

**Tommy G. Thompson,**  
Secretary.

For the reasons set forth in the preamble, the Department proposes to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to read as follows:

### **Mandatory Guidelines for Federal Workplace Drug Testing Programs**

#### **Subpart A—Applicability**

Sec.

- 1.1 Whom do these Guidelines cover?
- 1.2 Who is responsible for developing and implementing these Guidelines?
- 1.3 How does a Federal agency request a change from these Guidelines?
- 1.4 How are these Guidelines revised?
- 1.5 What do the terms used in these Guidelines mean?
- 1.6 What is an agency required to do to protect employee records?

#### **Subpart B—Specimens**

- 2.1 What types of specimens may be collected?
- 2.2 Under what circumstances can the different types of specimens be

collected?

- 2.3 Can more than one type of specimen be collected at the same time from the same donor?
- 2.4 How is each type of specimen to be collected?
- 2.5 What is the minimum quantity of specimen to be collected?

#### **Subpart C—Drug and Validity Tests**

- 3.1 Which tests must be performed on a specimen?
- 3.2 Can a specimen be tested for additional drugs?
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- 15.13 What action(s) does the MRO take after receiving the split urine specimen result from the second laboratory?
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- 16.2 What discrepancies require an HHS-certified laboratory or IITF to report a hair, oral fluid, sweat, or urine specimen as rejected for testing unless the discrepancy is corrected?
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**Authority:** E.O. 12564 and sec. 503 of Pub. L. 110-71.

**Subpart A—Applicability**

*Section 1.1 Whom Do These Guidelines Cover?*

- (a) These Guidelines apply to:
  - (1) Executive Agencies as defined in 5 U.S.C. 105;
  - (2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));
  - (3) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and
  - (4) The Intelligence Community, as defined by E.O. 12333, are subject to these Guidelines only to the extent agreed to by the head of the affected Agency; and
  - (5) Laboratories, instrumented initial test facilities, and point of collection tests that provide drug testing services to the Federal agencies.
- (b) The Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.<sup>1</sup>

<sup>1</sup> Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services

### Section 1.2 Who Is Responsible For Developing and Implementing These Guidelines?

(a) Executive Order 12564 and Public Law 100-71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for Federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

### Section 1.3 How Does a Federal Agency Request a Change From These Guidelines?

(a) Each Federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a Federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

### Section 1.4 How Are These Guidelines Revised?

(a) In order to ensure the full reliability and accuracy of drug and validity tests, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) The changes will be published in final as a notice in the **Federal Register**.

### Section 1.5 What Do the Terms Used in These Guidelines Mean?

The following definitions are adopted:

**Accessioner.** The individual who receives the specimens at the laboratory or IITF and signs the Federal drug testing custody and control form.

**Aliquot.** A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

**Adulterated.** A specimen containing either a substance that is not a normal constituent for that type of specimen or containing an endogenous substance at a concentration that is not a normal physiological concentration.

**Batch.** A number of specimens that are being handled and tested as a group.

**Calibrator.** A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

**Canceled Test.** The MRO determines that the result reported by the laboratory cannot support reporting either a positive or a negative test to the employer.

**Certifying Scientist (CS).** The individual responsible for verifying the chain of custody and scientific reliability of a non-negative or invalid test result.

**Certifying Technician (CT).** The individual responsible for verifying the chain of custody and scientific reliability of a negative test result.

**Chain of Custody (COC).** Procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from point of specimen collection to final disposition of the specimen and its aliquots.

**Chain of Custody Document.** A document used by a laboratory to maintain the security of the specimen and all aliquots of a specimen during testing and storage. The document, which may account for an entire test batch, must include the names and signatures of all individuals who handled the specimen or aliquots and the date and purpose of the access.

**Collection Site.** A place where donors present themselves for the purpose of providing a specimen.

**Collector.** A person who instructs and assists donors at a collection site and receives the specimen provided by the donor.

**Confirmatory Drug Test.** A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

**Confirmatory Validity Test.** A second test performed on a different aliquot of the original specimen to further support a validity test result.

**Control.** A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

**Cutoff.** The concentration used to establish and report a specimen as negative or positive.

**Dilute Specimen.** Refers to a specimen with less than normal physiological constituents.

**Donor.** The individual from whom a specimen is collected.

**Failed to Reconfirm.** The result reported when a laboratory is unable to corroborate the original result (*i.e.*, positive, adulterated, substituted) reported to the medical review officer.

**Federal Drug Testing Custody and Control Form (Federal CCF).** The Office of Management and Budget (OMB) approved form that is used to document the collection, custody, and transport of a specimen from the time the specimen is collected until it is received by the testing site (*i.e.*, certified laboratory, instrumented initial test facility). The form may also be used to report the test result to the Medical Review Officer.

**Follow-up Test.** A specimen collected from a donor to ensure that the donor remains drug-free after being reinstated to a testing designated position.

**HHS.** The Department of Health and Human Services.

**Initial Drug Test.** The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

**Initial Validity Test.** The first test used to determine if a specimen is adulterated, diluted, or substituted.

**Instrumented Initial Test Facility (IITF).** A location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

**Invalid Result.** The result reported when a scientifically supportable analytical test result cannot be established for a specimen.

**Laboratory.** A location where initial and confirmatory testing is performed under the supervision of an RP and where CSs perform the final review and release of test results.

**Medical Review Officer (MRO).** A licensed physician who reviews, verifies, and reports a specimen test result to the agency.

**Negative Result.** The result reported by an HHS-certified laboratory, IITF, or POCT tester to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class.

**Non-Negative Result.** The result reported by an HHS-certified laboratory when a specimen is either adulterated, substituted, or contains a drug or drug metabolite at or above the established cutoff concentration.

**Oxidizing Adulterant.** A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test. Examples of

scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines \* \* \* See, *e.g.*, 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR 40.81, and incorporates the scientific and technical aspects of the guidelines in its regulations. The DOT regulated industry should refer to the DOT regulations at 49 CFR part 40.

these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine, halogens, peroxidase, and peroxide.

**Performance Testing (PT) Sample.** A sample sent to a testing facility that is used to evaluate the performance of a facility's test procedure.

**Point of Collection Test (POCT).** A drug or validity test conducted at a collection site to obtain a preliminary result as to whether a specimen may contain a drug/drug metabolite or is not a valid specimen.

**POCT Site.** A collection site where a point of collection test is conducted.

**Positive Result.** The result reported by a laboratory when a specimen contains a drug or drug metabolite greater than or equal to the cutoff concentration.

**Post-accident Test.** A specimen collected from a donor after the donor is involved in a job-related accident.

**Pre-employment Test.** A specimen collected from a donor who is applying for a testing designated position.

**Quality Control (QC) Sample.** A calibrator, control, or negative sample. These samples are collectively referred to as "quality control samples" and each as a "sample."

**Random Test.** A specimen collected from a donor who is selected at random from a group of individuals who are included in a workplace drug testing program.

**Reasonable Suspicion/Cause Test.** A specimen collected from a donor when there is sufficient evidence to indicate that the donor may have used an illicit substance.

**Reconfirmed.** The result reported when a laboratory is able to corroborate the original result (*i.e.*, positive, adulterated, substituted) reported to the Medical Review Officer.

**Rejected for Testing.** The result reported by a laboratory or test facility when it does not perform any tests on the specimen because of a fatal flaw or an unrecovered correctable error.

**Responsible Person (RP).** The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

**Responsible Technician (RT).** The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified instrumented initial test facility.

**Return to Duty Test.** A specimen collected from a donor to ensure that the donor is drug free prior to being reinstated in a testing designated position.

**Sample.** A representative portion of a specimen or quality control material used for testing.

**Secretary.** The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

**Specimen.** Fluid or material derived from the body which may be subdivided, concurrently collected, or two specimens collected almost simultaneously if a split specimen is required.

**Split Specimen.** A specimen collected at the collection site that is fluid or material derived from the body which has been subdivided or concurrently collected and independently sealed in the presence of the donor. For urine, one void that is subdivided. For hair, one harvest that is subdivided by strands. For oral fluid, one specimen collected that is subdivided or two specimens collected almost simultaneously. For sweat, two separate patches that are applied and removed simultaneously.

**Standard.** Reference material of known purity or a solution containing a reference material at a known concentration.

**Substituted.** A specimen that could not have been derived from the donor's body at the time of collection because it is inconsistent with normal physiology.

#### Section 1.6 What Is an Agency Required To Do To Protect Employee Records?

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all agency contracts with laboratories, IITFs, POCT testers, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 522a. In addition, the contracts must require compliance with employee access and confidentiality provisions of section 503 of Public Law 100–71. The agency must establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

#### Subpart B—Specimens

##### Section 2.1 What Types of Specimens May Be Collected?

A Federal agency may collect head hair, oral fluid (saliva), sweat (patch), or urine for its workplace drug-testing program in keeping with section 2.2.

##### Section 2.2 Under What Circumstances Can the Different Types of Specimens Be Collected?

Type of specimen	Reason for test
Hair .....	Pre-employment, random, return to duty, follow-up
Oral Fluid .....	Pre-employment, random, reasonable suspicion/cause, post-accident
Sweat (patch)	Return to duty, follow-up
Urine .....	Pre-employment, random, reasonable suspicion/cause, post-accident, return to duty, follow-up

##### Section 2.3 Can More Than One Type of Specimen Be Collected at the Same Time From the Same Donor?

Yes, more than one type of specimen may be collected at the same time from the donor, but only in the following circumstances:

(a) When an oral fluid specimen is collected, a urine specimen must also be collected; or

(b) If a problem occurs during the collection of one type of specimen (*e.g.*, shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen.

##### Section 2.4 How Is Each Type of Specimen To Be Collected?

Each type of specimen is to be collected as a split specimen as described in section 2.5.

##### Section 2.5 What Is the Minimum Quantity of Specimen To Be Collected for Each Type of Specimen?

(a) Hair: 100 mg head hair (divided as follows: 2 samples with approximately 50 mg per sample)

(b) Oral Fluid: 2 mL collected as a "neat specimen" (divided as follows: at least 1.5 mL for the primary specimen and at least 0.5 mL for the split specimen)

(c) Sweat: 2 FDA-cleared patches worn up to 7 days

(d) Urine: 45 mL (divided as follows: at least 30 mL for the primary specimen and at least 15 mL for the split specimen)

#### Subpart C—Drug and Validity Tests

##### Section 3.1 Which Tests Must Be Performed on a Specimen?

(a) Federal agency applicant and random drug testing programs must at a minimum test for marijuana and cocaine;

(b) Federal agency applicant and random drug testing programs are also



authorized to test for opiates, amphetamines, and phencyclidine; and

(c) Each specimen must be tested to determine if it is a valid specimen.

**Section 3.2 Can a Specimen Be Tested for Additional Drugs?**

(a) Any specimen collected from a donor that is suspected to contain a Schedule I or II drug of the Controlled Substances Act (other than the drugs listed in section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law) may be tested for that drug on a case-by-case basis. The Federal agency must request the HHS-certified laboratory to test for that additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

**Section 3.3 May Any of the Specimens Be Used for Other Purposes?**

(a) Federal agency specimens collected pursuant to Executive Order 12564, Public Law 100-71, and these Guidelines must only be tested for drugs and to determine their validity unless otherwise authorized by law.

(b) These Guidelines are not intended to prohibit any Federal agency specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

**Section 3.4 What Are the Cutoff Concentrations for Hair Samples?**

**INITIAL TEST CUTOFF CONCENTRATION**

	(pg/mg)
Marijuana metabolites .....	1
Cocaine metabolites .....	500
Opiate metabolites <sup>1</sup> .....	200
Phencyclidine .....	300
Amphetamines <sup>2</sup> .....	500
MDMA .....	500

<sup>1</sup> Laboratories are permitted to initial test all specimens for 6-acetylmorphine (6-AM) using a 200 pg/mg cutoff.  
<sup>2</sup> Methamphetamine is the target analyte.

**CONFIRMATORY TEST CUTOFF CONCENTRATION**

	(pg/mg)
Marijuana metabolite <sup>1</sup> .....	0.05
Cocaine:	
Cocaine <sup>2</sup> .....	500
Cocaine metabolites <sup>2</sup> .....	50
Opiates:	
Morphine .....	200
Codeine .....	200
6-Acetylmorphine <sup>3</sup> .....	200
Phencyclidine .....	300
Amphetamines:	
Amphetamine .....	300
Methamphetamine <sup>4</sup> .....	300
MDMA .....	300
MDA .....	300
MDEA .....	300

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid.  
<sup>2</sup> Cocaine concentration is greater than or equal to confirmatory cutoff and Benzoylcegonine (BZE)/Cocaine ratio is greater than or equal to 0.05 or Cocaethylene (CE) greater than or equal to 50 pg/mg or norcocaine (NC) greater than or equal to 50 pg/mg.  
<sup>3</sup> Specimen must also contain Morphine at a concentration greater than or equal to 200 pg/mg.  
<sup>4</sup> Specimen must also contain Amphetamine at a concentration greater than or equal to 50 pg/mg.

**Section 3.5 What Are the Cutoff Concentrations for Oral Fluid Specimens?**

**INITIAL TEST CUTOFF CONCENTRATION**

	(ng/mL)
THC Parent drug and metabolite ...	4
Cocaine metabolites .....	20
Opiate metabolites <sup>1</sup> .....	40
Phencyclidine .....	10
Amphetamines <sup>2</sup> .....	50
MDMA .....	50

<sup>1</sup> Labs are permitted to initial test all specimens for 6-AM using a 4 ng/mL cutoff.  
<sup>2</sup> Methamphetamine is the target analyte.

**CONFIRMATORY TEST CUTOFF CONCENTRATION**

	(ng/mL)
THC Parent drug .....	2
Cocaine <sup>1</sup> .....	8
Opiates:	
Morphine .....	40
Codeine .....	40
6-Acetylmorphine .....	4
Phencyclidine .....	10
Amphetamines:	
Amphetamine .....	50
Methamphetamine <sup>2</sup> .....	50
MDMA .....	50
MDA .....	50
MDEA .....	50

<sup>1</sup> Cocaine or Benzoylcegonine.

<sup>2</sup> Specimen must also contain Amphetamine at a concentration greater than or equal to the limit of detection.

**Section 3.6 What Are the Cutoff Concentrations for Sweat Patch Samples?**

**INITIAL TEST CUTOFF CONCENTRATION**

	(ng/patch)
Marijuana metabolites .....	4
Cocaine metabolites .....	25
Opiate metabolites <sup>1</sup> .....	25
Phencyclidine .....	20
Amphetamines <sup>2</sup> .....	25
MDMA .....	25

<sup>1</sup> Labs are permitted to initial test all specimens for 6-AM at 25 ng/patch.  
<sup>2</sup> Methamphetamine is the target analyte.

**CONFIRMATORY TEST CUTOFF CONCENTRATION**

	(ng/patch)
THC parent drug .....	1
Cocaine <sup>1</sup> .....	25
Opiates <sup>2</sup> .....	25
Phencyclidine .....	20
Amphetamines:	
Amphetamine .....	25
Methamphetamine <sup>3</sup> .....	25
MDMA .....	25
MDA .....	25
MDEA .....	25

<sup>1</sup> Cocaine or Benzoylcegonine.  
<sup>2</sup> Morphine, Codeine, or 6-Acetylmorphine.  
<sup>3</sup> Specimen must also contain Amphetamine at a concentration greater than or equal to the limit of detection.

**Section 3.7 What Are the Cutoff Concentrations for Urine Specimens?**

**INITIAL TEST CUTOFF CONCENTRATION**

	(ng/mL)
Marijuana metabolites .....	50
Cocaine metabolites .....	150
Opiate metabolites <sup>1</sup> .....	2000
Phencyclidine .....	25
Amphetamines <sup>2</sup> .....	500
MDMA .....	500

<sup>1</sup> Labs are permitted to initial test all specimens for 6-AM using a 10 ng/mL cutoff.  
<sup>2</sup> Methamphetamine is the target analyte.

**CONFIRMATORY TEST CUTOFF CONCENTRATION**

	(ng/mL)
Marijuana metabolite <sup>1</sup> .....	15
Cocaine metabolite <sup>2</sup> .....	100
Opiates:	
Morphine .....	2000
Codeine .....	2000
6-acetylmorphine <sup>3</sup> .....	10
Phencyclidine .....	25
Amphetamines:	
Amphetamine .....	250

**CONFIRMATORY TEST CUTOFF  
CONCENTRATION—Continued**

	(ng/mL)
Methamphetamine <sup>4</sup> .....	250
MDMA .....	250
MDA .....	250
MDEA .....	250

<sup>1</sup> Delta-9-tetrahydrocannabinol-9-carboxylic acid.

<sup>2</sup> Benzoylcegonine.

<sup>3</sup> If a laboratory uses both initial test kits to screen a specimen concurrently, it may report 6-AM alone.

<sup>4</sup> Specimen must also contain Amphetamine at a concentration greater than or equal to 100 ng/mL.

**Section 3.8 What Validity Tests Must Be Performed on a Hair Sample?**

(a) For each primary (Sample A) head hair sample, an HHS-certified laboratory or IITF must:

(1) Determine the integrity of the head hair sample by performing a digestion test;

(2) Perform microscopic identification;

(3) Perform a dye test;

(4) Determine solubility of head hair in methanol; and

(5) Perform additional validity tests when the following conditions are observed:

(i) Abnormal physical characteristics (e.g., Sample A and Sample B have different hair color, mixture of different types of head hair);

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (5)(i) through (iii) of this section.

**Section 3.9 What Validity Tests Must Be Performed on an Oral Fluid Specimen?**

(a) For each primary (Tube A) oral fluid specimen, an HHS-certified laboratory or IITF must:

(1) Determine the immunoglobulins (IgG) concentrations on every specimen; and

(2) Perform additional validity tests when the following conditions are observed:

(i) Abnormal physical characteristics (e.g., unusual color or texture, unusual odor, semi-solid characteristics);

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (2)(i) through (iii) of this section.

**Section 3.10 What Validity Tests Must Be Performed on a Sweat Patch Sample?**

(a) For each primary (Patch A) sweat patch sample, an HHS-certified laboratory or IITF must:

(1) Determine the lactic acid concentration on every specimen; and

(2) Perform additional validity tests when the following conditions are observed:

(i) Abnormal physical characteristics (e.g., Patch A and Patch B have different color, unusual odor);

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (2)(i) through (iii) of this section.

**Section 3.11 What Validity Tests Must Be Performed on a Urine Specimen?**

(a) For each primary (Bottle A) urine specimen, an HHS-certified laboratory or IITF must:

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen;

(4) Perform one or more validity tests for oxidizing adulterants on every specimen; and

(5) Perform additional validity tests when the following conditions are observed:

(i) Abnormal physical characteristics (e.g., unusual odor or color, semi-solid characteristics);

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (5)(i) through (iii) of this section.

**Section 3.12 What Criteria Are Used To Report a Hair Sample as Adulterated?**

A primary (Sample A) head hair sample is reported adulterated when the

concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample.

**Section 3.13 What Criteria Are Used To Report an Oral Fluid Specimen as Adulterated?**

A primary (Tube A) oral fluid specimen is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the specimen.

**Section 3.14 What Criteria Are Used To Report a Sweat Patch Sample as Adulterated?**

A primary (Patch A) sweat patch sample is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample.

**Section 3.15 What Criteria Are Used To Report a Urine Specimen as Adulterated?**

A primary (Bottle A) urine specimen is reported adulterated when:

(a) The pH is less than 3 or greater than or equal to 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration greater than or equal to the limit of detection (LOD) of the confirmatory test on the second aliquot;

(d) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent

cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration greater than or equal to the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and gas chromatography/mass spectrometry (GC/MS) for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(f) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration greater than or equal to the LOD of the analysis on the second aliquot;

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in (c) through (g) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

**Section 3.16 What Criteria Are Used To Report an Oral Fluid Specimen as Substituted?**

A primary (Tube A) oral fluid specimen is reported substituted when the IgG concentration is less than 0.10 mcg/mL.

**Section 3.17 What Criteria Are Used To Report a Urine Specimen as Substituted?**

A primary (Bottle A) urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

**Section 3.18 What Criteria Are Used To Report a Urine Specimen as Dilute?**

A primary (Bottle A) urine specimen is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

**Section 3.19 What Criteria Are Used To Report a Hair Sample as an Invalid Result?**

A primary (Sample A) head hair sample is reported as an invalid result when:

(a) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(d) If the physical appearances of Samples A and B are clearly different, the test result for Sample A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

**Section 3.20 What Criteria Are Used To Report an Oral Fluid Specimen as an Invalid Result?**

A primary (Tube A) oral fluid specimen is reported as an invalid result when:

(a) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen is such that testing the

specimen may damage the laboratory's instruments; or

(d) If the physical appearances of Tubes A and B are clearly different, the test result for Tube A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

**Section 3.21 What Criteria Are Used To Report a Sweat Patch Sample as an Invalid Result?**

A primary (Patch A) sweat patch sample is reported as an invalid result when:

(a) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(d) If the physical appearances of Patches A and B are clearly different, the test result for Patch A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

**Section 3.22 What Criteria Are Used To Report a Urine Specimen as an Invalid Result?**

A primary (Bottle A) urine specimen is reported as an invalid result when:

(a) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial test

and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff greater than or equal to 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(e) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff greater than or equal to the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(g) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff, a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is greater than or equal to the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(i) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(j) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(k) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(l) If the physical appearances of Bottles A and B are clearly different, the test result for Bottle A is one of the reasons stated in (a) through (j) of this

section and/or was screened negative for drugs.

#### Subpart D—Collectors

##### Section 4.1 Who May Collect a Specimen?

(a) An individual who has been trained to collect a particular type of specimen (i.e., head hair, oral fluid, sweat, or urine).

(b) The immediate supervisor of a donor may not act as the collector when that donor is tested unless no other collector is available.

(c) An employee working for a testing facility must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

##### Section 4.2 What Are the Requirements To Be a Trained Collector For a Federal Agency?

An individual is considered to be a trained collector for a particular type of specimen when the individual has:

(a) Read and understands these Guidelines;

(b) Read and understands any guidance provided by the Federal agency, which is consistent with these Guidelines;

(c) Demonstrated proficiency by completing five consecutive error-free mock collections for a particular type of specimen; and

(d) Successfully completed a training course by an established organization for the particular type or types of specimen(s) for which the individual is being trained.

##### Section 4.3 How Is a Collector's Training Documented?

(a) A trainer must monitor and evaluate the knowledge and performance of the individual being trained, in person or by means that provides real-time observation and interaction between the trainer and trainee, and attest in writing that the mock collections are error-free.

(b) The trainer must be an individual who has demonstrated necessary knowledge, skills, and abilities by having:

(1) Regularly conducted collections for a period of at least one year; or

(2) Successfully completed a "train the trainer" course given by an established organization.

##### Section 4.4 What Must an Organization Do Before a Collector Is Permitted To Collect Specimens for a Federal Agency?

An organization (e.g., self-employed individual, third party administrator that provides a collection service,

Federal agency that employs its own collectors) must:

(a) Ensure that each individual that serves as a collector has been properly trained before the individual is permitted to collect a specimen;

(b) Maintain a copy of the records that document the collector's training; and

(c) Provide to the collector the name and telephone number of the Federal agency representative to contact about problems or issues that may arise during a specimen collection procedure.

#### Subpart E—Collection Sites

##### Section 5.1 Where Can a Collection for a Drug Test Take Place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) The selection of an appropriate collection site will depend on the type of specimen being collected. For example, a urine specimen is normally collected in some type of restroom, while a head hair sample may be collected in a private office.

##### Section 5.2 What Are the Requirements for a Collection Site?

A facility that is used as a collection site must have the following:

(a) A suitable clean surface for handling the specimen and completing the required paperwork;

(b) A secure temporary storage capability to maintain a specimen until it is tested or shipped to the laboratory;

(c) The ability to provide the donor privacy that is appropriate for the specimen being collected;

(d) The ability to restrict access to only authorized personnel during the collection;

(e) The ability to restrict access to collection supplies; and

(f) The ability to store records securely.

##### Section 5.3 How Long Must Collection Site Records Be Stored?

Collection site records must be stored for a minimum of 2 years by the collector or the collector's employer.

##### Section 5.4 How Does the Collector Ensure the Security of a Specimen at the Collection Site?

(a) A collector must do the following to maintain the security of a specimen:

(1) Not allow unauthorized personnel to enter the collection site during the collection;

(2) Perform only one specimen collection at a time;

(3) Restrict access to collection supplies before and during the collection;

(4) Ensure that he or she is the only person other than the donor to handle the unsealed specimen;

(5) Ensure that chain of custody is maintained and documented throughout the entire collection procedure;

(6) Ensure that specimens transported to an HHS-certified laboratory or IITF are placed in containers that will minimize the possibility of damage during shipment (e.g., specimen boxes or padded mailers); and

(7) Ensure that the Federal CCF is enclosed with the split specimens within each container that is sealed for shipment to the HHS-certified laboratory or IITF.

(b) Since specimens are sealed in packages that would indicate any tampering during transit to the HHS-certified laboratory or IITF and couriers, express carriers, and postal service personnel do not have access to the Federal CCF or split specimens, there is no requirement that such personnel document chain of custody for the package during transit.

#### *Section 5.5 What Are the Privacy Requirements When Collecting a Hair Sample?*

The collector collects head hair from the donor. The donor must be allowed privacy while the collector obtains the head hair sample.

#### *Section 5.6 What Are the Privacy Requirements When Collecting an Oral Fluid Specimen?*

The donor provides the sample directly into an appropriate container under the direct observation of the collector. Only the collector may be present while the donor provides the oral fluid specimen.

#### *Section 5.7 What Are the Privacy Requirements When Collecting a Sweat Patch Sample?*

The sweat patch is applied to the donor's upper arm or back by the collector. The donor must be allowed privacy while the collector applies or removes the patch.

#### *Section 5.8 What Are the Privacy Requirements When Collecting a Urine Specimen?*

The collector must give the donor visual privacy while providing the specimen unless:

(a) A previous drug test was reported either positive for a drug, adulterated, substituted, invalid result, or canceled because the split specimen was not tested;

(b) The drug test is a return-to-duty or a follow-up test;

(c) The agency believes that the donor may tamper with or substitute the specimen to be provided; or

(d) During a routine collection, the temperature of the specimen collected is outside the acceptable range, the collector observed materials brought to the collection site or donor conduct indicated a possible attempt to adulterate or substitute a specimen, or the collector believes that the specimen has been adulterated (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach).

### **Subpart F—Federal Drug Testing Custody and Control Forms**

#### *Section 6.1 What Form Is Used for Collecting a Specimen?*

(a) Federal agencies are required to use an OMB-approved Federal CCF to document the collection of each type of specimen at the collection site.

(b) There is a separate OMB-approved Federal CCF for each type of specimen collected.

#### *Section 6.2 What Happens if a Federal CCF Is Not Available or Is Not Used?*

(a) When the collector either by mistake or as the only means to document a collection under difficult circumstances (e.g., post-accident test with insufficient time to obtain the CCF) uses a non-Federal form for a Federal agency specimen collection, the use of a non-Federal form is not a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test.

(b) If the testing facility or the MRO discovers the use of the incorrect form, a signed statement must be obtained from the collector stating the reason why a Federal CCF was not used to collect the Federal agency specimen.

### **Subpart G—Collection Device**

#### *Section 7.1 What Is a Collection Device?*

A collection device, for the purposes of these Guidelines, is considered to be the following for each type of specimen collected:

(a) For urine, it is the single-use plastic specimen container.

(b) For head hair, it is the foil or other specimen guide and single-use plastic bag or other container in which the specimen is placed.

(c) For oral fluid, it is the single-use plastic specimen container.

(d) For sweat, it is the patch placed on the skin.

#### *Section 7.2 Which Collection Devices May Be Used?*

(a) Only a collection device that does not affect the specimen collected may be used.

(1) If a collection device has been cleared by the FDA for the purpose of testing a specimen for drugs, it is deemed not to affect the specimen collected.

(2) If a collection device has not been cleared by the FDA, a Federal agency must only use a device that does not affect the specimen collected.

(b) These Guidelines do not determine if a collection device must be cleared by the FDA.

### **Subpart H—Specimen Collection Procedure**

#### *Section 8.1 What Must the Collector Do Before Starting a Specimen Collection Procedure?*

The collector must:

(a) Provide identification to the donor if the donor asks;

(b) Explain the basic collection procedure to the donor;

(c) Request the donor to read the instructions on the back of the Federal CCF; and

(d) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure.

#### *Section 8.2 What Procedure Is Used To Collect a Head Hair Sample?*

(a) The collector must use the following procedure to collect a head hair sample:

(1) When the donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or an agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector must contact the agency to obtain guidance on the action to be taken.

(3) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket and any hat or hood.

(4) The collector must use a Federal CCF to document collecting a head hair sample.

(5) In the presence of the donor, the collector must clean the scissors that will be used to cut the head hair with an alcohol wipe prior to obtaining a head hair sample.

(6) If the collector sees any evidence that the donor has lice in his or her head hair, the collector immediately stops the collection procedure and contacts the



agency to obtain permission to collect a different type of specimen.

(7) Using scissors, the collector will cut the donor's head hair in a line near the rear of the crown toward the back and as close to the scalp as possible. Approximately one-and-one-half inches of the hair closest to the scalp is actually tested, even if the head hair is long. If the hair is less than one-and-one-half inches long, then the width of the sample collected will need to be increased. The weight of hair needed for testing is 100 mg. The head hair sample collected from the donor must meet that requirement.

(8) The collector places the head hair sample in the foil packet (collection device), root-end extending out approximately one-quarter inch from the slated end of the foil. The collector then subdivides the head hair sample into two approximately equal head hair samples (Sample A and Sample B). Sample B is placed in a second foil.

(9) The collector folds both foils lengthwise and each sample is placed inside an envelope with root-ends to the left.

(10) The collector places the seals from the Federal CCF on the bottom of the envelopes and records the date of the collection on the tamper-evident labels/seals.

(11) The donor initials the tamper-evident labels/seals.

(12) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the head hair samples were collected from him or her.

(13) The collector must sign the Federal CCF.

(14) The split head hair samples and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(15) The collector must send the split (Sample A and Sample B) head hair samples at the same time to the HHS-certified laboratory or IITF.

(b) If the split head hair samples and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF, they must be appropriately safeguarded until the head hair samples and Federal CCF are prepared for transfer to the laboratory.

### *Section 8.3 What Procedure Is Used To Collect an Oral Fluid Specimen?*

(a) The collector must use the following procedure to collect an oral fluid specimen:

(1) When a donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or an agency representative

who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector must contact the appropriate authority to obtain guidance on the action to be taken.

(3) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the donor's oral fluid specimen. The collector must ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet. The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into the pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." If an item is found that appears to have been brought to the collection site with the intent to adulterate or if the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) The collector must confirm with the donor that the donor has not had anything in his or her mouth for 10 minutes prior to providing the oral fluid specimen. If the donor has had anything in his or her mouth within the last 10 minutes, wait 10 minutes prior to beginning the collection process.

(5) The collector will give the donor a clean specimen tube.

(6) Under direct observation, the collector will instruct the donor to expectorate (to spit) 2 mL of oral fluid into the specimen tube. This can be accomplished over a 15 minute time period or until the appropriate volume of specimen is collected.

(7) Both the donor and the collector must keep the specimen tube in view at all times prior to its being sealed and labeled.

(8) The collector, in the presence of the donor, mixes the specimen and transfers the oral fluid into two specimen tubes that are labeled Tube A and Tube B. A minimum of 2 mL of oral fluid is required, *i.e.*, 1.5 mL for Tube A and 0.5 mL for Tube B.

(9) The Tube A specimen, containing a minimum of 1.5 mL of oral fluid, is to be used for the drug test. If there is no additional oral fluid available for the second specimen tube (Tube B), the first specimen tube (Tube A) shall nevertheless be processed for testing.

(10) A minimum of 0.5 mL of oral fluid shall be transferred into the second specimen tube (Tube B).

(11) The collector places a tamper-evident label/seal from the Federal CCF across the top of each tube and records the date of the collection on the tamper-evident labels/seals.

(12) The donor initials the tamper-evident labels/seals on the specimen tubes.

(13) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimen identified as having been collected from him or her.

(14) The collector must sign the Federal CCF.

(15) The split oral fluid specimen and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(16) After completing the oral fluid specimen collection procedure, the collector must also collect a urine specimen following the procedures described in section 8.5.

(17) The collector must send the oral fluid and urine split specimens at the same time to an HHS-certified laboratory or IITF or transfer the specimens to the POCT tester (if a POCT is being conducted).

(b) If the split specimens and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF or tested using a POCT, they must be appropriately safeguarded until the specimens and Federal CCF are prepared for transfer to an HHS-certified laboratory or IITF or tested using a POCT.

### *Section 8.4 What Procedure Is Used To Collect a Sweat Patch Sample?*

(a) The collector must use the following procedure to collect a sweat patch sample:

(1) When a donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or an agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector must

contact the appropriate authority to obtain guidance on the action to be taken.

(3) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the sweat patch. The collector must ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet. The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the sweat patch. If nothing is there that can be used to adulterate the sweat patch, the donor places the items back into the pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." If an item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) The collector will show the donor two clean sealed sweat patches.

(5) The collector asks the donor to thoroughly clean the skin area with soap and cool water or with a disposable towelette and then the collector must thoroughly clean the skin area with alcohol wipes where the sweat patches will be worn prior to application.

(6) The collector will place the two sweat patches on the upper arm (preferable location) or the back.

(7) The donor must wear the sweat patches for no less than three and no more than seven days before returning to the collection site. A unique number is imprinted on each patch to aid with chain-of-custody identification. On rare occasions, the sweat patch can produce an allergic reaction similar to that for other adhesive bandage products. When this occurs, the donor shall return to the collection site and the collector must remove the sweat patch and then request permission from the Federal agency to collect another type of specimen. The sweat patch procedure is cancelled by the collector and notifies the medical review officer and the Federal agency.

(8) After the sweat patches (Sample A and Sample B) are worn for the proper time, the donor returns to the collection site. The collector removes the two sweat patches from the donor within several minutes.

(9) Immediately before and after the sweat patches are removed, the collector must inspect the two sweat patches to determine if there are any signs

indicating that the sweat patches may not be valid samples (e.g., the donor tampered with the sweat patches).

(10) Samples suspected of not being valid sweat patch samples must be forwarded to an HHS-certified laboratory or IITF for testing with any unusual findings noted on the Federal CCF.

(11) The collector must place the sweat patches in appropriate containers and secure them with tamper-evident labels/seals. The collector must record the date of the collection on the tamper-evident labels/seals.

(12) The donor must initial the tamper-evident labels/seals.

(13) The donor must be asked to read and sign a statement on the Federal CCF certifying that the sweat patch identified as having been collected from him or her.

(14) The collector must sign the Federal CCF.

(15) The split sweat patch samples and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(16) The collector must send the split specimens at the same time to an HHS-certified laboratory or IITF.

(b) If the specimen and Federal CCF are not immediately prepared for transfer to the laboratory or IITF, they must be appropriately safeguarded until the specimen and Federal CCF are prepared for transfer to the laboratory or IITF.

#### *Section 8.5 What Procedure Is Used To Collect a Urine Specimen?*

(a) The collector must use the following procedure to collect a urine specimen:

(1) To deter the dilution of a specimen at the collection site, a toilet bluing agent shall be placed in a toilet tank wherever possible, so the reservoir of water in the toilet bowl always remains blue. There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When a donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor, the coordinator of the drug testing program, or any other agency official who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(3) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector must contact the appropriate authority to

obtain guidance on the action to be taken.

(4) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to adulterate or substitute the urine specimen. The collector must ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet. The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate or substitute the specimen. If nothing is there that can be used to adulterate or substitute a specimen, the donor places the items back into the pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, a direct observation collection procedure is used. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(5) The donor shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate the specimen.

(7) The collector will provide the donor a clean specimen collection container. The donor may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collector shall note any unusual behavior or appearance on the Federal CCF.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A person of the same gender as the donor shall accompany the donor into the public rest room which must be made secure during the collection procedure. If possible, a bluing agent shall be placed in the bowl and any accessible toilet tank. The collector shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution,

the collector shall instruct the donor not to flush the toilet until the specimen is delivered to the collector. After the collector has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collector in completing the chain of custody procedures.

(10) Upon receiving the specimen from the donor, the collector must determine the volume of urine in the specimen container.

(i) If the volume is at least 45 mL, the collector will proceed with step (11) below.

(ii) If the volume is less than 45 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen must be collected. The donor may be given a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces). If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collector must contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 45 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen must be collected using the procedure specified in step (13) below.

(11) After the donor has given the specimen to the collector, the donor shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collector must measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of the specimen is outside the range of 32° – 38 °C/90° – 100 °F, that is a reason to believe that the donor may have adulterated or substituted the specimen; another specimen must be collected under direct observation of a person of the same gender and both specimens (i.e., from the first and second collections) must be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available.

(14) Immediately after the specimen is collected, the collector shall also inspect the specimen to determine if this is any sign indicating that the specimen may not be a valid urine specimen. Any unusual finding shall be noted on the Federal CCF.

(15) A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(16) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under the direct observation of a person of the same gender and both specimens (i.e., from the first and second collections) shall be forwarded to an HHS-certified laboratory for testing. The agency shall select the observer if there is no collector of the same gender available.

(17) Both the donor and the collector must keep the specimen container in view at all times. The collector shall request the donor to observe the transfer of the specimen from the collection container to the two specimen bottles and the placement of the tamper-evident labels/seals on the bottles.

(18) The collector, in the presence of the donor, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B, 30 mL for Bottle A and 15 mL for Bottle B.

(19) The Bottle A specimen, containing a minimum of 30 mL of urine, is to be used for the drug test. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(20) A minimum of 15 mL of urine shall be poured into the second specimen bottle (Bottle B).

(21) The collector must place the tamper-evident labels/seals on the specimen bottles. The collector must record the date of the collection on the tamper-evident labels/seals.

(22) The donor must initial the tamper-evident labels/seals on the split specimen bottles.

(23) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimen identified was collected from him or her.

(24) Based on a reason to believe that the donor may adulterate or substitute the specimen to be provided, a higher level supervisor must review and concur in advance with any decision by a collector to obtain a specimen under direct observation. The person directly observing the specimen collection must be of the same gender. The agency shall select the observer if there is no collector of the same gender available.

(25) The collector must sign the Federal CCF.

(26) The split specimens and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF or

transfer to a POCT tester (if a POCT is being conducted).

(27) The collector must send the split specimens (Bottle A and Bottle B) at the same time to an HHS-certified laboratory or IITF or transfer to a POCT tester (if a POCT is being conducted).

(b) If the split specimen bottles and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF or transferred to a POCT tester, they must be appropriately safeguarded until the split specimen bottles and Federal CCF are prepared for transfer to an HHS-certified laboratory or IITF.

#### *Section 8.6 What Are the Responsibilities of a Federal Agency That Uses a Collection Site?*

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H when collecting agency specimens.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must conduct an annual inspection of each collection site used to collect agency specimens. Additionally, a Federal agency must respond to reports of collector and collection site deficiencies reported to them and must take appropriate action to preclude the recurrence of such deficiencies.

#### **Subpart I—HHS Certification of Laboratories and IITFs**

##### *Section 9.1 What Are the Goals and Objectives of HHS-Certification?*

(a) Drug testing is an important tool to identify drug users in a variety of settings. In the proper context, drug testing can be used to deter drug abuse in general. To be a useful tool, all testing must satisfy "good forensic laboratory practices" and the testing procedures must be capable of detecting drugs or metabolites at established cutoff concentrations.

(b) Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set in order to achieve maximum accuracy of test results.

(c) Because of the possible impact of a positive test result on an individual's livelihood or rights, extra care is required in the handling of the specimen and all other aspects of the testing procedure. Thus, the testing procedure must be carefully documented.

**Section 9.2 Who Has the Authority To Certify Laboratories and IITFs That Want To Test Specimens for Federal Agencies?**

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any laboratory or IITF suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any laboratory or IITF to send specimens or specimen aliquots to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is certified by HHS under these Guidelines to test a particular specimen unless it holds such certification for each type of specimen it wants to test for Federal agencies.

**Section 9.3 What Is the Process for a Laboratory or IITF To Become HHS-Certified and To Maintain That Certification?**

A laboratory or IITF that wants to become an HHS-certified laboratory or IITF must:

- (a) Read and understand these Guidelines;
- (b) Request an OMB-approved application;
- (c) Submit a completed application for each type of specimen and type of certification applied for;
- (d) Have its application reviewed as complete and accepted by HHS;
- (e) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples as required for each type of specimen for which certification is applied for;
- (f) Satisfy all the requirements for an initial inspection;
- (g) Receive a letter of certification from the Secretary before being able to test specimens for Federal agencies;

(h) Successfully participate in both the maintenance PT and inspection programs (i.e., successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections every 6 months thereafter);

(i) Respond in an appropriate, timely, and complete manner to required corrective action in the event of failure in either the maintenance PT or inspection program for which suspension and/or revocation are proposed by the Secretary;

(j) Satisfactorily complete a special inspection and corrective remedial action to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting;

(k) Stop testing Federal agency specimens should PT, maintenance inspection, special inspection, or other material deficiencies indicate that there is an imminent harm to the government and its employees requiring that immediate suspension and revocation procedures be imposed by the Secretary; and

(l) Follow the HHS procedures in subpart Q that will be used for all actions associated with the suspension and/or revocation of HHS-certification for each type of specimen and type of certification held.

**Section 9.4 How Does a Laboratory or IITF Apply To Become HHS-Certified?**

(a) A laboratory or IITF interested in becoming HHS-certified must submit an OMB-approved application form.

(b) The application form requires the applicant laboratory or IITF to provide detailed information on both the administrative and analytical procedures the laboratory or IITF proposes to use for testing Federal agency specimens after it is certified.

**Section 9.5 What Are the Qualitative and Quantitative Specifications of a Performance Test (PT) Sample?**

(a) A PT sample must satisfy one of the following criteria:

- (1) Contains one or more of the drugs and metabolites in the drug classes listed in sections 3.4, 3.5, 3.6, and 3.7.
- (2) The concentration of a drug or metabolite is at least 20 percent above the cutoff concentration for either the initial drug test or the confirmatory drug test depending on which is to be evaluated;
- (3) The concentration of a drug or metabolite is as low as 40 percent of the cutoff concentration when the PT sample is designated as a retest sample;

(4) The concentration of drug or metabolite is at another concentration for a special purpose;

(5) A negative sample will not contain a measurable amount of a drug or metabolite; or

(6) A PT sample may contain an interfering substance or an adulterant or satisfy the criteria for a substituted specimen (as appropriate).

(b) For each PT cycle, the set of PT samples going to each laboratory or IITF will vary but, within each calendar year, each laboratory or IITF will analyze essentially the same total set of samples.

(c) The laboratory or IITF must, to the greatest extent possible, handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

**Section 9.6 What Are the PT Requirements for an Applicant Laboratory To Conduct Hair Testing?**

(a) An applicant laboratory that seeks certification to conduct hair testing must satisfy the following criteria on 3 consecutive sets of PT samples:

- (1) Have no false positive results;
- (2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;
- (3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;
- (4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean; and

(5) For an individual drug, must correctly detect and quantify at least 50 percent of the total drug challenges.

(6) Must not obtain any quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

**Section 9.7 What Are the PT Requirements for an Applicant Laboratory To Conduct Oral Fluid Testing?**

(a) An applicant laboratory that seeks certification to conduct oral fluid testing must satisfy the following criteria on 3 consecutive sets of PT samples:



(1) Have no false positive results;  
 (2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;  
 (3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean;

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not obtain any quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.8 What are the PT Requirements for an Applicant Laboratory To Conduct Sweat Patch Testing?*

(a) An applicant laboratory that seeks certification to conduct sweat patch testing must satisfy the following criteria on 3 consecutive sets of initial PT samples:

(1) Have no false positive results;  
 (2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;  
 (3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean; and

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges.

(6) Must not obtain any quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.9 What Are the PT Requirements for an Applicant Laboratory To Conduct Urine Testing?*

(a) An applicant laboratory that seeks certification to conduct urine testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Have no false positive results;  
 (2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;  
 (3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean;

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must correctly identify and report at least 80 percent of the total validity testing challenges over the 3 sets of PT samples;

(7) For each specific validity test, must correctly report at least 80 percent of the challenges for the specific validity test over the 3 sets of PT samples;

(8) For quantitative specimen validity tests, must obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean;

(9) Must not obtain any quantitative value on a specimen validity testing sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  units for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means;

(10) For qualitative specimen validity tests, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over the 3 sets of PT samples; and

(11) Must not report any sample as adulterated with a compound that is not present in the sample, adulterated based

on pH when the calculated group reference mean is within the acceptable pH range, or substituted when the calculated group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.10 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Hair Testing?*

(a) A laboratory certified to conduct hair testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;  
 (2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within  $\pm 20$  percent or  $\pm 2$  standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for hair testing.

*Section 9.11 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Oral Fluid Testing?*

(a) A laboratory certified to conduct oral fluid testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;



(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within  $\pm 20$  percent or  $\pm 2$  standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for oral fluid testing.

#### *Section 9.12 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Sweat Patch Testing?*

(a) A laboratory certified to conduct sweat patch testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within  $\pm 20$  percent or  $\pm 2$  standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than  $\pm 50$  percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for sweat patch testing.

#### *Section 9.13 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Urine Testing?*

(a) A laboratory certified to conduct urine testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within  $\pm 20$  percent or  $\pm 2$  standard deviations of the appropriate reference or peer group mean (whichever range is larger) as measured over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated) or substituted (that is not substituted);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative specimen validity tests, must obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean;

(9) No more than one quantitative value on a specimen validity testing

sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  unit for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for urine testing.

#### *Section 9.14 What Are the PT Requirements for an Applicant IITF To Conduct Hair Testing?*

(a) An applicant IITF that seeks certification to conduct hair testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

#### *Section 9.15 What Are the PT Requirements for an Applicant IITF To Conduct Oral Fluid Testing?*

(a) An applicant IITF that seeks certification to conduct oral fluid testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a

specific initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.16 What Are the PT Requirements for an Applicant IITF To Conduct Sweat Patch Testing?*

(a) An applicant IITF that seeks certification to conduct sweat patch testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.17 What Are the PT Requirements for an Applicant IITF To Conduct Urine Testing?*

(a) An applicant IITF that seeks certification to conduct urine testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples;

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 3 sets of PT samples;

(5) For quantitative specimen validity tests, must obtain quantitative values for at least 80 percent of the total initial validity test challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean;

(6) Must not obtain any quantitative value on an initial validity test sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  units for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means; and

(7) For qualitative initial validity tests, must correctly identify and report at least 80 percent of the challenges for each qualitative initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

*Section 9.18 What Are the PT Requirements for an HHS-Certified IITF To Conduct Hair Testing?*

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct hair testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for hair testing.

*Section 9.19 What Are the PT Requirements for an HHS-Certified IITF To Conduct Oral Fluid Testing?*

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct oral fluid testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for oral fluid testing.

*Section 9.20 What Are the PT Requirements for an HHS-Certified IITF To Conduct Sweat Patch Testing?*

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct sweat patch testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for sweat patch testing.

*Section 9.21 What Are the PT Requirements for an HHS-Certified IITF To Conduct Urine Testing?*

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct urine testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles;

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a

specific initial validity test over 2 consecutive PT cycles;

(5) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total initial validity test challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within  $\pm 20$  percent or  $\pm 2$  standard deviations of the calculated reference group mean;

(ii) pH values are within  $\pm 0.3$  pH units of the calculated reference group mean; and

(iii) Specific gravity values are within  $\pm 0.0003$  specific gravity units of the calculated reference group mean;

(6) Must not obtain any quantitative value on an initial validity test sample that differs by more than  $\pm 50$  percent for nitrite and creatinine concentrations,  $\pm 0.8$  units for pH measurements, or  $\pm 0.0006$  units for specific gravity from the calculated reference group means; and

(7) For qualitative validity tests, must correctly identify and report at least 80 percent of the challenges for each qualitative initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for urine testing.

#### *Section 9.22 What Are the Inspection Requirements for an Applicant Laboratory or IITF?*

(a) An applicant laboratory or IITF is inspected by a team of at least two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

(c) To become certified, an applicant laboratory or IITF must satisfy the minimum requirements as stated in these Guidelines.

(d) An applicant laboratory or IITF must be separately inspected for each type of specimen for which it has applied. The inspection for each type of specimen may be conducted concurrently, but the inspectors must review all appropriate data in distinct audits.

(e) An applicant laboratory or IITF that applies for certification to conduct testing of different types of specimens, but does not satisfy the minimum requirements for each type of specimen, may be certified for those types of specimens for which it has satisfied the minimum requirements.

#### *Section 9.23 What Are the Maintenance Inspection Requirements for an HHS-Certified Laboratory or IITF?*

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and then an inspection every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors required is dependent on the workload of the laboratory or IITF.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures for each type of specimen and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines for that type of specimen.

#### *Section 9.24 Who Can Inspect an HHS-Certified Laboratory or IITF and When May the Inspection Be Conducted?*

(a) The Secretary or a Federal agency may conduct an inspection at any time.

(b) An individual may serve as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K for a laboratory or as a responsible technician as described in subpart M;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Submits an acceptable inspection report and performs acceptably as a trainee inspector on an inspection.

#### *Section 9.25 What Happens if an Applicant Laboratory or IITF Does Not Satisfy the Minimum Requirements for Either the PT Program or the Inspection Program?*

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the applicant laboratory must start the initial certification process from the beginning for the type of specimen for which they were applying to become certified.

#### *Section 9.26 What Happens if an HHS-Certified Laboratory or IITF Does Not Satisfy the Minimum Requirements for Either the PT Program or the Inspection Program?*

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (e.g., 5 or 30 working days depending on the nature of the issue) to provide any explanation for its performance and evidence that any deficiency has been corrected.

(b) A laboratory's or IITF's certification may be revoked, suspended, or no further action taken depending on the seriousness of the errors and whether there is evidence that any deficiency has been corrected and that current performance meets the requirements for a certified laboratory or IITF.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples, depending on the nature of the performance, to verify that any deficiency has been corrected.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in subpart Q, the laboratory or IITF is not permitted to test specimens for Federal agencies until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

#### *Section 9.27 What Factors Are Considered in Determining Whether Revocation of a Laboratory's or IITF's Certification Is Necessary?*

(a) The Secretary shall revoke certification of any laboratory or IITF certified in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of test results.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug and validity tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory or IITF by a Federal agency using the laboratory's or IITF's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory or IITF; or

(5) Any other cause that materially affects the ability of the laboratory or IITF to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of results.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug and validity testing of Federal employees.

*Section 9.28 What Factors Are Considered in Determining Whether To Suspend a Laboratory or IITF?*

(a) Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's certification to conduct drug and validity testing for Federal agencies.

(b) The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug and validity testing of Federal employees.

*Section 9.29 How Does the Secretary Notify a Laboratory or IITF That Action Is Being Taken Against the Laboratory or IITF?*

(a) When a laboratory or IITF is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory or IITF with written notice of the suspension or proposed revocation by facsimile mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

- (1) The reasons for the suspension or proposed revocation;
- (2) The terms of the suspension or proposed revocation; and
- (3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory or IITF will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart Q contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any laboratory or IITF that has its certification revoked or suspended under section 9.27 or section 9.28, respectively, and the name of any laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart Q.

*Section 9.30 May a Laboratory or IITF That Had Its Certification Revoked Be Recertified To Test Federal Agency Specimens?*

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under section 9.29(a) or the reviewing official's decision under section 17.9(e) or 17.14(a), a laboratory or IITF which has had its certification revoked may reapply for certification as an applicant laboratory or IITF.

*Section 9.31 Where Is the List of HHS-Certified Laboratories or IITFs Published?*

(a) The list of HHS-certified laboratories and IITFs and the type of specimen for which each is certified is published monthly in the **Federal Register**.

(b) An applicant laboratory or IITF is not included on the list.

**Subpart J—Blind Samples Submitted by an Agency**

*Section 10.1 What Are the Requirements for Federal Agencies To Submit Blind Samples to HHS-Certified Laboratories or IITFs?*

(a) Each Federal agency is required to have both negative and non-negative blind samples for each type of donor specimen being submitted to an HHS-certified laboratory or IITF.

(b) During the initial 90-day period of a new Federal agency drug testing

program, the agency must submit at least three percent blind samples along with its donor specimens.

(c) After the initial 90-day period, the agency must submit one percent blind samples along with its donor specimens based on the projected total number of specimens that will be collected per year. Every effort should be made to ensure that some of the blind samples are submitted quarterly.

(d) Of the blind samples submitted, approximately 80 percent of the blind samples must be negative and 20 percent non-negative.

*Section 10.2 What Are the Requirements for a Blind Sample?*

(a) A blind sample that is drug positive must be validated by the supplier as to its content using appropriate initial and confirmatory tests.

(b) A blind sample that is negative (*i.e.*, certified to contain no drug) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information regarding the shelf life of the blind sample.

(d) For a blind sample that is drug positive, the concentration of the drug it contains should be between 1.5 and 2 times the initial drug test cutoff concentration and must be spiked or contain one or more of the drugs or metabolites listed in sections 3.3, 3.4, 3.5, and 3.6.

(e) For hair, oral fluid, sweat patch, and urine, a blind sample that is adulterated must have the characteristics to clearly show that it is an adulterated sample at the time it is validated by the supplier.

(f) For oral fluid and urine, a blind sample that is substituted must have the characteristics to clearly show that it is a substituted sample at the time it is validated by the supplier.

*Section 10.3 How Is a Blind Sample Submitted to an HHS-Certified Laboratory or IITF?*

(a) A blind sample is submitted using the same Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the Federal CCF has been properly completed as well as providing fictitious initials on the specimen label/seal. The collector must indicate that the sample is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector must distribute the required number of blind samples throughout the total number of donor



specimens rather than submitting them as a single group of samples.

*Section 10.4 What Happens if an Inconsistent Result Is Reported on a Blind Sample?*

If an HHS-certified laboratory reports an inconsistent result on a blind sample (e.g., a laboratory reports a negative result on a blind sample that was supposed to be positive, a laboratory reports a positive result on a blind sample that was supposed to be negative, an IITF reports a negative result on a blind sample that was supposed to be positive, a laboratory or IITF cannot obtain a valid drug test result):

(a) The MRO must contact supplier of the blind sample and attempt to determine if the supplier made a mistake when preparing the blind sample;

(b) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for shipment to the laboratory;

(c) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(d) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken by the HHS-certified laboratory or IITF must be sent to the Federal agency. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory or IITF is engaged in drug testing and coordinate any necessary action to prevent the recurrence of the error.

**Subpart K—Laboratory**

*Section 11.1 What Is a Standard Operating Procedure Manual?*

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all laboratory operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

- (1) Chain-of-custody procedures;
- (2) Accessioning;
- (3) Security;
- (4) Quality control/quality assurance programs;
- (5) Analytical methods and procedures;
- (6) Equipment and maintenance programs;
- (7) Personnel training;

(8) Reporting procedures; and  
(9) Computers, software, laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained for 2 years to allow the laboratory to retrieve the procedures that were used to test a specimen.

*Section 11.2 What Are the Responsibilities of the Responsible Person (RP)?*

(a) Manage the day-to-day operations of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(b) Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. The RP must ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel in the drug testing laboratory, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP(s) whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory.

(d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results, and deficiencies identified during inspections. This individual must ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(f) Qualify as a certifying scientist for positive, adulterated, and substituted test results.

*Section 11.3 What Scientific Qualifications in Analytical Toxicology Must the RP Have?*

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Be certified as a laboratory director by the State in forensic or clinical laboratory toxicology; have a Ph.D. in one of the natural sciences or have training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Have experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Have experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology; and

(d) Be found to fulfill RP responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the laboratory.

*Section 11.4 What Happens When the RP Is Absent or Leaves an HHS-Certified Laboratory?*

(a) All HHS-certified laboratories must have multiple RPs or an alternate RP. Extremely small certified laboratories may request a waiver from the Secretary to this requirement under special circumstance. An alternate RP must be able to fulfill the responsibilities of an RP, and must meet the qualifications of a certifying scientist. The laboratory must submit documentation satisfactory to the Secretary which shows the credentials of the prospective RP and which must be approved by the Secretary, and found acceptable during on-site inspections of the laboratory.

(b) When an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (e.g., vacation, illness, business trip), the certified laboratory may continue testing Federal agency specimens under the direction of a certifying scientist.

(c) When an RP permanently leaves an HHS-certified laboratory:

(1) An HHS-certified laboratory may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RP.

(2) The Secretary, in accordance with these Guidelines, will suspend a



laboratory's certification for all specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(d) When a new RP candidate has been identified, the laboratory must submit to the Secretary the candidate's current resume or curriculum vitae, arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RP position, and an itemized defense of the candidate's qualifications compared to the minimum RP qualifications described in the Guidelines.

(e) The laboratory must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RP.

*Section 11.5 What Qualifications Must an Individual Have To Certify a Result Reported By an HHS-Certified Laboratory?*

(a) The individual (*i.e.*, the certifying scientist) who certifies a non-negative or invalid result test must have:

- (1) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;
- (2) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and
- (3) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

(b) The individual (*i.e.*, the certifying technician) who certifies a negative test result must have:

- (1) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and
- (2) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

*Section 11.6 What Qualifications and Training Must Other Laboratory Personnel Have?*

(a) All laboratory staff (*e.g.*, technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.*, receive training in each area of work that the individual will be performing) before he or she is

permitted to work independently with regulated specimens.

*Section 11.7 What Security Measures Must an HHS-Certified Laboratory Maintain?*

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.*, for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (such as, firefighters and medical rescue teams).

(c) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas.

*Section 11.8 What Are the Internal Laboratory Chain of Custody Requirements for a Specimen or an Aliquot?*

(a) An HHS-certified laboratory must use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) An HHS-certified laboratory must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either hard copy procedures or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the chain of custody document when the specimen or aliquot is received.

*Section 11.9 Which Type of Specimens May an HHS-Certified Laboratory Test?*

A laboratory must be HHS-certified separately for each type of specimen that it wants to test for a Federal agency.

*Section 11.10 What Test(s) Does an HHS-Certified Laboratory Conduct on a Specimen Received After a POCT?*

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

*Section 11.11 What Test(s) Does an HHS-Certified Laboratory Conduct on a Specimen Received From an IITF?*

An HHS-certified laboratory conducts the confirmatory test(s) for the non-negative result(s) identified by the IITF.

*Section 11.12 What Are the Requirements for an Initial Drug Test?*

(a) An initial drug test must be an immunoassay test or a test that combines a chromatographic separation coupled with an appropriate detector.

(b) A laboratory must validate an initial drug test before using it to test specimens.

(c) Initial drug test kits must meet the FDA requirements for commercial distribution.

(d) A laboratory may conduct a second initial drug test on a specimen prior to the confirmatory drug test. If the laboratory uses a second initial drug test, the second initial drug test is subject to the same requirements as the first initial drug test.

*Section 11.13 What Must an HHS-Certified Laboratory Do To Validate an Initial Drug Test?*

(a) The laboratory must demonstrate and document for each initial test:

- (1) The ability to differentiate positive and negative samples;
- (2) The performance of the test around the cutoff concentration; and
- (3) The performance of the test results at several concentrations between 0 and 150 percent of the cutoff concentration.

(b) Performance of new lots must be verified prior to being placed into service.

*Section 11.14 What Are the Batch Quality Control Requirements When Conducting an Initial Drug Test?*

(a) Each batch of specimens must contain the following QC samples:

- (1) At least one control certified to contain no drug or metabolite;
- (2) At least one positive control with the drug or metabolite targeted at 25 percent above the cutoff;
- (3) At least one control with the drug or metabolite targeted at 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the laboratory analysts.

(b) At least 10 percent of the samples in the batch must be calibrators and controls.

(c) A laboratory must document that any carryover that may occur between aliquots during the initial testing process is detectable and corrected.

**Section 11.15 What Are the Requirements for a Confirmatory Drug Test?**

(a) The analytical method used must combine chromatographic separation and mass spectrometric identification (e.g., GC/MS, liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS).

(b) A confirmatory drug test must be validated before the laboratory can use it to test specimens.

**Section 11.16 What Must an HHS-Certified Laboratory Do To Validate a Confirmatory Drug Test Method?**

An HHS-certified laboratory must demonstrate and document for each confirmatory drug test:

- (a) The linear range of the analysis;
- (b) The limit of detection;
- (c) The limit of quantitation;
- (d) The accuracy and precision at the cutoff concentration;
- (e) The accuracy and precision at 40 percent of the cutoff concentration; and
- (f) The potential for interfering substances.

**Section 11.17 What Are the Quality Control Requirements When Conducting a Confirmatory Drug Test?**

(a) Each batch of specimens must contain, at a minimum, the following QC samples:

- (1) A single-point calibrator with its drug concentration at the cutoff;
- (2) At least one control certified to contain no drug or metabolite;
- (3) At least one positive control with the drug or metabolite targeted at 25 percent above the cutoff; and
- (4) At least one control targeted at or below 40 percent of the cutoff.

(b) At least 10 percent of the samples in each batch must be calibrators and controls.

(c) The linear range, limit of detection, and limit of quantitation must be documented and periodically re-evaluated for each confirmatory drug test.

(d) A laboratory must document that any carryover that may occur between aliquots/extracts in the confirmatory batch is detectable and corrected.

**Section 11.18 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Hair Samples?**

(a) Each validity test result must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(b) Each analytical run of hair samples for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

**Section 11.19 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Oral Fluid Specimens?**

(a) Each validity test result must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(b) Each analytical run of specimens for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

**Section 11.20 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Sweat Patch Samples?**

(a) Each validity test result must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(b) Each analytical run of sweat patch samples for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

**Section 11.21 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Urine Specimens?**

(a) Each validity test result must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(b) Each analytical run of specimens for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

**Section 11.22 What Are the Requirements for Conducting Each Validity Test on a Hair Sample?**

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration; and

(c) Each initial and confirmatory validity test that is qualitative must include a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

**Section 11.23 What Are the Requirements for Conducting Each Validity Test on an Oral Fluid Specimen?**

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration; and

(c) Each initial and confirmatory validity test that is qualitative must include a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

**Section 11.24 What Are the Requirements for Conducting Each Validity Test on a Sweat Patch Sample?**

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration; and

(c) Each initial and confirmatory validity test that is qualitative must include a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

**Section 11.25 What Are the Requirements for Conducting Each Validity Test on a Urine Specimen?**

(a) The requirements for measuring creatinine concentration are as follows:

(1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;

(2) The initial creatinine test must have a calibrator at 2 mg/dL;

(3) The initial creatinine test must have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL; and

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a

calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, and a control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) The refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a laboratory information management system (LIMS), computer, and/or generate a hard copy of the digital electronic display to document the numerical result;

(2) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and

(3) The initial and confirmatory specific gravity tests must have the following controls:

(i) One control targeted at 1.0020;

(ii) One control in the range of 1.0040 to 1.0180; and

(iii) One control greater than or equal to 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH validity test must be performed;

(2) pH screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use;

(3) An initial colorimetric pH test must have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 11;

(iii) One control in the range of 2 to 2.8;

(iv) One control in the range 3.2 to 4;

(v) One control in the range of 4.5 to 9;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(4) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 2 to 2.8;

(v) One control in the range 3.2 to 4;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12;

(5) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 2 to 2.8; and

(iv) One control in the range 3.2 to 4; and

(6) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff specified in sections 11.29(d)(3), (4), and (6) for the compound of interest, a control without the compound of interest (*i.e.*, a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (*i.e.*, certified negative urine), one control in the range of 200 mcg/mL to 400 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

(f) The requirements for performing other adulterant tests are that the initial and confirmatory tests for any "other" adulterant that may be identified in the future must include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

#### Section 11.26 What Are the Requirements for an HHS-Certified Laboratory to Report a Hair Test Result?

(a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the sample using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by a certifying scientist.

(b) A primary (Sample A) head hair sample is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the sample is a valid head hair sample.

(c) A primary (Sample A) head hair sample is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Sample A) head hair sample is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Sample A) head hair sample is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) An HHS-certified laboratory shall reject a head hair sample for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all non-negative test results for a sample. For example, a head hair sample can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(i) An HHS-certified laboratory must report numerical values that support a sample that is reported adulterated or invalid (as appropriate).

(j) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than or equal to (insert the value for the upper limit of the linear range), or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the dissolved head hair sample.

(k) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(l) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 11.27 What Are the Requirements for an HHS-Certified Laboratory to Report an Oral Fluid Test Result?*

(a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by a certifying scientist.

(b) A primary (Tube A) oral fluid specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the specimen is a valid oral fluid specimen.

(c) A primary (Tube A) oral fluid specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive. For only those oral fluid tests that result in a confirmed positive for marijuana, the laboratory must not report the result for the oral fluid specimen to the MRO but, instead must test the primary (Bottle A) urine specimen for marijuana and report that result in accordance with section 11.29.

(d) A primary (Tube A) oral fluid specimen is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Tube A) oral fluid specimen is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) A primary (Tube A) oral fluid specimen is reported substituted if the sample does not exhibit the characteristics of a normal oral fluid specimen.

(g) An HHS-certified laboratory shall reject an oral fluid specimen for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(h) An HHS-certified laboratory must report all non-negative test results for a specimen. For example, an oral fluid specimen can be positive for a specific drug and adulterated.

(i) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(j) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(k) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than or equal to (insert the value for the upper limit of the linear range), or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.

(l) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(m) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 11.28 What Are the Requirements for an HHS-Certified Laboratory To Report a Sweat Patch Test Result?*

(a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the sample using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by a certifying scientist.

(b) A primary (Patch A) sweat patch sample is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the sample is a valid sweat patch sample.

(c) A primary (Patch A) sweat patch sample is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Patch A) sweat patch sample is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Patch A) sweat patch sample is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) An HHS-certified laboratory shall reject a primary (Patch A) sweat patch sample for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 is not recovered. The laboratory will indicate on the Federal CCF that the sample was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all non-negative test results for a sample. For example, a sweat patch sample can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(i) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than or equal to (insert the value for the upper limit of the linear range), or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the eluted sweat patch sample.

(k) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.



(l) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

*Section 11.29 What Are the Requirements for an HHS-Certified Laboratory To Report a Urine Test Result?*

(a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by a certifying scientist.

(b) A primary (Bottle A) urine specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (Bottle A) urine specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Bottle A) urine specimen is reported adulterated when:

(1) The pH is less than 3 or greater than or equal to 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration greater than or equal to the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration greater than or equal to the LOD of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in 4(iii) through 4(vii) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (Bottle A) urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the

initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(f) A primary (Bottle A) urine specimen is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) A primary (Bottle A) urine specimen is reported as an invalid result when:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff greater than or equal to 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff greater than or equal to the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde



present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff, a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is greater than or equal to the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the immunoassay drug tests on two separate aliquots (*i.e.*, valid immunoassay drug test results cannot be obtained);

(10) Interference with the GC/MS drug confirmation assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(12) If the physical appearances of Bottles A and B are clearly different, the test result for Bottle A is one of the reasons stated in (i) through (xi) of this section and/or was screened negative for drugs.

(h) An HHS-certified laboratory shall reject a primary (Bottle A) urine specimen for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(i) An HHS-certified laboratory must report all non-negative test results for a specimen. For example, a specimen can be positive for a specific drug and adulterated.

(j) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(k) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(l) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified

laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than or equal to (insert the value for the upper limit of the linear range), or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.

(m) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(n) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

#### *Section 11.30 How Long Must an HHS-Certified Laboratory Retain a Specimen?*

(a) An HHS-certified laboratory must retain a specimen that was reported either drug positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) A retained specimen must be kept in a secured location that is appropriate for that type of specimen (*e.g.*, frozen storage (-20°C or less) for urine) to ensure its availability for any necessary retesting during an administrative or judicial proceeding.

(c) Within the 1-year storage period, a Federal agency may request a laboratory to retain a specimen for an additional period of time. If no such request is received, a specimen may be discarded, except that the laboratory must be required to maintain any specimens under legal challenge for an indefinite period.

#### *Section 11.31 How Long Must an HHS-Certified Laboratory Retain Records?*

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may instruct, in writing, the laboratory to maintain records associated with a particular specimen under legal challenge for an indefinite period.

#### *Section 11.32 What Statistical Summary Report Must an HHS-Certified Laboratory Provide?*

(a) An HHS-certified laboratory must provide to each Federal agency for which testing is conducted a semiannual statistical summary report for each type of specimen tested that contains the following information:

Reporting Period: (inclusive dates)  
Laboratory Name and Address  
Federal Agency Name

(1) Specimens Results Reported (total number)

By Type of Test:

(i) Pre-employment (number)  
(ii) Post-Accident (number)  
(iii) Random (number)  
(iv) Reasonable Suspicion/Cause (number)  
(v) Return-to-Duty (number)  
(vi) Follow-up (number)  
(vii) Type of Test Not Noted on CCF (number)

(2) Specimens Reported

(i) Negative (number)  
(ii) Negative and Dilute (number)  
(3) Specimens Reported as Rejected for Testing (total number)

By Reason:

(i) Fatal flaw (number)  
(ii) Uncorrected Flaw (number)  
(4) Specimens Reported as Positive (total number)

By Drug:

(i) Marijuana Metabolite (number)  
(ii) Cocaine Metabolite (number)  
(iii) Opiates:  
(A) Codeine (number)  
(B) Morphine (number)  
(C) 6-AM (number)  
(iv) Phencyclidine (number)  
(v) Amphetamines:  
(A) Amphetamine (number)  
(B) Methamphetamine (number)  
(C) MDMA  
(D) MDA  
(E) MDEA  
(5) Adulterated (number)  
(6) Substituted (number)  
(7) Invalid Result (number)

(b) The report must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information.

(c) The HHS-certified laboratory must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.

(d) The HHS-certified laboratory must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified laboratory.

**Section 11.33 What Information Is Available to the Donor?**

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified laboratory must consist of the following items:

(1) A cover sheet that provides a brief description of the drug testing procedures and any specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the laboratory, and a copy of the electronic report (if any) generated by the laboratory;

(4) A brief description of the laboratory's initial drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests;

(5) A brief description of the laboratory's confirmatory drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the confirmatory test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the confirmatory tests; and

(6) A copy of the resume or curriculum vitae for the certifying scientist that certified the test result.

**Section 11.34 What Type of Relationship Is Prohibited Between an HHS-Certified Laboratory and an MRO?**

(a) An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having a Federal agency use a specific HHS-certified laboratory that may be construed as a potential conflict of interest.

**Section 11.35 What Information Must an HHS-Certified Laboratory Provide To Its Private Sector Clients?**

When an HHS-certified laboratory uses procedures to test private sector client specimens that are different from those for which it is certified, it must inform the private sector client that its specimens are not being tested under the Guidelines.

**Subpart L—Point of Collection Test (POCT)**

**Section 12.1 What Is the Goal of This Subpart?**

(a) Employees of Federal agencies are in some cases located in remote areas of the country if they are serving with the Department of Interior, or overseas if they are serving with the Department of State. They are often in locations with few employees as is often the case when they are serving on American Indian reservations or in embassies in small foreign countries. It is often unrealistic to expect that a drug testing program in such places would operate in the same fashion as one that serves employees in the Washington, DC, area. It is in these circumstances and in cases where it is critical to receive an immediate test result that POCT tests play an important role.

(b) Yet a POCT offers a particular challenge to the Federal Workplace Drug Testing Program because the device that is used to produce a negative test result is really equivalent to a laboratory test to which the normal laboratory procedures and requirements cannot readily apply. Thus, while the sections of the Guidelines related to specimens, collection procedures, collections sites, chain of custody, drug and validity testing and others do apply, it is necessary to establish requirements particular to POCTs.

(c) This subpart establishes the criteria for POCT devices that may be used as part of the Federal Workplace Drug Testing Program, when Federal agencies may use a POCT, what the responsibilities are of a Federal agency which chooses to use a POCT, and the procedures that must be followed in using a POCT.

**Section 12.2 What POCT Devices May Be Used in a Federal Workplace Drug Testing Program?**

(a) A POCT device that may be used in a Federal Workplace Drug Testing Program is one which:

- (1) Is FDA-cleared; and
- (2) Effectively determines the presence or absence of drugs and determines the validity of a specimen, either as an integral function of the

POCT device, or as a set of compatible devices or procedures as established in section 12.6.

(b) The Secretary will publish a list of the POCT devices that are SAMHSA-certified for use in the Federal Workplace Drug Testing Program in the **Federal Register**.

**Section 12.3 What Is the Rationale for the Additional Requirements To Use POCT Devices Besides FDA Clearance?**

The FDA clears POCT drug test devices by making a finding of substantial equivalence to a legally marketed device. FDA's determination of substantial equivalence does not ensure that the test will satisfy minimum performance requirements that are necessary for use in the Federal Workplace Drug Testing Program. Therefore, due to the critically important nature of testing under these Guidelines, there is need for additional assurance in the Federal Workplace Drug Testing Program that the FDA-cleared kits are effectively finding drugs at the specified cutoff concentrations and effectively determining the absence of drugs.

**Section 12.4 What Types of POCT Devices Are There?**

POCT devices are:

- (a) Non-instrumented for which the endpoint result is obtained by visual evaluation (*i.e.*, read by human eye); or
- (b) Instrumented for which the result is obtained by instrumental evaluation (*e.g.*, densitometer, spectrophotometer, fluorometer).

**Section 12.5 What Must a POCT Device Manufacturer Submit to the Secretary To Have Its POCT Device Initially Included on the List of SAMHSA-Certified POCTs?**

A POCT device manufacturer must submit the following to the Secretary:

- (a) A copy of the FDA letter stating that the FDA has cleared the specific POCT device;
- (b) A copy of the labeling submitted to FDA for the cleared device;
- (c) A self-certification that the device meets the requirements contained in the FDA's good manufacturing practices regulations;
- (d) A description of the storage requirements for the device;
- (e) A total of 100 POCT devices and related testing procedures in representative numbers from all currently available manufactured lots of the device for HHS testing to evaluate the performance of the POCT device(s) for drug and validity testing; and
- (f) An accounting of the expiration date and number of devices for each existing manufactured lot of the device.

*Section 12.6 What Criteria Will the Secretary Use To Place a POCT Device on the List of SAMHSA-Certified POCTs?*

(a) The Secretary shall evaluate the POCT devices submitted by the manufacturer using the following criteria:

- (1) Correctly identify at least 80 percent of the total drug challenges;
- (2) For an individual drug, correctly identify at least 80 percent of the total drug challenges;
- (3) Correctly identify at least 80 percent of the total validity test challenges;
- (4) For each specific validity test, correctly report at least 80 percent of the challenges for the specific validity test; and
- (5) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) The Secretary will use PT samples as described in section 12.9 to evaluate the POCT device.

*Section 12.7 What Is Required for a FDA Cleared POCT Device To Continue on the List of SAMHSA-Certified Devices?*

To maintain a POCT device on the SAMHSA-certified list, the manufacturer:

- (a) Must agree to submit any design changes or alterations made to the device after it has been SAMHSA-certified, so that the Secretary may determine whether additional testing is required; and
- (b) Must submit 50 POCT devices and related testing procedures annually to the Secretary in representative numbers from all currently available manufactured lots of the device for HHS testing to evaluate the performance of the POCT device(s) for drug and validity testing using criteria established in section 12.6.

*Section 12.8 What Are the Responsibilities of a Federal Agency That Wishes To Conduct POCT?*

A Federal agency which seeks to conduct POCT as part of its Federal Workplace Drug Testing Program must:

- (a) Use only POCT devices that are on the SAMHSA-certified list published by the Secretary in accordance with section 12.2(b);
- (b) Develop a standard operating procedure manual for POCT testers to use;
- (c) Ensure that POCT testers meet the requirements of section 12.16;
- (d) Ensure that all other pertinent requirements of these Guidelines are adhered to including the requirements with regard to POCT sites;

(e) Inspect the POCT sites periodically to ensure compliance with these Guidelines;

(f) Ensure that on a quarterly basis sets of HHS-contractor prepared PT samples (that satisfy the requirements in section 12.9) are submitted to challenge the performance of each POCT drug and validity test device at each site;

(g) Maintain records on those who have been SAMHSA-certified as POCT testers including records of their training;

(h) Retain records on the results of the PT samples and the results of all POCTs by test and by specimen;

(i) Provide semiannual reports to the Secretary with regard to the use of the POCT device(s) in keeping with section 12.25;

(j) Investigate each failure as provided in section 12.12 and determine whether it was related to failure to follow procedure in which case to take action against the POCT tester or whether it was related to the POCT device itself; and

(k) If any failure under (j) of this section is related to the device itself, immediately inform the Secretary who shall temporarily suspend the use of the POCT device.

*Section 12.9 What Are the Qualitative and Quantitative Specifications for PT Samples That Are Used To Evaluate Test Devices Submitted by Manufacturers or for a Federal Agency To Evaluate a POCT Site and Tester?*

A PT sample that is used to evaluate test devices submitted by manufacturers or to challenge a POCT drug or validity test device is a sample:

(a) That contains one or more drugs or metabolites in the drug classes for which each POCT device must have the capability to test.

(b) The concentration of the drugs and/or metabolites are at least 20 percent above the cutoff concentration or between 50 and 75 percent of the cutoff concentration for the initial test.

(c) That contains no measurable amount of a target drug and/or metabolite (*i.e.*, a negative sample).

(d) That may contain an interfering substance, an adulterant, or a specimen that meets the criteria for a substituted specimen that would challenge the POCT validity tests.

(e) For urine only PT samples, the nitrite concentration must be between 650 mcg/mL and 800 mcg/mL or between 250 mcg/mL and 400 mcg/mL.

(f) For urine only PT samples, the creatinine concentration must be between 5 mg/dL and 20 mg/dL or between 1 mg/dL and 5 mg/dL.

(g) For urine only PT samples, the specific gravity must be between 1.0000 and 1.0010 or between 1.0200 and 1.0300.

(h) For urine only PT samples, the pH must be between 1 and 3 or between 10 to 12.

(i) For oral fluid only PT samples, the IgG must be between 0.1 and 1.0.

*Section 12.10 What Are the Inspection Requirements for a Federal Agency Wishing To Use a POCT?*

(a) Each Federal agency is to inspect each POCT site periodically to ensure compliance with these Guidelines; and

(b) The Federal agency must maintain a record of the inspections for a minimum of 2 years.

*Section 12.11 What Is the Responsibility of the Secretary To Inspect a Federal Agency Using POCT?*

(a) The Secretary shall conduct a semiannual inspection of each Federal agency that uses POCT.

(b) The inspection will review the Federal agency's records to include:

- (1) The Federal agency's standard operating procedure manual;
- (2) POCT tester training records;
- (3) POCT device quarterly PT results; and
- (4) POCT quality assurance data maintained by each POCT tester and site.

*Section 12.12 What Is a Failure for the Purposes of the POCT?*

A failure means the following:

(a) For a drug POCT, the device failed to properly identify a negative or positive PT sample;

(b) For a validity POCT, the device failed to identify a PT sample that was adulterated, substituted or diluted; or

(c) The device reported a false negative after confirmation by a laboratory in keeping with section 12.21(b).

*Section 12.13 What Is the Responsibility of the Secretary When a Failure Is Reported?*

(a) If, after reviewing the information from the Federal agency and all other agencies using the same device as well as the circumstances of the failure, the Secretary determines that there is a problem with the device, the Secretary may:

(1) Temporarily suspend the use of the device in the Federal Workplace Drug Testing Program if immediate action is necessary in order to protect the interests of the United States and its employees; or

(2) Remove the device from the SAMHSA-certified list.

(b) If the Secretary suspends the use of the device, the Secretary shall:

(1) Inform all Federal agencies which are using the device of the action by placing notice in the *Federal Register* of such action; and

(2) Notify the manufacturer that the device may be removed from the list of SAMHSA-certified devices. In this event, the manufacturer has 30 days from the date of notification to reply.

(3) Based on the Secretary's investigation and any information provided by the manufacturer, the Secretary shall decide whether the device should remain on the list of SAMHSA-certified devices.

(i) If the Secretary determines that the device is to be removed from the list of SAMHSA-certified devices, the list will be revised accordingly.

(ii) If the Secretary decides that it is not to be removed from the list of SAMHSA-certified devices, the suspension will be lifted by publication of a notice in the *Federal Register*.

(c) If the Secretary has cause to remove the device from the list of SAMHSA-certified devices in the absence of a need for immediate action, the Secretary shall notify the manufacturer that the device may be removed from the list of SAMHSA-certified devices. In this event, the manufacturer has 30 days from the date of notification to reply. Based on the Secretary's investigation and any information provided by the manufacturer, the Secretary will decide whether the device should remain on the approved list.

(d) If the Secretary determines that there is a problem with the device, the Secretary shall notify the FDA so that the FDA can evaluate whether any action under the Food, Drug, and Cosmetic Act is necessary.

*Section 12.14 How Can a Manufacturer Apply To Have a Device Reinstated on the List of SAMHSA-Certified Devices?*

(a) The manufacturer may reapply for SAMHSA-certification in accordance with section 12.5.

(b) Upon reapplication, the manufacturer must submit a statement describing what has been done to overcome the problems that resulted in the device being removed from the list of SAMHSA-certified devices.

*Section 12.15 Which Types of Specimens May Be Tested Using a POCT?*

- (a) Oral fluid (saliva)
- (b) Urine

*Section 12.16 What Are the Requirements To Be a POCT Tester?*

(a) An individual is considered to be a POCT tester for a specific POCT device when the Federal agency documents that the individual has:

(1) Received supervised and validated training in how to use and interpret the results of the POCT device;

(2) Received training on chain of custody, reporting, and recordkeeping procedures;

(3) Read and understands these Guidelines; and

(4) Demonstrated proficiency that has been documented by the Federal agency by completing five consecutive error-free POCTs.

(b) An individual may be trained to use all or some of the devices on the list of SAMHSA-certified devices.

*Section 12.17 What Happens if a POCT Site or Tester Does Not Satisfy the Minimum Technical Requirements?*

The POCT site or tester may not perform POCTs for a Federal agency until acceptable performance has been documented.

*Section 12.18 What Are the Requirements for Conducting a POCT?*

(a) A donor must not have access to the POCT device.

(b) After the donor leaves the collection site and after the split specimens are labeled and sealed by the collector, a POCT tester (which may be the collector) is permitted to break the label/seal on the primary specimen and remove an aliquot to conduct the POCT.

(c) The POCT tester must maintain and document chain of custody for the primary specimen and the aliquot used for the POCT on an OMB-approved custody and control form.

(d) If the aliquot tests negative on the drug POCTs, the aliquot, primary, and split specimens must be discarded unless the split specimens are to be submitted as part of the quality assurance program.

(e) If the aliquot tests presumptive drug positive, adulterated, substituted, or invalid on the POCTs, the primary specimen must be resealed using a new tamper-evident label/seal and sent with the split specimen to an HHS-certified laboratory for testing. The POCT tester must initial and date the new label/seal that was used to reseat the primary specimen. The POCT tester must report the POCT result on the OMB-approved custody and control form. The aliquot used to conduct the POCTs is discarded. When a POCT is conducted on an oral fluid specimen aliquot and it is presumptive positive for marijuana, the

POCT tester must send the urine split specimen bottles to an HHS-certified laboratory for testing rather than the oral fluid specimen tubes. For all other presumptive positive drug test results on an oral fluid POCT, the POCT tester may only send the oral fluid split specimen tubes to the HHS-certified laboratory for testing.

(f) The POCT tester must complete the POCTs on an aliquot before beginning the testing of another specimen using POCTs.

*Section 12.19 What Are the Quality Control Requirements When Conducting POCTs?*

(a) For drug POCTs:

(1) Each day testing is performed using devices with visually read endpoints (i.e., a color appearing or disappearing that indicates a positive result using that device), each individual performing drug tests using these devices must test at least one negative control (i.e., a sample certified to contain no drug or drug metabolite) and one positive control (i.e., a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) before donor specimens are tested. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.

(2) Each day testing is performed using devices with semi-automated or automated testing devices with machine read endpoints (i.e., spectrophotometer), at least one negative control (i.e., a sample certified to contain no drug or drug metabolite) and one positive control (i.e., a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) must be tested on each device used. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.

(b) For validity POCTs, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested.

(c) At least one specimen out of every 10 specimens that test negative must be submitted to an HHS-certified laboratory as part of a quality assurance program.

**Section 12.20 What Action Must Be Taken When a POCT Quality Control Sample Fails?**

For (a) or (b) in section 12.19, the failed quality control sample must be sent to an HHS-certified laboratory. The POCT tester must successfully test QC samples until acceptable results are obtained before testing donor specimens. If acceptable QC results cannot be obtained, donor specimens must be sent directly to an HHS-certified laboratory.

**Section 12.21 What Does a POCT Tester Do With a Specimen After Conducting a POCT?**

(a) Each presumptive positive, adulterated, or substituted specimen together with its split is sent to an HHS-certified laboratory for additional testing.

(b) A POCT tester must send one of every 10 negative specimens together with its split to an HHS-certified laboratory to be tested for quality control purposes. Other negative specimens must be discarded.

**Section 12.22 How is a POCT Negative Result Reported?**

(a) A negative result is reported directly to an MRO within 3 (on average) working days after the POCT is conducted.

(b) A POCT tester may report a negative test result to an MRO using an electronic report format. The electronic report must be transmitted to the MRO in a manner that ensures the confidentiality and security of the information.

(c) A POCT tester may not report test results telephonically. However, the MRO may contact the POCT tester by telephone if he or she has any concern regarding the negative result.

**Section 12.23 How Long Must Records Generated at the POCT Site Be Retained?**

All records must be retained for at least 2 years by the POCT tester or the tester's employer.

**Section 12.24 What POCT Information Is Available to the Donor?**

(a) An employee tested by a Federal agency workplace drug testing program may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant review of the POCT, and have access to a documentation package.

(b) The documentation package must contain the following:

(1) A brief description of the POCT procedures, quality control requirements, copies of the POCT test data for the donor's specimen with all calibrators and controls identified as related to the POCTs;

(2) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the POCT tester, and a copy of the report generated by the POCT tester;

(3) A copy of the resume or curriculum vitae for the POCT tester; and

(4) A copy of the Federal agency documentation of training of the POCT tester for the specific POCT device.

**Section 12.25 What Statistical Summary Report Must a Federal Agency Provide to the Secretary?**

(a) A Federal agency must provide the Secretary a semiannual statistical summary report that contains the following information:

(1) The number of specimens tested  
(2) The number grouped by reason for test as follows:

(i) Random  
(ii) All others reasons combined  
(3) The number that were:

(i) Screened positive for each drug (listed separately)  
(ii) Screened as adulterated  
(iii) Screened as substituted  
(iv) Invalid Result

(4) The total number of quality control samples tested

(i) The number of acceptable QC sample results  
(ii) The number of failed QC sample results

(b) The report must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period.

(c) The Federal agency must make available copies of an agency's POCT drug and validity test results when requested by the Secretary.

(d) The Federal agency must make available the POCT tester to testify in a proceeding against a Federal employee when that proceeding is based on a test result that begins with a POCT.

**Section 12.26 What Type of Relationship Is Prohibited Between a Manufacturer of a POCT Device or a POCT Site Operation and an MRO?**

(a) An MRO must not be an employee, agent of, or have any financial interest in a manufacturer of a POCT device or POCT site operation for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency

use a specific POCT device that may be construed as a potential conflict of interest.

**Section 12.27 What Type of Relationship Can Exist Between a Manufacturer of a POCT Device or a POCT Site Operation and an HHS-Certified Laboratory?**

A manufacturer of a POCT device or a POCT site operation can freely enter into any relationship with an HHS-Certified laboratory.

**Subpart M—Instrumented Initial Test Facility (IITF)**

**Section 13.1 What Is an HHS-Certified IITF?**

An HHS-certified IITF:

(a) Is a facility at a permanent location that conducts only instrumented initial drug and validity tests (as described for an HHS-certified laboratory in subpart K);

(b) Has satisfied the certification requirements for each type of specimen the IITF wants to test;

(c) Has passed 3 consecutive sets of PT samples for each type of specimen to be tested and an initial inspection before becoming HHS-certified;

(d) Participates in a quarterly maintenance PT sample program and is inspected every 6 months; and

(e) Is managed by a full-time responsible technician (RT).

**Section 13.2 Which Types of Specimens May Be Tested at an HHS-Certified IITF?**

(a) Hair  
(b) Oral fluid (saliva)  
(c) Sweat (patch)  
(d) Urine

**Section 13.3 What Cutoff Concentrations Are Used by an HHS-Certified IITF for the Drug Tests?**

An HHS-certified IITF must use the same cutoff concentrations for its initial drug tests as listed for a hair sample in section 3.3, for an oral fluid specimen in section 3.4, for a sweat patch sample in section 3.5, and for a urine specimen in section 3.6.

**Section 13.4 What Must Be Included in the HHS-Certified IITF's Standard Operating Procedure Manual?**

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all IITF operations.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

(1) Chain-of-custody procedures;  
(2) Accessioning;  
(3) Security;



(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance documents.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained by the HHS-certified IITF to allow the IITF to retrieve the procedures that were used to test a specimen.

#### *Section 13.5 What Must the HHS-Certified IITF Do To Validate an Initial Drug Test?*

The HHS-certified IITF must satisfy the same validation requirements as described in section 11.13.

#### *Section 13.6 What Qualifications Must the Responsible Technician (RT) Have?*

An RT must have the following qualifications:

(a) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;

(b) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results;

(c) Training and experience in reviewing and reporting test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise; and

(d) Be found to fulfill RT responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the HHS-certified IITF.

#### *Section 13.7 What Are the Responsibilities of an RT?*

An RT must:

(a) Manage the day-to-day operations of the IITF.

(b) Ensure that there are enough personnel with adequate training and experience to conduct and operate the work of the IITF. The RT must ensure the continued competency of testing facility personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel at the IITF, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RT

whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the IITF.

(d) Verify and maintain a quality assurance program to assure the proper performance and reporting of all test results; monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each device/system used at that testing facility.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the testing facility in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual must ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(f) Qualify as an operator of the initial test analyzers used at the IITF.

#### *Section 13.8 What Happens When the RT Is Absent or Leaves an HHS-Certified IITF?*

(a) All HHS-certified IITFs must have an RT and an alternate RT. An alternate RT must be able to fulfill the responsibilities of an RT and must meet the qualifications of a certifying scientist. The laboratory must submit documentation satisfactory to the Secretary which shows the credentials of the prospective RT and which must be approved by the Secretary, and found acceptable during on-site inspections of the IITF.

(b) When the HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (e.g., vacation, illness, business trip), the certified IITF may continue testing Federal agency specimens under the direction of a certifying scientist.

(c) When an RT permanently leaves a certified IITF:

(1) The HHS-certified IITF may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RT.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's certification for all specimens if the IITF does not have a permanent replacement RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(d) When a new RT candidate has been identified, the IITF must submit to the Secretary the candidate's current resume or curriculum vitae, arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RT position, and an itemized defense of the candidate's qualifications compared to the minimum RT qualifications described in the Guidelines.

(e) The HHS-certified IITF must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RT.

#### *Section 13.9 What Qualifications Must an Individual Have To Certify a Test Result Reported By an HHS-Certified IITF?*

The individual who certifies a negative test result must have:

(a) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

#### *Section 13.10 What Qualifications and Training Must Other IITF Personnel Have?*

(a) All IITF staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified IITF must be properly trained before he or she is permitted to work independently in any area of the facility with Federal agency specimens.

(c) The training file for each individual must include, at a minimum, a resume, documentation of training provided, and any applicable professional certifications or licenses. Training files should be maintained separate from personnel files.

#### *Section 13.11 What Security Measures Must an HHS-Certified IITF Maintain?*

(a) An HHS-certified IITF must control access to the facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.

(b) Authorized visitors must be escorted at all times except for individuals authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies or emergency personnel (e.g., firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors and authorized escorts to accessing secured areas.

*Section 13.12 What Are the Internal IITF Chain of Custody Requirements for a Specimen or an Aliquot?*

(a) An HHS-certified IITF must use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) An HHS-certified IITF must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either hard copy procedures or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the chain of custody document when the specimen or aliquot is received.

*Section 13.13 What Are the Batch Quality Control Requirements When Conducting the Initial Tests for Drugs?*

The HHS-certified IITF must satisfy the same quality control requirements as described in section 11.14 for an HHS-certified laboratory.

*Section 13.14 What Are the Analytical and Quality Control Requirements for Conducting Initial Validity Tests?*

An HHS-certified IITF must satisfy the same initial validity test requirements described in sections 11.18, 11.19, 11.20, and 11.21 and sections 11.22, 11.23, 11.24, and 11.25 for each type of specimen, as appropriate.

*Section 13.15 What Action Is Taken After an HHS-Certified IITF Tests a Specimen?*

(a) A specimen that is negative on initial drug tests and has acceptable initial validity test results is discarded and reported as negative to the MRO within 3 days (on average) working days after receipt of the specimen.

(b) A specimen that is presumptive drug positive, adulterated, substituted, or invalid is immediately forwarded

using chain of custody procedures to an HHS-certified laboratory for confirmatory testing.

*Section 13.16 How Long Must an HHS-Certified IITF Retain Records?*

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may request the HHS-certified IITF to maintain records associated with a particular specimen under legal challenge for an indefinite period.

*Section 13.17 What Statistical Summary Report Must an HHS-Certified IITF Provide?*

(a) An HHS-certified IITF must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:

- (1) Number of specimens tested
- (2) The number grouped by reason for test as follows:

- (i) Random
- (ii) All others reasons combined

(3) The number that were:

- (i) Screened positive for each drug (listed separately)
- (ii) Screened as adulterated
- (iii) Screened as substituted
- (iv) Rejected for Testing
- (v) Invalid Result

(b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period.

(c) The HHS-certified IITF must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the IITF is performing drug-testing services.

(d) The HHS-certified IITF must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF.

*Section 13.18 What IITF Information Is Available to the Donor?*

(a) An employee tested by a Federal agency workplace drug testing program may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified IITF must contain the following items:

- (1) A cover sheet that provides a brief description of the drug testing

procedures and any specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the IITF, and a copy of the electronic report (if any) generated by the IITF;

(4) A brief description of the laboratory's initial drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests; and

(5) A copy of the resume or curriculum vitae for the certifying scientist that certified the test result.

*Section 13.19 What Type of Relationship Is Prohibited Between an HHS-Certified IITF and an MRO?*

(a) An MRO must not be an employee, agent of, or have any financial interest in an IITF for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific instrumented initial test facility or have any agreement with the IITF that may be construed as a potential conflict of interest.

*Section 13.20 What Type of Relationship Can Exist Between an HHS-Certified IITF and an HHS-Certified Laboratory?*

An HHS-certified IITF can freely enter into any relationship with an HHS-certified laboratory.

*Section 13.21 How Does an HHS-Certified IITF Report a Negative Test Result?*

(a) An HHS-certified IITF may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. An IITF must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(b) For all test results, an HHS-certified IITF may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report.

**Section 13.22 How Does an HHS-Certified IITF Handle a Specimen That Is Presumptive Drug Positive, Adulterated, Substituted, or Invalid?**

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal;

(c) The resealed specimen and split specimen are sent to an HHS-certified laboratory for confirmatory testing within one day after completing the initial drug and/or validity tests; and

(d) The HHS-certified IITF provides the test result(s) on the OMB-approved chain of custody form used to report initial test results.

**Section 13.23 Where Is the List of HHS-Certified IITFs Published?**

(a) The list of current HHS-certified IITFs is published monthly in the **Federal Register**.

(b) An applicant IITF is not included on the list.

**Subpart N—Medical Review Officer (MRO)**

**Section 14.1 Who May Serve as an MRO?**

(a) A licensed physician who:  
(1) Has either a Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Has knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) Has the training necessary to serve as an MRO as set out in section 14.2; and

(4) Has satisfactorily completed an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary.

(b) Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the **Federal Register** of those entities and boards that have been approved.

**Section 14.2 What Are the Training Requirements Before a Physician Can Serve as an MRO?**

A physician must receive training that includes a thorough review of:

(a) The collection procedures for each type of specimen collected;

(b) The procedures for conducting POCT tests;

(c) How to interpret test results reported by laboratories;

(d) Chain of custody, reporting, and recordkeeping requirements for regulated specimens; and

(e) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

**Section 14.3 What Are the Responsibilities of the MRO?**

(a) The MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory, HHS-certified IITF, or POCT site;

(2) Interview the donor when required;

(3) Make a determination regarding the test result;

(4) Report the verified result to the Federal agency; and

(5) Maintain the records (for a minimum of 2 years) and the confidentiality of the information.

(b) The review of a non-negative test result must be performed by the MRO before the result is transmitted to the agency's designated representative. Staff under the direct, personal supervision of the MRO may review and report a negative test result to the agency's designated representative. The MRO must cancel the result for any agency's specimen that is not collected or tested in accordance with these Guidelines.

**Section 14.4 What Must an MRO Do When Reviewing a Hair Test Result?**

(a) When the HHS-certified laboratory or IITF reports a negative result on the primary (Sample A) head hair sample, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports a positive result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is a valid medical explanation for the adulterated result. If the donor is unable to provide a valid explanation, the MRO reports a refusal

to test to the agency because the specimen was adulterated.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is a valid medical explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result (e.g., lice) on the primary (Sample A) head hair sample, the MRO reports a test cancelled result to the agency and directs the agency to collect another sample from the donor.

**Section 14.5 What Must an MRO Do When Reviewing an Oral Fluid Test Result?**

(a) When a HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative result on the primary (Tube A) oral fluid specimen, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory reports a positive result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated or substituted result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is a valid explanation for the adulterated or substituted result. If the donor is unable to provide a valid explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated or substituted.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is a valid explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected exhibits the same behavior as the first specimen, the MRO

again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Tube A) oral fluid specimen, the MRO reports a test cancelled result to the agency and directs the agency to collect another specimen from the donor.

#### *Section 14.6 What Must an MRO Do When Reviewing a Sweat Patch Test Result?*

(a) When an HHS-certified laboratory or IITF reports a negative result on the primary (Patch A) sweat patch sample, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory reports a positive result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is a valid explanation for the adulterated result. If the donor is unable to provide a valid explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is a valid explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected using a direct observed collection procedure exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Patch A) sweat patch sample, the MRO reports a test cancelled result to the agency and directs the agency to collect another sample.

#### *Section 14.7 What Must an MRO Do When Reviewing a Urine Test Result?*

(a) When an HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative result on the primary (Bottle A) urine specimen, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative and dilute result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any possible explanation for the urine specimen being dilute. If there appears to be a legitimate medical explanation, the MRO reports a negative result to the agency without indicating that the specimen was dilute. If there is no legitimate medical explanation, the MRO directs the agency to immediately collect another specimen from the donor.

(c) When an HHS-certified laboratory reports a positive result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency. If a laboratory also reports that the specimen is dilute, the MRO directs the agency to have the donor provide another specimen using a direct observed collection procedure (when the MRO was reporting the result as negative). For a positive result, the MRO may ignore the dilute result.

(d) When an HHS-certified laboratory reports a positive result for opiates on the primary (Bottle A) urine specimen, the MRO must determine that there is clinical evidence in addition to the urine test result of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (i.e., the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is greater than or equal to 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(e) When an HHS-certified laboratory reports an adulterated or substituted

result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a valid medical explanation for the adulterated or substituted result. If the donor is unable to provide a valid medical explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated or substituted.

(f) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a valid medical explanation for the invalid result. If the donor is unable to provide an explanation, provides a valid prescription for some medications (e.g., Tolmetin, Flagyl, Cipro), or denies having tampered with the specimen, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor using a direct observed collection. If the second specimen collected using a direct observed collection procedure exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required because the donor is taking a valid prescription medication that interferes with the drug test or there is some unknown endogenous substance present in the donor's urine that prevents getting a valid drug test result.

(g) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Bottle A) urine specimen, the MRO reports a test cancelled result to the agency and directs the agency to immediately collect another specimen from the donor.

#### *Section 14.8 Who May Request a Test of a Split Specimen?*

(a) For a positive, adulterated, or substituted result reported on a primary specimen, a donor may request through the MRO that the split specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a test of the split specimen. The MRO must inform the donor that he or she has the right to request a test of the split specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary specimen.



**Section 14.9 How Does the MRO Report a Primary Specimen Test Result to an Agency?**

(a) The MRO must report all verified results to an agency by either faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a hard copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all non-negative results.

(d) The MRO must not disclose numerical values to the Federal agency.

**Section 14.10 What Type of Relationship Is Prohibited Between an MRO and an HHS-Certified Laboratory, POCT Tester, or an HHS-Certified IITF?**

(a) An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory, POCT tester, or HHS-certified IITF for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory, POCT tester, or HHS-certified IITF or have any agreement with the laboratory, POCT tester, or IITF that may be construed as a potential conflict of interest.

**Subpart O—Split Specimen Tests**

**Section 15.1 When May a Split Specimen Be Tested?**

(a) A donor has the right to request through the MRO that the split specimen be tested at a different HHS-certified laboratory when the primary specimen was determined by the MRO to be positive, adulterated, or substituted (as appropriate for each type of specimen collected).

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The donor must document this request in writing to the MRO.

(c) If the split specimen cannot be tested by a second laboratory (e.g., insufficient specimen, lost in transit, split not available), the MRO shall direct the Federal agency to immediately collect another specimen.

(d) If a donor chooses not have the split specimen tested by a second HHS-certified laboratory, a Federal agency may have a split specimen retested as part of a legal or administrative proceeding to defend an original

positive, adulterated, or substituted result.

**Section 15.2 How Does an HHS-Certified Laboratory Test a Split Hair, Oral Fluid, Sweat, or Urine Specimen When the Primary Specimen Was Reported Positive?**

(a) The testing of a split head hair, oral fluid, sweat, or urine specimen for a drug or metabolite is not subject to the testing cutoff concentrations established for each type of specimen collected.

(b) The laboratory is only required to confirm the presence of the drug or metabolite that was reported present in the primary head hair, oral fluid, sweat, or urine specimen.

(c) For urine only, if the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same validity tests as it would conduct on a primary specimen and reports those results to the MRO.

**Section 15.3 How Does an HHS-Certified Laboratory Test a Split Hair Sample for Adulterants When the Primary Sample Was Reported Adulterated?**

(a) The second laboratory must test the split head hair sample using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary sample.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

**Section 15.4 How Does an HHS-Certified Laboratory Test a Split Oral Fluid Specimen for Adulterants When the Primary Specimen Was Reported Adulterated?**

(a) The second laboratory must test the split oral fluid specimen using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary specimen.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

**Section 15.5 How Does an HHS-Certified Laboratory Test a Split Sweat Patch Sample for Adulterants When the Primary Sample Was Reported Adulterated?**

(a) The second laboratory must test the split sweat patch sample using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary sample.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

**Section 15.6 How Does an HHS-Certified Laboratory Test a Split Urine Specimen for Adulterants When the Primary Specimen Was Reported Adulterated?**

(a) A laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (Bottle B) specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i.e., either less than 3 or greater than or equal to 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of greater than or equal to 500 mcg/mL; or

(3) For adulterants without a specified cutoff (e.g., glutaraldehyde, surfactant, chromium (VI), pyridine, halogens (such as bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory validity test at an established limit of detection (LOD) to reconfirm the presence of the adulterant.

(b) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the adulterant result reported by the primary laboratory.

**Section 15.7 How Does an HHS-Certified Laboratory Test a Split Oral Fluid Specimen for Substitution When the Primary Specimen Was Reported Substituted?**

The second laboratory must test the split (Tube B) specimen using the laboratory's confirmatory IgG test and determine that the IgG concentration is less than 0.10 mcg/mL.

**Section 15.8 How Does an HHS-Certified Laboratory Test a Split Urine Specimen for Substitution When the Primary Specimen Was Reported Substituted?**

(a) A laboratory must use the following criteria to reconfirm a



substituted result when testing a split (Bottle B) specimen:

(1) The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 2 mg/dL; and

(2) The specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than 1.0010 or greater than or equal to 1.0200.

(b) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the validity test result(s) reported by the primary laboratory.

*Section 15.9 Who Receives the Split Specimen Result?*

The second laboratory must transmit the result directly to the MRO.

*Section 15.10 What Action(s) Does the MRO Take After Receiving the Split Hair Sample Result From the Second Laboratory?*

The MRO takes the following actions when the second laboratory reports the result for the split head hair sample as:

(a) *Reconfirmed the drug(s)*. The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s)*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration result*. The MRO reports to the agency a failed to reconfirm result (specify not adulterated), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

*Section 15.11 What Action(s) Does the MRO Take After Receiving the Split Oral Fluid Specimen Result From the Second Laboratory?*

The MRO takes the following actions when the second laboratory reports the result for the split oral fluid specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result*. The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s)*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)),

cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration or substitution result*. The MRO reports to the agency a failed to reconfirm result (specify not adulterated or substituted), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

*Section 15.12 What Action(s) Does the MRO Take After Receiving the Split Sweat Patch Sample Result From the Second Laboratory?*

The MRO takes the following actions when the second laboratory reports the result for the split sweat patch sample as:

(a) *Reconfirmed the drug(s) and/or adulteration result*. The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s)*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration result*. The MRO reports to the agency a failed to reconfirm result (specify not adulterated), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

*Section 15.13 What Action(s) Does the MRO Take After Receiving the Split Urine Specimen Result From the Second Laboratory?*

The MRO takes the following actions when the second laboratory reports the result for the split urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result*. The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and adulterated*. If the donor provides a legitimate medical

explanation for the adulteration result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test to the agency and indicates the adulterant that is present in the urine specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and substituted*. If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the primary specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and not adulterated or substituted*. The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and invalid result*. The MRO reports to the agency a failed to reconfirm result (specify drug(s) and gives the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office

responsible for coordination of the drug-free workplace program.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace

program regarding the test results for the specimen.

(k) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(l) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and specify adulterant or substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(m) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s) and adulterated) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(n) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s) and specify adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(o) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result ((specify adulterant) and not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(p) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (specify adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(q) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a

failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

#### *Section 15.14 How Does an MRO Report a Split Specimen Test Result to an Agency?*

(a) The MRO must report all verified results to an agency by either faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a hard copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all non-negative results.

(d) The MRO must not disclose numerical values to the agency.

#### *Section 15.15 How Long Must an HHS-Certified Laboratory Retain a Split Specimen?*

A split specimen is retained for the same period of time that a primary specimen is retained and under the same storage conditions. This applies even for those cases when the split specimen is tested by a second laboratory and the second laboratory does not confirm the original result reported by the first laboratory on the primary specimen.

#### **Subpart P—Criteria for Rejecting a Specimen for Testing**

##### *Section 16.1 What Discrepancies Require an HHS-Certified Laboratory or IITF to Report a Hair, Oral Fluid, Sweat, or Urine Specimen as Rejected for Testing?*

The following discrepancies are considered to be fatal flaws and the laboratory or IITF must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF:

(a) The specimen ID number on the specimen label/seal does not match the ID number on the Federal CCF or the ID number is missing either on the Federal CCF or on the specimen label/seal;

(b) The specimen label/seal is broken or shows evidence of tampering on the primary specimen and the split specimen cannot be re-designated as the primary specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF; or

(d) There is an insufficient amount of specimen/sample for analysis in the primary specimen unless the split specimen can be re-designated as the primary specimen.

(e) For hair only, an HHS-certified laboratory or IITF may reject a head hair sample if it contains lice.

**Section 16.2 What Discrepancies Require an HHS-Certified Laboratory or IITF to Report a Hair, Oral Fluid, Sweat, or Urine Specimen as Rejected for Testing Unless the Problem is Corrected?**

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the laboratory or IITF must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the laboratory or IITF may report the test result for the specimen. If the laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If the laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

**Section 16.3 What Discrepancies Are Not Sufficient To Require a Laboratory or IITF To Reject a Hair, Oral Fluid, Sweat, or Urine Specimen for Testing or an MRO To Cancel a Test?**

(a) The following omissions and discrepancies on the Federal CCF that is received by the HHS-certified laboratory or IITF are considered insignificant and should not cause an HHS-certified laboratory or IITF to reject a specimen or cause an MRO to cancel a test:

- (1) An incorrect laboratory name and address appears at the top of the form;
- (2) Incomplete/incorrect/unreadable employer name or address;
- (3) MRO name is missing;
- (4) Incomplete/incorrect MRO address;
- (5) A transposition of numbers in the donor's SSN;

(6) A phone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A "reason for test" box is not marked;

(9) A "drug tests to be performed" box is not marked;

(10) A specimen collection box is not marked;

(11) The observed box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) For urine only, the collector failed to check the specimen temperature box and the "Remarks" line did not have a comment regarding the temperature being out of range. If the collector cannot provide a memorandum for record (MFR) to attest to the fact that he or she did measure the specimen temperature, the laboratory may report the test result for the specimen but indicates that the collector could not provide an MFR to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the laboratory or IITF are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist fails to print his or her name;

(4) The certifying scientist accidentally initials the Federal CCF rather than providing a signature for a non-negative result (CS initials are acceptable for a negative result);

(5) The accessioner fails to mark one of the "primary specimen bottle seal intact" boxes, but the laboratory reported a "rejected for testing" result with an appropriate comment on the "Remarks" line.

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory and IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector, laboratory, or IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

**Section 16.4 What Discrepancies May Require an MRO To Cancel a Test?**

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the hard copy (Copy 1) of the Federal CCF for a specimen being reported drug positive, adulterated, substituted, rejected for testing, or invalid test result (as appropriate for each type of specimen collected); or

(3) The electronic report provided by the HHS-certified laboratory or IITF does not contain all the data elements required for the HHS standard electronic laboratory or IITF report for a specimen being reported drug positive, adulterated, substituted, rejected for testing, or invalid test result.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the CS that he or she inadvertently forgot to sign the CCF, but did, in fact, properly conduct the certification review.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or IITF and require the HHS-certified laboratory or IITF to modify its electronic reports and to retransmit a corrected electronic report.

**Subpart Q—Laboratory or IITF Suspension/Revocation Procedures**

**Section 17.1 When May an HHS-Certified Laboratory or IITF Be Suspended?**

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug

testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

#### *Section 17.2 What Definitions Are Used for This Subpart?*

**Appellant.** Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform drug and/or validity testing and has requested an informal review thereof.

**Respondent.** Means the person or persons designated by the Secretary in implementing these Guidelines.

**Reviewing Official.** Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

#### *Section 17.3 Are There Any Limitation on Issues Subject To Review?*

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

#### *Section 17.4 Who Represents the Parties?*

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

#### *Section 17.5 When Must a Request for Informal Review Be Submitted?*

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of

suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

#### *Section 17.6 What Is an Abeyance Agreement?*

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

#### *Section 17.7 What Procedure Is Used To Prepare the Review File and Written Argument?*

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) **Appellant's Documents and Brief.** Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) **Respondent's Documents and Brief.** Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug and/or validity testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) **Reply Briefs.** Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) **Cooperative Efforts.** Whenever feasible, the parties should attempt to develop a joint review file.

(e) **Excessive Documentation.** The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

#### *Section 17.8 When Is There an Opportunity for Oral Presentation?*

(a) **Electing Oral Presentation.** If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) **Presiding Official.** The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) **Preliminary Conference.** The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the



hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*  
(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for

summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

#### *Section 17.9 Are There Expedited Procedures for Review of Immediate Suspension?*

(a) *Applicability.* When the Secretary notifies a laboratory or IITF in writing that its certification to perform drug and/or validity testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the

party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with section 17.8(c) and will conduct the oral presentation in accordance with the procedures of sections 17.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in section 17.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile or overnight mail.

#### *Section 17.10 Are Any Types of Communications Prohibited?*

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

#### *Section 17.11 How Are Communications Transmitted by the Reviewing Official?*

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.



*Section 17.12 What Is the Authority and Responsibilities of the Reviewing Official?*

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

*Section 17.13 What Administrative Records Are Maintained?*

The administrative record of review consists of the review file; other

submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

*Section 17.14 What Are the Requirements for a Written Decision?*

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will

immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

*Section 17.15 Is There a Review of the Final Administrative Action?*

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under section 17.9(e) or 17.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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# Federal Register

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Tuesday,  
April 13, 2004

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## Part IV

### Environmental Protection Agency

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40 CFR Part 63

Site-Specific Rulemaking for Packaging  
Corporation of America's Pulp and Paper  
Mill Located in Tomahawk, WI, in  
Pursuant to the Joint State/EPA  
Agreement To Pursue Regulatory  
Innovation; Direct Final Rule and  
Proposed Rule

**ENVIRONMENTAL PROTECTION  
AGENCY**
**40 CFR Part 63**
**[FRL-7646-6]**
**RIN 2090-AA33**
**Site-Specific Rulemaking for  
Packaging Corporation of America's  
Pulp and Paper Mill Located in  
Tomahawk, WI, Pursuant to the Joint  
State/EPA Agreement To Pursue  
Regulatory Innovation**
**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA or the Agency) is taking direct final action to approve revisions to the National Emissions Standards for Hazardous Air Pollutants from the Pulp and Paper Industry (Pulp and Paper Industry NESHAP). Collectively, these revisions comprise a site-specific rule to control Hazardous Air Pollutants (HAPs) applicable only to the semi-chemical pulp and paper mill currently owned and operated by Packaging Corporation of America (PCA) in Tomahawk, Wisconsin (the Tomahawk Mill). EPA is adopting these revisions pursuant to the Clean Air Act (CAA) and the Joint State/EPA Agreement to Pursue Regulatory Innovation (Innovations Agreement).

The Pulp and Paper Industry NESHAP currently requires semi-chemical pulp and paper mills to control the HAP emissions from the air stack for the collection of equipment comprising the Low Volume High Concentration (LVHC) system. Neither the Pulp and Paper Industry NESHAP, nor any other Federal or State regulation, requires such mills to control HAPs that may be contained in the liquid condensates from the LVHC system. This site-specific rule allows PCA's Tomahawk Mill to control the HAPs generated in the LVHC system by condensing them into a liquid and treating them via anaerobic biodegradation in the facility's wastewater treatment system. In other words, the site-specific rule allows PCA's Tomahawk Mill to control the HAPs generated in the LVHC system from an emission point and with a technology not addressed by the Pulp and Paper Industry NESHAP.

As a result, PCA will maintain compliance with the CAA and achieve a reduction in HAPs emitted to the environment significantly superior to that which would have been achieved through compliance with the control

methodology currently prescribed by the Pulp and Paper Industry NESHAP. Additionally, the revisions are consistent with the Innovations Agreement by allowing PCA's Tomahawk Mill to achieve superior environmental performance through regulatory flexibility.

**DATES:** This direct final rule will be effective on June 14, 2004 without further notice, unless EPA receives adverse comments by May 13, 2004. If EPA receives adverse comments, the Agency will publish a timely withdrawal in the *Federal Register* informing the public that this rule will not take effect.

**ADDRESSES:** Comments may be submitted by mail by sending two (2) copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OAR-2003-0205. Comments may also be submitted electronically, or through hand delivery/courier, following the detailed instructions as provided in the proposed rule action with the same title located in the "Proposed Rules" section of today's *Federal Register*.

**FOR FURTHER INFORMATION CONTACT:** Ms. Eileen L. Furey or Mr. Eaton R. Weiler at U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. Ms. Furey or Mr. Weiler can be reached at (312) 886-7950 or (312) 886-6041, respectively (or by e-mail at: [furey.eileen@epa.gov](mailto:furey.eileen@epa.gov) or [weiler.eaton@epa.gov](mailto:weiler.eaton@epa.gov)).

**SUPPLEMENTARY INFORMATION:**
**Regulated Entities**

This site-specific revision to the Pulp and Paper Industry NESHAP, which governs the emission of HAPs from the pulp and paper industry, applies only to a single source, PCA's Tomahawk, Wisconsin pulp and paper mill.

**Direct Final Rule**

EPA is issuing these revisions as a direct final rule, without prior proposal, because we consider the revisions to be noncontroversial and anticipate no significant adverse comments. Additionally, EPA is aware that most persons with an interest in this proposed rule have already been afforded at least two opportunities to comment on its merits. In April 2003, and again in September 2003, PCA sponsored public meetings regarding the project that is described at length in today's rule. EPA believes that PCA made every reasonable effort to invite all potential stakeholders to those

public meetings. Nevertheless, in the "Proposed Rules" section of this *Federal Register*, EPA is publishing a separate document with the same title that will serve as the proposal to amend the Pulp and Paper Industry NESHAP if significant adverse comments are filed.

If we receive any significant adverse comments, we will publish a timely withdrawal in the *Federal Register* informing the public that this direct final rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this direct final rule. Any parties interested in commenting must do so at this time.

**Docket**

EPA has established an official public docket for this action under Docket ID No. OAR-2003-0205. 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 statutorily restricted from disclosure. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation 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 Air and Radiation Docket is (202) 566-1742.

**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. Once in the system, select "search," then key in the appropriate docket identification number.

## Outline of Today's Document

The information presented in this preamble is arranged as follows:

- I. Authority
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  - A. Background of the Pulp and Paper Industry NESHAP
    - 1. Background of the Pulp and Paper Industry NESHAP Generally
    - 2. The Requirements of the Pulp and Paper Industry NESHAP as Applied to PCA's Tomahawk Mill
  - B. Overview of the Regulatory Innovation Agreements
    - 1. The Joint State/EPA Agreement To Pursue Regulatory Innovation (Innovations Agreement)
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  - H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
  - I. National Technology Transfer Advancement Act
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  - K. Executive Order 12998: Civil Justice Reform
  - L. Congressional Review Act

### I. Authority

EPA issues this regulation under the authority provided by sections 112 and 301(a)(1) of the CAA, 42 U.S.C. 7412 and 7601(a)(1). EPA has determined that this rulemaking is subject to the provisions of section 307(d) of the CAA, 42 U.S.C. 7607(d).

### II. Background

#### A. Background of the Pulp and Paper Industry NESHAP

##### 1. Background of the Pulp and Paper Industry NESHAP Generally

Section 112 of the CAA, 42 U.S.C. 7412 *et seq.*, requires EPA first to identify, by industrial category or subcategory, "major sources" of HAPs, and then to promulgate regulations to

control HAPs emitted by such sources. "Major sources" are those that emit (or have the potential to emit) at least 10 tons per year of any single HAP (*e.g.* methanol), or 25 tons per year of any combination of HAPs. Additionally, section 112 specifies that EPA's regulations promulgated thereunder must require major sources of HAPs to attain the maximum achievable reduction in HAP emissions, taking into consideration cost, non-air quality health and environmental impacts, and energy requirements. In essence, regulations promulgated pursuant to section 112 must ensure that all regulated HAP sources achieve the level of control that is already being achieved by the lower (12% lowest) emitting sources in each industrial category or subcategory. *See* 42 U.S.C. 7412(d)(3). This approach provides assurance to U.S. citizens that regulated sources will employ good control measures to limit their HAP emissions.

EPA identified the pulp and paper industry as a major source requiring regulation under section 112 of the CAA. Accordingly, on April 15, 1998, EPA promulgated the Pulp and Paper Industry NESHAP (*See* 63 FR 18503). The Pulp and Paper Industry NESHAP, 40 CFR 63.440 through 63.459, subcategorized the pulp and paper industry according to seven different pulping processes (kraft, sulfite, semi-chemical, soda, mechanical wood pulping, secondary fiber pulping, or non-wood pulping), and established different emissions standards for each such process. For a thorough and detailed discussion on the background, development, and promulgation of the Pulp and Paper Industry NESHAP, the reader is referred to the following Web site: <http://www.epa.gov/ttn/atw/pulp/pulppg.html>. The website contains links to all relevant **Federal Register** notices, background documents, enabling documents, fact sheets, and rule summary documents.

##### 2. The Requirements of the Pulp and Paper Industry NESHAP as Applied to PCA's Tomahawk Mill

PCA uses a sodium carbonate semi-chemical process to produce unbleached corrugating medium at the Tomahawk Mill. In order to prevent pollution of the air by HAPs generated during semi-chemical pulping processes, the Pulp and Paper Industry NESHAP requires the collection and control of HAP emissions from a collection of equipment systems. This collection of equipment systems (which includes the digester and evaporator systems) is referred to in the Pulp and Paper Industry NESHAP as the LVHC

system. Semi-chemical mills must enclose the numerous equipment systems comprising the LVHC system, and route the HAP-containing air emissions through a closed-vent system to a control device. The positive pressure portions of the closed vent system must be designed and operated with no detectable leaks. Regulated mills may choose among four control device options for destroying the collected HAPs. The control device must: (1) Reduce the total HAP emissions by 98 percent or more by weight; (2) reduce total HAP concentration at the outlet of the thermal oxidizer to 20 parts per million or less by volume, corrected to 10 percent oxygen on a dry basis; (3) reduce total HAP emissions using a thermal oxidizer designed and operated at a minimum temperature of 871 degrees Centigrade and a minimum residence time of 0.75 seconds; or (4) reduce the total HAP emissions using a boiler, lime kiln, or recovery furnace by introducing the HAP emission stream with the primary fuel or into the flame zone. *See* 40 CFR 63.443(d). Neither the Pulp and Paper Industry NESHAP, nor any other federal or state regulation, requires semi-chemical pulp and paper mills to control the HAPs that may be contained in the liquid condensates generated in the LVHC system ("pulping process condensates").

#### B. Overview of the Regulatory Innovation Agreements

##### 1. The Joint State/EPA Agreement To Pursue Regulatory Innovation (Innovations Agreement)

EPA announced the Innovations Agreement on May 5, 1998 (63 FR 24874). Through this agreement, EPA and senior State environmental officials jointly committed to encouraging new and innovative approaches to improvement of the nation's environment. The parties to the Innovations Agreement agreed that the following seven principles would guide the process of developing, testing and implementing regulatory innovations: experimentation; environmental performance; smarter approaches; stakeholder involvement; measuring and verifying results; accountability/enforcement; and State-EPA partnership. The Innovations Agreement encouraged "prudent risk taking" as a necessary component of the effort to continue the nation's progress towards protection of human health and the environment.

The Innovations Agreement established a process by which the States would develop innovation

proposals and obtain prompt review and acceptance or rejection by EPA. The success of any innovation project would be measured by its environmental impact, improved efficiency, or other relevant indicator of superior performance.

## 2. The WDNR/EPA Memorandum of Agreement

To carry out the purposes of the Innovations Agreement, on March 25, 1999 the Wisconsin Department of Natural Resources (WDNR) and Region 5 EPA entered into a Memorandum of Agreement (MOA). The MOA recognized that the Wisconsin legislature had established an Environmental Cooperation Pilot Program, which provided WDNR the statutory authority to develop up to ten pilot projects with companies willing to test alternative approaches to traditional command and control regulations. (Wis. Stat. Sec. 299.80). Many of the goals of the Wisconsin pilot program were similar to those articulated in the Innovations Agreement. The Wisconsin pilot program required any participating company to enter into an environmental cooperative agreement with WDNR. In return for operational flexibility and variances from applicable state regulations, participating pilot companies agreed to achieve environmental performance superior to that which would be achieved through compliance with existing regulations. Participating companies further agreed to establish environmental management systems at their facilities to ensure regular auditing and reporting of environmental performance and compliance.

WDNR and Region 5 recognized in the MOA that EPA would not be a party to these state-company agreements, but provided that when Federal involvement was needed or helpful, Region 5 would promptly identify and, when appropriate, take the necessary federal steps to implement a pilot project. WDNR and EPA agreed that when a project undertaken pursuant to a Wisconsin environmental cooperative agreement required a change in the regulatory requirements of a federally authorized or delegated program, the agencies would follow applicable Federal procedures for the necessary rule or program changes. The agencies specifically intended that any such changes would be federally enforceable.

## 3. The WDNR/PCA Environmental Cooperative Agreement

As explained at greater length below, when PCA began to investigate what changes would be necessary at its

Tomahawk Mill to comply with the then recently-enacted Pulp and Paper Industry NESHAP, the company discovered that, due to its unique process configuration, the vast majority of HAPs generated in the LVHC system partition to the pulping process condensates. PCA used these condensates as process water in other facility operations, which allowed the HAPs in the condensates to be emitted to the air. Recognizing the opportunity to destroy a far greater quantity of HAPs by treating the condensates instead of the LVHC air stack emissions, PCA proposed an environmental pilot project to WDNR. In lieu of treatment of the LVHC air stack emissions via thermal destruction (as contemplated by the Pulp and Paper Industry NESHAP), PCA proposed to treat the condensed HAPs via biodegradation in the Tomahawk Mill's anaerobic wastewater treatment system.

WDNR concurred with PCA's conclusions about the environmental benefits of the proposed project and, on August 27, 1999, submitted PCA's proposal to Region 5 as one appropriate for evaluation under the terms of the MOA. EPA's Office of Air Quality Planning and Standards (OAQPS) thereafter requested PCA to conduct a full-scale study of the ability of its anaerobic wastewater treatment system to achieve a level of HAP destruction superior to that which would be achieved through compliance with the Pulp and Paper Industry NESHAP. The full-scale treatability study successfully established that PCA's anaerobic system could: (1) Destroy the same HAPs as are required to be controlled under the Pulp and Paper Industry NESHAP; and (2) destroy a significantly greater quantity of those HAPs than would be destroyed through compliance with the Pulp and Paper Industry NESHAP. In June 2001, OAQPS and Region 5 approved PCA's innovation project as one appropriate to pursue.

On September 10, 2002, pursuant to the Wisconsin Environmental Cooperation Pilot Program, and with Region 5 EPA's support under the MOA, WDNR and PCA entered into an Environmental Cooperative Agreement (WDNR/PCA Agreement). The WDNR/PCA Agreement required PCA's Tomahawk Mill to achieve approximately double the destruction of HAPs over what would be achieved through compliance with 40 CFR 63.443(c) and (d) (as explained below, EPA actually believes the facility will achieve a greater than five-fold increase in HAP destruction over what would have been achieved through compliance with the Pulp and Paper Industry

NESHAP.) In lieu of controlling the HAPs from the LVHC system at the LVHC air stack, the WDNR/PCA Agreement allowed PCA to route the LVHC air emissions at its Tomahawk Mill through a series of indirect contact condensers and hardpipe the resulting pulping process condensates to an anaerobic digester for biodegradation. Additionally, the WDNR/PCA Agreement required PCA to conduct a second full-scale performance test of its wastewater treatment system in order to identify and develop enforceable operating parameters and a monitoring plan, acceptable to EPA, that would ensure continuous compliance with the more stringent level of HAP destruction. Finally, the WDNR/PCA Agreement identified certain provisions of the Pulp and Paper Industry NESHAP with which PCA's Tomahawk Mill would be required to comply regardless of, or because of, its use of an alternative treatment technology. See 68 FR 7706, 7707-7708 (February 18, 2003), where EPA adopted a similar amendment to the Pulp and Paper NESHAP.

Pursuant to the WDNR/PCA Agreement, during October of 2002, PCA performed the second full-scale performance test of the Tomahawk Mill's anaerobic wastewater treatment system. The test further verified that PCA's anaerobic wastewater treatment system was capable of achieving a more stringent level of HAP destruction than would be accomplished through compliance with the Pulp and Paper Industry NESHAP. Importantly, through the test results, PCA, EPA and WDNR identified enforceable operating parameters, and also developed a monitoring plan that ensures continuous achievement of the more stringent level of HAP destruction.

The WDNR/PCA Agreement specified that in the event a site-specific rule for PCA's Tomahawk Mill was not finalized, the WDNR/PCA Agreement would terminate. EPA agreed to take no enforcement action against PCA for violations of the requirements of 40 CFR 63.443(c) and (d) at the Tomahawk facility until EPA either revised the Pulp and Paper Industry NESHAP to include a Federal site-specific rule for PCA's Tomahawk Mill, or notified the company that EPA had decided that a site-specific rule was inappropriate, improper or inadequate. Finally, the WDNR/PCA Agreement specified that, provided certain conditions were satisfied and subject to the approval of U.S. EPA and WDNR, PCA's rights and obligations under the agreement could be transferred to any subsequent owner of the Tomahawk Mill. Among other things, a transferee would be obligated



to demonstrate that it had the financial and technical capability to assume the obligations of the WDNR/PCA Agreement.

For a copy of the WDNR/PCA Agreement, and associated fact sheets and public notices, the reader is referred to the following Web site: <http://www.dnr.state.wi.us/org/caer/cea/ecpp/agreements/pca/>.

### III. The Site-Specific Rule

#### A. Rationale and Background of the Site-Specific Rule

Existing semi-chemical mills subject to the Pulp and Paper Industry NESHAP, including PCA's Tomahawk Mill, were required to comply with the applicable provisions of the Pulp and Paper Industry NESHAP by April 16, 2001. In 1999, while preparing to comply with the Pulp and Paper Industry NESHAP at its Tomahawk Mill, PCA recognized that to properly design and operate a Pulp and Paper Industry NESHAP-compliant incineration control device, it needed to condition the air emissions from the digester system. Accordingly, PCA installed two in-series indirect contact condensers following the digester system, which conditioned the air emissions by reducing the moisture content.

Before designing the incineration control device, PCA next sought to characterize (for HAP content, flow rate, moisture content, etc.) the air emissions from the two new indirect contact condensers. PCA's testing surprisingly revealed that the HAP content in the LVHC air emissions was far less than the company had expected. The air emissions from the digester system at the Tomahawk Mill contained approximately 0.4 pounds of HAPs, as methanol, per Oven Dried Ton of Pulp (ODTP). Background studies for the Pulp and Paper Industry NESHAP had led PCA to believe that these air emissions would contain greater than two pounds of HAPs, as methanol, per ODTP.

PCA then undertook a study to determine why the HAP content of the digester system's air emissions was far less than expected. PCA determined that, because of the unique process configuration at its Tomahawk Mill, the vast majority of the HAPs contained in the air emissions from the digester system partitioned to the condensate stream produced by the indirect contact condensers. Under the Pulp and Paper Industry NESHAP (or any other Federal or State regulation), the Tomahawk Mill is not required to treat any pulping process condensates and, at that time,

the Tomahawk Mill mixed the pulping process condensates with other reuse water streams and routed them to other uncontrolled production processes at the mill. Testing conducted by PCA revealed that the condensates from the two indirect contact condensers following the digester system contained approximately 2.5 pounds of HAPs per ODTP—in other words, approximately six times the quantity of HAPs, as methanol, that could potentially be treated as LVHC air emissions, as currently prescribed by the Pulp and Paper Industry NESHAP.

EPA, WDNR, and PCA concluded that the destruction of HAPs contained in the pulping process condensates from the Tomahawk Mill's LVHC system—rather than destruction of HAPs contained in the air stack emissions from the LVHC system—would result in greater overall reduction of HAPs emitted to the environment. EPA, WDNR, and PCA further reasoned that PCA's Tomahawk Mill would be able to treat the HAPs contained in the pulping process condensates by hardpiping them to the basins of PCA Tomahawk's state-of-the-art wastewater treatment plant for anaerobic biodegradation. Such alternative treatment would yield significant cost savings to PCA, since the company would not need to design and install an incinerator to control the HAPs contained in the air emissions from the LVHC system at the Tomahawk Mill.

EPA then authorized PCA to proceed to implement the project for the entire LVHC system (as opposed to just the digester system), and requested PCA to conduct full scale testing upon completion of the project. PCA proceeded thereafter to install a third indirect contact condenser, and collect and route the HAP-containing air emissions from the entire LVHC system through the third indirect contact condenser.

#### B. Environmental Benefit of the Site-Specific Rule

PCA's subsequent full-scale testing demonstrated that, with the installation of the third indirect contact condenser, approximately 85 percent of the HAPs in the entire LVHC system partition to the pulping process condensates. While the air emissions from the entire LVHC system contain approximately 0.6 pounds of HAPs per ODTP, the pulping process condensates contain approximately 3.0 pounds of HAPs per ODTP. Full-scale testing at PCA's Tomahawk Mill further verified that between 96 and 100 percent of the HAPs contained in the pulping process condensates and hardpiped to the

wastewater treatment plant are destroyed by anaerobic biodegradation.<sup>1</sup>

The maximum quantity of HAPs available for destruction at PCA's Tomahawk Mill through compliance with 40 CFR 63.443(d) is approximately 0.6 pounds of HAP per ODTP. The Pulp and Paper Industry NESHAP requires that 98 percent of the approximately 0.6 pounds (*i.e.* 0.59 pounds HAPs/ODTP) be destroyed. As indicated above, by hardpiping the pulping process condensates to the anaerobic basins of the wastewater treatment plant, approximately 3.0 pounds of HAPs per ODTP are available for destruction and, in actuality, more than 96 percent of the approximately 3.0 pounds (*i.e.* at least 2.9 pounds/ODTP) are destroyed. In short, by condensing the HAPs from the entire LVHC system and routing them to the anaerobic wastewater treatment system for treatment, PCA is able to destroy approximately five times the mass of HAPs that it would otherwise destroy through compliance with the Pulp and Paper Industry NESHAP.

#### C. Overview of the Site-Specific Rule

EPA's rule allows PCA, in lieu of controlling HAPs in the Tomahawk Mill's LVHC air stack emissions, to control the HAPs partitioning from those air emissions to the pulping process condensates. More particularly, EPA's rule allows PCA to: (1) install a closed-vent system to collect the HAP-containing air emissions from the LVHC system; (2) route the emissions through a series of indirect contact condensers; and (3) hardpipe the resulting pulping process condensates to the anaerobic basins of the facility's wastewater treatment plant. The anaerobic basins of the wastewater treatment plant must achieve a destruction efficiency of at least 1.0 pound of HAPs per ODTP by anaerobic biodegradation, *i.e.* approximately twice the quantity of what would have been achieved by the facility under the current Pulp and Paper Industry NESHAP. EPA and PCA actually anticipate that the HAP destruction in the wastewater treatment plant anaerobic basins will significantly exceed the 1.0 pound per ODTP requirement. As stated above, the average HAP destruction efficiency of the wastewater treatment system is approximately 3.0 pounds per ODTP.

<sup>1</sup> For purposes of calculating a HAP destruction efficiency, EPA required PCA to assume that the concentration of HAPs in the wastewater treatment plant effluent was equal to the detection limit concentration. Use of the detection limit concentration result in a 96 percent HAP destruction efficiency calculation. No HAPs were actually detected in the wastewater treatment plant effluent, potentially signifying a 100% destruction efficiency.

To allow PCA to achieve this superior environmental performance and remain in compliance with the CAA, EPA is promulgating limited revisions to the Pulp and Paper Industry NESHAP, Subpart S, 40 CFR 63.440 through 63.459. The revisions collectively comprise a site-specific rule applicable only to PCA's Tomahawk Mill. Under the site-specific rule, PCA's Tomahawk Mill may comply with either the otherwise applicable control technology requirements of the Pulp and Paper Industry NESHAP, or the control technology requirements of the site-specific rule.

Like the otherwise applicable provisions of the Pulp and Paper Industry NESHAP, the site-specific rule requires PCA's Tomahawk Mill to enclose the LVHC system and vent the air emissions to a closed-vent system. The standards and monitoring requirements for the enclosures and closed-vent system included in the rule are equivalent (except for formatting and reference changes) to the otherwise applicable Pulp and Paper Industry NESHAP requirements.

The site-specific rule allows PCA's Tomahawk Mill to use an alternative treatment technology to control the HAPs collected in the closed-vent system. The rule allows PCA to treat its HAPs at an emission point not addressed by the Pulp and Paper Industry NESHAP. PCA may route the collected air emissions through a series of indirect contact condensers and hardpipe the resulting pulping process condensates in a closed collection system to the wastewater treatment plant for anaerobic biodegradation. The standards and monitoring requirements for the closed collection system are equivalent (except for formatting and reference changes) to those required by the Pulp and Paper Industry NESHAP for kraft mills (which must collect and treat pulping process condensates).

The site-specific rule establishes a minimum destruction efficiency standard of 1.0 pound of HAPs per ODTP, and further requires PCA to monitor, and maintain within specified limits, several operating parameters to ensure continuous compliance with the HAP destruction efficiency standard. PCA must conduct quarterly performance testing of the anaerobic wastewater treatment system to verify compliance with the minimum HAP destruction efficiency standard. Finally, PCA's Tomahawk Mill must continue to comply with all applicable recordkeeping and reporting requirements of the general provisions at subpart A, 40 CFR 63.10.

Under the site-specific rule (and analogous to the excess emission allowance of 40 CFR 63.443(e)(1)), PCA's Tomahawk Mill will be deemed in compliance with the Pulp and Paper Industry NESHAP so long as it complies with all applicable provisions, including the requirement that it achieve the established destruction efficiency standard, no less than 99 percent of the operating time.

#### IV. Statutory and Executive Order Reviews.

##### A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735), the Agency must determine whether this regulatory action is "significant" and therefore subject to formal review by the Office of Management and Budget (OMB) and to the requirements of the Executive Order, which include assessing the costs and benefits anticipated as a result of this regulatory action. The Order defines "significant regulatory" action as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Because this rule affects only one facility, it is not a rule of general applicability. EPA has determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

##### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, since it applies to only one facility. It is exempt from OMB review under the Paperwork Reduction Act because it is a site-specific rule, directed to fewer than ten persons. 44 U.S.C. 3502(3), (10); 5 CFR 1320.3(c), 1320.4 and 1320.5.

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.

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.

##### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and public comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. The subject of this site-specific rulemaking, PCA, is not a small business. This rule does not apply to small businesses, small not-for-profit enterprises, or small governmental jurisdictions. Further, it is a site-specific rule with limited applicability to only one pulp and paper mill in the nation. After considering the economic impacts of today's final rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

##### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and Tribal governments in the aggregate, or by the private sector, of \$100 million or

more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of the EPA regulatory proposal with significant Federal mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. As used here, "small government" has the same meaning as that contained under 5 U.S.C. 601(5), that is, governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.

As discussed above, this rule will have limited application. It applies only to the PCA's pulp and paper mill located in Tomahawk, Wisconsin. This site-specific rule does not impose any additional costs on PCA's Tomahawk Mill. EPA has determined that this site-specific rule does not contain a Federal mandate that may result in expenditures by State, local, or Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. Thus, this rule is not subject to the requirements of section 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

#### *E. Executive Order 13132: Federalism*

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." The phrase, "Policies that have federalism implications" is

defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

To the extent that this rule gives rise to federalism concerns, they have been addressed via EPA's direct consultation with Wisconsin, the affected State. As noted above, this rule was developed pursuant to the State-sponsored WDNR/PCA Agreement and the MOA between WDNR and Region 5 EPA.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop a process that is accountable to ensure "meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." "Policies that have Tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This rule does not have Tribal implications. It will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### *G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant," as defined in Executive Order 12886; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to potentially effective and

feasible alternatives considered by the Agency.

This rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency believes the environmental health or safety risks addressed by this action do not present a disproportionate risk to children. This rule will require PCA to achieve a greater reduction of HAPs emitted to the environment by allowing it to use an alternative treatment technology not currently allowed by the existing the Pulp and Paper Industry NESHAP. Therefore, no additional risk to public health, including children's health, is expected to result from this action.

#### *H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It will not result in increased energy prices, increased cost of energy distribution, or an increased dependence on foreign supplies of energy.

#### *I. National Technology Transfer Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless such practice is inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, material specifications, test methods, sampling procedures, and business practices) developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule uses all available and applicable voluntary consensus standards.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (February 11,

1994) is designed to address the environmental and human health conditions of minority and low-income populations. EPA is committed to addressing environmental justice concerns and has assumed a leadership role in environmental justice initiatives to enhance environmental quality for all citizens of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, income, or net worth bears disproportionately high adverse human health or environmental impacts as a result of EPA's policies, programs, and activities. Today's action applies to one facility in Tomahawk, Wisconsin, and will have no disproportionate impacts on minority or low income communities. Overall, the project being undertaken at PCA's Tomahawk Mill, if successful, will produce environmental performance superior to that expected through compliance with existing regulations.

*K. Executive Order 12988: Civil Justice Reform*

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled Civil Justice Reform (61 FR 4729, February 7, 1996).

*L. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as amended 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. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability.

**List of Subjects in 40 CFR Part 63**

Air pollution control, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 7, 2004.

Michael O. Leavitt,  
Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

**PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES**

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

**Subpart S—National Emission Standards for Hazardous Air Pollutants From the Pulp and Paper Industry**

■ 2. Amend § 63.459 by adding paragraph (b) to read as follows:

**§ 63.459 Alternative standards.**

\* \* \* \* \*

(b) *Tomahawk Wisconsin Mill. (1) Applicability.* (i) The provisions of this paragraph (b) apply to the owner or operator of the stand-alone semi-chemical pulp and paper mill located at N9090 County Road E in Tomahawk, Wisconsin, referred to as the Tomahawk Mill.

(ii) The owner or operator is not required to comply with the provisions of this paragraph (b) if the owner and operator chooses to comply with the otherwise applicable sections of this subpart and provides the EPA with notice.

(iii) If the owner or operator chooses to comply with the provisions of this paragraph (b) the owner or operator shall comply with all applicable provisions of this part, including this subpart, except the following:

- (A) Section 63.443(b);
- (B) Section 63.443(c); and
- (C) Section 63.443(d).

(2) *Collection and routing of HAP emissions.* (i) The owner or operator shall collect the total HAP emissions from each LVHC system.

(ii) Each LVHC system shall be enclosed and the HAP emissions shall be vented into a closed-vent system. The enclosures and closed-vent system shall meet requirements specified in paragraph (b)(6) of this section.

(iii) The HAP emissions shall be routed as follows:

(A) The HAP emissions collected in the closed-vent system from the digester system shall be routed through the primary indirect contact condenser, secondary indirect contact condenser, and evaporator indirect contact condenser; and

(B) The HAP emissions collected in the closed-vent system from the evaporator system and foul condensate standpipe shall be routed through the evaporator indirect contact condenser.

(3) *Collection and routing of pulping process condensates.* (i) The owner or operator shall collect the pulping process condensates from the following equipment systems:

- (A) Primary indirect contact condenser;
- (B) Secondary indirect contact condenser; and
- (C) Evaporator indirect contact condenser.

(ii) The collected pulping process condensates shall be conveyed in a closed collection system that is designed and operated to meet the requirements specified in paragraph (b)(7) of this section.

(iii) The collected pulping process condensates shall be routed in the closed collection system to the wastewater treatment plant anaerobic basins for biodegradation.

(iv) The pulping process condensates shall be discharged into the wastewater treatment plant anaerobic basins below the liquid surface of the wastewater treatment plant anaerobic basins.

(4) *HAP destruction efficiency requirements of the wastewater treatment plant.* (i) The owner or operator shall achieve a destruction efficiency of at least one pound of HAPs per ton of ODP by biodegradation in the wastewater treatment plant.

(ii) The following calculation shall be performed to determine the HAP destruction efficiency by biodegradation in the wastewater treatment plant:

$$HAP_d = \frac{[(RME_{fr} \times RME_c) + (PPC_{fr} \times PPC_c) - (ABD_{fr} \times ABD_c)] \times 8.34}{ODP}$$



Where:

HAP<sub>d</sub> = HAP destruction efficiency of wastewater treatment plant (pounds of HAPs per ton of ODP);

RME<sub>fr</sub> = flow rate of raw mill effluent (millions of gallons per day);

RME<sub>c</sub> = HAP concentration of raw mill effluent (milligrams per liter);

PPC<sub>fr</sub> = flow rate of pulping process condensates (millions of gallons per day);

PPC<sub>c</sub> = HAP concentration of pulping process condensates (milligrams per liter);

ABD<sub>fr</sub> = flow rate of anaerobic basin discharge (millions of gallons per day);

ABD<sub>c</sub> = HAP concentration of anaerobic basin discharge (milligrams per liter); and

ODP<sub>r</sub> = rate of production of oven dried pulp (tons per day).

(5) *Monitoring requirements and parameter ranges.* (i) The owner or operator shall install, calibrate, operate, and maintain according to the manufacturer's specifications a continuous monitoring system (CMS, as defined in § 63.2), using a continuous recorder, to monitor the following parameters:

(A) Evaporator indirect contact condenser vent temperature;

(B) Pulping process condensates flow rate;

(C) Wastewater treatment plant effluent flow rate; and

(D) Production rate of ODP.

(ii) The owner or operator shall additionally monitor, on a daily basis, in each of the four anaerobic basins, the ratio of volatile acid to alkalinity (VA/A ratio). The owner or operator shall use the test methods identified for determining acidity and alkalinity as specified in 40 CFR 136.3, Table 1B.

(iii) The temperature of the evaporator indirect contact condenser vent shall be maintained at or below 140 °F on a continuous basis.

(iv) The VA/A ratio in each of the four anaerobic basins shall be maintained at or below 0.5 on a continuous basis.

(A) The owner or operator shall measure the methanol concentration of the outfall of any basin (using NCASI Method DI/MEOH 94.03) when the VA/A ratio of that basin exceeds the following:

(1) 0.38, or

(2) The highest VA/A ratio at which the outfall of any basin has previously measured non-detect for methanol (using NCASI Method DI/MEOH 94.03).

(B) If the outfall of that basin measures detect for methanol, the owner or operator shall verify compliance with the emission standard specified in

paragraph (b)(4) of this section by conducting a performance test pursuant to the requirements specified in paragraph (b)(8) of this section.

(v) The owner or operator may seek to establish or reestablish the parameter ranges, and/or the parameters required to be monitored as provided in paragraphs (b)(5)(i) through (v) of this section, by following the provisions of § 63.453(n)(1) through (4).

(6) *Standards and monitoring requirements for each enclosure and closed-vent system.*

(i) The owner or operator shall comply with the design and operational requirements specified in paragraphs (b)(6)(ii) through (iv) of this section, and the monitoring requirements of paragraphs (b)(6)(v) through (x) of this section for each enclosure and closed-vent system used for collecting and routing of HAP emissions as specified in paragraph (b)(2) of this section.

(ii) Each enclosure shall be maintained at negative pressure at each enclosure or hood opening as demonstrated by the procedures specified in § 63.457(e). Each enclosure or hood opening closed during the initial performance test shall be maintained in the same closed and sealed position as during the performance test at all times except when necessary to use the opening for sampling, inspection, maintenance, or repairs.

(iii) Each component of the closed-vent system that is operated at positive pressure shall be designed for and operated with no detectable leaks as indicated by an instrument reading of less than 500 parts per million by volume above background, as measured by the procedures specified in § 63.457(d).

(iv) Each bypass line in the closed-vent system that could divert vent streams containing HAPs to the atmosphere without meeting the routing requirements specified in paragraph (b)(2) of this section shall comply with either of the following requirements:

(A) On each bypass line, the owner or operator shall install, calibrate, maintain, and operate according to the manufacturer's specifications a flow indicator that provides a record of the presence of gas stream flow in the bypass line at least once every 15 minutes. The flow indicator shall be installed in the bypass line in such a way as to indicate flow in the bypass line; or

(B) For bypass line valves that are not computer controlled, the owner or operator shall maintain the bypass line valve in the closed position with a car seal or seal placed on the valve or

closure mechanism in such a way that the valve or closure mechanism cannot be opened without breaking the seal.

(v) For each enclosure opening, the owner or operator shall perform, at least once every 30 days, a visual inspection of the closure mechanism specified in paragraph (b)(6)(ii) of this section to ensure the opening is maintained in the closed position and sealed.

(vi) For each closed-vent system required by paragraph (b)(2) of this section, the owner or operator shall perform a visual inspection every 30 days and at other times as requested by the Administrator. The visual inspection shall include inspection of ductwork, piping, enclosures, and connections to covers for visible evidence of defects.

(vii) For positive pressure closed-vent systems, or portions of closed-vent systems, the owner or operator shall demonstrate no detectable leaks as specified in paragraph (b)(6)(iii) of this section, measured initially and annually by the procedures in § 63.457(d).

(viii) For each enclosure that is maintained at negative pressure, the owner or operator shall demonstrate initially and annually that it is maintained at negative pressure as specified in § 63.457(e).

(ix) For each valve or closure mechanism as specified in paragraph (b)(6)(iv)(B) of this section, the owner or operator shall perform an inspection at least once every 30 days to ensure that the valve is maintained in the closed position and the emissions point gas stream is not diverted through the bypass line.

(x) If an inspection required by paragraph (b)(6) of this section identifies visible defects in ductwork, piping, enclosures, or connections to covers required by paragraph (b)(6) of this section, or if an instrument reading of 500 parts per million by volume or greater above background is measured, or if the enclosure openings are not maintained at negative pressure, then the following corrective actions shall be taken as soon as follows:

(A) A first effort to repair or correct the closed-vent system shall be made as soon as practicable but no later than 5 calendar days after the problem is identified.

(B) The repair or corrective action shall be completed no later than 15 calendar days after the problem is identified.

(7) *Standards and monitoring requirements for the pulping process condensates closed collection system.* (i) The owner or operator shall comply with the design and operational requirements specified in paragraphs



(b)(7)(ii) through (iii) of this section, and monitoring requirements of paragraph (b)(7)(iv) for the equipment systems in paragraph (b)(3) of this section used to route the pulping process condensates in a closed collection system.

(ii) Each closed collection system shall meet the individual drain system requirements specified in §§ 63.960, 63.961, and 63.962, except that the closed vent systems shall be designed and operated in accordance with paragraph (b)(6) of this section, instead of in accordance with § 63.693 as specified in § 63.692(a)(3)(ii), (b)(3)(ii)(A), and (b)(3)(ii)(B)(5)(iii); and

(iii) If a condensate tank is used in the closed collection system, the tank shall meet the following requirements:

(A) The fixed roof and all openings (e.g., access hatches, sampling ports, gauge wells) shall be designed and operated with no detectable leaks as indicated by an instrument reading of less than 500 parts per million above background, and vented into a closed-vent system that meets the requirements of paragraph (b)(6) of this section and routed in accordance with paragraph (b)(2) of this section; and

(B) Each opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that the tank contains pulping process condensates or any HAPs removed from a pulping process condensate stream except when it is necessary to use the opening for sampling, removal, or for equipment inspection, maintenance, or repair.

(iv) For each pulping process condensate closed collection system used to comply with paragraph (b)(3) of this section, the owner or operator shall perform a visual inspection every 30 days and shall comply with the inspection and monitoring requirements specified in § 63.964 except for the closed-vent system and control device inspection and monitoring requirements specified in § 63.964(a)(2).

(8) *Quarterly performance testing.* (i) The owner or operator shall, within 45 days after the beginning of each quarter, conduct a performance test.

(ii) The owner or operator shall use NCASI Method DI/HAPS-99.01 to collect a grab sample and determine the HAP concentration of the Raw Mill Effluent, Pulping Process Condensates, and Anaerobic Basin Discharge for the quarterly performance test conducted during the first quarter each year.

(iii) For each of the remaining three quarters, the owner or operator may use NCASI Method DI/MEOH 94.03 as a surrogate to collect and determine the HAP concentration of the Raw Mill Effluent, Pulping Process Condensates, and Anaerobic Basin Discharge.

(iv) The sample used to determine the HAP or Methanol concentration in the Raw Mill Effluent, Pulping Process Condensates, or Anaerobic Basin Discharge shall be a composite of four grab samples taken evenly spaced over an eight hour time period.

(v) The Raw Mill Effluent grab samples shall be taken from the raw mill effluent composite sampler.

(vi) The Pulping Process Condensates grab samples shall be taken from a line tap on the closed condensate collection system prior to discharge into the wastewater treatment plant.

(vii) The Anaerobic Basin Discharge grab samples shall be taken subsequent to the confluence of the four anaerobic basin discharges.

(viii) The flow rate of the Raw Mill Effluent, Pulping Process Condensates, and Anaerobic Basin Discharge, and the production rate of ODP shall be averaged over eight hours.

(ix) The data collected as specified in paragraphs (b)(5) and (b)(8) of this section shall be used to determine the HAP destruction efficiency of the wastewater treatment plant as specified in paragraph (b)(4)(ii) of this section.

(x) The HAP destruction efficiency shall be at least as great as that specified by paragraph (b)(4)(i) of this section.

(9) *Recordkeeping requirements.* (i) The owner or operator shall comply with the recordkeeping requirements as specified in Table 1 of subpart S of part 63 as it pertains to § 63.10.

(ii) The owner or operator shall comply with the recordkeeping requirements as specified in § 63.454(b).

(iii) The owner or operator shall comply with the recordkeeping requirements as specified in § 63.453(d).

(10) *Reporting requirements.* (i) Each owner or operator shall comply with the reporting requirements as specified in Table 1 of § 63.10.

(ii) Each owner or operator shall comply with the reporting requirements as specified in § 63.455(d).

(11) *Violations.* (i) Failure to comply with any applicable provision of this part shall constitute a violation.

(ii) Periods of excess emissions shall not constitute a violation provided the time of excess emissions (excluding periods of startup, shutdown, or malfunction) divided by the total process operating time in a semi-annual reporting period does not exceed one percent. All periods of excess emission (including periods of startup, shutdown, and malfunction) shall be reported, and shall include:

(A) Failure to monitor a parameter, or maintain a parameter within minimum or maximum (as appropriate) ranges as specified in paragraph (b)(5), (b)(6), or (b)(7) of this section; and

(B) Failure to meet the HAP destruction efficiency standard specified in paragraph (b)(4) of this section.

(iii) Notwithstanding paragraph (b)(11)(ii) of this section, any excess emissions that present an imminent threat to public health or the environment, or may cause serious harm to public health or the environment, shall constitute a violation.

[FR Doc. 04-8311 Filed 4-12-04; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Part 63

[FRL-7646-7]

RIN 2090-AA33

**Site-Specific Rulemaking for Packaging Corporation of America's Pulp and Paper Mill Located in Tomahawk, WI, Pursuant to the Joint State/EPA Agreement To Pursue Regulatory Innovation****AGENCY:** Environmental Protection Agency.**ACTION:** Proposed rule.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA or the Agency) is proposing to adopt limited revisions to the National Emissions Standards for Hazardous Air Pollutants from the Pulp and Paper Industry (Pulp and Paper Industry NESHAP). Collectively, these revisions comprise a site-specific rule to control Hazardous Air Pollutants (HAPs) applicable only to the semi-chemical pulp and paper mill currently owned and operated by Packaging Corporation of America (PCA) in Tomahawk, Wisconsin (the Tomahawk Mill). EPA is proposing these revisions pursuant to the Clean Air Act (CAA) and the Joint State/EPA Agreement to Pursue Regulatory Innovation (Innovations Agreement).

The Pulp and Paper Industry NESHAP currently requires semi-chemical pulp and paper mills to control the HAP emissions from the air stack for the collection of equipment comprising the Low Volume High Concentration (LVHC) system. Neither the Pulp and Paper Industry NESHAP, nor any other federal or state regulation, requires such mills to control HAPs that may be contained in the liquid condensates from the LVHC system. The proposed revisions allow PCA's Tomahawk Mill to control the HAPs generated in the LVHC system by condensing them into a liquid and treating them via anaerobic biodegradation in the facility's wastewater treatment system. In other words, the proposed revisions allow PCA's Tomahawk Mill to control the HAPs generated in the LVHC system from an emission point and with a technology not addressed by the Pulp and Paper Industry NESHAP.

Under the proposed revisions, PCA would maintain compliance with the CAA and achieve a reduction in HAPs emitted to the environment significantly superior to that which would have been achieved through compliance with the

control methodology currently prescribed by the Pulp and Paper Industry NESHAP. Additionally, the proposed revisions are consistent with the Innovations Agreement by allowing PCA's Tomahawk Mill to achieve superior environmental performance through regulatory flexibility.

**DATES:** Comments on this rulemaking must be received on or before May 13, 2004.

Public Hearing: Commenters may request a public hearing no later than April 27, 2004. Commenters requesting a public hearing should specify the basis for their request. If EPA determines that there is sufficient reason to hold a public hearing, it will be held on May 17, 2004, at 10 a.m. Requests to present oral testimony must be made by May 3, 2004. Persons interested in requesting a hearing, attending a hearing, or presenting oral testimony at a hearing should call Ms. Eileen L. Furey or Mr. Eaton R. Weiler at (312) 886-7950 or (312) 886-6041, respectively.

**ADDRESSES:** To make comments by mail, send two (2) copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID OAR-2003-0205. Comments also may be submitted electronically, or through hand delivery/courier. Follow the detailed instructions as provided in the **SUPPLEMENTARY INFORMATION** section.

If a public hearing is held, it will take place at the Valdas V. Adamkus Environmental Resource Center meeting rooms on the 12th floor of the Metcalf Federal Building, 77 West Jackson Blvd, Chicago, Illinois.

**FOR FURTHER INFORMATION CONTACT:** Ms. Eileen L. Furey or Mr. Eaton R. Weiler at U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. Ms. Furey or Mr. Weiler can be reached at (312) 886-7950 or (312) 886-6041, respectively (or by e-mail at: [furey.eileen@epa.gov](mailto:furey.eileen@epa.gov) or [weiler.eaton@epa.gov](mailto:weiler.eaton@epa.gov)).

**SUPPLEMENTARY INFORMATION:****Regulated Entities**

This site-specific revision to the Pulp and Paper Industry NESHAP, which governs the emission of HAPs from the pulp and paper industry, applies only to a single source, PCA's Tomahawk, Wisconsin pulp and paper mill.

**Direct Final Rule**

In a document with the same title that is located in the "Rule and Regulations" section of today's **Federal Register**, EPA

is taking direct final action to approve the revisions, without prior proposal, because we consider the revisions to be noncontroversial and anticipate no significant adverse comments. Additionally, EPA is aware that most persons with an interest in this proposed rule have already been afforded at least two opportunities to comment on its merits. In April 2003, and again in September 2003, PCA sponsored public meetings regarding the project that is described at length in today's rule. EPA believes that PCA made every reasonable effort to invite all potential stakeholders to those public meetings. EPA has explained its reasons for the revisions in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

**Docket**

EPA has established an official public docket for this action under Docket ID No. OAR-2003-0205. 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 the disclosure of which is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation 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 Air and Radiation Docket is (202) 566-1742.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information statutorily restricted from disclosure, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed,

paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. 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 above. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information statutorily restricted from disclosure. 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 EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket. Public comments submitted on computer disks that are mailed or delivered to the Docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

#### 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. Once in the system, select "search," then key in the appropriate docket identification number.

#### Submission of Comments

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

#### Electronically

If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

#### By EPA's Electronic Public Docket

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." Once in the system, select "search," and then key in Docket ID No. OAR-2003-0205.

The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

#### By E-mail

Comments may be sent by electronic mail (e-mail) to *a-and-r-Docket@epa.gov*, Attention Docket ID No. OAR-2003-0205. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

#### By Disk or CD ROM

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in the next paragraph. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

#### By Mail

Send two (2) copies of your comments to the Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. OAR-2003-0205.

#### By Hand Delivery or Courier

Deliver your comments to: Environmental Protection Agency, EPA Docket Center, 1301 Constitution Avenue, NW., Washington, DC 20004, Attention Docket ID No. OAR-2003-0205. Such deliveries are only accepted during the Docket's normal hours of operation as identified in above.

#### By Facsimile

Fax your comments to: (202) 566-1741, Attention Docket ID No. OAR-2003-0205.

Dated: April 7, 2004.

**Michael O. Leavitt,**

*Administrator.*

[FR Doc. 04-8312 Filed 4-12-04; 8:45 am]

BILLING CODE 6560-50-P



# Federal Register

Tuesday,  
April 13, 2004

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Part V

**Department of  
Housing and Urban  
Development**

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24 CFR Part 320

**Removal of Regulation Specifying  
Minimum Face Value of Ginnie Mae  
Securities; Proposed Rule**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Part 320**

[Docket No. FR-4856-P-01]

RIN 2503-AA17

**Removal of Regulation Specifying Minimum Face Value of Ginnie Mae Securities**

**AGENCY:** The Government National Mortgage Association (Ginnie Mae), HUD.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would remove the regulation that specifies the current minimum face amount of any security issued by the Government National Mortgage Association (Ginnie Mae). The proposed removal of the regulation would allow Ginnie Mae to offer alternative denominations of its securities.

**DATES:** *Comment Due Date:* June 14, 2004.

**ADDRESSES:** Interested persons are invited to submit comments regarding this rule to the Regulations Division, Office of the General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

**FOR FURTHER INFORMATION CONTACT:** Tom Weakland, Senior Vice President, Office of Program Operations, Government National Mortgage Association, Room 6216, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708-2884 (this is not a toll-free number). Speech- or hearing-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:** Ginnie Mae is a wholly owned corporation of the Federal government that increases the flow of credit for the housing market. Ginnie Mae guarantees securities that are issued by private lenders and backed by pools of mortgage loans insured by HUD or guaranteed by the Department of Veterans Affairs, or other government agencies. Ginnie Mae guarantees the timely payment of principal and interest on the securities.

In its continual pursuit to ensure efficient secondary mortgage market operations, Ginnie Mae routinely evaluates and enhances its offerings and services to remain attractive to investors. To this end, Ginnie Mae would like to offer investors different denominations of Ginnie Mae guaranteed securities. Accordingly, this proposed rule would remove the existing regulation at 24 CFR 320.5(c), which provides, "The face amount of any security cannot be less than \$25,000." After this rule becomes effective, the minimum face amount for various Ginnie Mae securities will be published in Ginnie Mae's Mortgage-Backed Securities Guide.

**Findings and Certifications**

*Environmental Impact*

This rule would remove an existing regulation. The rule would not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Therefore, in accordance with 24 CFR 50.19(c)(1), this rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

*Executive Order 12866, Regulatory Planning and Review*

The Office of Management and Budget (OMB) reviewed this rule under Executive Order 12866 (entitled *Regulatory Planning and Review*). OMB determined that this rule is a "significant regulatory action" as defined in section 3(f) of the order (although not economically significant, as provided in section 3(f)(1) of the order). Any changes made to the rule subsequent to its submission to OMB are identified in the docket file, which is available for public inspection in the Regulations Division, Room 10276, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500.

*Unfunded Mandates Reform Act*

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This proposed rule would not impose a Federal mandate on any State, local, or

tribal government, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

*Regulatory Flexibility Act*

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule would not have a significant economic impact on a substantial number of small entities. There are no anti-competitive discriminatory aspects of the rule with regard to small entities, and there are no unusual procedures that would need to be complied with by small entities. The rule would remove an existing regulation. Although HUD has determined that this rule would not have a significant economic impact on a substantial number of small entities, HUD welcomes comments regarding any less burdensome alternative to this rule that will meet HUD's objectives as described in this preamble.

*Executive Order 13132, Federalism*

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments and does not preempt State law within the meaning of the Executive Order.

**List of Subjects in 24 CFR Part 320**

Mortgages, Securities.

Accordingly, for the reasons described in the preamble, HUD proposes to amend 24 CFR part 320 as follows:

**PART 320—GUARANTY OF MORTGAGE-BACKED SECURITIES**

1. The authority citation for part 320 continues to read as follows:

**Authority:** 12 U.S.C. 1721(g) and 1723a(a), and 42 U.S.C. 3535(d).

2. Amend § 320.5 by removing and reserving paragraph (c).

**§ 320.5 Securities.**

\* \* \* \* \*

(c) [Reserved]

\* \* \* \* \*



Dated: March 18, 2004.

**Ronald A. Rosenfeld,**

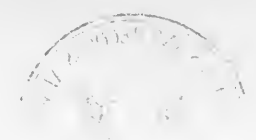
*President, Government National Mortgage Association.*

[FR Doc. 04-8341 Filed 4-12-04; 8:45 am]

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# Federal Register

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Tuesday,  
April 13, 2004

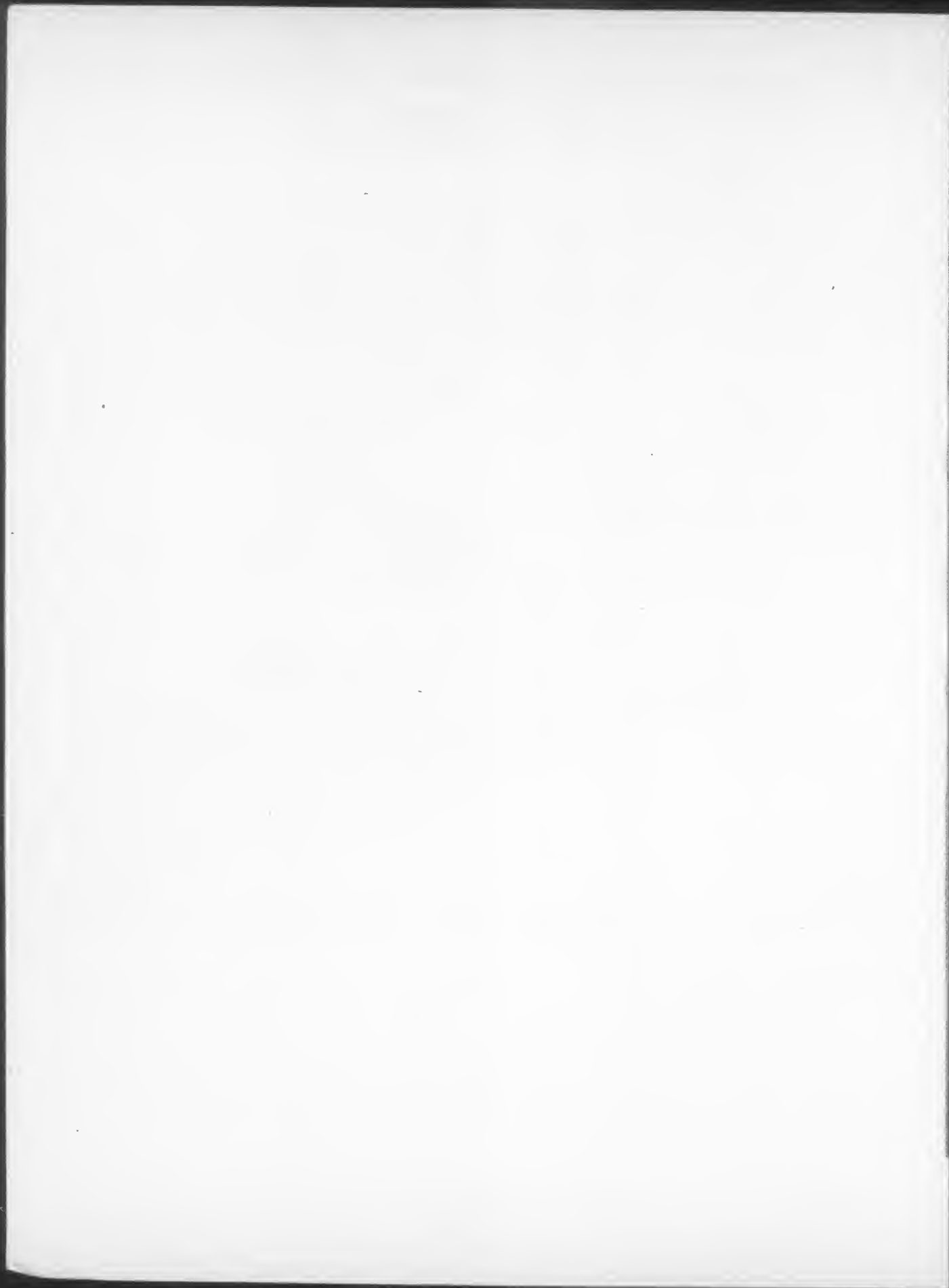
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Part VI

## The President

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Proclamation 7770—National Former  
Prisoner of War Recognition Day, 2004



**Presidential Documents**

Title 3—

Proclamation 7770 of April 9, 2004

The President

National Former Prisoner of War Recognition Day, 2004

By the President of the United States of America

**A Proclamation**

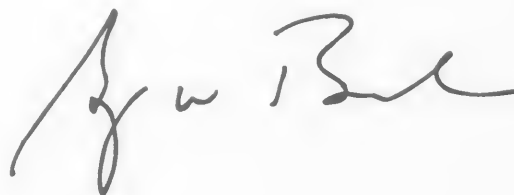
Americans look to our veterans as examples of honor and patriotism. These loyal citizens have risked capture, imprisonment, and their lives to protect our homeland and advance freedom abroad. As we observe National Former Prisoner of War Recognition Day, we honor brave Americans who have demonstrated extraordinary courage in the face of hardship and terror.

Today, nine out of ten former prisoners of war are veterans of World War II. These Americans helped to liberate millions and defeat tyranny around the world, and survived unspeakable horrors for the cause of freedom. From enduring hard labor in German and Japanese POW camps to the torturous Bataan Death March, these proud patriots showed strength of character and incredible resolve in captivity. Their devotion to duty and love of country stand as a measure of service few others will attain.

America will never forget these quiet heroes and all of our former prisoners of war who suffered adversity in Korea, Vietnam, the Persian Gulf, Somalia, Kosovo, Iraq, and other conflicts. Our Nation is grateful to our former prisoners of war for their sacrifice to help protect the democratic ideals that make our country strong. Because of the dedication of these men and women in uniform, people in our own country and in lands far away can live in freedom. These citizens inspire us, and we will always remember their service for liberty's blessings.

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 April 9, 2004, as National Former Prisoner of War Recognition Day. I call upon all Americans to join me in remembering all former American prisoners of war who suffered the hardships of enemy captivity. I also call upon Federal, State, and local government officials and private organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of April, in the year of our Lord two thousand four, and of the Independence of the United States of America the two hundred and twenty-eighth.







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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Maine; Open for comments until further notice; published 2-17-04 [FR 04-03374]

#### TRANSPORTATION DEPARTMENT

##### Federal Aviation Administration

Air carrier certification and operations:

National air tour safety standards; comments due by 4-19-04; published 1-16-04 [FR 04-01129]

Airworthiness directives:

Airbus; comments due by 4-19-04; published 3-5-04 [FR 04-04936]

BAE Systems (Operations) Ltd.; comments due by 4-23-04; published 3-24-04 [FR 04-06504]

Boeing; comments due by 4-19-04; published 3-5-04 [FR 04-04928]

General Electric Co.; comments due by 4-23-04; published 2-23-04 [FR 04-03679]

McDonnell Douglas; comments due by 4-19-04; published 3-5-04 [FR 04-04927]

Pratt & Whitney; comments due by 4-20-04; published 2-20-04 [FR 04-03682]

Rolls-Royce Corp.; comments due by 4-23-04; published 2-23-04 [FR 04-03681]

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Boeing Model 727-100/-200 series airplanes; comments due by 4-19-04; published 3-19-04 [FR 04-06150]

GenTex Aerospace, Inc.; diamond DA20-C1 katana airplanes; comments due by 4-22-04; published 3-23-04 [FR 04-06454]

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##### Federal Railroad Administration

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#### TRANSPORTATION DEPARTMENT

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04; published 3-9-04 [FR 04-05168]

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#### TREASURY DEPARTMENT

##### Comptroller of the Currency

Agency information collection activities; proposals, submissions, and approvals; comments due by 4-20-04; published 1-21-04 [FR 04-01161]

#### TREASURY DEPARTMENT

##### Thrift Supervision Office

Agency information collection activities; proposals, submissions, and approvals; comments due by 4-20-04; published 1-21-04 [FR 04-01161]

#### LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-741-6043. This list is also available online at [http://www.archives.gov/federal\\_register/public\\_laws/public\\_laws.html](http://www.archives.gov/federal_register/public_laws/public_laws.html).

The text of laws is not published in the *Federal Register* but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-1808). The text will also be made available on the Internet from GPO Access at <http://www.gpoaccess.gov/plaws/index.html>. Some laws may not yet be available.

#### H.R. 254/P.L. 108-215

To authorize the President of the United States to agree to certain amendments to the Agreement between the Government of the United States of America and the Government of the United Mexican States concerning the establishment of a Border Environment Cooperation Commission and a North American Development Bank, and for other purposes. (Apr. 5, 2004; 118 Stat. 579)

#### H.R. 3926/P.L. 108-216

Organ Donation and Recovery Improvement Act (Apr. 5, 2004; 118 Stat. 584)



**H.R. 4062/P.L. 108-217**

To provide for an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958 through June 4, 2004,

and for other purposes. (Apr. 5, 2004; 118 Stat. 591)

Last List April 5, 2004

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**Public Laws Electronic  
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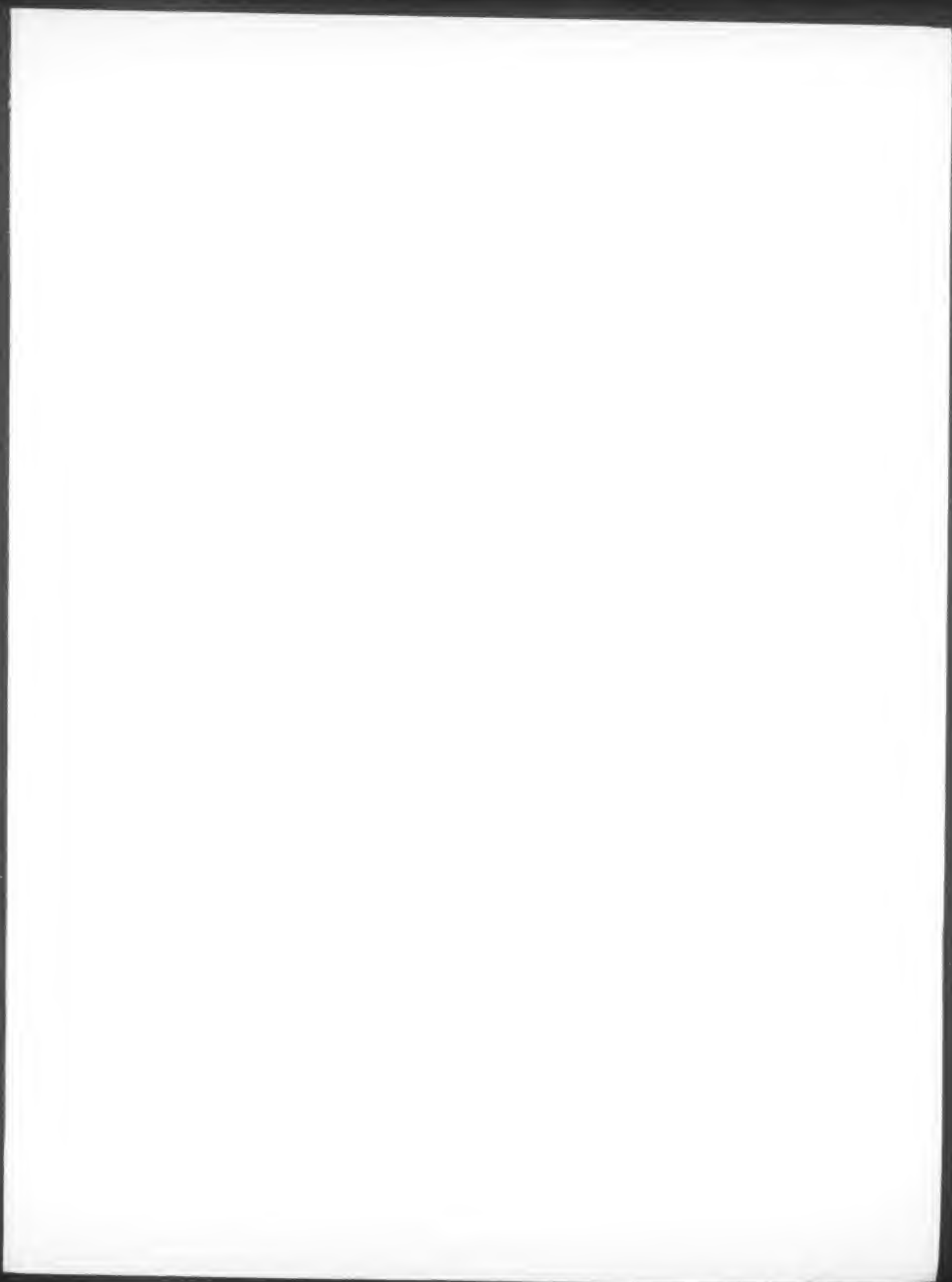
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