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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM392; Special Conditions No. 25–371–SC]

Special Conditions: AmSafe, Inc., Various Transport Category Airplanes; Inflatable Restraints

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the transport category airplanes listed in Table 1. These airplanes, as modified by AmSafe, Inc., will have a novel or unusual design feature associated with the lap belt or shoulder harness portion of the safety belt that contains an integrated inflatable airbag installed on passenger seats. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is May 7, 2008. We must receive your comments by June 19, 2008.

ADDRESSES: You must mail two copies of your comments to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM392, 1601 Lind Avenue, SW., Renton, Washington, 98057–3356. You may deliver two copies to the Transport Airplane Directorate at the above address. You must mark your comments: Docket No. NM392. You can inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Jeff Gardlin, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington, 98057–3356; telephone (425) 227–2136; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. 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.

Comments Invited

We invite interested people to take part in this rulemaking by sending 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. You can inspect the docket 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 by 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 us to let you know we received your comments on these special conditions, send us 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 21, 2006, AmSafe Inc., 1043 N. 47th Ave., Phoenix, AZ 85043, applied for a supplemental type certificate to install the AmSafe Aviation Inflatable Restraint (AAIR) for head injury protection on passenger seats on various transport category airplanes. The AAIR is designed to limit passenger forward excursion in the event of an accident, thus reducing the potential for head injury.

The AAIR will reduce the potential for head injury and head entrapment. The AAIR behaves like an automotive inflatable airbag except that the airbag is integrated into the lap belt and inflates away from the seated passenger. While inflatable airbags are standard in the automotive industry, the use of an inflatable lap belt is novel for commercial aviation.

Title 14, Code of Federal Regulations (CFR), section 25.785 requires that passengers be protected from head injury by either the elimination of any injurious object within the striking radius of the head or by padding. Traditionally, compliance has required either a setback of 35 inches from any bulkhead, front seat or other rigid interior feature or padding where a setback was not practical. The relative effectiveness of these two means of injury protection was not quantified. The adoption of Amendment 25–64 to 14 CFR part 25, specifically § 25.562, created a new standard for protection from head injury.

Section 25.562 requires that dynamic tests be conducted for each seat type installed in the airplane. In particular, the regulation requires that persons not suffer serious head injury under the conditions specified in the tests and that a Head Injury Criterion (HIC) measurement of not more than 1000 units be recorded, should the head contact the cabin interior. While the test conditions described in this section are specific, it is the intent of the requirement that an adequate level of head injury protection be provided for crash severity up to and including that specified.

Section 25.562, including HIC, is part of the certification basis of some of the airplanes covered by these special conditions. While § 25.562 is not part of the certification basis of other airplanes covered by these special conditions, some applicants elected to comply with

portions of § 25.562—not including §§ 25.562(c)(5) and (c)(6) which specify protection from femur injury and the HIC (this is summarized in table 1). Therefore, on those airplanes, the seat installations with AAIR are not required to meet the requirement of § 25.562 that HIC of less than 1000 be demonstrated for occupants of seats incorporating the AAIR. Although HIC may not be part of the certification basis for some of the covered airplanes, references to HIC are included in these special conditions for consistency with other projects that do require compliance with HIC.

Because §§ 25.562 and 25.785 do not adequately address seats with AAIRs, the FAA recognizes that we need to develop appropriate pass/fail criteria that do address the safety of occupants of those seats.

The AAIR has two potential advantages over other means of head impact protection. The first is that it can provide significantly greater protection than would be expected with energy-absorbing pads; the second is that it can provide essentially equivalent protection for occupants of all stature. These are significant advantages from a safety standpoint, since such devices will likely provide a level of safety that exceeds the minimum 14 CFR part 25 standards.

On the other hand, AAIRs are active systems and must activate properly when needed, as opposed to an energy-absorbing pad or upper torso restraint that is passive and always available. Therefore, the potential advantages must be balanced against potential disadvantages in order to develop standards that will provide an equivalent level of safety to that intended by the regulations.

There are two primary safety concerns with the use of AAIRs: one is that they perform properly under foreseeable operating conditions, and two, that they do not perform in a way that would constitute a hazard to the airplane or occupants. This latter point has the potential to be the more rigorous of the requirements, owing to the active nature of the system.

The AAIR will rely on electronic sensors for signaling and pyrotechnic charges for activation, so that it is available when needed. These same devices could be susceptible to inadvertent activation, causing deployment in a potentially unsafe manner. The consequences of such deployment must be considered in establishing the reliability of the system. AmSafe must substantiate that the effects of an inadvertent deployment in flight are either not a hazard to the airplane or that such deployment is an extremely improbable occurrence (occurring less than 10^{-9} per flight hour). The effect of an inadvertent deployment on a passenger sitting or standing close to the AAIR must also be considered. A minimum reliability level will have to be established for this case, depending upon the consequences, even if the effect on the airplane is negligible.

The potential for an inadvertent deployment could be increased as a result of conditions in service. The installation must take into account wear and tear, so that the likelihood of an inadvertent deployment is not increased to an unacceptable level. In this context, an appropriate inspection interval and self-test capability are necessary.

Other outside influences are lightning and high intensity radiated fields (HIRF). Since the sensors that trigger deployment are electronic, they must be protected from the effects of these threats. Existing regulations regarding lightning (§ 25.1316) and HIRF (§ 25.1317) are applicable in lieu of any other lightning and HIRF special conditions that have been adopted for the affected airplanes.

For the purposes of compliance, if inadvertent deployment could cause a hazard to the airplane, the AAIR is considered a critical system; if inadvertent deployment could cause injuries to persons, the AAIR is considered an essential system. Finally, the AAIR installation should be protected from the effects of fire, so that an additional hazard is not created by, for example, a rupture of the pyrotechnic squib.

In order to be an effective safety system, the AAIR must function properly and must not introduce any additional hazards to occupants as a result of its functioning. There are several areas where the AAIR differs from traditional occupant protection systems, and requires special conditions to ensure adequate performance.

Because the AAIR is essentially a single use device, there is the potential that it could deploy under crash conditions that are not sufficiently severe as to require head injury protection from the AAIR. Since an actual crash is frequently composed of a series of impacts before the airplane comes to rest, this could render the AAIR useless if a larger impact follows the initial impact. This situation does not exist with energy absorbing pads or upper torso restraints, which tend to provide protection according to the severity of the impact. Therefore, the AAIR installation should be such that the AAIR will provide protection when it is required and will not expend its protection when it is not needed. There is no requirement for the AAIR to provide protection for multiple impacts, where more than one impact would require protection.

Since each passenger's restraint system provides protection for that occupant only, the installation must address seats that are unoccupied. It will be necessary to show that the required protection is provided for each occupant regardless of the number of occupied seats and considering that unoccupied seats may have AAIR that are active.

Since there is a wide range in the size of passengers, the inflatable seatbelt restraint must be effective over the entire range. The FAA has historically considered the range from the fifth percentile female to the ninety-fifth percentile male as the range of passengers to take into account. In this case, the FAA is proposing consideration of an even broader range of passengers, due to the nature of the inflatable seatbelt restraint installation and its close proximity to the passenger. In a similar vein, passengers may assume the brace position for those accidents where an impact is anticipated. Test data indicate that passengers in the brace position do not require supplemental protection, so that it will not be necessary to show that the AAIR will enhance the brace position. However, the inflatable seatbelt restraint must not introduce a hazard in that case by deploying into the seated, braced passenger.

Another area of concern is the use of seats so equipped by children, whether lap-held, in approved child safety seats, or occupying the seat directly. Similarly, if the seat is occupied by a pregnant woman, the installation needs to address such usage, either by demonstrating that it will function properly, or by adding an appropriate limitation on usage.

Since the AAIR will be electrically powered, there is the possibility that the system could fail due to a separation in the fuselage. Since this system is intended as a means of protection in a crash or after a crash, failure due to fuselage separation is not acceptable. As with emergency lighting, the system should function properly, if such a separation occurs at any point in the fuselage.

Since the AAIR is likely to have a large volume displacement, the inflated bag could potentially impede egress of passengers. Since the bag deflates to absorb energy, it is likely that an AAIR would be deflated at the time that persons would be trying to leave their seats. Nonetheless, it is considered appropriate to specify a time interval

after which the AAIR may not impede rapid egress. Ten seconds has been chosen as a reasonable time, since it corresponds to the maximum time allowed for an exit to be openable. In actuality, it is unlikely that an exit would be prepared this quickly in an accident severe enough to warrant deployment of the AAIR, and the AAIR will likely deflate much quicker than ten seconds.

Finally, it should be noted that the special conditions are applicable to the AAIR system, as installed. The special conditions are not an installation approval. Therefore, while the special conditions relate to each such system installed, the overall installation approval is a separate finding and must consider the combined effects of all such systems installed.

In automobile installations, the airbag is a supplemental system and works in conjunction with an upper torso restraint. In addition, the crash event is more definable and of typically shorter duration, which can simplify the activation logic. The airplane-operating environment is also quite different from automobiles and includes the potential for greater wear and tear and unanticipated abuse (due to galley loading, passenger baggage, etc.); airplanes also operate where exposure to high intensity electromagnetic fields could affect the activation system.

Type Certification Basis

Under the provisions of § 21.101, AmSafe Inc. must show that the multiple airplane models as changed, continue to meet the applicable provisions of the regulations incorporated by reference in the Type Certificate (TC) numbers listed in Table 1 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 for each individual airplane model listed in Table 1 are defined within each Type Certificate Data Sheet (TCDS).

In addition, the certification basis includes other regulations and special conditions that are not pertinent to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for each airplane model listed in Table 1 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, each airplane model listed in Table 1 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.

The FAA issues special conditions, as defined in § 11.19, under § 11.38 and they become part of the type certification basis under § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

TABLE 1.—AIRPLANE MODEL LIST

Make	Model	TC holder	TCDS
Boeing	737–500 Series [1]	The Boeing Company	A16WE Revision 40.
	737–700 Series [3]		
	737–800 Series [3]		
	737–600 Series [3]		
	737–700C Series [4]		
	737–900 Series [3]		
	737–900ER Series [3]		
Boeing	747–400 Series [1]	The Boeing Company	A20WE Revision 38.
	747–400D Series [1]		
	747–400F Series [1]		
Boeing	767–300 Series [1]	The Boeing Company	A1NM Revision 25.
	767–300F Series [1]		
	767–400ER Series [3]		
Boeing	777–200 Series	The Boeing Company	T00001SE Revision 19.
	777–300 Series		
	777–300ER Series		
	777–200LR Series		
Airbus	A318 Series:.		
	A318–111 [1]		
	A318–112 [1]		
	A318–121 [5]		
	A318–122 [5]		
	A319 Series: [5]		
	A319–111		
	A319–112		
	A319–113		
	A319–114		
	A319–115		
	A319–131		
	A319–132		
	A319–133		
	A320 Series: [5]		
	A320–111		
	A320–211		
	A320–212		
	A320–214		
	A320–231		

TABLE 1.—AIRPLANE MODEL LIST—Continued

Make	Model	TC holder	TCDS
	A320–232		
	A320–233		
	A321 Series: [5]		
	A321–111		
	A321–112		
	A321–131		
	A321–211		
	A321–212		
	A321–213		
	A321–231		
	A321–232		
Airbus	A330–200 Series: [6]	Airbus	A28NM Revision 10.
	A330–201		
	A330–202		
	A330–203		
	A330–223		
	A330–243		
	A330–300 Series: [6]		
	A330–301		
	A330–321		
	A330–322		
	A330–323		
	A330–341		
	A330–342		
	A330–343		
Airbus	A340–200 Series: [6]	Airbus	A46NM Revision 10.
	A340–211		
	A340–212		
	A340–213		
	A340–300 Series: [6]		
	A340–311		
	A340–312		
	A340–313		
	A340–500 Series:		
	A340–541		
	A340–600 Series:		
	Models: A340–642		
Airbus	A380–8007	Airbus	A43NM Revision 10.
Bombardier Inc	BD–100–1A10	Airbus	A58NM Revision 1.
Bombardier	BD–700–1A10	Bombardier Inc	T00005NY Revision 5.
	BD–700–1A11		
Bombardier	DHC–8–100 Series [1]	Bombardier Inc	T00003NY Revision 13.
	DHC–8–200 Series [1]		
	DHC–8–300 Series [1]		
	DHC–8–400 Series [1]		
Bombardier	CL–600–1A11 CL–600) [1]	Bombardier Inc	A13NM Revision 15.
	CL–600–2A12 (CL–601) [1].		
	CL–600–2B16 (CL–601–3A Variant) [1].		
	CL–600–2B16 (CL–601–3R Variant) [1].		
	CL–600–2B16 (CL–604 Variant) [1]	.	
	CL–600–2B19 (Regional Jet Series 100 & 440) [1]		
	CL–600–2C10 (Regional Jet Series 700, 701 & 702)		
	CL–600–2D15 (Regional Jet Series 705)		
	CL–600–2D24 (Regional Jet Series 900)		
Embraer	EMB–145	Bombardier Inc	A21EA Revision 26.
	EMB–145ER		
	EMB–145MR		
	EMB–145LR		
	EMB–135ER		
	EMB–135LR		
	EMB–135KE		
	EMB–135KL		
	EMB–135BJ		
	EMB–145XR		
	EMB–145MP		
	EMB–145EP		

TABLE 1.—AIRPLANE MODEL LIST—Continued

Make	Model	TC holder	TCDS
Embraer	ERJ 170–100 STD ERJ 170–100 LR ERJ 170–100 SU ERJ 170–100 SE ERJ 170–200 STD ERJ 170–200 LR ERJ 170–200 SU	Embraer-Empresa Brasileira de Aeronautica S.A.	T00011AT Revision 26.
Embraer	ERJ 190–100 STD ERJ 190–100 LR ERJ 190–100 IGW	Embraer-Empresa Brasileira de Aeronautica S.A.	A56NM Revision 6.
McDonnell Douglas	MD–88 MD–90–30 MD–717–200 [2]	McDonnell Douglas Corporation ..	A6WE Revision 26.

All models listed include Amendment 25–64 in their certification basis with exceptions as noted.
[1] Does not include § 25.562 (Amendment 25–64) in certification basis.
[2] Does not include § 25.562(c)(5) HIC in certification basis.
[3] Does not include § 25.562(c)(5) HIC in certification basis; only flight attendant and flight deck observer seats meet HIC.
[4] Does not include § 25.562(c)(5) HIC in certification basis; only flight deck observer seat meets HIC.
[5] Does not include Amendment 25–64 in certification basis, but applicant elected to meet § 25.562, except § 25.562(c)(5) HIC.
[6] Cockpit seats do not comply with § 25.562 but will meet § 25.561; § 25.785 front row seats behind bulkhead met by 35-inch free head strike envelope.
[7] Includes § 25.562 in certification basis with exemption from § 25.562(b)(2) only.

Novel or Unusual Design Features

The airplane model list in Table 1 will incorporate the following novel or unusual design features: These airplanes as modified by AmSafe, Inc. will have a lap belt or shoulder harness portion of the safety belt that contains an integrated inflatable airbag device or AAIR installed on passenger seats. The AAIR will be installed to reduce the potential for head injury in the event of an accident. The AAIR works like an automotive airbag, except that the airbag is integrated with the lap belt or harness of the restraint system. The AAIR is considered a novel design for transport category airplanes and were not considered as part of the original type certification basis.

Section 25.785 states the performance criteria for head injury protection in objective terms. However, none of these criteria are adequate to address the specific issues raised concerning seats with AAIR. The FAA has therefore determined that, in addition to the requirements of 14 CFR part 25, special conditions are needed to address requirements particular to installation of seats with AAIR.

Accordingly, in addition to the passenger injury criteria specified in § 25.785, these special conditions are adopted for the airplane model list in Table 1 equipped with AAIR. Other conditions may be developed, as needed, based on further FAA review and discussions with the manufacturer and civil aviation authorities.

Discussion

From the standpoint of a passenger safety system, the airbag is unique in that it is both an active and entirely autonomous device. While the automotive industry has good experience with airbags, the conditions of use and reliance on the airbag as the sole means of injury protection are quite different. In automobile installations, the airbag is a supplemental system and works in conjunction with an upper torso restraint. In addition, the crash event is more definable and of typically shorter duration, which can simplify the activation logic. The airplane-operating environment is also quite different from automobiles and includes the potential for greater wear and tear, and unanticipated abuse conditions (due to galley loading, passenger baggage, etc.); airplanes also operate where exposure to high intensity electromagnetic fields could affect the activation system.

The following special conditions can be characterized as addressing either the safety performance of the system, or the system's integrity against inadvertent activation. Because a crash requiring use of the airbags is a relatively rare event, and because the consequences of an inadvertent activation are potentially quite severe, these latter requirements are probably the more rigorous from a design standpoint.

Applicability

As discussed above, these special conditions are applicable to the airplane models listed in Table 1. Should AmSafe, Inc. apply at a later date for a supplemental type certificate to modify any other model included on the airplane model list in Table 1 to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the airplane models listed in Table 1. It is not a rule of general applicability and affects only the applicant which applied to the FAA for approval of these features on the airplane models listed in these special conditions.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable and that good cause exists for adopting these special conditions upon issuance. 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 type certification basis for the airplane models listed in Table 1 of these special conditions, as modified by installation of the AmSafe Aviation Inflatable Restraint (AAIR).

1. *Seats with AAIRs.* It must be shown that the AAIR will deploy and provide protection under crash conditions where it is necessary to prevent serious head injury or head entrapment. The means of protection must take into consideration a range of stature from a two-year-old child to a ninety-fifth percentile male. The AAIR must provide a consistent approach to energy absorption throughout that range. In addition, the following situations must be considered:

a. The seat occupant is holding an infant.

b. The seat occupant is a child in a child restraint device.

c. The seat occupant is a child not using a child restraint device.

d. The seat occupant is a pregnant woman.

2. The AAIR must provide adequate protection for each occupant regardless of the number of occupants of the seat assembly, considering that unoccupied seats may have active seatbelts.

3. The design must prevent the AAIR from being either incorrectly buckled or incorrectly installed such that the AAIR would not properly deploy. Alternatively, it must be shown that such deployment is not hazardous to the occupant and will provide the required head injury protection.

4. It must be shown that the AAIR system is not susceptible to inadvertent deployment as a result of wear and tear or inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings), likely to be experienced in service.

5. Deployment of the AAIR must not introduce injury mechanisms to the seated occupant or result in injuries that could impede rapid egress. This assessment should include an occupant who is in the brace position when it deploys and an occupant whose belt is loosely fastened.

6. It must be shown that an inadvertent deployment that could cause injury to a standing or sitting person is improbable.

7. It must be shown that inadvertent deployment of the AAIR, during the most critical part of the flight, will either not cause a hazard to the airplane or is extremely improbable.

8. It must be shown that the AAIR will not impede rapid egress of occupants 10 seconds after its deployment.

9. The AAIR must function properly after loss of normal aircraft electrical power and after a transverse separation of the fuselage at the most critical location. A separation at the location of the lap belt does not have to be considered.

10. It must be shown that the AAIR will not release hazardous quantities of gas or particulate matter into the cabin.

11. The AAIR installation must be protected from the effects of fire such that no hazard to occupants will result.

12. There must be a means for a crewmember to verify the integrity of the AAIR activation system prior to each flight or it must be demonstrated to reliably operate between inspection intervals.

Issued in Renton, Washington, on May 7, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11297 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0554; Directorate Identifier 2008–NM–100–AD; Amendment 39–15522; AD 2008–10–15]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, 747–100B, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Boeing Model 747–100, 747–100B, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes. This AD requires an inspection to determine if acceptable external skin doublers are installed at the stringer 6 (S–6) lap splices, between station (STA) 340 and STA 400. For airplanes without the acceptable external skin doublers, this AD requires repetitive related investigative actions and corrective actions if necessary. This AD also provides an optional terminating modification for the repetitive related investigative actions. This AD results from a report of cracked fastener holes at the right S–6 lap splice between STA 340 and STA 380. We are issuing this AD to detect and correct cracking in the fuselage skin, which could result in rapid decompression and loss of structural integrity.

DATES: This AD is effective May 20, 2008.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 20, 2008.

We must receive comments on this AD by July 21, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Discussion

We have received a report of cracking found at fourteen adjacent fastener holes where protruding head fasteners were installed in the upper row of the right stringer 6 (S–6) lap splice, between station (STA) 360 and STA 380. The airplane had accumulated 23,132 total

flight cycles. The protruding head fasteners had been installed without external skin doublers 9,757 flight cycles earlier as one of several modification options provided in Boeing Service Bulletin 747–53–2253 (AD 90–06–06, amendment 39–6490 (55 FR 8374, March 7, 1990), requires that one of the modifications specified in the service bulletin be done). Analysis by Boeing indicates that the protruding head fastener modification and the post-modification inspections are not adequate to prevent and detect cracks at the upper row of fasteners in the S–6 lap splices before the cracks reach critical length. The post-modification inspections are given in Boeing Service Bulletin 747–53–2253 and are required by AD 90–23–14, amendment 39–6801 (55 FR 46652, November 6, 1990). Cracking in the fuselage skin, if not corrected, could result in rapid decompression and loss of structural integrity.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin 747–53A2748, dated May 9, 2008. The alert service bulletin describes procedures for an external inspection to determine if acceptable external skin doublers are installed at the left- and right-side S–6 lap splices, between STA 340 and STA 400. For airplanes without the acceptable external skin doublers, the alert service bulletin specifies doing repetitive related investigative actions and corrective actions if necessary. Related investigative actions include external high frequency eddy current (HFEC) and low frequency eddy current (LFEC) inspections of the skin for cracking, as applicable. Corrective actions include repairing cracking and repeating related investigative actions, or modifying the airplane by installing acceptable external skin doublers at both the left- and right-side S–6 lap splices (includes doing an open-hole HFEC inspection of the skin for cracking, and trimming out cracking if necessary). Doing the modification would end the repetitive related investigative actions.

Boeing Alert Service Bulletin 747–53A2748 refers to Boeing Service Bulletin 747–53–2253, Revision 3, dated March 24, 1994; and Boeing Service Bulletin 747–53–2272, Revision 18, dated May 16, 2002; as additional sources of service information for accomplishment of the modification (installation of acceptable external skin doublers).

FAA's Determination and Requirements of This AD

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. This AD requires an external inspection to determine if acceptable external skin doublers are installed at the S–6 lap splices, between STA 340 and STA 400. For airplanes without the acceptable external skin doublers, this AD requires repetitive related investigative actions, as applicable, and corrective actions if necessary. This AD also provides an optional terminating modification for the repetitive related investigative actions.

Interim Action

We consider this AD interim action. We are currently considering requiring the modification (installation of acceptable external skin doublers), which would terminate the repetitive related investigative actions. However, the planned compliance time for the modification would allow enough time to provide notice and opportunity for prior public comment on the merits of the modification.

FAA's Justification and Determination of the Effective Date

We have determined that cracking of multiple adjacent fastener holes at the S–6 lap splices adjacent to the flight deck windows could join together and result in large cracks. Considering the number of accumulated flight cycles on the affected Boeing Model 747 airplanes and the consequences of cracking, we have determined that immediate inspections are necessary. Because of our requirement to promote safe flight of civil aircraft and thus, the critical need to assure the structural integrity of the fuselage and the short compliance time involved with this action, this AD must be issued immediately.

Because an unsafe condition exists that requires the immediate adoption of this AD, we find that notice and opportunity for prior public comment hereon are impracticable and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0554; Directorate Identifier 2008–NM–100–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

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

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

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

2008–10–15 Boeing: Amendment 39–15522. Docket No. FAA–2008–0554; Directorate Identifier 2008–NM–100–AD.

Effective Date

(a) This airworthiness directive (AD) is effective May 20, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 747–100, 747–100B, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes, certificated in any category; as identified in Boeing Alert Service Bulletin 747–53A2748, dated May 9, 2008.

Unsafe Condition

(d) This AD results from a report of cracked fastener holes at the right stringer 6 (S–6) lap splice between station (STA) 340 and STA 380. We are issuing this AD to detect and correct cracking in the fuselage skin, which could result in rapid decompression and loss of structural integrity.

Compliance

(e) Comply with this AD within the compliance times specified, unless already done.

Service Bulletin Reference Paragraph

(f) The term ''alert service bulletin,'' as used in this AD, means the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2748, dated May 9, 2008.

Inspection for Acceptable External Skin Doublers

(g) For airplanes identified as Group 1, Configuration 2, in Boeing Alert Service Bulletin 747–53A2748, dated May 9, 2008: At the latest of the times specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, do an external general visual inspection to determine if acceptable external skin doublers are installed at the left- and right-side S–6 lap splices, in accordance with Part 1 of the alert service bulletin.

(1) Prior to the accumulation of 10,000 total flight cycles.

(2) Within 8,000 flight cycles after a modification was done in accordance with Boeing Service Bulletin 747–53–2253.

(3) Within 15 days or 100 flight cycles after the effective date of this AD, whichever occurs first.

Acceptable External Skin Doublers Found at Both Sides

(h) If, during the inspection required by paragraph (g) of this AD, acceptable external skin doublers in accordance with the alert service bulletin are found installed at both the left- and right-side S–6 lap splices, no further work is required by this AD.

Acceptable External Skin Doublers Not Found—Repetitive Related Investigative Actions and Corrective Actions

(i) If, during the inspection required by paragraph (g) of this AD, acceptable external skin doublers in accordance with alert service bulletin are not found installed at either the left- or right-side S–6 lap splice: Before further flight, do all applicable related investigative and corrective actions by doing all actions specified in Part 2 of the alert service bulletin. Repeat the applicable related investigative actions thereafter at intervals not to exceed 300 flight cycles until the modification specified in paragraph (j) of this AD is done.

Optional Terminating Modification

(j) Modifying the airplane by installing acceptable external skin doublers at both the left- and right-side S–6 lap splices (including doing an open-hole HFEC inspection of the skin for cracking, and trimming out cracking as applicable) in accordance with the alert service bulletin terminates the repetitive related investigative actions required by this AD.

Note 1: The alert service bulletin refers to Boeing Service Bulletins 747–53–2253, Revision 3, dated March 24, 1994; and 747–53–2272, Revision 18, dated May 16, 2002; as additional sources of service information for accomplishment of the modification (installation of acceptable external skin doublers).

Note 2: AD 90–06–06, amendment 39–6490, requires, among other actions, one of the modification options specified in Boeing Service Bulletin 747–53–2253, dated December 14, 1984.

Note 3: AD 90–23–14, amendment 39–6801, requires that inspections of modifications done in accordance with Boeing Service Bulletin 747–53–2253, and applicable repairs, be done in accordance with Boeing Service Bulletin 747–53–2253, Revision 2, dated March 29, 1990.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office, FAA, ATTN: Ivan Li, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6437; fax (425) 917–6590; has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

Material Incorporated by Reference

(l) You must use Boeing Alert Service Bulletin 747–53A2748, dated May 9, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on May 13, 2008.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11330 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 270

[Release No. IC–28266; File No. S7–37–04]

RIN 3235–AJ31

Definition of Eligible Portfolio Company Under the Investment Company Act of 1940

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Final rule.

SUMMARY: The Commission is adopting an amendment to a rule under the Investment Company Act of 1940 to

more closely align the definition of eligible portfolio company, and the investment activities of business development companies (''BDCs''), with the purpose that Congress intended. The amendment expands the definition of eligible portfolio company to include certain companies that list their securities on a national securities exchange.

DATES: *Effective Date:* July 21, 2008.

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, Office of Chief Counsel, Division of Investment Management, (202) 551–6840, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–5030.

SUPPLEMENTARY INFORMATION: The Commission today is adopting amendments to Rule 2a–46 [17 CFR 270.2a–46] under the Investment Company Act of 1940 [15 U.S.C. 80a]. [1]

Table of Contents

I. Executive Summary

A BDC is a closed-end investment company that Congress established for the purpose of making capital more readily available to certain types of companies. Under the Investment Company Act (''Investment Company Act'' or ''Act''), a BDC must invest at least 70 percent of its assets in ''eligible portfolio company'' securities and certain other securities. Rule 2a–46 defines the term eligible portfolio company to include any company whose securities are not listed on a national securities exchange (''Exchange''). [2] When we adopted Rule 2a–46 in 2006, we also requested comment on whether to further expand the definition to include Exchange-listed companies that have (i) less than $75 million in public float or (ii) less than $150 million in market capitalization or less than $250 million in market capitalization. [3] Today we are amending Rule 2a–46 to expand the definition of eligible portfolio company to include Exchange-listed companies that have less than $250 million in market capitalization.

II. Background

Congress established BDCs as a new category of closed-end investment companies when it enacted the Small Business Investment Incentive Act (''SBIIA'') in 1980. [4] Congress intended that BDCs would make capital more readily available to certain types of companies. [5] To accomplish this purpose, the Investment Company Act generally prohibits a BDC from making any investment unless, at the time of the investment, at least 70 percent of its total assets (''70% basket'') are invested in securities of certain specific types of companies, including ''eligible portfolio companies.'' [6]

The Investment Company Act defines eligible portfolio company to include any domestic operating company [7] that does not have a class of securities with respect to which a member of an Exchange, broker, or dealer may extend margin credit pursuant to rules promulgated by the Federal Reserve Board under Section 7 of the Securities Exchange Act of 1934 (''Exchange Act''). [8] At the time that Section 2(a)(46) was adopted, Congress generally perceived the Federal Reserve Board's definition of ''margin security'' to be a ''rational and objective test for determining whether an issuer has ready access to the securities markets.'' [9] Nevertheless, Congress recognized that the definition of eligible portfolio company as adopted, and, in particular, the definition's reliance on the Federal Reserve Board's margin rules, might need to be adjusted in the future. [10] Accordingly, Congress specifically gave the Commission rulemaking authority under Section 2(a)(46)(C)(iv) of the Investment Company Act to expand the definition of eligible portfolio company. [11]

Since 1980, the Federal Reserve Board has periodically amended its definition of margin security to increase the types of securities that would fall within that definition under its rules. In 1998, for reasons unrelated to small business capital formation, the Federal Reserve Board amended its definition of margin

[1] The amendments were proposed in Definition of Eligible Portfolio Company under the Investment Company Act of 1940, Investment Company Act Release No. 27539 (Oct. 25, 2006) [71 FR 64093 (Oct. 31, 2006)] (''Reproposing Release'').

[2] Definition of Eligible Portfolio Company under the Investment Company Act of 1940, Investment Company Act Release No. 27538 (Oct. 25, 2006) [71 FR 64086 (Oct. 31, 2006)] (''Adopting Release'').

[3] *See* Reproposing Release, *supra* note 1.

[4] Small Business Investment Incentive Act of 1980, Public Law No. 96–477, 94 Stat. 2274 (1980) (codified at scattered sections of the United States Code).

[5] *See generally* H.R. Rep. No. 1341, 96th Cong., 2d Sess. 21 (1980) (''House Report'').

[6] *See* Section 2(a)(46) of the Investment Company Act (statutory definition of eligible portfolio company) [15 U.S.C. 80a–2(a)(46)]. *See also* Section 55(a) of the Investment Company Act (regulating the activities of BDCs) [15 U.S.C. 80a–54(a)]. Among other things, the 70% basket may include securities of eligible portfolio companies purchased in transactions not involving any public offering, securities of eligible portfolio companies already controlled by the BDC without regard to the nature of the offering, and securities of certain financially distressed companies that do not meet the definition of eligible portfolio company and that are purchased in transactions not involving any public offering. *See* Section 55(a).

[7] Section 2(a)(46) of the Investment Company Act defines eligible portfolio company to include any company that satisfies the criteria set forth in each of Section 2(a)(46)(A) and Section 2(a)(46)(B) in addition to one of the three criteria set forth in Section 2(a)(46)(C). Section 2(a)(46)(A) defines eligible portfolio company to include any company organized under the laws of, and with its principal place of business in, one or more states of the United States. Section 2(a)(46)(B) of the Investment Company Act generally excludes from the definition of eligible portfolio company any company that meets the definition of investment company under Section 3 of the Investment Company Act, or that is excluded from the definition of investment company by Section 3(c) of the Act, but includes as an eligible portfolio company any small BDC that is licensed by the Small Business Administration and that is a wholly-owned subsidiary of a BDC.

[8] Section 2(a)(46)(C)(i). *See also* Section 2(a)(46)(C)(ii) (defines eligible portfolio company to include companies that are controlled by the investing BDC or certain of its affiliates); Section 2(a)(46)(C)(iii) (defines eligible portfolio company to include certain very small companies).

[9] House Report at 31. The House Report also indicated that Section 2(a)(46)(C)(i) was ''intended to cover companies which are unable to borrow money through conventional sources or which do not have ready access to the public capital markets.'' Id. at 30. In 1980, the Federal Reserve Board periodically published lists of each company that had a class of securities that was marginable under its rules. Companies that were not listed as having a class of marginable securities qualified as eligible portfolio companies.

[10] *See* House Report at 31.

[11] Under Section 2(a)(46)(C)(iv), the term eligible portfolio company includes any issuer that, in addition to meeting the requirements of Sections 2(a)(46)(A) and (B), ''meets such other criteria as the Commission may, by rule, establish as consistent with the public interest, the protection of investors, and the purposes fairly intended by the policy and provisions of [the Act].'' *See* House Report at 23 (''* * * the Commission is given rulemaking authority to expand the class of eligible portfolio companies, following certain specific standards.''). The legislative history of the SBIIA also makes clear that the intent of this provision ''is to enable the Commission through the administrative process to broaden, if appropriate, the category of eligible portfolio company.'' Congress also noted its expectation that ''the Commission would institute [rulemaking] proceedings to consider whether the definition of eligible portfolio company can be expanded, consistent with the purpose of the legislation, to increase the flow of capital to small, developing businesses or financially troubled businesses.'' *See* House Report at 31. In providing the Commission with rulemaking authority, Congress noted ''[a]mong the objective factors which the Commission may consider in [rulemaking] proceedings are the size of such companies, the extent of their public ownership, and their operating history as going concerns and public companies.'' *Id.*

security to include all equity securities that trade on an Exchange or are listed on the NASDAQ Stock Market, and most debt securities. This amendment had the result of significantly reducing the companies that qualify as eligible portfolio companies under Section 2(a)(46) of the Investment Company Act. [12]

In 2006, we adopted two rules, Rules 2a–46 and 55a–1 under the Act, to address the impact of the Federal Reserve Board's amendment to its definition of margin security on the definition of eligible portfolio company. [13] Rule 2a–46 defines eligible portfolio company to include all domestic operating companies [14] whose securities are not listed on an Exchange. [15] Rule 55a–1 conditionally permits a BDC to continue to invest in any company that qualified as an eligible portfolio company under Rule 2a–46 when the BDC made its initial investment(s) in it, but that subsequently does not meet the definition of eligible portfolio company because it no longer meets the requirements of that rule. [16]

When we adopted Rules 2a–46 and 55a–1, we also proposed to amend Rule 2a–46 to expand the definition of eligible portfolio company to include certain public domestic operating companies that list their securities on an Exchange. [17] This proposal was designed to address concerns that part of the rule (proposed in 2004, but not adopted [18]) would be unworkable and too narrow. [19]

In the Reproposing Release, we requested comment on alternatives that would expand the definition of eligible portfolio company to include domestic operating companies with securities listed on an Exchange. We asked whether we should expand the definition to include any such company with (i) a public float of less than $75 million or (ii) market capitalization of less than $150 million or market capitalization of less than $250 million. [20] We explained that the $75 million public float standard incorporates the size-based standard used in Form S–3 and Rule 12b–2 which the Commission has used to delineate between small, unseasoned companies, and larger seasoned companies whose securities are listed on an Exchange. [21] We explained that the market capitalization alternatives are similar to definitions of ''micro-cap'' company used generally by market participants. [22] We also noted that some who had commented on Rule 2a–46 when it was initially proposed had stated that companies with market capitalizations in this range generally have limited (if any) analyst coverage, have lower trading volume and are owned by fewer institutional investors than companies with higher market capitalizations. [23] These commenters concluded that such companies have difficulty accessing the public capital markets. [24]

We received letters from fifteen commenters (including eight BDCs and one legal counsel to BDCs). [25] Fourteen commenters favored the $250 million market capitalization standard. [26] Several commenters specifically noted that companies meeting such a standard ''often have difficulty accessing traditional capital sources.'' [27] Commenters also stated that the $250 million market capitalization standard is similar to what most market participants use to identify micro-cap companies, and that these companies have less analyst coverage, institutional ownership and lower trading volume. [28]

In addition, in support of the $250 million market capitalization standard, one commenter provided information about public companies that have received financing over the past several years and the types of financing that they have received. [29] Specifically, the commenter submitted information regarding public companies that were able to access the public markets, either by engaging in initial public offerings or by issuing follow-on equity and debt financing. [30] The commenter also provided information regarding the public companies that had obtained capital through private investment transactions. [31] In addition, the commenter provided information regarding the average institutional leveraged loan size and average high yield issuance size. [32] Based on this information, the commenter concluded that companies with less than $250 million market capitalization are having difficulty accessing traditional capital sources. [33] Accordingly, the commenter urged the Commission to adopt the $250

[12] Securities Credit Transactions; Borrowing By Brokers and Dealers, 63 FR 2805 (1998) (adopting final rule amendment). As a result of these amendments, companies that would have been considered eligible portfolio companies in 1980 may no longer meet that definition. *See* Definition of Eligible Portfolio Company under the Investment Company Act of 1940, Investment Company Act Release No. 26647 (Nov. 1, 2004) [69 FR 64815 (Nov. 8, 2004)] (''2004 Proposing Release'') at nn.19–24.

[13] *See* Adopting Release, *supra* note 2.

[14] Rule 2a–46 incorporates the provisions of Sections 2(a)(46)(A) and (B). *See supra* note 7.

[15] 17 CFR 270.2a–46.

[16] 17 CFR 270.55a–1.

[17] *See* Reproposing Release, *supra* note 1.

[18] *See* 2004 Proposing Release, *supra* note 12 (proposed a definition of eligible portfolio company that would have included certain financially-troubled Exchange-listed companies).

[19] For example, some commenters had stated that the proposed rule would not include some small companies that list their securities on an Exchange but that nevertheless may have difficulties accessing conventional sources of capital and raising additional capital on the public markets. *See* Reproposing Release, *supra* note 1 at n.12 and accompanying text.

[20] *See* Reproposing Release, *supra* note 1.

[21] *See, e.g.*, Form S–3 [17 CFR 239.13]; Rule 12b–2 under the Exchange Act [17 CFR 240.12b–2].

[22] *See* Reproposing Release, *supra* note 1 at nn.38–40 and accompanying text.

[23] *Id.* at nn.34–43 and accompanying text.

[24] *E.g.,* comments of Williams & Jensen (Feb. 17, 2006); comments of Representatives Sue Kelly and Nydia Velászquez (Jan. 5, 2005) (commenting on the 2004 Proposing Release).

[25] The eight BDCs were Allied Capital Corp., American Capital Strategies Ltd., Apollo Investment Corp., Ares Capital Corp., Gladstone Management, Harris & Harris Group, Inc., MCG Capital Corp. and NGP Capital Resources Company. We also received comments from two trade associations (The Financial Roundtable and U.S. Chamber of Commerce), one legal counsel to BDCs (Williams & Jensen), one investment banker (Ferghana Partners Inc.), one investment adviser (ThinkEquity Partners LLC) and two individuals. These letters are available for inspection in the Commission's Public Reference Room at 100 F Street, NE., Washington, DC 20549 (File No. S7–37–04), and may be viewed at *http://www.sec.gov/rules/proposed/s73704.shtml #27539.*

[26] One commenter did not address this issue. Comments of Kathryn Ellis (Nov. 26, 2006). In addition, commenters generally disagreed with the adoption of a public float standard. *See infra* Section III.B.

Two commenters also suggested that we include a provision that would in the future adjust the standard that we adopt today to reflect inflation. Comments of American Capital Strategies Ltd. (Dec. 24, 2006); comments of Apollo Investment Corp. (Jan. 2, 2007). We did not propose such a provision and therefore have not included it in Rule 2a–46.

[27] *See, e.g.*, comments of Apollo Investment Corp. (Jan. 2, 2007); comments of Gladstone Management (Nov. 2, 2006). *See also* comments of Allied Capital Management (Dec. 21, 2006) (''Public companies with a market capitalization of up to $250 million . . . often have trouble accessing the traditional capital markets despite the fact that their shares are listed on an exchange.'').

[28] *See, e.g.*, comments of Gladstone Management (Nov. 2, 2006); comments of American Capital Strategies Ltd. (Dec. 24, 2006); comments of Apollo Investment Corp. (Jan. 2, 2007).

[29] Comments of Williams & Jensen (Apr. 19, 2007, May 30, 2007). This commenter also provided information regarding the investment practices of BDCs. The commenter, focusing on five of the largest BDCs, provided a description of each BDC's investment focus, the number of companies in each BDC's portfolio, and the number of individual investments each BDC made that was greater than $100 million. The commenter also provided the average revenue of the portfolio companies that are held by four BDCs. Comments of Williams & Jensen (May 30, 2007).

[30] Comments of Williams & Jensen (Apr. 19, 2007).

[31] Comments of Williams & Jensen (May 30, 2007).

[32] *Id.*

[33] Comments of Williams & Jensen (Apr. 19, 2007, May 30, 2007).

million market capitalization standard. [34]

III. Discussion

A. Rule 2a–46(b)

After carefully considering the comments received in response to both the Reproposing Release and the 2004 Proposing Release, we are amending Rule 2a–46 to include new paragraph (b). [35] Rule 2a–46(b) expands the definition of eligible portfolio company to include any domestic operating company that has a class of securities listed on an Exchange and that has a market capitalization [36] of less than $250 million (calculated using the price at which the company's common equity is last sold, or the average of the bid and asked prices of the company's common equity, in the principal market for such common equity) on any day in the 60-day period immediately before the BDC's acquisition of its securities. [37] We believe that the new rule is consistent with the public interest, the protection of investors and the purposes fairly intended by the policy and provisions of the Investment Company Act.

B. Use of Standard Based on Market Capitalization

As discussed above, one of the alternatives that we proposed used a public float standard, and the options proposed in the other alternative used a market capitalization standard. [38] We have decided to adopt a market capitalization standard for the reasons discussed below. For purposes of Rule 2a–46(b), market capitalization is the aggregate value of a company's outstanding voting and non-voting equity securities. [39] In contrast, a company's public float is a company's market capitalization minus the aggregate market value of common equity held by the company's affiliates. [40]

We requested comment on whether it would be burdensome for a BDC to determine a company's eligible portfolio company status if the standard is based on public float rather than market capitalization. [41] Adopting a public float standard in Rule 2a–46(b) would have imposed burdens that are not present in other Commission rules that incorporate such a standard. These other Commission rules typically are rules in which a company is responsible for calculating its own public float to determine its eligibility in connection with certain registration or reporting requirements. [42] Section 55 of the Investment Company Act, however, effectively requires a BDC to determine whether a target company qualifies as an eligible portfolio company before investing in it as part of the BDC's 70% basket. [43] Consequently it is the BDC, rather than the target company, that must determine whether a target company meets the definition of eligible portfolio company under Rule 2a–46(b).

Accordingly, although several commenters stated that both public float and market capitalization are good indicators of whether a company is small and unseasoned, all commenters who addressed this issue preferred a market capitalization standard. [44] Commenters stated that information about a company's market capitalization is readily available through third-party sources, while information about a company's public float is not. [45] Commenters generally explained that, in order for a BDC to calculate a company's public float, as proposed, it would have to determine the number of shares owned by the company's affiliates, which is information not readily available on a current basis through third-party sources. [46] The BDC therefore would have to communicate with possible target companies to determine whether they would qualify under the definition of eligible portfolio company before making any investment decision.

Commenters argued that requiring BDCs to determine a company's public float within the requirements of the proposed rule would place an unnecessary burden on BDCs and thereby impede appropriate investment activity. [47] In contrast, under the adopted market capitalization standard, a BDC may use information obtained from third parties to assist it in determining whether a possible investment target is an eligible portfolio company. In this regard, we note that under the adopted market capitalization standard, a BDC may use information obtained from independent third parties to assist it in determining whether a possible target company is an eligible portfolio company without communicating with the target company directly. In light of these burdens and the general public availability of information regarding a company's market capitalization, we agree with commenters that a market capitalization standard is appropriate for purposes of Rule 2a–46.

C. Dollar Level of Standard

We are adopting new Rule 2a–46(b) to define eligible portfolio company to include any company that is listed on an Exchange with market capitalization of less than $250 million. The new standard, consistent with legislative intent, broadens the definition of eligible portfolio company. [48] We estimate that, based on January 31, 2008 data, 6,062 companies, representing 61.3% (6,062/9,883) of all public domestic operating companies, qualify as eligible portfolio companies under Rule 2a–46(a). We further estimate that 1,649 Exchange-listed companies qualify as eligible portfolio companies under Rule 2a–46(b). [49] Accordingly, we estimate that 7,711 companies, representing 78% (7,711/9,883) of all public domestic operating companies

[34] Comments of Williams & Jensen (Feb. 17, 2006, Apr. 19, 2007, May 30, 2007).

[35] We are also designating the current text of Rule 2a–46 as paragraph (a) of the rule.

[36] A company's market capitalization for purposes of the rule is the aggregate market value of the company's outstanding voting and non-voting common equity securities. *See, e.g.*, Reproposing Release, *supra* note 1 at n.16.

[37] Rule 2a–46(b). This method of calculating market capitalization was used in both of the proposed market capitalization alternatives in the reproposal. *See* Reproposing Release, *supra* note 1 at n.16. We received no comment on this method, and we are adopting it as proposed.

We note that the method of calculating market capitalization is stated solely for purposes of determining a company's qualification as an eligible portfolio company. A BDC is required to value its interests in portfolio companies for purposes of calculating the BDC's net asset value consistent with Section 2(a)(41) of the Investment Company Act.

[38] *See supra* note 20 and accompanying text.

[39] *See supra* note 36.

[40] *See, e.g.*, Reproposing Release, *supra* note 1 at n.16.

[41] *Id.* at text following n.51.

[42] *See supra* note 21.

[43] Section 55(a) of the Investment Company Act.

[44] *See, e.g.*, comments of American Capital Strategies Ltd. (Dec. 24, 2006); comments of Gladstone Management (Nov. 2, 2006); comments of Apollo Investment Corp. (Jan. 3, 2007).

[45] *See, e.g., id.*

[46] *See, e.g.*, comments of American Capital Strategies Ltd. (Dec. 24, 2006); comments of Ares Capital Corp. (Jan. 2, 2007). Although Exchange Act reporting companies are required to disclose their public float on the cover of Form 10–K [17 CFR 249.310], the form requires a filer to disclose its public float as of the last business day of the filer's most recently completed second fiscal quarter. Because Rule 2a–46(b) defines an eligible portfolio company to be a company that meets the requisite size standard on any day in the 60-day period immediately before the BDC's acquisition of the company's securities, the public float information on a company's Form 10–K always would have been outdated for purposes of the proposed public float alternative.

[47] *See, e.g.*, comments of American Capital Strategies Ltd. (Dec. 24, 2006).

[48] *Supra* note 11. As discussed above, the $250 million market capitalization standard is a level similar to what most market participants generally view to be ''micro-cap'' companies, a term used to identify small public companies. *See* Reproposing Release, *supra* note 1 at nn.38–40 and accompanying text.

[49] We note that our estimates reflect only companies with less than $250 million market capitalization whose securities are listed on Nasdaq, the New York Stock Exchange (''NYSE'') and the American Stock Exchange (''Amex'').

qualify as eligible portfolio companies under Rule 2a–46 as amended.

In the Reproposing Release, we noted a general concern raised by commenters in response to the 2004 Proposing Release [50] that companies with market capitalization up to $300 million are followed by fewer analysts, have lower institutional ownership and have lower trading volume than companies at higher levels of market capitalization. [51] These commenters concluded that companies having market capitalization below that amount may have more difficulty accessing public capital. We generally agreed that there may be some correlation between the size of a company, based on these factors, and the ability of a company to access public capital. [52] We specifically requested comment on whether any of the alternative standards would better align the definition of eligible portfolio company with the purpose that Congress intended when it adopted the SBIIA.

Commenters universally favored the $250 million market capitalization standard. Commenters argued that companies with market capitalization of less than $250 million often have difficulty accessing traditional forms of capital and that adoption of the standard thus would be consistent with Congressional intent. [53] One commenter also provided information regarding the limited number of follow-on offerings of equity and debt securities by Exchange-listed companies and stated that this information ''clearly demonstrates that the vast majority of companies with market capitalizations of $250 million or less * * * have significantly limited access'' to the public equity and debt markets. [54] This commenter also argued that market participants that provide public capital are not servicing the needs of these companies. [55]

Most commenters responding to the alternatives proposed in the Reproposing Release also argued that companies with less than $250 million market capitalization have difficulty accessing public capital because generally these companies are followed by fewer analysts, have lower institutional ownership and lower trading volume than larger companies. [56] One commenter specifically noted that companies with less than $250 million market capitalization ''have spotty analyst coverage at best, * * * few or no institutional investors, and * * * thin trading volumes'' and that ''these are characteristics of companies that would not in today's market have ready access to public capital.'' [57] This commenter referred to information developed by our Office of Economic Analysis (''OEA'') about those factors that were prepared for purposes other than this rulemaking. [58]

As we stated in the Reproposing Release, we believe that there is some correlation between analyst coverage, institutional ownership and trading volume and the ability of a company to access public capital. [59] Based on the comments we received, and our review of those factors with respect to companies with less than $250 million market capitalization, we believe that a distinction can be made with respect to a company's ability to access public capital at $250 million market capitalization. OEA has considered this information and determined that fewer than 50% of companies with market capitalizations of less than $250 million are followed by more than two analysts and that these companies generally have lower institutional ownership and are more thinly traded than larger companies.

Moreover, in the Reproposing Release we requested comment on whether adoption of a $250 million market capitalization standard would result in BDCs focusing their investment activities in companies at the higher end of the standard to the detriment of smaller companies. [60] Commenters responded that adoption of a $250 million market capitalization standard would not have this result, with some arguing further that larger companies do not necessarily present a more attractive investment in comparison to smaller companies. [61] Commenters also argued that historically, BDCs have not invested in larger non-public companies at the expense of smaller non-public companies, and that there is no reason to suggest that this would occur in the context of public companies. [62] In light of these comments, we are persuaded that our adoption of the $250 million market capitalization standard is not likely to result in BDCs focusing their investment activity on larger companies to the detriment of smaller companies.

Accordingly, we conclude that adoption of the $250 million market capitalization standard is an appropriate standard for purposes of the amended rule and we believe that it is consistent with the public interest, the protection of investors and the purposes fairly intended by the policies and provisions of the Investment Company Act. [63]

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[50] *Supra* note 12.

[51] Comments of Representatives Sue Kelly and Nydia Velázquez at n.12 (Jan. 5, 2005); comments of Williams & Jensen (Feb. 17, 2006). These commenters also referred to analysis prepared by our Office of Economic Affairs (''OEA'') in connection with Securities Offering Reform. *See* memorandum dated December 3, 2004 (''OEA Memorandum'') attached to comments of Williams & Jensen (Feb. 17, 2006), *infra* note 58.

[52] *See* Reproposing Release, *supra* note 1 at text following n.36.

[53] *E.g.,* comments of Allied Capital Management (Dec. 21, 2006); comments of Apollo Investment Corp. (Jan. 2, 2007).

[54] *See* comments of Williams & Jensen (Apr. 19, 2007).

[55] Comments of Williams & Jensen (May 30, 2007).

[56] *See, e.g.*, comments of Gladstone Management (Nov. 2, 2006); comments of Apollo Investment Corp. (Jan. 2, 2007); comments of Ares Capital Corp. (Jan. 2, 2007).

[57] Comments of Williams & Jensen (Apr. 19, 2007).

[58] The commenter had attached to its comment letter statistics that were prepared in connection with the Final Report of the Advisory Committee on Smaller Public Companies. *See* Background Statistics: Market Capitalization & Revenue of Public Companies, August 1, 2005, at Table 7 (Analyst Coverage and Institutional Holdings by Market Capitalization), attached to comments of Williams & Jensen (Apr. 19, 2007). This commenter had attached to a prior comment letter an earlier memorandum prepared by OEA that sets forth data regarding analyst coverage, institutional ownership and average daily trading for publicly traded companies between 1997 and 2003. *See* OEA Memorandum dated December 3, 2004 attached to comments of Williams & Jensen (Feb. 17, 2006) (exhibit entitled ''SEC Data Demonstrates Lack of Market Following for Companies with Market Capitalizations of $300 million or Less''). OEA prepared this memorandum in connection with the Securities Offering Reform rulemaking. *See* Securities Offering Reform, Securities Act Release No. 8591 (July 19, 2005) [70 FR 44722 (Aug. 3, 2005)].

[59] *See* Reproposing Release, *supra* note 1 at n.37 and accompanying text.

[60] *See id.* at n.47 and accompanying text. We requested comment on this issue in response to a comment made by one commenter to the 2004 Proposing Release. This commenter raised the concern that BDCs might not provide financing for smaller Exchange-listed companies if the Commission adopts a standard higher than $100 million market capitalization. *See* comments of Capital Southwest Corp. (Dec. 28, 2004).

[61] *See, e.g.*, comments of MCG Capital Corp. (Dec. 27, 2006); comments of American Capital Strategies Ltd. (Dec. 24, 2006).

[62] *See* comments of Harris & Harris Group (Jan. 3, 2007); comments of ThinkEquity Partners LLC (Dec. 6, 2006).

[63] We are persuaded that our adoption of the $250 million market capitalization standard is not inconsistent with our other rules that distinguish between smaller and larger companies because of the different purposes of these rules. For example, Form S–3 incorporates a $75 million public float standard (in addition to other factors) to identify those companies about which sufficient information is publicly available to allow them to take advantage of our integrated disclosure system. *See* Revisions to the Eligibility Requirements for Primary Securities Offerings on Forms S–3 and F–3, Securities Act Release No. 8878 (Dec. 19, 2007) [72 FR 73534 (Dec. 27, 2007)]; Simplification of Registration for Primary Securities Offerings, Securities Act Release No. 6943 (July 16, 1992) [57 FR 32461 (July 22, 1992)]. In contrast, Rule 2a–46(b) incorporates a $250 million market capitalization standard to identify companies that are having difficulty accessing public capital and may benefit from greater access to BDC financing.

IV. Cost-Benefit Analysis

We are sensitive to the costs and benefits that result from our rules. In the Reproposing Release we requested public comment and specific data regarding the costs and benefits of reproposed Rule 2a–46(b). As discussed below, we received one comment regarding the Commission's estimate of the companies that would benefit from the reproposed rule. [64]

A. Benefits

Rule 2a–46(b) more closely aligns the definition of eligible portfolio company, and the investment activities of BDCs, with the purpose that Congress intended. Specifically, Rule 2a–46(b) expands the definition of eligible portfolio company to include any domestic operating company with a class of securities listed on an Exchange that has a market capitalization of less than $250 million.

Many public companies that are included as eligible portfolio companies under Rule 2a–46(b) may need capital for continued development and growth, but, notwithstanding that their securities are listed on an Exchange, may find it difficult to raise capital through additional offerings or borrow money through other sources. By amending the definition of eligible portfolio company to include these companies, such companies will benefit because of the expanded sources of capital from which the companies may seek to obtain financing. Increased competition among capital providers will benefit shareholders of companies seeking capital.

Rule 2a–46(b) also benefits BDCs by expanding the universe of investments that BDCs may include as part of their 70% basket. This will allow BDCs to make additional investments to companies that qualify as eligible portfolio companies under the rule, which in turn could benefit BDC shareholders. Rule 2a–46(b) also benefits BDCs by addressing the uncertainty caused by changes in the margin rules in the operation of BDCs.

In the Reproposing Release, OEA estimated, using June 30, 2006 data, that there were a total of 1,562 domestic operating companies whose securities were listed on Nasdaq, the NYSE and Amex that have a market capitalization of less than $250 million. At that time OEA estimated that 6,041 domestic operating companies that qualified as eligible portfolio companies under Rule 2a–46 as initially adopted. Accordingly, OEA calculated that 7,603 companies, representing 77.2% (7,603/9,845 [65]) of public domestic operating companies, would qualify as eligible portfolio companies if the $250 million market capitalization standard was adopted.

Using January 31, 2008 data, OEA estimates that there were a total of 1,649 domestic operating companies whose securities were listed on Nasdaq, the NYSE and the Amex that have a market capitalization of less than $250 million. OEA further estimates that approximately 6,062 companies qualify as eligible portfolio companies under Rule 2a–46, as initially adopted (now Rule 2a–46(a)). Accordingly, OEA calculates that 7,711 companies, representing 78% percent (7,711/9,883 [66]) of public domestic operating companies, qualify as eligible portfolio companies under amended Rule 2a–46.

OEA reached its estimates by first calculating the number of companies whose securities were listed on Nasdaq, the NYSE and the Amex. OEA then deducted from this estimate all foreign companies, investment companies and companies that are excluded from the definition of investment company by Section 3(c) of the Investment Company Act (because both Section 2(a)(46) of the Investment Company Act and Rule 2a–46 exclude these types of companies from the definition of eligible portfolio company), and corrected for cases where individual companies had multiple classes of securities listed. OEA then determined the number of companies that had a market capitalization of less than $250 million. [67] Using the same methodology, OEA determined the number of companies that qualify as eligible portfolio companies under Rule 2a–46(a). [68] OEA then calculated the total number of eligible portfolio companies and the percentage of the total public domestic operating companies that would qualify as eligible portfolio companies under amended Rule 2a–46. [69]

As noted above, one commenter stated that the Reproposing Release overstated the percentage of companies that would benefit under Rule 2a–46, as amended by the reproposed rule. [70] The commenter noted, however, that regardless of whether or not the Commission overstated the percentage of companies, ''the percentage in and of itself adds little analytical weight in describing which public companies need access to capital. * * *'' The commenter concluded that ''we believe that there is no precise percentage of public companies that can or should be targeted. * * *'' [71] While the commenter agreed that foreign companies, investment companies and most companies that are excluded from the definition of investment company by Section 3(c) of the Investment Company Act are excluded from qualifying as eligible portfolio companies under the Investment Company Act, the commenter suggested that these companies should still be included as part of the total number of public companies. Thus, the commenter suggested that the benefits of the rule should be calculated by comparing the total number of companies that would be eligible portfolio companies under the rule to the total number of public companies.

As discussed previously, Section 2(a)(46) excludes from the definition of eligible portfolio companies foreign companies, investment companies and most companies that are excluded from the definition of investment company by Section 3(c). Therefore, in determining the benefits of Rule 2a–46 as amended for purposes of this analysis, we believe that it is appropriate to compare the number of companies that meet the definition of eligible portfolio company under the rule with the number of companies that are not statutorily precluded from being treated as eligible portfolio companies.

This commenter also argued that public companies listed on the OTC Bulletin Board with market capitalizations of between $0 and $25 million should be excluded from OEA's calculations. [72] The commenter explained that although these companies qualify as eligible portfolio companies, ''they are not likely to seek or be seriously considered appropriate investments for a BDC.'' [73] OEA's calculations are intended to show the number of all companies that would fall within the definition of eligible portfolio company under Rule 2a–46(b), however, regardless of whether any particular company or size of company

[64] Comments of Williams & Jensen (Apr. 19, 2007).

[65] *See infra* note 69.

[66] *Id.*

[67] *See supra* note 49.

[68] *See* Adopting Release, *supra* note 2 at text preceding n.31.

[69] OEA estimated the total number of public domestic operating companies by calculating the number of companies whose securities were listed on Nasdaq, the NYSE and the Amex, in addition to those companies whose securities were trading through the over-the-counter bulletin board and on Pink Sheets LLC, correcting these figures for cases where individual companies had multiple classes of securities listed, and then removing from these figures foreign companies, investment companies, and companies that are excluded from the definition of investment company by Section 3(c).

[70] Williams & Jensen (Apr. 19, 2007).

[71] *Id.*

[72] *Id.*

[73] *Id.*

would be seriously considered by a BDC for investment purposes. Accordingly, we have not recalculated the numbers and percentages stated above to reflect the commenter's view.

B. Costs

We received no comments on the potential costs of our adoption of the new standard. Although Rule 2a–46(b) might impose certain administrative compliance costs on BDCs, it is our understanding that these costs are similar to the types of compliance costs that a BDC currently undertakes when it invests in a company. Specifically, a BDC will need to determine, prior to investing in a company, if the company has a class of securities listed on an Exchange and whether that company's market capitalization was less than $250 million as of a date within 60 days prior to the date of the BDC's investment. Costs in obtaining this information, however, will be minimal because information about the market capitalization of companies is readily available from third-party sources. Finally, we anticipate that Rule 2a–46(b) will impose only minimal, if any, costs on portfolio companies.

V. Consideration of Promotion of Efficiency, Competition and Capital Formation

Section 2(c) of the Investment Company Act mandates that the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation.[74] In the Reproposing Release, we requested comment on our analysis of the impact of Rule 2a–46(b) on efficiency, competition and capital formation. As discussed in Section II of this Release, commenters generally supported expanding the definition to include Exchange-listed companies with less than $250 million market capitalization because of their belief that these companies often have difficulty accessing capital.[75] Some commenters also argued that expanding the rule to include Exchange-listed companies with less than $250 million market capitalization would allow BDCs to compete with other capital providers, and that such competition would benefit shareholders of companies seeking capital.[76] We have decided to amend Rule 2a–46 to expand the definition of eligible portfolio company to include Exchange-listed companies that have a market capitalization of less than $250 million.

Rule 2a–46(b) is designed to promote efficiency, competition and capital formation. Efficiency will be enhanced because Rule 2a–46(b) expands the definition of eligible portfolio company so as to allow BDCs to compete with other entities that provide capital to certain companies. Competition for financing may result in lower cost capital for current funding needs or may replace higher cost capital previously issued, which could potentially allow companies desiring capital to take on additional or different investment projects. Thus, Rule 2a–46(b) will promote a more efficient allocation of capital. Rule 2a–46(b) in our view also will promote efficiency by providing a workable test for determining whether a company is an eligible portfolio company.

We also believe Rule 2a–46(b) will promote competition. Rule 2a–46(b) allows BDCs more easily to compete with other capital providers, and such competition benefits shareholders of BDCs, companies receiving the capital and shareholders of companies receiving capital. The market for private equity and debt investments can be highly competitive. Since their establishment, BDCs have competed with various sources of capital, including private equity funds (including venture capital funds), hedge funds, investment banks and other BDCs, to provide financing to certain companies. We believe that Rule 2a–46(b) will encourage such competition. Such competition also benefits the qualifying companies in need of capital and their shareholders because such companies can more readily consider BDCs as a source of financing. To the extent that BDCs provide either additional or less expensive capital to these companies, those companies may be more competitive in the marketplace.

Finally, we believe that Rule 2a–46(b) may promote capital formation. BDC investments represent additional capital to companies. By expanding the definition of eligible portfolio company, Rule 2a–46(b) may result in additional capital investments by BDCs. We estimate that a total of 1,649 public domestic operating companies would qualify as eligible portfolio companies under Rule 2a–46(b). The rule provides greater access to public capital by increasing these companies' access to BDC financing.

VI. Paperwork Reduction Act

The Commission has determined that Rule 2a–46 as amended does not involve a collection of information pursuant to the provisions of the Paperwork Reduction Act [44 U.S.C. 3501 *et seq.*].

VII. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis has been prepared in accordance with 5 U.S.C. 604. It relates to Rule 2a–46(b) under the Investment Company Act. An Initial Regulatory Flexibility Analysis (''IRFA'') was prepared in accordance with 5 U.S.C. 603 and was published in the Reproposing Release.[77]

A. Reasons for and Objectives of the Amendment

As described previously in this Release, Rule 2a–46(b) more closely aligns the definition of eligible portfolio company, and the investment activities of BDCs, with the purpose that Congress intended. Specifically, Rule 2a–46(b) will expand the definition of eligible portfolio company to include any domestic operating company with a class of securities listed on an Exchange that has a market capitalization of less than $250 million. These companies may need BDC financing for continued growth and development, but, notwithstanding the fact that their securities are listed on an Exchange, may find it difficult to raise additional capital in new offerings or borrow money through other conventional sources.

B. Significant Issues Raised by Public Comment

When the Commission reproposed Rule 2a–46(b), comment was requested on the reproposal and the accompanying IRFA. None of the comment letters specifically addressed the IRFA.

C. Small Entities Subject to the Rule

Rule 2a–46(b) will affect BDCs and companies that qualify as small entities under the Regulatory Flexibility Act. For purposes of the Regulatory Flexibility Act, a BDC is a small entity if it, together with other investment companies in the same group of related investment companies, has net assets of $50 million or less as of the end of its

[74] 15 U.S.C. 80a–2(c).

[75] *See supra* note 27 and accompanying text.

[76] *See, e.g.*, comments of Williams & Jensen (Apr. 19, 2007); comments of Apollo Investment Corp. (Jan. 2, 2007).

[77] Reproposing Release *supra* note 1 at Section VII.

most recent fiscal year. [78] As of June 2007, there were 73 BDCs, of which 43 were small entities. A company other than an investment company is a small entity under the Regulatory Flexibility Act if it had total assets of $5 million or less on the last day of its most recent fiscal year. [79] We estimate there are approximately 20 Exchange-listed companies that may be considered small entities. [80]

As discussed in this Release, Rule 2a–46(b) is intended to benefit certain companies that need capital for continued development and growth, but may be unable to borrow money through conventional sources despite their securities being listed on an Exchange. Rule 2a–46(b) will also benefit BDCs, including those that are small entities, by expanding the number of companies that BDCs may include as part of their 70% basket. Because none of the comment letters specifically addressed the IRFA, we continue to believe that those BDCs and companies that are small entities for purposes of the Regulatory Flexibility Act would not be disproportionately affected by the amended rule.

D. Reporting, Recordkeeping and Other Compliance Requirements

Rule 2a–46(b) will not impose any new reporting or recordkeeping requirements on BDCs or on companies. It also will impose only minimal, if any, compliance requirements on portfolio companies.

Rule 2a–46(b) will impose minimal compliance requirements on BDCs, including small entities. A BDC would need to determine, prior to investing in a company, if the company has a class of securities listed on an Exchange and whether that company's market capitalization was less than $250 million as of a date within 60 days prior to the date of the BDC's investment. We anticipate that the costs associated with obtaining this information would be minimal because such information is readily available from third-party sources. Furthermore, it is our understanding that these costs are similar to the types of compliance costs that a BDC currently undertakes when it invests in an issuer.

E. Commission Action To Minimize Adverse Impact on Small Entities

The Regulatory Flexibility Act directs us to consider significant alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small entities. Alternatives in this category would include: (1) Establishing different compliance or reporting standards that take into account the resources available to small entities; (2) clarifying, consolidating, or simplifying the compliance requirements for small entities; (3) the use of performance rather than design standards; and (4) exempting small entities from the coverage of the rules, or any part thereof.

Establishing different compliance or reporting requirements for small entities would not be appropriate under Rule 2a–46(b). Rule 2a–46 will not impose any reporting requirements on BDCs or on companies. It will also not impose any compliance requirements on portfolio companies. Rule 2a–46(b) will, however, impose some compliance requirements on BDCs that are intended to ensure that BDCs invest primarily in certain types of companies. These requirements should, however, impose only minimal burdens on BDCs.

We believe that clarifying, consolidating or simplifying the compliance requirements for small entities would be inappropriate. As discussed above, Rule 2a–46(b) will not impose any compliance requirements on portfolio companies. As noted, Rule 2a–46(b) will impose some compliance requirements on BDCs, which we believe will impose minimal burdens on BDCs. These requirements are designed to ensure that BDCs will invest in companies in accordance with the rule.

We believe that using performance rather than design standards would add unnecessary complexity. Rule 2a–46(b) provides a clear, bright-line, workable test for determining whether a company is an eligible portfolio company. A standard based on performance could be unduly complicated and cause further uncertainty to BDCs, including those that are small entities, when determining whether a company is an eligible portfolio company. Likewise, the use of a performance standard would bring uncertainty to companies in determining whether they meet the definition of eligible portfolio company.

Finally, we believe that it would be inappropriate to exempt BDCs that are small entities from the coverage of Rule 2a–46(b). Rule 2a–46(b) should benefit BDCs and companies, including those that are small entities, by expanding the definition of eligible portfolio company to include certain companies whose securities are listed on an Exchange. Exempting BDCs and companies that are small entities from the amended rule would be contradictory to the purpose of this rulemaking.

VIII. Statutory Authority

We are amending Rule 2a–46 pursuant to our rulemaking authority under Sections 2(a)(46)(C)(iv) and 38(a) of the Investment Company Act.

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Rule

For reasons set forth in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 1. The authority citation for part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a–1 *et seq.,* 80a–34(d), 80a–37, and 80a–39, unless otherwise noted.

* * * * *

■ 2. Revise § 270.2a–46 to read as follows:

§ 270.2a–46 Certain issuers as eligible portfolio companies.

The term *eligible portfolio company* shall include any issuer that meets the requirements set forth in paragraphs (A) and (B) of section 2(a)(46) of the Act (15 U.S.C. 80a–2(a)(46)(A) and (B)) and that:

(a) Does not have any class of securities listed on a national securities exchange; or

(b) Has a class of securities listed on a national securities exchange, but has an aggregate market value of outstanding voting and non-voting common equity of less than $250 million. For purposes of this paragraph:

(1) The *aggregate market value* of an issuer's outstanding voting and non-voting common equity shall be computed by use of the price at which the common equity was last sold, or the average of the bid and asked prices of such common equity, in the principal market for such common equity as of a date within 60 days prior to the date of acquisition of its securities by a business development company; and

(2) *Common equity* has the same meaning as in 17 CFR 230.405.

Dated: May 15, 2008.

[78] 17 CFR 270.0–10.

[79] 17 CFR 230.157; 17 CFR 240.0–10.

[80] We noted in the Reproposing Release that at that time we calculated that there were approximately 2,500 companies, other than investment companies, that may be considered small entities. *See* Reproposing Release *supra* note 1 at text following n.72. This figure inadvertently included companies whose securities are not listed on an Exchange. Rule 2a–46(b), however, only pertains to companies whose securities are listed on an Exchange. As discussed above, we estimate that there are only approximately 20 Exchange-listed companies that may be considered small entities.

By the Commission.

Nancy M. Morris,

Secretary.

[FR Doc. E8–11254 Filed 5–19–08; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2008–N–0231]

Medical Devices; Immunology and Microbiology Devices; Classification of Plasmodium Species Antigen Detection Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying *Plasmodium* species antigen detection assays into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule is effective June 19, 2008. The classification was effective June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0712.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on February 22, 2007, classifying the Binax NOW® Malaria Test in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On March 22, 2007, Binax, Inc., submitted a petition requesting classification of the Binax NOW® Malaria Test under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Binax NOW® Malaria Test can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''*Plasmodium* species antigen detection assays.'' It is identified as a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae*, and aids in the differential diagnosis of *P. falciparum* infections from other less virulent *Plasmodium* species. The device is intended for use in conjunction with other clinical laboratory findings.

FDA has identified the following risks to health associated with the device. Failure of the test to perform as indicated may lead to improper patient management and/or inappropriate public health responses. For example, false negative results may lead to delays in providing, or even failure to provide, definitive diagnosis and appropriate treatment. A false positive test result may subject individuals to unnecessary and/or inappropriate treatment for malaria, and failure to appropriately diagnose and treat the actual disease condition. The unnecessary use of alternative drugs, such as quinine, mefloquine and artemisinin, typically used in high resistance areas outside the United States, is problematic because these drugs are less safe than the first and second line treatments.

In addition, malaria is a significant public health issue and is a reportable disease to the Centers for Disease Control and Prevention. Local and state health departments are required to conduct case investigations upon receiving a report of a malaria infection. A false positive test result could place an undue burden on local and state health department resources and could also lead to unnecessary public health actions (e.g., unnecessary or inappropriate treatment and management of others in the community). On the other hand, a false negative result could lead to a delay in recognition of increased transmission of the parasitic infection.

An error in interpretation of results could also pose a risk, especially decisions about treatment without confirmation of negative results by

microscopy, which is more sensitive than antigen detection assays for detecting malaria parasites in blood.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risks	Mitigation Measures
Failure of the assay to perform properly, i.e., false negative or false positive results which can lead to improper patient management and/or inappropriate public health responses	Section 6. of the guidance—Performance Characteristics Section 7. of the guidance—Labeling
Failure to properly interpret test results	Section 6. of the guidance—Performance Characteristics Section 7. of the guidance—Labeling

FDA believes the class II special controls guidance document generally addresses the risks to health identified in the previous paragraphs. FDA believes the class II special controls guidance document will aid in mitigating potential risks by providing recommendations on labeling and validation of performance characteristics. The guidance document also provides information on how to meet 510(k) premarket notification submission requirements for the device. FDA believes that the special controls, in addition to general controls, address the risks to health identified previously and provide reasonable assurances of the safety and effectiveness of the device type. Therefore, on June 13, 2007, FDA issued an order to the petitioner classifying the device into class II (Ref. 2). FDA is codifying this classification by adding 21 CFR 866.3402.

Following the effective date of this final classification rule, any firm submitting a premarket notification submission for a *Plasmodium* species antigen detection assay will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, however, FDA has determined that premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of the device and, therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the *Plasmodium* species antigen detection assays they intend to market.

II. What Is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) 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.

III. What Is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no new information collection provisions. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

VI. What References Are on Display?

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Binax, Inc., dated March 22, 2007.

2. Order classifying Binax NOW® Malaria Test, dated June 13, 2007.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Section 866.3402 is added to subpart D to read as follows:

§ 866.3402 Plasmodium species antigen detection assays.

(a) *Identification.* A *Plasmodium* species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae*, and aids in the differential diagnosis of *Plasmodium falciparum* infections from other less virulent *Plasmodium* species. The device is intended for use in conjunction with other clinical laboratory findings.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: *Plasmodium* species Antigen Detection Assays.'' See § 866.1(e) for the availability of this guidance document.

Dated: April 30, 3008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–11263 Filed 5–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9399]

RIN 1545–BE93

Guidance Under Section 7874 for Determining the Ownership Percentage in the Case of Expanded Affiliated Groups

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations under section 7874 of the Internal Revenue Code (Code) relating to the disregard of certain affiliate-owned stock in determining whether a corporation is a surrogate foreign corporation under section 7874(a)(2)(B) of the Code.

DATES: *Effective Date:* These regulations are effective on May 20, 2008.

Applicability Date: For the date of applicability, see § 1.7874–1(g).

FOR FURTHER INFORMATION CONTACT: Milton Cahn, 202–622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 7874 provides rules for expatriated entities and their surrogate foreign corporations. An expatriated entity is defined in section 7874(a)(2)(A) as a domestic corporation or partnership with respect to which a foreign corporation is a surrogate foreign corporation, and any U.S. person related (within the meaning of section 267(b) or section 707(b)(1)) to such domestic corporation or partnership. Generally, a foreign corporation is a surrogate foreign corporation under section 7874(a)(2)(B) if, pursuant to a plan or a series of related transactions, certain conditions are met. One such condition depends on the percentage of owner continuity in the foreign corporation after the acquisition. This condition is satisfied if, after the acquisition, at least 60 percent of the stock (by vote or value) of the foreign corporation is held (in the case of an acquisition with respect to a domestic corporation) by former shareholders of the domestic corporation by reason of holding stock in the domestic corporation, or (in the case of an acquisition with respect to a domestic partnership) by former partners of the domestic partnership by reason of holding a capital or profits interest in the domestic partnership. See section 7874(a)(2)(B)(ii).

The treatment of expatriated entities and surrogate foreign corporations varies depending on this percentage (ownership fraction). If the ownership fraction is 80 percent or more, the surrogate foreign corporation is treated as a domestic corporation for all purposes of the Code. If the ownership fraction is 60 percent or more (but less than 80 percent), the surrogate foreign corporation is treated as a foreign corporation, but certain income or gain recognized by the expatriated entity generally cannot be offset by net operating losses or credits from the first date properties are acquired pursuant to the plan through the end of the 10-year period following the completion of the acquisition.

Section 7874(c)(2)(A) provides that stock held by members of the ''expanded affiliated group'' which includes the foreign corporation is not taken into account for purposes of the ownership fraction (affiliate-owned stock rule). Section 7874(c)(1) defines the term expanded affiliated group (EAG) as an affiliated group defined in section 1504(a), but without regard to the exclusion of foreign corporations in section 1504(b)(3) and with a reduction of the 80 percent ownership threshold of section 1504(a) to a more-than-50 percent threshold.

Section 7874(g) provides that ''[t]he Secretary shall provide such regulations as are necessary to carry out this section, including regulations providing for such adjustments to the application of this section as are necessary to prevent the avoidance of the purposes of this section, including the avoidance of such purposes through * * *. the use of related persons, pass-through or other noncorporate entities, or other intermediaries * * *.'' Section 7874(c)(6) provides that ''[t]he Secretary shall prescribe such regulations as may be appropriate to determine whether a corporation is a surrogate foreign corporation, including regulations * * * to treat stock as not stock.''

On December 28, 2005, a temporary regulation (TD 9238) was published in the **Federal Register** (70 FR 76685) that related to the disregard of affiliate-owned stock under section 7874(c)(2)(A). A notice of proposed rulemaking (REG–143244–05) cross-referencing the temporary regulation was published in the **Federal Register** for the same day (70 FR 76732). No public hearing was requested or held. Written and electronic comments responding to the notice of proposed rulemaking were received. After consideration of all the comments, the proposed regulation is adopted, as amended by this Treasury decision, as final, and the corresponding temporary regulation is removed. The revisions are discussed below.

Summary of Comments and Revisions

A. Temporary and Proposed Regulations

Treasury regulation § 1.7874–1T provides guidance under the affiliated-owned stock rule. Generally, § 1.7874–1T provides that stock owned by members of an EAG is excluded from both the numerator and denominator of the ownership fraction. However, affiliate-owned stock is excluded from the numerator of the ownership fraction, but is included in the denominator of the ownership fraction, in two instances: (1) Certain transactions occurring as part of an internal group restructuring involving a domestic entity; and (2) certain acquisitive business transactions between unrelated

parties where the former shareholders or partners of the domestic entity have a minority interest in the acquired properties after the acquisition.

With respect to internal group restructurings, the special rule applies where the common parent of the EAG after the acquisition owns directly or indirectly at least 80 percent of the domestic entity before the acquisition, and non-members of the EAG hold, by reason of holding an interest in the domestic entity, no more than 20 percent of the stock (by vote or value) of the foreign corporation after the acquisition. With respect to transactions between unrelated parties, the special rule applies where, after the acquisition, the former owners of the domestic entity do not own, in the aggregate, directly or indirectly, more than 50 percent of the stock (by vote or value) of any member of the EAG.

Section 1.7874–1T also provides guidance regarding the treatment of certain ''subsidiary-owned'' interests (which include so-called ''hook stock'') for purposes of the exceptions to the general application of the ownership fraction. These rules apply to stock or partnership interests owned by an entity in which at least 50 percent of the stock (by vote or value), or at least 50 percent of the capital or profits interest, is owned directly or indirectly by the issuer of such stock or by the partnership in question.

These rules are included in the final regulations, with revisions as noted below.

B. Section 1504(a)(4) Preferred Stock

Both the numerator and denominator of the ownership fraction take into account stock described in section 1504(a)(4) (so-called ''plain vanilla preferred stock''). For purposes of determining whether an affiliated group constitutes an EAG, however, such stock is not treated as stock because of the reference to the rules of section 1504(a). See section 7874(c)(1). Commentators have noted the inconsistent treatment of plain vanilla preferred stock in section 7874. In addition, they point out that, due to the debt-like nature of such stock, it should not be treated as stock for any purpose of section 7874, including the ownership fraction.

The Treasury Department and the IRS note that Congress has expressly stated that section 1504(a)(4) preferred stock is not treated as stock in several Code provisions, including certain provisions of section 7874, as noted above. See, for example, sections 243(c)(1), 246A(c)(4), and 355(g)(2)(B)(iv)(III). In contrast, Congress specifically chose not to exclude plain vanilla preferred stock from the ownership fraction. Although section 7874 grants the Treasury Department and the IRS the authority to treat stock as not stock when such treatment would further the purposes of section 7874, the legislative history to section 7874 does not suggest that the treatment of plain vanilla preferred stock in the ownership fraction is inconsistent with the purposes of section 7874. The Treasury Department and the IRS therefore decline to exercise the regulatory authority to exclude plain vanilla preferred stock in the calculation of the ownership fraction. Accordingly, all classes of stock, including plain vanilla preferred stock, are included in the ownership fraction and treated as stock for purposes of section 7874, other than for purposes of determining the EAG.

The Treasury Department and the IRS considered whether the treatment of plain vanilla preferred stock in the EAG definition should be made consistent with the treatment of plain vanilla preferred stock in the ownership fraction. After studying the issue, the Treasury Department and the IRS believe that taking plain vanilla preferred stock into account for purposes of the definition of an EAG may facilitate the avoidance of the rules regarding EAGs. Consequently, the Treasury Department and the IRS also decline to exercise regulatory authority to amend the treatment of plain vanilla preferred stock for purposes of defining an EAG.

The Treasury Department and the IRS will, however, continue to monitor the use of plain vanilla preferred stock and its treatment under section 7874.

C. Internal Restructuring Exception

Treasury regulation § 1.7874–1T(c)(1) provides that stock held by a member of an EAG is included in the denominator, but not the numerator, of the ownership fraction if two conditions are satisfied. First, the common parent of the EAG must own directly or indirectly at least 80 percent of the stock (by vote or value) or the capital or profits interest in the domestic entity prior to the acquisition. Second, following the acquisition non-members of the EAG, by reason of holding stock or a capital or profits interest in the domestic entity, must not own more than 20 percent of the stock (by vote or value) of the foreign corporation.

One commentator suggested that the requirement should merely look to the stock ownership of the common parent of the EAG both before and after the acquisition. The Treasury Department and the IRS agree with this suggestion. In addition, the Treasury Department and the IRS have determined that the rule should be modified to consider the stock by vote and value held by the common parent of the EAG. Consequently, stock of a member of an EAG is included in the denominator, but not the numerator of the ownership fraction, if the common parent of the EAG held directly or indirectly at least 80 percent of the stock (by vote and value) or the capital and profits interest, as applicable, of the domestic entity before the acquisition, and holds at least 80 percent of the stock (by vote and value) of the foreign acquiring corporation after the acquisition. Corresponding revisions have been made to the examples.

D. Hook Stock

One commentator requested clarification of the wording of § 1.7874–1T(d) regarding the treatment of hook stock. In response to this comment, the provision is clarified to exclude hook stock from both the numerator and denominator of the fractions that are used to determine whether the exceptions to the general rule apply (that is, the determination of whether the acquisition resulted in an internal group restructuring or a loss of control of the domestic entity).

Regulations Addressing Avoidance of the Purposes of Section 7874

The Treasury Department and the IRS understand that taxpayers may be taking the position that a foreign corporation that acquires substantially all of the properties of a domestic corporation in a title 11 or similar case may not be a surrogate foreign corporation because it fails to satisfy the stock ownership requirement described in section 7874(a)(2)(B)(ii). These taxpayers maintain that creditors of the domestic corporation, which typically receive all of the stock of the acquiring foreign corporation issued in the title 11 or similar case, are not considered former shareholders of the domestic corporation for purposes of section 7874(a)(2)(B)(ii). Thus, they take the position that the creditors do not hold the stock of the foreign acquiring corporation received by reason of holding stock in the domestic corporation. Under this position, there often would be little or no continuity of ownership for purposes of section 7874(a)(2)(B)(ii) and, as a result, the foreign corporation would not be a surrogate foreign corporation. Taxpayers take this position even though the creditors, in substance, are the equity owners of the domestic corporation at the time of the title 11 or similar case and acquire the stock issued by the

acquiring foreign corporation by reason of their status as creditors of the domestic corporation. *Helvering* v. *Alabama Asphaltic Limestone Co.,* 315 U.S. 179 (1942).

The Treasury Department and the IRS disagree with this characterization under current law and are considering issuing regulations to clarify the proper application of the rules to such transactions. Section 7874(c)(6) provides that the Secretary shall prescribe such regulations as may be appropriate to determine whether a corporation is a surrogate foreign corporation, including regulations: (i) To treat warrants, options, contracts to acquire stock, convertible debt interests, and other similar interests as stock, and (ii) to treat stock as not stock. These regulations would provide, as appropriate, that for purposes of section 7874(a)(2)(B)(ii), creditors of a domestic corporation emerging from a title 11 or similar case are treated as former shareholders of such corporation. The regulations would further provide, as appropriate, that for this purpose, stock issued by the foreign acquiring corporation to such creditors is held by reason of holding stock in the domestic corporation. Similar rules may apply to acquisitions of substantially all the properties constituting a trade or business of a domestic partnership.

The Treasury Department and the IRS also understand that some taxpayers may be taking the position that, where two or more domestic entities described in section 7874(a)(2)(B)(i) are acquired pursuant to an overall plan, section 7874(a)(2)(B) is applied separately to each such domestic entity. For example, taxpayers may take this position where a foreign corporation is formed to acquire, in exchange for its stock, 100 percent of the stock of two domestic corporations that have approximately the same value. In such a case, after the acquisition the former shareholders of the two domestic corporations, in the aggregate, would hold 100 percent of the stock of the foreign acquiring corporation by reason of holding stock in the domestic corporations. However, the taxpayers may claim that the ownership fraction applies separately to each acquisition such that the ownership fraction would be approximately 50 percent, rather than 100 percent. Under this interpretation, the acquiring foreign corporation would not be a surrogate foreign corporation because the condition described in section 7874(a)(2)(B)(ii) would not be satisfied.

The Treasury Department and the IRS disagree with this interpretation under current law and are considering issuing regulations to clarify the proper application of the rules. These regulations would clarify that the references in section 7874(a)(2)(B) to ''a domestic corporation'' shall, as appropriate, mean ''one or more domestic corporations'' where the properties of such corporations are, directly or indirectly, acquired pursuant to the same plan. Similar clarifications will be made with respect to acquisitions involving properties of domestic partnerships.

Finally, the Treasury Department and the IRS understand that some taxpayers may be attempting to avoid the application of section 7874 by structuring acquisitions of domestic entities by foreign corporations through the use of intervening partnerships. For example, a foreign acquiring corporation may issue new shares to a newly formed domestic partnership in exchange for a 99 percent interest in the partnership. The shares transferred to the domestic partnership constitute 70 percent of the outstanding stock of the foreign acquiring corporation. An affiliate of the foreign acquiring corporation would transfer cash or other property to the partnership for the remaining one percent interest. The foreign acquiring corporation then transfers its 99 percent interest in the domestic partnership to the shareholders of a domestic corporation in exchange for 100 percent of the stock of the domestic corporation.

The taxpayers take the position that this transaction is not subject to section 7874 even though, in substance, the foreign acquiring corporation acquired 100 percent of the stock of the domestic corporation and the former shareholders of the domestic corporation, through their 99 percent interest in the domestic partnership, hold more than 60 percent of the stock of the foreign acquiring corporation by reason of holding stock in the domestic corporation. Under this interpretation, which relies on treating the partnership as an entity (rather than as an aggregate of its partners), the ownership fraction would be zero because none of the foreign acquiring corporation stock held by the partnership was held by former shareholders of the domestic corporation. Thus, section 7874 would not apply to the transaction.

The Treasury Department and the IRS disagree with this characterization under current law and are considering issuing regulations to clarify the proper application of the rules to these transactions. The regulations would provide, as appropriate, that for purposes of applying section 7874(a)(2)(B)(i) to these structures, the exchange of an interest in a domestic entity for an interest in a partnership shall be treated as an exchange of the interest in the domestic entity for a pro rata share of the assets of the partnership.

The regulations described above, which may be issued in conjunction with the finalization of the § 1.7874–2T regulations, may be effective as of May 20, 2008. However, no inference is intended as to the potential applicability of other Code or regulatory provisions, or judicial doctrines (including substance over form) to the transactions described above.

Effective/Applicability Date

Section 1.7874–1 applies to acquisitions completed on or after May 20, 2008, subject to transition relief for certain acquisitions entered into pursuant to binding commitments. In addition, taxpayers may elect to apply this section to prior acquisitions, but must apply it consistently to all acquisitions within its scope.

Special Analyses

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

Drafting Information

The principal author of this regulation is Milton Cahn, Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in its development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry

in numerical order to read, in part, as follows:

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

Section 1.7874–1 also issued under 26 U.S.C. 7874(c)(6) and (g).

§ 1.7874–1T [Removed]

■ **Par. 2.** Section 1.7874–1T is removed.

■ **Par. 3.** Section 1.7874–1 is added to read as follows:

§ 1.7874–1 Disregard of affiliate-owned stock.

(a) *Scope.* Section 7874(c)(2)(A) provides that stock of the foreign corporation referred to in section 7874(a)(2)(B) held by members of the expanded affiliated group (EAG) that includes such foreign corporation shall not be taken into account in determining ownership for purposes of section 7874(a)(2)(B)(ii). This section provides rules under section 7874(c)(2)(A). The rules provided in this section are also subject to section 7874(c)(4).

(b) *General rule.* Except as provided in paragraph (c) of this section, for purposes of the ownership percentage determination required by section 7874(a)(2)(B)(ii), stock held by one or more members of the EAG is not included in either the numerator or the denominator of the fraction that determines such percentage (ownership fraction).

(c) *Exceptions to general rule*—(1) *Overview.* Stock held by one or more members of the EAG shall be included in the denominator, but not in the numerator, of the ownership fraction, if the acquisition qualifies as an *internal group restructuring* or results in a *loss of control*, as described in paragraph (c)(2) and (c)(3) of this section.

(2) *Internal group restructuring.* For purposes of paragraph (c)(1) of this section, an acquisition qualifies as an internal group restructuring if:

(i) Before the acquisition, 80 percent or more of the stock (by vote and value) or the capital and profits interest, as applicable, of the domestic entity was held directly or indirectly by the corporation that is the common parent of the EAG after the acquisition; and

(ii) After the acquisition, 80 percent or more of the stock (by vote and value) of the acquiring foreign corporation is held directly or indirectly by such common parent.

(3) *Loss of control.* For purposes of paragraph (c)(1) of this section, the acquisition results in a loss of control if after the acquisition, the former shareholders or partners of the domestic entity do not hold, in the aggregate, directly or indirectly, more than 50 percent of the stock (by vote or value) of any member of the EAG.

(d) *Treatment of certain hook stock.* This paragraph applies to stock of a corporation that is held by an entity in which at least 50 percent of the stock (by vote or value) or at least 50 percent of the capital or profits interest, as applicable, in such entity, is held directly or indirectly by the corporation. The stock to which this paragraph applies shall not be included in either the numerator or denominator of any fraction for the following purposes:

(1) For applying paragraph (c)(1) of this section; and

(2) For determining whether the acquisition qualifies as an internal group restructuring (described in paragraph (c)(2) of this section) or results in a loss of control (described in paragraph (c)(3) of this section).

(e) *Stock held by a partnership.* For purposes of section 7874, stock held by a partnership shall be considered as held proportionately by its partners.

(f) *Examples.* The application of this section is illustrated by the following examples. It is assumed that all transactions in the examples occur after March 4, 2003. In all the examples, if an entity or other person is not described as either domestic or foreign, it may be either domestic or foreign. In addition, each entity has only a single class of equity outstanding. Finally, the analysis of the following examples is limited to a discussion of issues under section 7874, even though the examples may raise other issues (for example, under section 367).

Example 1. Disregard of hook stock—(i) *Facts.* USS, a domestic corporation, has 100 shares of stock outstanding. USS's stock is held by a group of individuals. Pursuant to a plan, USS forms FS, a foreign corporation, and transfers to FS the stock of several wholly owned foreign corporations, in exchange for 90 shares of FS stock. FS then forms Merger Sub, a domestic corporation. Under a merger agreement and state law, Merger Sub merges into USS, with USS surviving the merger. In exchange for their USS stock, the former shareholders of USS receive, in the aggregate, 100 shares of newly issued FS stock. As a result of the merger FS holds 100 percent of the USS stock. USS continues to hold 90 shares of FS stock.

(ii) *Analysis.* FS has indirectly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. After the acquisition, the former shareholders of USS hold 100 shares of FS stock by reason of holding stock in USS, and USS holds 90 shares of FS stock. Under paragraph (b) of this section, the 90 shares of FS stock held by USS, a member of the EAG, are not included in either the numerator or the denominator of the ownership fraction. Accordingly, the ownership fraction is 100/100. If the condition in section 7874(a)(2)(B)(iii) is satisfied, FS is a surrogate foreign corporation which is treated as a domestic corporation under section 7874(b).

Example 2. Internal group restructuring; wholly owned corporation—(i) *Facts.* P, a corporation, owns all 100 outstanding shares of USS, a domestic corporation. USS forms FS, a foreign corporation, and transfers all its assets to FS in exchange for all 100 shares of the stock of FS, in a reorganization described in section 368(a)(1). P exchanges its USS stock for FS stock under section 354.

(ii) *Analysis.* FS has directly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. The acquisition is an internal group restructuring described in paragraph (c)(2) of this section because P, the common parent of the EAG after the acquisition, held directly or indirectly 80 percent or more of the stock (by vote and value) of USS before the acquisition, and after the acquisition, P holds directly or indirectly 80 percent or more of the stock (by vote and value) of FS. Accordingly, under paragraph (c)(1) of this section, the FS stock held by P is included in the denominator, but not in the numerator of the ownership fraction. Therefore, the ownership fraction is 0/100. FS is not a surrogate foreign corporation.

Example 3. Internal group restructuring; wholly owned corporation—(i) *Facts.* The facts are the same as in *Example 2*, except that USS does not transfer any of its assets to FS. Instead, P transfers all 100 shares of USS stock to FS in exchange for all 100 shares of FS stock.

(ii) *Analysis.* FS has indirectly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. The acquisition is an internal group restructuring described in paragraph (c)(2) of this section because P, the common parent of the EAG after the acquisition, held directly or indirectly 80 percent or more of the stock (by vote and value) of USS before the acquisition, and after the acquisition, P holds directly or indirectly 80 percent or more of the stock (by vote and value) of FS. Accordingly, under paragraph (c)(1) of this section, the FS stock held by P is included in the denominator, but not in the numerator of the ownership fraction. Accordingly, the ownership fraction is 0/100. FS is not a surrogate foreign corporation.

Example 4. Internal group restructuring; less than wholly owned corporation—(i) *Facts.* The facts are the same as in *Example 3*, except that P holds 85 shares of USS stock. The remaining 15 shares of USS stock are held by A, a person unrelated to P. P and A transfer their shares of USS stock to FS in exchange for 85 and 15 shares of FS stock, respectively.

(ii) *Analysis.* FS has indirectly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. The acquisition is an internal group restructuring described in paragraph (c)(2) of this section because P, the common parent of the EAG after the acquisition, held directly or indirectly 80 percent or more of the stock (by vote and value) of USS before the acquisition, and after the acquisition P holds directly or indirectly 80 percent or more of the stock (by vote and value) of FS. Therefore, under

paragraph (c)(1) of this section, the FS stock held by P is included in the denominator, but not in the numerator of the ownership fraction. Accordingly, the ownership fraction is 15/100. FS is not a surrogate foreign corporation.

Example 5. Internal group restructuring exception not applicable; less than 80 percent owned corporation—(i) *Facts.* The facts are the same as in Example 2, except that P owns 55 shares of USS stock, and A, a person unrelated to P, holds 45 shares of USS stock. P and A exchange their shares of USS stock for 55 shares and 45 shares of FS stock, respectively.

(ii) *Analysis.* FS has acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. P, the common parent of the EAG after the acquisition, did not hold directly or indirectly 80 percent or more of the stock (by vote and value) of USS before the acquisition, and after the acquisition P does not hold directly or indirectly 80 percent or more of the stock (by vote and value) of FS. Thus, the acquisition is not an internal group restructuring described in paragraph (c)(1) of this section, and the general rule of paragraph (b) of this section applies. Under paragraph (b) of this section, the FS stock held by P, a member of the EAG, is not included in either the numerator or the denominator of the ownership fraction. Accordingly, the ownership fraction is 45/45. If the condition in section 7874(a)(2)(B)(iii) is satisfied, FS is a surrogate foreign corporation which is treated as a domestic corporation under section 7874(b).

Example 6. Internal group restructuring; hook stock—(i) *Facts.* USS, a domestic corporation, has 100 shares of stock outstanding. P, a corporation, holds 80 shares of USS stock. The remaining 20 shares of USS stock are held by A, a person unrelated to P. USS owns all 30 outstanding shares of FS, a foreign corporation. Pursuant to a plan, FS forms Merger Sub, a domestic corporation. Under a merger agreement and state law, Merger Sub merges into USS, with USS surviving the merger as a subsidiary of FS. In exchange for their USS stock, P and A, the former shareholders of USS, respectively receive 56 and 14 shares of FS stock. USS continues to hold 30 shares of FS stock.

(ii) *Analysis.* FS has indirectly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. Under paragraph (b) of this section, the shares of FS stock held by P and USS, both of which are members of the EAG, are not included in either the numerator or denominator of the ownership fraction, unless the acquisition results in an internal group restructuring or loss of control of USS such that the exception of paragraph (c)(1) of this section applies. In determining whether the acquisition of USS is an internal group restructuring, under paragraph (d)(2) of this section, the FS stock held by USS is disregarded. Because P held directly or indirectly 80 percent or more of the stock (by vote and value) of USS before the acquisition, and after the acquisition P holds directly or indirectly 80 percent or more of the stock (by vote and value) of FS (when disregarding the FS stock held by USS), the acquisition is an internal group restructuring and the exception of paragraph (c)(1) of this section applies. Accordingly, when determining whether FS is a surrogate foreign corporation, the FS stock held by P is included in the denominator, but not the numerator of the ownership fraction. However, under paragraph (b) of this section, the FS stock held by USS is not included in either the numerator or denominator of the ownership fraction. Accordingly, the ownership fraction is 14/70, or 20 percent, since only the stock held by A is included in the numerator, and the stock held by both P and A is included in the denominator. Accordingly, FS is not a surrogate foreign corporation.

Example 7. Loss of control—(i) *Facts.* P, a corporation, holds all the outstanding stock of USS, a domestic corporation. B, a corporation unrelated to P, holds all 60 outstanding shares of FS, a foreign corporation. P transfers to FS all the outstanding stock of USS in exchange for 40 newly issued shares of FS.

(ii) *Analysis.* FS has indirectly acquired substantially all the properties held directly or indirectly by USS pursuant to a plan. After the acquisition, B holds 60 percent of the outstanding shares of the FS stock. Accordingly, B, FS and USS are members of an EAG. After the acquisition, P does not hold directly or indirectly more than 50 percent of the stock (by vote or value) of any member of the EAG and, thus, the acquisition results in a loss of control described in paragraph (c)(3) of this section. Accordingly, under paragraph (c)(1) of this section, the FS stock owned by B is included in the denominator, but not in the numerator, of the ownership fraction. Therefore, the ownership fraction is 40/100. FS is not a surrogate foreign corporation.

Example 8. Internal group restructuring; partnership—(i) *Facts.* LLC, a Delaware limited liability company, is engaged in the conduct of a trade or business. P, a corporation, holds 90 percent of the interests of LLC. A, a person unrelated to P, holds 10 percent of the interests of LLC. LLC has not elected to be treated as an association taxable as a corporation. P and A transfer their interests in LLC to FS, a newly formed foreign corporation, in exchange for 90 shares and 10 shares, respectively, of FS's stock, which are all of the outstanding shares of FS. Accordingly, LLC becomes a disregarded entity.

(ii) *Analysis.* Prior to the FS's acquisition of the interests of LLC, LLC was a domestic partnership for Federal income tax purposes. FS has acquired substantially all the properties constituting a trade or business of LLC pursuant to a plan. After the acquisition, P holds 90 percent of FS's stock (by vote and value) by reason of holding a capital and profits interest in LLC, and A holds 10 percent of FS's stock (by vote and value) by reason of holding a capital and profits interest in LLC. The internal group restructuring exception under paragraph (c)(2) of this section applies, because before the acquisition, P held 80 percent or more of the capital and profits interest in LLC, and after the acquisition, P holds 80 percent or more of the stock (by vote and value) of FS. Under paragraph (c)(1) of this section, the FS stock held by P is included in the denominator, but not the numerator, of the ownership fraction. Accordingly, the ownership fraction is 10/100. FS is not a surrogate foreign corporation.

(g) *Effective/applicability date.* Except as otherwise provided in this paragraph, this section shall apply to acquisitions completed on or after May 20, 2008. This section shall not, however, apply to an acquisition that was completed on or after May 20, 2008, provided such acquisition was entered into pursuant to a written agreement which was (subject to customary conditions) binding prior to May 20, 2008, and at all times thereafter (binding commitment). For purposes of the preceding sentence, a binding commitment shall include entering into options and similar interests in connection with one or more written agreements described in the preceding sentence. Notwithstanding the general application of this paragraph, taxpayers may elect to apply this section to prior acquisitions, but must apply it consistently to all acquisitions within its scope.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

Approved: May 8, 2008.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E8–11285 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB55

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of enforcement of DPM final limit; withdrawal of intent to issue a proposed rule.

SUMMARY: This notice informs the public of MSHA's decision to implement the diesel particulate matter (DPM) final permissible exposure limit (PEL) of 160 micrograms of total carbon (TC) per cubic meter of air (160_{TC} g/m^3). MSHA has developed a practical sampling strategy to account for interferences from non-diesel exhaust sources when TC is used as a surrogate for measuring a miner's exposure to DPM. The Agency

will begin enforcement of the 160 TC limit under existing 30 CFR 57.5060(b)(3) on May 20, 2008. MSHA will post details of its sampling strategy on the Agency's DPM Single Source Page prior to enforcement. The sampling strategy is based on the best available scientific evidence and will be specific to each mine.

DATES: *Effective Date:* May 20, 2008.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations and Variances at *silvey.patricia@dol.gov* (E-mail), 202–693–9440 (Voice), or 202–693–9441 (Fax).

SUPPLEMENTARY INFORMATION:

A. Background

MSHA measures a miner's personal exposure to DPM by analyzing the sample for a DPM surrogate, TC. TC is the sum of elemental carbon (EC) and organic carbon (OC). The 160 TC limit was promulgated in the 2001 final rule ''Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners'' which was published in the **Federal Register** on January 19, 2001 (66 FR 5706) and amended on June 6, 2005 (70 FR 32868) and May 18, 2006 (71 FR 28924).

When the Agency published the 2006 final rule, MSHA stated its intent to issue a proposed rule to convert the 160 TC PEL to a comparable EC PEL prior to the effective date of May 20, 2008, provided sufficient scientific data were available to support a proposed rule. MSHA is not issuing a proposed rule to uniformly convert the 160 TC limit to a comparable EC limit. Instead, MSHA provides a protocol for calculating a location specific adjustment for situations in which the EC on the miner's personal sample is less than 160 micrograms per cubic meter of air times the error factor (EF) for EC, and TC on the miner's personal sample is greater than 160 micrograms per cubic meter of air times the EF for TC. The decision not to issue a uniform conversion factor is based on MSHA's assessment that there is still insufficient evidence suggesting an appropriate conversion factor, and the latest available scientific evidence regarding the relationship between TC and EC at levels as low as 160 TC. MSHA will continue to monitor and encourage research in this field.

The DPM rulemaking record established that a miner's exposure could not be validated simply by adding the EC and OC of a TC sample due to the potential for non-diesel exhaust sources to deposit on the OC part of the sample and interfere with the MSHA sample analysis. These interferences include environmental tobacco smoke, drill oil mist, and ammonium nitrate/fuel oil (ANFO) vapors. When measuring EC, interferences are not a factor in assuring the accuracy of the sample analysis.

Currently, MSHA determines a miner's exposure to the PEL of 350_{TC} $\mu g/m^3$ (350 TC) by conducting an EC analysis to validate that the miner's overexposure to TC is not the result of interferences. In each analysis, MSHA incorporates an error factor to account for variability in sampling and analysis resulting from such things as pump flow rate, filters, and the NIOSH Analytical Method 5040. If the TC measurement is above 350 TC micrograms times the error factor for TC, MSHA looks at the EC measurement from the sample obtained through the NIOSH Analytical Method 5040, and multiplies EC by a conversion factor of 1.3 to produce a statistically valid estimate of what the TC result is without interferences. MSHA issues a citation when the EC measurement times the multiplier is above 350 micrograms times the error factor for EC. The 1.3 multiplier that MSHA uses to estimate TC (*i.e.*, EC × 1.3 = estimated TC) is the median value of all TC to EC ratios obtained from valid TC samples (*i.e.*, without OC interferences) collected by MSHA during the 31-Mine Study, and it is consistent with NIOSH's determination that TC is 60–80% EC.

In the 2006 final rule (71 FR 28924, May 18, 2006), MSHA retained the 2001 final limit of 160 TC but determined that it should be phased in over a two-year period and stated that:

> Consequently, on May 20, 2006, the initial final limit will be 308 micrograms of EC per cubic meter of air (308_{EC} $\mu g/m^3$), which is the same as the existing interim limit; on January 20, 2007, the final limit will be reduced by 50 micrograms and will be a TC limit of 350_{TC} $\mu g/m^3$; and on May 20, 2008, the final limit of 160_{TC} $\mu g/m^3$ will become effective. Note that the 350_{TC} $\mu g/m^3$ final limit and the 160_{TC} $\mu g/m^3$ final limit are established as TC-based limits in this final rule. (*Id.* at 28934).

Also in the 2006 final rule, MSHA discussed its concerns regarding the relationship between TC, EC and OC at lower concentrations and its intent to conduct a separate rulemaking to determine the most appropriate way to convert the 160 TC PEL to a comparable EC PEL by stating:

> Moreover, we intend to convert the final limits of 350_{TC} $\mu g/m^3$ and 160_{TC} $\mu g/m^3$ in a separate rulemaking by January 2007. As we said in the 2005 NPRM, if we do not complete this rulemaking by that time, we will use the EC equivalent as a check to validate that an overexposure to the 350_{TC} $\mu g/m^3$ final limit is not the result of interferences. This enforcement policy, which is based on the Second Partial Settlement Agreement and data in the rulemaking record, would be the same that we used to implement the 400_{TC} $\mu g/m^3$ interim limit before we converted it to 308_{EC} $\mu g/m^3$ in the June 2005 final rule. Whereas we have evidence that we can obtain an accurate sample analysis of the final limit of 350_{TC} $\mu g/m^3$, there is no evidence in the rulemaking record suggesting that the 1.3 conversion factor is appropriate for substantially lower limits, such as the final limit of 160_{TC} $\mu g/m^3$. (*Id.* at 28976).

Although in the 2006 final rule MSHA acknowledged the limitations of sampling a miner's exposure to TC and preferred EC rather than TC as a DPM surrogate, the Agency did not conclude that TC could not be used as an appropriate surrogate for measuring a miner's exposure to DPM. In addition, the court decision in *Kennecott Greens Creek Mining Company* v. *Mine Safety and Health Administration*, 476 F.3d 946, 956 (DC Cir. 2007), upholding the DPM standard, allows MSHA to enforce either the 160 TC PEL or a converted elemental carbon (EC) PEL. The court upheld MSHA's selection of TC and EC as appropriate surrogates for DPM. See *Id.* at 956.

Subsequent to the DPM court decision, MSHA decided to wait for further scientific evidence regarding whether MSHA could reasonably convert the 160 TC PEL using a fixed conversion factor such as the 1.3 conversion factor currently used. The latest available scientific evidence is the study titled ''Relationship between Elemental Carbon, Total Carbon, and Diesel Particulate Matter in Several Underground Metal/Non-metal Mines'' which was published on February 1, 2007 (J. D. Noll; A. D. Bugarski; L. D. Patts; S. E. Mischler; L. McWilliams, *Environ. Sci. & Technol.*, Vol. 41, No. 3: February 1, 2007, 710–716). The authors concluded that the variability of the TC-to-EC ratio increases below 230 TC and is high at 160 TC. Therefore, MSHA could not identify a single, constant conversion factor for EC at any level below 230 TC.

In March 2007, MSHA hired an outside expert with experience in DPM sampling methodology and analysis to advise the Agency in developing an enforcement strategy for accurately determining a miner's exposure to TC. The expert also reviewed the latest available data to attempt to devise a scientific method for converting the 160 TC PEL to a comparable EC PEL. The expert was unable to recommend such a method. As an alternative to developing a conversion factor, the

expert recommended sampling strategy options for the Agency's consideration in enforcing the DPM final limit in a September 2007 report. MSHA was reviewing the expert's recommendations when it published its December 10, 2007 Semi-Annual Regulatory Agenda in which the Agency continued to state its intent to propose a rule to convert the 160 TC limit. MSHA now has determined that insufficient data exist to proceed with further rulemaking to convert the DPM final limit using a single, constant conversion factor, such as the 1.3 factor currently used for EC for all mines.

B. Notice of Enforcement of DPM Final Limit

MSHA has developed an enforcement strategy for implementation of the DPM 160 TC PEL beginning May 20, 2008. MSHA will continue to determine a miner's exposure to DPM based on a single personal sample taken over the miner's full shift as specified in existing 30 CFR § 57.5061 of the DPM standard. MSHA will use an EC analysis and appropriate sampling methods to ensure that a citation for a miner's overexposure to the 160 TC PEL is valid and not the result of interferences.

C. Reason for Withdrawal of Intent To Issue a Proposed Rule

MSHA is withdrawing its intent to issue a proposed rule to convert the 160 TC PEL because it has determined that insufficient data exist to support such a rule, and because it has determined that the enforcement strategy it will begin to use on May 20, 2008, is an accurate and effective way of enforcing the DPM standard. This enforcement strategy will provide effective health protections for miners at underground metal and nonmetal mines. In light of MSHA's enforcement action, this notice does not reduce health protections for underground metal and nonmetal miners.

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners is withdrawn from the Regulatory Agenda. This document does not preclude future agency action that MSHA may find to be appropriate.

Dated: May 15, 2008.

John P. Pallasch,

Deputy Assistant Secretary for Mine Safety and Health.

[FR Doc. E8–11329 Filed 5–19–08; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 104

46 CFR Parts 10 and 15

[Docket No. USCG–2008–0028]

RIN 1625–AB26

Implementation of Vessel Security Officer Training and Certification Requirements—International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as Amended

AGENCY: Coast Guard, DHS.

ACTION: Interim rule with request for comments.

SUMMARY: The Coast Guard is amending its regulations to implement the vessel security officer training and certification amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended, and the Seafarers' Training, Certification and Watchkeeping Code. These amendments incorporate the training and qualification requirements for vessel security officers into the requirements for the credentialing of United States merchant mariners. The vessel security officer requirements would apply to all vessels subject to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended, under current regulations. This includes all seagoing vessels, as defined in 46 CFR 15.1101, to mean self-propelled vessels engaged in commercial service that operate beyond the Boundary Line established by 46 CFR Part 7, except those vessels which have been determined to be otherwise exempt from STCW as per 46 CFR 15.103(e) and (f).

DATES: This interim rule is effective June 19, 2008. Comments and related material must reach the Docket Management Facility on or before July 21, 2008. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before July 21, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0028 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

For public submission of comments on collection of information, the subject line should reference the docket number and say Attention: Desk Officer for U.S. Coast Guard, DHS. You must also send comments on collection of information to the Office of Information and Regulatory Affairs, Office of Management and Budget. To ensure that the comments are received on time, the preferred method is by e-mail at *oira_submission@omb.eop.gov* or fax at 202–395–6566. An alternate, though slower, method is by U.S. mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

FOR FURTHER INFORMATION CONTACT: If you have questions on this interim rule, contact Ms. Mayte Medina, Maritime Personnel Qualifications Division, Coast Guard, by telephone 202–372–1406 or by e-mail at *Mayte.Medina2@uscg.mil.* If you have questions on viewing or submitting material to the docket, contact Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to the docket located at *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0028), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you

include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. For example, we may ask you to resubmit your comment if we are not be able to read your original submission. 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 your comments and material 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 this rule in view of them.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on ''Search for Dockets,'' and enter the docket number for this rulemaking (USCG–2008–0028) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

C. Privacy Act

Anyone can 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 Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

D. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

II. Acronyms

DOT Department of Transportation
GRT Gross Registered Tons
GT Gross Tons
IMO International Maritime Organization
ISPS International Ship and Port Facility Security Code
MARAD Maritime Administration
MISLE Marine Information for Safety and Law Enforcement
NEPA National Environmental Policy Act
NPRM Notice of Proposed Rulemaking
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
QSS Quality Standards System
REC Regional Examination Center
SOLAS International Convention for the Safety of Life at Sea, 1974
STCW International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978
STCW Code Seafarer's Training, Certification and Watchkeeping Code
VSO Vessel Security Officer

III. Regulatory Information

The Coast Guard is issuing this interim final rule without prior notice and opportunity to comment pursuant to section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to these amendments because providing opportunity for public comment is unnecessary and would be contrary to the public interest.

The Coast Guard is implementing VSO training and certification requirements that the U.S. has agreed to as a party to the STCW. This will ensure consistency and harmonize U.S. and international standards for VSO training and certification while at the same time ensuring that the U.S. observes its international obligations. Because the STCW VSO training and certification standards are exhaustive and well-established, pre-publication notice and comment procedures are not necessary to further inform the rulemaking, which follows those requirements.

This interim rule also enhances national maritime safety and security by ensuring careful vetting by the Coast Guard of the qualifications of individuals wishing to serve as VSOs. A delay in implementing this rule would be contrary to the public interest in national maritime safety and security.

This interim rule will also permit mariners to continue working in the industry on U.S. seagoing vessels outside of U.S. territorial waters by bringing their training and certification into compliance with STCW requirements. This permits U.S. seagoing vessels to continue to travel to and operate in foreign waters and ports without being subject to possible detention for noncompliance with STCW requirements. The Coast Guard believes that permitting U.S. seagoing vessels to continue to operate internationally consistent with STCW VSO training and certification requirements, and without delay, is clearly within the public interest. For these reasons, it is unnecessary and would be contrary to the public interest to further delay implementation of these requirements.

This interim rule will have a 60-day comment period and the rule will be effective 30 days after publication in the **Federal Register**. Coast Guard will address comments received on this interim rule before and after the effective date as part of the final rule process. You may submit a request for a public meeting if you believe one would be beneficial. If you would like to request a public meeting, submit your request as described above in PUBLIC MEETING explaining why one would be beneficial. If we determine a public meeting is necessary, the time and place of the public meeting will be announced by a notice in the **Federal Register**.

IV. Background and Purpose

On July 1, 2007, the International Maritime Organization's (IMO) Maritime Safety Committee adopted the 2006 amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended (STCW) and the Seafarer's Training, Certification and Watchkeeping Code (STCW Code) related to training and certification requirements for a vessel security officer (VSO). These amendments support the security requirements in the International Ship and Port Facility Security Code (ISPS) and International Convention for the Safety of Life at Sea (SOLAS), 1974, Amendments, adopted December 2002.

The amendments to the STCW and STCW Code set certification and qualification requirements for VSOs. The STCW set forth qualification standards for Masters, officers and watch personnel on seagoing merchant ships. STCW entered into force in 1984 and the U.S. became a party to the Convention in 1991. As a party to the STCW, the U.S. is committed to implementing the adopted amendments.

The STCW amendments became effective January 1, 2008. Under the STCW amendments, those persons who became vessel security officers (VSOs) on or after January 1, 2008, needed to comply with the new requirements as of January 1, 2008. Those persons who already worked as VSOs prior to January 1, 2008, need to comply with those new requirements by July 1, 2009. This rulemaking is being carried out as expeditiously as possible to ensure that mariners are issued the appropriate international certificates, therefore avoiding vessel detentions for non-compliance with the STCW requirements at foreign ports. Furthermore, the implementation of the rule at this time is meant to ensure there is time for training courses to be developed that comply with the proposed interim regulation and provide all new and existing VSOs with the opportunity to take the course and apply for a VSO endorsement prior to July 1, 2009.

The STCW and STCW Code amendments include: 1. Certification by the Coast Guard of VSOs; 2. completion of sea service requirements; 3. VSO training in accordance with the STCW Code's standard of competence; 4. approval of training courses by the Coast Guard; and 5. continuous monitoring by the Coast Guard through a quality standards system (QSS) of the training courses it accepts. The amendments also contain transitional provisions for persons already serving as VSOs that will expire on July 1, 2009. The STCW and STCW Code amendments were based on the IMO model course for Ship Security Officer.

Currently, 33 CFR 104.215 requires VSOs to have maritime security knowledge which can be obtained through training or equivalent job experience, as self-certified by the owner/operator of the vessel employing the individual. The existing regulations do not require certification by the Coast Guard.

This interim rule amends the current regulations to adopt the STCW and STCW Code amendments related to VSO training and qualifications. To address the primary STCW and STCW Code amendments, the Coast Guard is amending 46 CFR Part 10 to require owner/operators to employ a certified VSO on board each vessel subject to the STCW under current regulations. This includes all seagoing vessels, as defined in 46 CFR 15.1101, to mean self-propelled vessels engaged in commercial service that operate beyond the Boundary Line established by 46 CFR Part 7, except those vessels which have been determined to be otherwise exempt from STCW as per 46 CFR 15.103(e) and (f).

The Coast Guard will also add VSO training requirements in 33 CFR 104.215 to align the regulations with competence-based training requirements in STCW. The regulations currently require VSOs to have maritime security knowledge in a number of areas contained in 33 CFR 104.210 and in 33 CFR 104.215. The Coast Guard has determined that the VSO training requirements should be contained in one place and that the training requirements should be fully aligned with STCW.

The Coast Guard will also add VSO sea service requirements in 33 CFR 104.215 to align the regulations with the STCW requirements. The existing regulations do not include sea service requirements. The Coast Guard will now require sea service of 12 months or, with knowledge of vessel operations, six months. The Coast Guard determined that these two options were necessary to account for traditional mariners and for other personnel, such as security experts, who already possess knowledge and experience of vessel operations.

V. Discussion of the Interim Rule

Section 104.215 of title 33 of the Code of Federal Regulations currently requires VSOs to have maritime security knowledge. This knowledge can be obtained through training or equivalent job experience, as self-certified by the owner/operator of the vessel employing the individual. The existing regulations do not require certification.

33 CFR 104.215

In 33 CFR 104.215, the regulation will require Coast Guard certification in the form of a VSO endorsement for persons performing duties as VSOs on board vessels subject to the STCW under current regulations. This includes all seagoing vessels, as defined in 46 CFR 15.1101, to mean self-propelled vessels engaged in commercial service that operate beyond the Boundary Line established by 46 CFR part 7, except those vessels which have been determined to be otherwise exempt from STCW as per 46 CFR 15.103(e) and (f).

Section 104.215 will also require that VSOs meet entry requirements such as: 1. Be at least 18 years old; 2. be able to speak and understand the English language sufficiently as related to VSO duties; 3. hold valid credentials; 4. complete VSO training; and 5. have approved sea service. The training requirements will include competence-based mandatory training in order to qualify for a VSO endorsement. VSOs will be required to be trained to meet six competencies that fully align with the STCW Code, Table A–VI/5, Specifications of minimum standards of proficiency for ship security officers, which may be found in the docket [USCG–2008–0028].

The sea service requirements in § 104.215 will provide two options: 1. 12 months; or 2. 6 months with knowledge of ship operations. In addition to providing evidence of sea service, mariners seeking to qualify for an endorsement using the six-month option will also be required to furnish evidence of knowledge of basic ship operations. A list of ship operations areas is included in this rulemaking at 33 CFR 104.215(d)(3). The list was derived using input from merchant mariners and from maritime instructors.

The STCW requires that all training be approved by the Coast Guard and that the training be continuously monitored through a quality-standard system to ensure achievement of defined objectives. To fulfill this requirement, VSO training courses will be approved and monitored by a Coast Guard-accepted Quality Standards System (QSS) organization acting on behalf of the Coast Guard. The Coast Guard will not directly approve any VSO courses. Any fees charged by the Coast Guard-accepted QSS organizations will be the responsibility of the VSO course provider. As of the publication date of this interim rule, there are three Coast-Guard accepted QSS organizations that may approve and monitor training on behalf of the Coast Guard. The list of these organizations can be found on the following Internet Web site: *http://www.uscg.mil/STCW/mmic-appcourses.htm.*

It is expected that courses accepted for VSO endorsement by the Coast Guard will be based on the IMO model course for ship security officer, or the MARAD VSO model course. Vessel Security Officer courses must also ensure that persons completing the course can successfully demonstrate proficiency in the basic competencies in 33 CFR 104.215(d)(2). Information on MARAD VSO full and refresher courses can be found on the following Internet Web site: *http://www.marad.dot.gov/MTSA/MARAD%20Web%20Site%20for%20MTSA%20Course.html.* The Coast Guard will also accept courses approved by MARAD on behalf of the Coast Guard under section 109 of the Maritime Transportation Security Act of 2002, Public Law 107–295 as meeting the requirements of STCW for purposes of fulfilling the regulatory requirements in 33 CFR 104.215(d)(1)(iv) and (d)(2), as

referenced in 33 CFR 104.215(d)(6). Information on these approved courses can be found on the following Internet Web site: *http://www.marad.dot.gov/MTSA/MARAD%20Web%20Site%20for%20MTSA%20Course.html.*

The Coast Guard will also accept a QSS-approved refresher course for persons who can document six months of experience as a VSO, or have successfully completed a course on vessel security that was not approved by MARAD prior to the effective date of this interim rule.

46 CFR 10.811

Section 10.811 will require proof of compliance with the entry requirements in 33 CFR 104.215 for mariners seeking a VSO endorsement. It will also require the individual to meet the physical examination requirements in 46 CFR 10.205(d)(1)–(2).

46 CFR 15.1113

We are adding 46 CFR 15.1113 which will require that VSOs serving on board vessels subject to the STCW hold an endorsement as VSO. This includes all seagoing vessels, as defined in 46 CFR 15.1101 to mean self-propelled vessels engaged in commercial service that operate beyond the Boundary Line established by 46 CFR Part 7, except those vessels which have been determined to be otherwise exempt from STCW as per 46 CFR 15.103(e) and (f).

VI. Regulatory Evaluation

We developed this interim rule after considering numerous statutes and executive orders related to rulemaking. Below, we summarize our analysis based on 13 of these statutes or executive orders.

A. Regulatory Analysis

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. It has not been reviewed by the Office of Management and Budget (OMB) under that Order.

A combined Regulatory Analysis and an Initial Regulatory Flexibility Analysis is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. A summary of the analysis follows:

The interim rule would require vessel security officers (VSOs) serving on U.S.-flag vessels subject to the International Convention on Standards of Training, Certification, and Watchkeeping for Seafarers, 1978 as amended (STCW) to complete training requirements consistent with STCW amendments on VSO training and qualifications. This would require existing VSOs and persons that intend to serve as VSOs to hold a Coast Guard-issued credential with a VSO endorsement. The affected vessels would be U.S.-flag self-propelled vessels engaged in commercial service that operate beyond the boundary line as specified in 46 CFR part 15.1101.

The Coast Guard does not plan to directly approve any VSO courses. Instead, VSO training must be Coast Guard-accepted. This means that the courses must be approved and monitored by a Coast Guard-accepted Quality Standards System (QSS) organization acting on behalf of the Coast Guard. Any fees charged by the Coast Guard-accepted QSS organizations will be the responsibility of the course provider.

In addition, persons that have already completed a Maritime Administration (MARAD)-approved VSO course before the effective date of this rule would be considered in compliance with the training requirement and would only need to successfully meet the qualification requirements. Persons that have completed a non-MARAD training course before the effective date of this rule can meet the training requirement by completing a Coast-Guard accepted VSO refresher course. They would be able to serve as a VSO upon completion of the training and they would have until July 1, 2009, to complete the refresher course. After that time, they will be required to take a full VSO training course.

There are four cost elements associated with this interim rule (1) A VSO refresher course cost, (2) a full VSO course cost, (3) a training provider cost from a Coast Guard-approved QSS, and (4) a VSO endorsement and travel cost to a regional examination center (REC). We estimate that approximately 716 VSOs would need refresher course training and approximately 237 would need to enroll in a full training course. During the first full year the rule is in effect, or 2009, about 1,769 VSOs will incur a cost associated with an REC, and annually, about 190 VSOs will incur the REC cost (we chose 2009 as the first year of the analysis period since most VSOs would complete the required training during that year). The total population of VSOs potentially affected by this interim rule is approximately 1,974, depending upon the training requirement. Under the current rule, VSO training is optional. The number of training providers affected is dependent upon when the training provider courses expired and the renewal date. We estimate the interim rule to affect about 879 U.S.-flag seagoing vessels engaged in commercial service that operate beyond the boundary line as specified in 46 CFR part 15.1101.

We present the costs of this interim rule in 2007 dollars and discount these costs to their present value (PV) over a 10-year period of analysis, 2009–2018, using both seven and three percent discount rates. We estimate the annuitized costs of this interim rule over the 10-year period of analysis to be about $1.5 million at both seven and three percent discount rates. We estimate the total 10-year (2009–2018) present discounted value or cost of this interim rule to industry to be between $10.5 and $12.3 million at both seven and three percent discount rates, respectively. Table 1 below summarizes the costs of the interim rule.

TABLE 1.—SUMMARY OF TOTAL DISCOUNTED COSTS OF INTERIM RULE

[2009–2018, 7 and 3 percent discount rates, 2007 dollars ($millions)]

Cost item	Discount rates	
	7 percent	3 percent
Coast Guard-approved QSS VSO Training Provider Cost	$0.25	$0.32
VSO Refresher Course	1.9	2.0
VSO Full Course	6.6	8.0
VSO Travel Cost to REC	1.9	2.1
Total Interim Rule Cost	10.5	12.3

Totals may not sum due to independent rounding.

From our Marine Information for Safety and Law Enforcement (MISLE) database, we estimate the interim rule to affect about 879 U.S.-flag vessels. Based on guidance from industry representatives, we were able to obtain the number of crews per vessel class assuming one VSO per crew. Based on our discussions with industry representatives, we found that, on average, there are two vessel crews per vessel in a specific vessel class (freight ships have three crews per vessel). See Table 2 below.

The column labeled ''VSOs in Compliance'' presents the number of VSOs that have completed the MARAD (Maritime Administration)-approved training and would be in compliance with this interim rule. The last column of Table 2 labeled ''Requiring Refresher Training'' shows the number of VSOs in each vessel class that would require refresher training. We assume these persons that would like to serve as VSOs qualify for the refresher course training, either because they have recently served at least six months as a VSO or because they have completed non-MARAD-approved VSO training. Table 2 below summarizes the number of vessels affected per class of vessels, the number of VSOs affected per class of vessel, and the number of VSOs that would need the required training.

TABLE 2.—VSOs AFFECTED BY MARITIME SECURITY TRAINING REQUIREMENT SERVING ON U.S.-FLAGGED SOLAS VESSELS

Vessel service class	U.S.-flagged SOLAS vessels	Crews per vessel	VSOs	VSOs	
				VSOs in compliance	Requiring refresher training
Freight Ship	216	3	648	518	130
Offshore Supply Vessel	197	2	394	197	197
Towing Vessel	179	2	358	179	179
Passenger (Inspected)	132	2	264	53	211
Tank Ship	73	2	146	117	29
Other	82	2	164	98	66
Total	879		1,974	1,162	812

Source: Based on MISLE and industry data.

We assume that VSOs would incur different travel and lodging costs depending upon whether a VSO commuted daily to the training site, drove to the training site city and took lodging during the training period, or flew to the training site city and took lodging.

We used a loaded hourly wage rate of $61 for all VSOs. A loaded labor rate is what a company pays per hour to employ the person, not what the person makes in hourly wages. The loaded labor rate includes the cost of benefits (health insurance, vacation, etc.). We also used this hourly wage when we estimated the opportunity cost of a VSO's time when a VSO engages in duties or activities in order to comply with the requirements of this interim rule. Furthermore, the Coast Guard has found that VSOs perform maritime security training on their employer's time. Therefore, we made the conservative assumption that VSOs' compliance activities related to obtaining the required training would be performed on their employers' time. As a result, we applied the $61 loaded hourly wage to these activities rather than the unloaded hourly wage rate of $44.

Our estimation of costs that VSOs would incur as a result of this interim rule must take into account costs associated with travel to the training site and is dependent upon the distance VSOs live from available training sites. We estimated this distance using the regulatory analysis that supports the Coast Guard's interim rule ''Validation of Merchant Mariners'' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry'', published on January 13, 2006 (71 FR 2159). In that analysis, the portion of mariners that reside within 50 miles and 100 miles of their RECs was determined. Given the location of the training sites from the various RECs, and assuming that the distribution of VSOs from their RECs is directly proportional to the distribution of mariners from their RECs, we estimated the portion of VSOs who reside within 50 miles and 100 miles of the training sites. There are 17 RECs located throughout the country and 22 training sites or schools. There are only seven RECs that have training schools within their geographic vicinity. If we draw 50 and 100-mile radius circles around the 17 REC cities and the 22 training provider sites, we would find that these circles do not neatly overlap one another. However, for the seven RECs that have a training site within their geographic area, some mariners who reside 100 miles from the REC reside within 50 miles of the training site. We based our calculations for all VSOs on these seven RECs in order to determine the share or percentage of VSOs that call a particular REC their REC and that would need to travel to an associated training facility for the required training. Schools are close enough in proximity to these seven RECs in order for us to estimate the share of VSOs that would need to commute, drive and lodge, or fly and lodge.

Based on mariner address information from the Coast Guard's National Maritime Center (NMC) and the regulatory analysis that supports the Coast Guard's interim rule ''Validation of Merchant Mariners'' Vital Information and Issuance of Coast Guard Merchant Mariner's Licenses and Certificates of Registry'', published on January 13, 2006 (71 FR 2159), we used the percentages presented in the regulatory analysis for that rule as listed in Table 3 below.

TABLE 3.—VSO TRAVEL SHARE BASED ON 50 AND 100-MILE RADIUS CIRCLES AROUND RECS

	Travel mode			
	Commute	Drive/lodge	Fly/lodge	Total
Share	60.0%	30.0%	10.0%	100.0%

In order for us to obtain the share or percentage of VSOs requiring training that would commute, drive/lodge, and fly/lodge around the country for training, we utilized the law of cosines to determine how much of an REC's 50-mile radius circle and 100-mile radius circle overlaps a school's 50-mile radius circle or 100-mile radius circle. We performed this exercise and calculations for all of the seven RECs that have schools in their geographic vicinity. The relevant REC cities are Baltimore, MD; Miami, FL; New York, NY; Oakland, CA; Seattle, WA; New Orleans, LA; and Portland, OR.

Based on our calculations, we arrived at the share or percentage of VSOs that would attend the required training schools by travel modes listed in Table 4 below.

TABLE 4.—TOTAL NATIONAL SHARE OR PERCENTAGE OF VSOS THAT WILL COMMUTE, DRIVE/LODGE, AND FLY/LODGE

REC cities	Commute share (%)	Drive/lodge share (%)	Fly/lodge share (%)*
Baltimore	4.9	1.95	0.8
Miami	7.7	2.9	1.2
New York	4.4	1.8	0.7
Oakland	1.0	2.0	1.1
New Orleans	2.5	5.0	2.7
Portland	2.3	1.2	0.4
Seattle	3.7	1.8	0.6
Total	26.5	16.7	7.5 + 49.3 = 56.8

Note: The remaining 10 REC cities have no schools associated with them; therefore, we added together the share or percentage of VSOs that call those cities their respective REC for a total of 49.3 percent. VSOs that attend schools in these cities would fly and lodge; therefore, we added these percentages to the fly/lodge category. From our calculations of the seven REC cities, we found the percentage of VSOs that would fly/lodge to be about 7.5 percent. Therefore, the total share or percentage of VSOs that will fly/lodge is about 56.8 percent (0.493 + 0.075).

Totals may not sum due to independent rounding.

From Table 1, there are 1,974 VSOs that serve on U.S.-flag SOLAS vessels under STCW. To obtain the number of VSOs that will need refresher training, we must subtract from the total number of VSOs (1,974) those VSOs that have completed MARAD-approved training (1,162) to obtain 812 VSOs that will need refresher training (1,974 − 1,162 = 812 VSOs). We also introduce an annual industry turnover rate of 0.12 or 12 percent. This turnover rate measures the annual flow of personnel leaving and entering the water transportation industry, rather than the flow of personnel leaving or entering the average firm in this industry. We assume that existing VSOs also leave at this rate and that all persons replacing these VSOs would be required to enroll in the full course training. We now multiply the number of VSOs requiring refresher course training from Table 1 (812) by 0.88 (the complement of the turnover rate, which is the retention rate) to obtain 716 or the number of VSOs that would need refresher course training. Cost for a refresher course is an initial-year cost only.

To obtain the number of VSOs that would need to enroll in a full course, we multiplied the total number of VSOs (1,974) by the turnover rate (0.12) to obtain about 237 VSOs who would need to enroll in a full course annually. Full course training is an annual recurring cost.

To obtain the number of VSOs by mode of travel, we simply multiplied the final percentages in Table 4 by the number of VSOs that require refresher course and full course training, respectively. For example, we calculated the total percentage of VSOs that would commute to be about 0.265 or 26.5 percent. The number of VSOs that would need full course training is about 237, so we multiplied 0.265 by 237 to obtain 63. Restated, the number of VSOs that will need full course training and will commute to the training school is about 63. See Table 5 below for the remaining population figures.

TABLE 5.—SUMMARY OF NUMBER OF VSOS BY TRAVEL MODE AND BY TRAINING TYPE

Training type	VSOs by travel mode			
	Commuting	Drive/lodge	Fly/lodge	Total
Full Course Training	63	39	135	237
Refresher Training	190	120	407	716

Totals may not sum due to independent rounding.

Readers should refer to the regulatory analysis in the docket for a summary of all of the individual VSO costs associated with the full training course.

Next, we multiplied the total costs per VSO by the population figures for full

course training in Table 5 to obtain a total initial and annual cost (non-discounted) for VSOs who take the full training course of $934,476. We performed the same analysis for the refresher course and obtained a total initial-year cost (non-discounted) of about $2,008,822 for VSOs that need refresher course training. Again, readers should refer to the regulatory analysis in the docket for all of the individual VSO costs associated with the refresher course.

We estimate the total present discounted value or cost for the training requirements of the interim rule to be between $8.4 and $9.9 million at both seven and three percent discount rates, respectively. The training requirement is the most costly element of the interim rule.

The third cost element of this interim rule is the cost that a VSO will incur to obtain an endorsement on their Merchant Mariner Credential from an REC. A merchant mariner document expires every five years, so we assume that one-fifth (0.20 or 20 percent) of the VSOs every year would currently be required to make a trip to the REC to renew this document. Of the 1,974 VSOs in our population, 80 percent (1.00–0.20) of these VSOs in the initial year would be required to make an additional trip to an REC to get an endorsement, or about 1,579.

During the initial year and annually, only VSOs that take the full course will be affected by this element of the interim rule. We estimate about 190 VSOs will be required to make an additional trip to an REC (237×0.80) each year to get an endorsement.

Some VSOs would have to travel to an REC anyway once every five years to renew their merchant mariner document. We estimate that 395 VSOs out of the total number of VSOs would have had to travel to an REC anyway without the rule in place ($1,974 \times 0.20$). From the number of VSOs that need to take the full course, we estimate that about 47 also would have had to travel to an REC anyway without the rule in place (237×0.20) in order to renew their merchant mariner document. Table 6 summarizes these figures below.

TABLE 6.—DISTRIBUTION OF VSO TRAVEL TO AN REC FOR ENDORSEMENT

Time	Required to make an additional trip to an REC	Not required to make an additional trip to an REC	Total
Initial Year	1,579	395	1,974
Initial and Annual Year	190	47	237

Individual VSOs that need to obtain an endorsement from an REC would also incur travel costs similar to those presented for the training requirements (readers should refer to the regulatory analysis in the docket for all of the individual VSO costs associated with the endorsement requirement). We estimate VSOs would incur an initial-year cost of about $1.2 million (non-discounted) and an annual cost of about $0.13 million (non-discounted). We estimate the total presented discounted value or cost to be about $2.0 million at both seven and three percent discount rates over the period of analysis.

Lastly, the final cost element associated with this interim rule is the cost that training providers will incur for security training course evaluation and oversight. Since the Coast Guard does not approve VSO training courses, the onus is on the training provider to pay a Coast Guard-approved Quality Standards System (QSS) organization to evaluate its VSO course for approval. Approval from a QSS organization would constitute Coast Guard acceptance of the course. Currently, MARAD pays one of the Coast Guard-approved organizations to approve courses on behalf of MARAD and the Coast Guard. Under this interim rule, the cost burden for course approval and oversight shifts to the training provider. There are 22 training providers throughout the U.S. The cost per course evaluation is about $7,500 and is valid for five years. We estimate the total present discounted value or cost of the interim rule to training providers to be about $0.30 million at both discount rates over the period of analysis.

Readers should refer to the regulatory analysis in the docket for a detailed analysis of the costs associated with this interim rule.

The interim rule has several qualitative benefits associated with it. The current training regime requires the designation of a VSO, but it does not require formal training, instead it allows owners/operators to self-certify their VSOs as having the security training. Under this regime, the expertise and knowledge varies from person to person and from vessel to vessel. This regime has proven to be less effective since there in no consistency in the attainment of the knowledge throughout the industry.

Development of mandatory training requirements is necessary to ensure consistency of training in support of the domestic and international security regime. Seafarers constantly transfer from vessel to vessel; therefore, mandatory training would ensure consistency no matter where they serve. A course approval process in support of the mandatory requirements would lead to a higher quality of security training.

The STCW requires that the Coast Guard issue a certificate of proficiency to the mariner. An endorsement to the STCW certificate would serve as proof that a VSO has met the certificate of proficiency requirement and would eliminate the issuance of a separate Coast Guard-issued document.

Issuance of endorsements is also beneficial for U.S. vessels trading worldwide, since they would not be subject to detentions for non-compliance with the STCW. These new requirements would provide a systematic and verifiable program of certification and oversight, providing effectiveness, sufficient rigor, and consistency to maritime security education and training. The absence of a systematic and verifiable program of external certification and oversight, insufficient rigor, and a lack of consistency may render maritime security education and training less effective than it should be.

B. 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. This interim rule does not require a general notice of proposed rulemaking and, therefore, is exempt from the

requirements of the Regulatory Flexibility Act. Although this interim rule is exempt, we have reviewed it for potential economic impact on small entities.

From the Coast Guard's MISLE database, there are 879 vessels, owned by 157 entities, impacted by the interim rule. For the purpose of this initial analysis, we estimate average impacts per owner. Discussions with industry revealed that there are approximately 245 VSOs leaving the industry each year, requiring the average vessel owner to hire (245 VSOs/879 vessels) 0.3 new VSOs per vessel each year. In addition, an average of about one (716 VSOs/879 vessels) partially trained VSO per vessel would be required to take a refresher course.

Using data from the two business databases, we researched all 157 companies and found annual sales and employment information for 56 of them. We identified 43 of these 56 entities as small businesses (about 77 percent) using the SBA's criteria and assumed the 101 companies with no revenue data were also small for a total of 144 of 157 of the entities (92 percent).

To estimate the impact on small entities, we multiplied the cost for full and refresher VSO courses by the average number of VSOs per vessel attending training each year. Vessel owners would incur a first-year cost for the refresher course and an annually recurring cost for the full course. We estimate the full course cost per vessel to be about $1,331 ($4,435 × 0.3 VSOs per vessel) and the refresher course cost per vessel to be about $3,326 ($3,326 × 1.0 VSOs per vessel). Table 7 summarizes the costs for a full VSO course and the shorter refresher course.

TABLE 7.—PER VESSEL COST FOR VSO TRAINING (NON-DISCOUNTED)

Course	Total course cost ***	VSOs per vessel	Total
VSO Full Course *	$4,435	0.3	$1,331
VSO Refresher **	3,326	1.0	3,326

* The full course cost is an annually recurring cost based on the industry VSO turnover rate.
** The VSO refresher cost is a first-year cost for partially-trained VSOs.
*** To be conservative, we used the higher cost estimates for mariners that fly in order to reflect the maximum potential economic impact on a given small business. The cost includes tuition, opportunity costs, transportation costs, etc.

We estimate the revenue impact as the total cost per vessel multiplied by the number of vessels each affected entity owns. In the first year, vessel owners would incur the cost for the refresher course and the full course. Using publicly available and proprietary data on owner revenue, we estimate the impact to small entities as a percentage of revenue. The first year cost of the interim rule would have less than a 3 percent impact on 72 percent of the small entities. Table 8 presents the number of small entities in the sample and the estimated range of the initial year impact on revenue as a result of the interim rule requirements. The percentage of small entities in each impact range in the sample is then projected to the total estimate of small entities.

TABLE 8.—INITIAL YEAR IMPACT TO SMALL ENTITIES (NON-DISCOUNTED)

Percent impact on annual revenue	Number of small entities with known revenue data	Percent of small entities with known revenue data (percent)	Total small entities
0% to 1%	31	72	104
>1% to 3%	0	0	0
>3% to 5%	5	12	17
>5% to 10%	5	12	17
Above 10%	2	5	7
Total	43	100	144

Totals may not sum due to independent rounding.

After the initial year of the rulemaking, the annual impact on small businesses is lower because vessel owner and operators would no longer incur the cost of the refresher course for VSOs. We found that annual costs would have less than a 3 percent impact on 79 percent of small entities. Table 9 below presents the estimated annual impact on small entities.

TABLE 9.—ANNUAL IMPACT TO SMALL ENTITIES (NON-DISCOUNTED)

Percent impact on annual revenue	Number of small entities with known revenue data	Percent of small entities with known revenue data (percent)	Total small entities
0% to 1%	31	72	104
>1% to 3%	3	7	10
>3% to 5%	3	7	10
>5% to 10%	5	12	17

TABLE 9.—ANNUAL IMPACT TO SMALL ENTITIES (NON-DISCOUNTED)—Continued

Percent impact on annual revenue	Number of small entities with known revenue data	Percent of small entities with known revenue data (percent)	Total small entities
Above 10%	1	2	3
Total	43	100	144

Totals may not sum due to independent rounding.

To the extent that new courses open after publication of the interim rule, there would be a reduction in the travel costs associated with the preliminary cost estimates in the RA. However, the revenue impacts provide a conservative estimate of the impact to small entities.

Training providers would incur a cost for security training course evaluation and oversight. The NAICS codes for training providers were varied with 541618—Other Management Consulting Services—being the only code to appear more than once. The SBA annual revenue threshold for this NAICS code is $6,500,000.

Most training providers do not offer all types or progressions of training discussed in this interim rule. Based on Coast Guard data, we identified 22 maritime training providers that offer some type of Coast Guard-approved training and could be affected by this rulemaking. Of the 22 training providers that offer training impacted by the interim rule, we were able to collect revenue data for 12. Of the 12 with revenue data, 10 are small entities as defined by the SBA and we assume the remaining 10 to be small, for a total of 20 of the 22 entities being classified as small. Of the small entities with revenue data, we found five (50 percent) would incur an impact of less than 1 percent of annual revenues in the year a course was registered and the remaining five (50 percent) would incur a cost of less than 3 percent of annual revenues.

We anticipate that new or existing training providers that do not currently offer the training described in this rulemaking would only begin to offer the training described if they expect it to be net-beneficial. To the extent that training providers are able to pass the cost to mariners, the impact would be less than estimated above.

Lastly, the onus of obtaining an endorsement from an REC is on an individual VSO. The interim rule does not require a VSO's employer to pay for this endorsement. We note that for the purposes of the Regulatory Flexibility Act an individual is not considered to be a small entity. However, previously in this small entity impact analysis, we have shown the cost to the employer if the employer voluntarily chooses to incur or reimburse the employee for costs related to receiving the VSO endorsement. We are interested in the potential direct impacts of this interim rule on small businesses and we request public comment on these potential direct impacts. If you think that this interim rule would have a significant economic impact on you, your business, or your organization, please submit a comment to the Docket [USCG–2008–0028]. In your comment, explain why, how, and to what degree you think this rule would have an economic impact on you.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this interim rule so that they can better evaluate its effects on them and participate in the rulemaking. If the interim rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call the contact provided in For Further Information Contact above. The Coast Guard will not retaliate against small entities that question or complain about this interim rule or any policy or action of the Coast Guard.

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).

D. Collection of Information

This interim rule calls for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Vessel Security Officers must meet minimum training requirements and receive an endorsement from a regional examination center (REC). Vessel Security Officers would be required to complete form CG–719B and deliver the form to an REC for endorsement. This collection is in addition to the current collection of information estimate for VRPs and FRPs [Office of Management and Budget (OMB) 1625–0040].

Title: Continuous Discharge Book, Application, Physical Exam Report, Sea Service Report, Chemical Testing, Entry Level Physical.

OMB Control Number: 1625–0040.

Summary of the Collection of Information: Vessel Security Officers would be required to obtain an endorsement on their merchant mariner document from an REC to prove a minimum level of training has been completed. Mariners currently complete form CG–719B every 5 years, but the interim rule would require many VSOs to obtain an endorsement prior to the expiration of their existing document.

Need for Information: The information is necessary to show evidence that VSOs have completed the necessary training requirements to assess risk, threats, and vulnerabilities of a vessel.

Use of Information: The Coast Guard would use this information to document that the VSO training level meets international requirements.

Description of the Respondents: The respondents are the VSOs that would be required to complete form CG–719B.

Number of Respondents: From Table 11, the number of respondents is 1,579

in the first year plus an additional 190 recurring annually, including the first year for a 3-year total of 2,149 [1,579 + (3 × 190)].

Frequency of Response: Respondents are required to complete form CG–719B every 5 years. The interim rule would require 1,579 new applications in the first year and an additional 190 new applications recurring annually.

Burden of Response: Completing the information on CG–719B would take a VSO approximately 10 minutes. In the first year, 20 percent of VSOs are assumed to be completing the form due to the expiration of their merchant mariner document, but the remaining 80 percent detailed in the Number of Respondents section would incur the 10-minute burden.

Estimate of Total Annual Burden: The existing OMB-approved total annual burden, as adjusted in July 2006, is 329,356 hours. This interim rule would increase the burden for 2,149 VSOs over a 3-year approval period by approximately 10 minutes. The total additional hours requested for this rulemaking is 358 [2,149 × (10 minutes/60 minutes)] and the average annual increase over the 3-year period is about 119 (358/3). The new annual burden as a result of this rulemaking is 329,475 hours.

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted a copy of this interim rule to OMB for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining burden are; how we can improve the quality, usefulness, and clarity of the information; and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket where indicated under **ADDRESSES**, by the date under **DATES** in the interim rule.

You need not respond to a collection of information unless we have published a currently valid control number from OMB for that collection in the **Federal Register**. Before the requirements for this collection of information become effective, we will publish notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the collection. If OMB approves the collection, our publication of that control number in the **Federal Register** or the CFR will constitute display of that number; see 5 CFR 1320.3(f)(3), as required under 44 U.S.C. 3506(c)(1)(B).

E. 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.

It is well settled that States may not regulate in categories reserved for regulation by the Coast Guard. It is also well settled, now, that all of the categories covered in 46 U.S.C. 3306, 3703, 7101, and 8101 (design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels), as well as the reporting of casualties and any other category in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, are within the field foreclosed from regulation by the States. (See the decision of the Supreme Court in the consolidated cases of *United States* v. *Locke and Intertanko* v. *Locke*, 529 U.S. 89, 120 S.Ct. 1135 (March 6, 2000).) Because the States may not regulate within this category, preemption under Executive Order 13132 is not an issue.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

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

H. 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.

I. Protection of Children

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

J. 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.

K. 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.

L. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this rule under Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969

(NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List'' supporting this determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. We seek any comments or information that may lead to discovery of a significant environmental impact from this proposed rule.

List of Subjects

33 CFR Part 104

Maritime security, Reporting and recordkeeping requirements, Security measures, Vessels.

46 CFR Part 10

Reporting and recordkeeping requirements, Schools, Seamen.

46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 104, and 46 CFR parts 10 and 15 as follows:

TITLE 33 CFR—NAVIGATION AND NAVIGABLE WATERS

PART 104—MARITIME SECURITY: VESSELS

■ 1. The authority citation for part 104 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–11, 6.14, 6.16, and 6.19; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 104.215 by re-designating paragraph (c) as paragraph (e) and adding new paragraphs (c) and (d).

§ 104.215 Vessel Security Officer (VSO).

* * * * *

(c) *Certification required.* After July 1, 2009, persons performing duties as VSO on-board a seagoing vessel subject to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended, must hold a valid Coast Guard-issued credential with a Vessel Security Officer endorsement. The Coast Guard will issue this endorsement only if the person meets the requirements in paragraph (d) of this section. This endorsement serves as proof that the person meets the ship security officer requirements of Regulation VI/5 of the STCW.

(d) *Requirements for Coast Guard Endorsement:* (1) To qualify for a VSO endorsement, a person must:

(i) Be at least 18 years of age;

(ii) Be able to speak and understand the English language as would be relevant to the duties of a VSO;

(iii) Hold any valid Coast Guard-issued credential under the regulations specified in 46 CFR Subchapter B;

(iv) Successfully complete a Coast Guard-accepted VSO course;

(v) Sea Service. Fulfill one of the following:

(A) Have approved sea service of not less than 12 months on any vessel subject to § 104.105 of this part, credited in accordance with 46 CFR 10.205(e), 10.211, and/or 10.213; or

(B) Have approved sea service of not less than 90 days on any vessel subject to § 104.105 of this part, credited in accordance with 46 CFR 10.205(b), 10.211, and/or 10.213, and have knowledge of vessel operations.

(2) To qualify as a Coast Guard-accepted course a VSO course under paragraph (d)(1)(iv) of this section must require candidates to demonstrate knowledge, understanding, and proficiency in the following competencies:

(i) Maintaining and supervising the implementation of a vessel security plan;

(ii) Assessing security risk, threat and vulnerability;

(iii) Undertaking regular inspections of the vessel to ensure that appropriate security measures are implemented and maintained;

(iv) Ensuring that security equipment and systems, if any, are properly operated, tested and calibrated;

(v) Encouraging security awareness and vigilance; and

(vi) Ensuring compliance with the TWIC program requirements.

(3) Candidates meeting the knowledge of vessel operations requirement under paragraph (d)(1)(v)(B) of this section must provide evidence through training or equivalent job experience, in the following areas:

(i) Basic vessel layout and construction:

(A) Understanding layout, including decks, rooms and space numbering; and

(B) Understanding of various vessel types; and working knowledge of nautical terms and definitions, especially those used to describe areas and parts of a vessel.

(ii) Shipboard organization: familiarity with the various departments and related functions, the titles used for personnel, the roles and responsibilities of these persons, and the chain of command.

(iii) Shipboard safety:

(A) Understanding of the importance of creating and maintaining safe working and living conditions for passengers and crew alike;

(B) General shipboard safety rules, emergency alarms and signals, and responses to and reporting of accidents;

(C) Proper usage of protective equipment and general knowledge of procedures for entering enclosed spaces;

(D) Proper usage of lifesaving equipment and where such equipment is normally stowed aboard various vessel types;

(E) Understanding of the operating principles of and proper use of watertight and fire screen doors; and

(F) Understanding where it is safe to smoke and not safe to smoke on board and in port.

(iv) Protection of the marine environment:

(A) Understanding of vessel personnel's responsibility to preserve the marine environment; and

(B) Basic working knowledge of pollution prevention regulations and techniques.

(v) Familiarity with key definitions, terminology, and operational practices employed in the maritime industry.

(4)(i) Persons meeting the criteria in paragraphs (d)(4)(i)(A) and (B) of this section prior to the effective date of this regulation may successfully complete a refresher Coast Guard-accepted VSO course no later than July 1, 2009, to fulfill (d)(1)(iv) of this section. Persons must have:

(A) At least six months of VSO experience during the preceding three years; or

(B) Successfully completed a VSO course that was not approved by the Maritime Administration (MARAD) on behalf of the Coast Guard. Maritime Administration approves VSO courses under section 109 of the Maritime Transportation Security Act of 2002, Public Law 107–295.

(ii) To be eligible to take a refresher Coast Guard-accepted VSO course, a person must present to the course provider documentary evidence that he or she meets the criteria in (d)(4)(i) of this section.

(5) Vessel Security Officer courses meeting the training requirements in paragraphs (d)(2) and (d)(4) of this section are subject to Coast Guard acceptance under 46 CFR 10.309(a)(10)(ii).

(6) Vessel Security Officer courses approved by MARAD on behalf of the Coast Guard under section 109 of the Maritime Transportation Security Act of 2002, Public Law 107–295 will be accepted by the Coast Guard under 46 CFR 10.309 as meeting the requirements of paragraphs (d)(1)(iv) and (d)(2) of this section.

(7) Persons who hold a valid ''Vessel Security Officer'' endorsement may serve as vessel or company personnel with security duties (33 CFR 104.220), and as all other vessel personnel (33 CFR 104.225), without meeting any additional requirements.

TITLE 46 CFR—SHIPPING

PART 10—LICENSING OF MARITIME PERSONNEL

■ 3. The authority citation for part 10 continues to read as follows:

Authority: 14 U.S.C. 633; 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, and 2110; 46 U.S.C. chapter 71; 46 U.S.C. 7502, 7505, 7701, and 8906; Executive Order 10173; Department of Homeland Security Delegation No. 0170.1. Section 10.107 is also issued under the authority of 44 U.S.C. 3507.

■ 4. In § 10.104, add the definition of Vessel Security Officer in alphabetical order to read as follows:

§ 10.104 Definitions of terms used in this part.

* * * * *

Vessel Security Officer (VSO) means a person onboard the vessel accountable to the Master, designated by the Company as responsible for security of the vessel, including implementation and maintenance of the Vessel Security Plan, and for liaison with the Facility Security Officer and vessel's Company Security Officer.

* * * * *

■ 5. Add § 10.811 to read as follows:

§ 10.811 Requirements to qualify for an STCW endorsement as vessel security officer.

(a) The applicant for an endorsement as vessel security officer must present satisfactory documentary evidence in accordance with the requirements in 33 CFR 104.215.

(b) All applicants for an endorsement must meet the physical examination requirements in § 10.205(d)(1)–(2) of this chapter.

PART 15—MANNING REQUIREMENTS

■ 6. The authority citation for part 15 continues to read as follows:

Authority: 46 U.S.C. 2101, 2103, 3306, 3703, 8101, 8102, 8104, 8105, 8301, 8304, 8502, 8503, 8701, 8702, 8901, 8902, 8903, 8904, 8905(b), 8906, 9102, and 8103; and Department of Homeland Security Delegation No. 0170.1.

■ 7. Amend § 15.301 by adding paragraph (b)(10) and revising paragraph (b)(11) to read as follows:

§ 15.301 Definitions of terms used in this part.

* * * * *

(b) * * *

(10) GMDSS radio operator; and

(11) Vessel Security Officer.

* * * * *

■ 8. In § 15.1101, add paragraph (a)(6) to read as follows:

§ 15.1101 General.

(a) * * *

(6) *Vessel Security Officer (VSO)* means a person onboard the vessel accountable to the Master, designated by the Company as responsible for security of the vessel, including implementation and maintenance of the Vessel Security Plan, and for liaison with the Facility Security Officer and vessel's Company Security Officer.

* * * * *

■ 9. Add § 15.1113 to read as follows:

§ 15.1113 Vessel Security Officer (VSO).

After July 1, 2009, on board seagoing vessel, all persons performing duties as VSO must hold a valid endorsement as Vessel Security Officer.

Dated: May 6, 2008.

Brian M. Salerno,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Stewardship.

[FR Doc. E8–11225 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–15–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 201

[Docket No. RM 2008–5]

Late–Filed and Underpaid Royalties

AGENCY: Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: The Copyright Office is amending its rules governing the payment of interest on late or underpaid royalty fees under the Copyright Act to clarify when interest for late and underpayments is due in light of the Copyright Office's electronic funds transfer requirement. In addition, the Copyright Office amends the rules to add text that was inadvertently deleted by a previous rulemaking action. The Copyright Office also makes a technical correction to its satellite carrier requirements to recognize changes made to Section 119 in 2004.

EFFECTIVE DATE: May 20, 2008.

FOR FURTHER INFORMATION CONTACT: Ben Golant, Assistant General Counsel, and Tanya M. Sandros, General Counsel, Copyright GC/I&R, P.O. Box 70400, Washington, DC 20024. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION: On August 10, 2006, the Copyright Office published a final rule requiring the submission of royalty fees to be made by electronic funds transfer (''EFT''). 71 FR 45739 (August 10, 2006). The purpose of this notice is to make technical amendments to Section 201.17(i) and other similar rules for satellite carriers and digital audio recording technologies to clarify when interest accrues for late and underpayments in light of the recent EFT requirement. In addition, we intend to re–insert regulatory text, originally contained in Section 201.17(i)(2), that was incorrectly deleted from Title 37 CFR when the EFT requirements were adopted.

I. Electronic Funds Transfer Requirement

Under the new EFT regulations, 37 CFR 201.17(i), a number of changes were made regarding the payment of copyright royalties. The most important change was that payment could only be made through an electronic funds transfer. This change eliminates the options of payment by certified or cashier's check, or money order. Most payors already use EFTs, and requiring the use of EFTs substantially enhances the efficiency of the collection process. The regulations also require that the parties submit specific identifying and linking information as part of the EFT, and/or as part of a ''remittance advice'' which accompanies Statement(s) of Account, and that the ''remittance advice'' be faxed or emailed to the Licensing Division. Failure to submit the EFT in accordance with the rules may require the remitter to resubmit the EFT correctly. Should this occur, the remitter will be responsible for any assessed interest charge that accrues as a result of a late payment or an underpayment.

The rules now include a waiver provision for those situations where there may be circumstances which make it virtually impossible for a remitter to use the electronic payment option or imposes a financial or other hardship. Requests for a waiver must include a statement setting forth the reasons why the waiver should be granted and the statement must be signed by a duly authorized representative of the entity making the payment, certifying that the

information provided is true and correct.

II. Proposed Amendments

Section 201.17(c)(1) states that:

Statements of Account shall cover semiannual accounting periods of (i) January 1 through June 30, and (ii) July 1 through December 31, and shall be deposited in the Copyright Office, together with the total royalty fee for such accounting periods . . . .by not later than the immediately following August 29, if the Statement of Account covers the January 1 through June 30 accounting period, and by not later than the immediately following March 1, if the Statement of Account covers the July 1 through December 31 accounting period.

Section 201.17(i)(2) (before it was deleted) stated that:

Royalty fee payments submitted as a result of late or amended filings shall include interest. Interest shall begin to accrue beginning on the first day after the close of the period for filing statements of account for all underpayments of royalties for the cable compulsory license occurring within that accounting period. The accrual period shall end on the date appearing on the certified check, cashier's check, money order or electronic payment submitted by a cable system, provided that such payment is received by the Copyright Office within five business days of that date. If the payment is not received by the Copyright Office within five business days of its date, then the accrual period shall end on the date of the actual receipt by the Copyright Office.

Morever, Section 201.17(i)(2)(iii) (before it was deleted) stated that ''Interest is not required to be paid on any royalty underpayment or late payment from a particular accounting period if the interest charge is less than or equal to five dollars ($5.00).''

It is important to note that the Copyright Office's regulations concerning interest and accrual vis–a–vis late–filed SOAs for satellite carriers is different than that for cable operators. Section 201.11(i)(1) states:

Royalty fee payments submitted as a result of late or amended filings will include interest. Interest will begin to accrue beginning on the first day after the close of the period for filing statements of account for all underpayments or *late payments* of royalties for the satellite carrier statutory license for secondary transmissions for private home viewing occurring within that accounting period. The accrual period will end on the date appearing on the certified check, cashier's check, money order, or electronic payment submitted by a satellite carrier, provided that such payment is received by the Copyright Office within five business days of that date. If the payment is not received by the Copyright Office within five business days of its date, the accrual period will end on the date of actual receipt by the Copyright Office. (Emphasis added)

The Copyright Office's regulations regarding interest and accrual vis–a–vis late–filed SOAs for digital audio recording devices is comparable to that for satellite carriers. Section 201.28(l)(1) states:

Royalty payments submitted as a result of *late payments* or underpayments shall include interest, which shall begin to accrue on the first day after the close of the period for filing Statements of Account for all *late payments* or underpayments of royalties occurring within that accounting period. The accrual period for interest shall end on the date appearing on the certified check, cashier's check, money order, or electronic payment submitted by the manufacturing or importing party, if the payment is received by the Copyright Office within five business days of that date. If the payment is not received by the Copyright Office within five business days of its date, the accrual period shall end on the date of actual receipt by the Copyright Office. (Emphasis added)

We note that the five–day language, contained in Section 201.17(i)(2) of the Copyright Office's rules (before it was deleted), does not extend the Statement of Account filing period deadlines. However, the appropriate interest accrual period for late–filed SOAs has been subject to dispute because the ''five business day'' language of Section 201.17(i)(2) applies, on its face, to underpayments, not to late payments. It has been the Copyright Office's Licensing Division's practice that interest on late payments begins to accrue on the first day after the close of the period for filing statements of account until the date payment is received by the Copyright Office. If the ''five business day'' language applied in the instance of late payments, which it does not under the practices of the Copyright Office, then the amount of interest due would be less.

Given the facts and circumstances, and the need for clarity and administrative consistency, technical amendments to the existing regulations are appropriate. We propose to amend Section 201.17(i) by adding the phrase ''late payments'' to the existing regulatory language. In the interest of consistency, this change would make the rule largely parallel to Sections 201.11(i) and 201.28(l). As such, all royalty payments made by EFT must be made the day they are due. Interest will begin to accrue the next day for all late–filed submissions and on royalties that are underpaid. The accrual period ends when a full royalty payment is received by the Copyright Office.

We also propose to modify the ''five business day'' rule, currently found in all three regulations, and apply it only to those circumstances where a waiver of the EFT rule is granted by the Copyright Office. While the Office has received very few waivers since the EFT regulations were implemented, we still believe that special provisions concerning royalty payments by check are appropriate. In cases where a waiver is granted, the accrual period ends on the date the mailed payment is postmarked. However, if the payment is not received by the Copyright Office within five business days of its due date, then the accrual period shall end on the date of the actual receipt by the Copyright Office.

Finally, Section 201.11(i) is amended to recognize that in 2004, Congress expanded Section 119 to include secondary transmissions to commercial establishments. Satellite Home Viewer Extension and Reauthorization Act of 2004, a part of the Consolidated Appropriations Act of 2004. *See* Pub. L. No. 108–447, 118 Stat. 3394 (2004) (''Section 107'').

List of Subjects in 37 CFR Part 201

Copyright.

Proposed Regulation

■ In consideration of the foregoing, the Copyright Office is amending part 201 of 37 CFR, chapter II in the manner set forth below:

PART 201–GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Revise § 201.11(i)(1) to read as follows:

§ 201.11 Satellite carrier statements of account covering statutory licenses for secondary transmissions.

* * * * *

(i) * * *

(1) *Interest.* Royalty fee payments submitted as a result of late or amended filings will include interest. Interest will begin to accrue beginning on the first day after the close of the period for filing statements of account for all underpayments or late payments of royalties for the satellite carrier statutory license for secondary transmissions for private home viewing and viewing in commercial establishments occurring within that accounting period. The accrual period shall end on the date the electronic payment submitted by a satellite carrier is received by the Copyright Office. In cases where a waiver of the electronic funds transfer requirement is approved by the Copyright Office, and royalties payments are either late or underpaid, the accrual period shall end on the date the payment is postmarked. If the payment is not received by the Copyright Office within five business

days of its date, then the accrual period shall end on the date of the actual receipt by the Copyright Office.

* * * * *

■ 3. Amend § 201.17 by adding paragraph (i)(4) to read as follows:

§ 201.17 Statements of account covering compulsory licenses for secondary transmissions by cable systems.

* * * * *

(i) * * *

(4) Royalty fee payments submitted as a result of late or amended filings shall include interest. Interest shall begin to accrue beginning on the first day after the close of the period for filing statements of account for all late payments and underpayments of royalties for the cable statutory license occurring within that accounting period. The accrual period shall end on the date the electronic payment submitted by a cable operator is received. The accrual period shall end on the date the electronic payment submitted by a satellite carrier is received by the Copyright Office. In cases where a waiver of the electronic funds transfer requirement is approved by the Copyright Office, and royalties payments are either late or underpaid, the accrual period shall end on the date the payment is postmarked. If the payment is not received by the Copyright Office within five business days of its date, then the accrual period shall end on the date of the actual receipt by the Copyright Office.

* * * * *

■ 4. Revise § 201.28(l))(1) to read as follows:

§ 201.28 Statements of account for digital audio recording devices or media.

* * * * *

(l) * * *

(1) Royalty payments submitted as a result of late payments or underpayments shall include interest, which shall begin to accrue on the first day after the close of the period for filing Statements of Account for all late payments or underpayments of royalties for the digital audio recording obligation occurring within that accounting period. The accrual period shall end on the date the electronic payment submitted by the remitter is received. In cases where a waiver of the electronic funds transfer requirement is approved by the Copyright Office, and royalties payments are either late or underpaid, the accrual period shall end on the date the payment is postmarked. If the payment is not received by the Copyright Office within five business days of its date, then the accrual period shall end on the date of the actual receipt by the Copyright Office.

* * * * *

Dated: April 30, 2008.

Marybeth Peters,

Register of Copyrights.

Approved by:

James H. Billington,

The Librarian of Congress.

[FR Doc. E8–11274 Filed 5–19–08; 8:45 am]

BILLING CODE 1410–30–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R09–OAR–2008–0435; FRL–8568–3]

Designation of Areas for Air Quality Planning Purposes; California; Ventura Ozone Nonattainment Area; Reclassification to Serious

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Effective June 15, 2004, EPA classified the Ventura County ozone nonattainment area as ''subpart 2/moderate'' for the 8-hour ozone standard with an attainment date of no later than June 15, 2010. On February 14, 2008, the California Air Resources Board submitted a request for reclassification of the Ventura County ozone nonattainment area from ''moderate'' to ''serious.'' Under section 181(b)(3) of the Clean Air Act, EPA is granting California's request for voluntary reclassification of the Ventura County ozone nonattainment area to ''serious'' in today's document.

DATES: *Effective Date:* This rule is effective on June 19, 2008.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2008–0435 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., confidential business information). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Dave Jesson, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3957, *jesson.david@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

I. Reclassification of Ventura County to Serious Ozone Nonattainment

Effective June 15, 2004, we classified the Ventura County ozone nonattainment area under the Clean Air Act (''Act'' or CAA) as ''subpart 2/moderate'' for the 8-hour ozone national ambient air quality standard (NAAQS). See 69 FR 23858, at 23889 (April 30, 2004); and 40 CFR 81.305. Our classification of Ventura County as a ''moderate'' ozone nonattainment area establishes a requirement that the area attain the 8-hour ozone NAAQS as expeditiously as practicable, but no later than six years from designation, i.e., June 15, 2010. By letter dated February 14, 2008, the Executive Officer for the California Air Resources Board (CARB) submitted a request to reclassify three California areas designated nonattainment for the 8-hour ozone standard. Ventura was one of the three areas, and for the Ventura County ozone nonattainment area, CARB has requested reclassification from ''moderate'' to ''serious.'' We are acting on the request for Ventura in today's document. In a separate document, we will propose a schedule for required plan submittals for Ventura County under the new classification.

We will also act on the requests for the other two areas listed in CARB's February 14, 2008 letter, as well as the reclassification requests previously received from CARB for the San Joaquin Valley, South Coast, and Coachella Valley ozone nonattainment areas, in a separate document. We are deferring action on the State's reclassification requests for the five other areas to allow for notification to, and the opportunity for consultation with, the Indian tribes located within the five areas. No Indian tribes are located within Ventura County. In the separate document, we will also propose schedules for required plan submittals under the new classifications for these areas.

We are reviewing this request as one made pursuant to section 181(b)(3) of the Act which provides for ''voluntary reclassification'' and states: ''The Administrator shall grant the request of any State to reclassify a nonattainment area in that State in accordance with table 1 of subsection (a) of this section to a higher classification. The Administrator shall publish a notice in the **Federal Register** of any such request and of action by the Administrator

granting the request.'' While section 181 relates to the 1-hour ozone NAAQS, the same option exists with respect to the 8-hour ozone NAAQS. See 40 CFR 51.903(b) (''A State may request a higher classification for any reason in accordance with section 181(b)(3) of the CAA.''). We find that the plain language of section 181(b)(3) mandates that we approve such a request, and, as such, EPA is granting CARB's request for voluntary reclassification under section 181(b)(3) for the Ventura County ozone nonattainment area from ''moderate'' to ''serious'' in today's document. As a result of this action, Ventura County must now attain the 8-hour ozone NAAQS as expeditiously as practicable, but not later than nine years from designation, i.e., June 15, 2013.

EPA has determined that today's action falls under the ''good cause'' exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding ''good cause,'' authorizes agencies to dispense with public participation where public notice and comment procedures are ''impracticable, unnecessary or contrary to the public interest.'' EPA has determined that public notice and comment for today's action is unnecessary because our action to approve voluntary reclassification requests under CAA section 181(b)(3) is nondiscretionary both in its issuance and in its content. As such, notice and comment rulemaking procedures would serve no useful purpose.

II. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. EPA has determined that the voluntary reclassification would not result in any of the effects identified in Executive Order 12866 section 3(f). Voluntary reclassifications under section 181(b)(3) of the CAA are based solely upon request by the State and EPA is required under the CAA to grant them. These actions do not, in and of themselves, impose any new requirements on any sector of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classification, reclassification cannot be said to impose a materially adverse impact on State, local or tribal governments or communities. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

In addition, I certify 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.*). This action does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), because EPA is required to grant requests by States for voluntary reclassifications and such reclassifications in and of themselves do not impose any federal intergovernmental mandate. This rule also does not have tribal implications because it will 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Because EPA is required to grant requests by States for voluntary reclassifications and such reclassifications in and of themselves do not impose any federal intergovernmental mandate, this action also does not have Federalism implications as it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. As discussed above, a voluntary reclassification under section 181(b)(3) of the CAA is based solely on the request of a State and EPA is required to grant such a request. In this context, it would thus be inconsistent with applicable law for EPA, when it grants a State's request for a voluntary reclassification, to use voluntary consensus standards. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 21, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, National parks, Ozone, Wilderness areas.

Dated: May 13, 2008.

Wayne Nastri,

Regional Administrator, Region IX.

■ Part 81, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart C—[Amended]

■ 2. Section 81.305 is amended in the table for ''California-Ozone (8-Hour Standard)'' by revising the entry for ''Ventura County, CA'' to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Classification	
	Date [1]	Type	Date [1]	Type
* *	*	* *	*	*
Ventura County, CA:				
Ventura County (part)—That part of Ventura County excluding the Channel Islands of Anacapa and San Nicolas Islands.		Nonattainment	6/19/08	Subpart 2/Serious.
Remainder of County		Unclassifiable/Attainment.		
* *	*	* *	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.*
[1] This date is June 15, 2004, unless otherwise noted.

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[FR Doc. E8–11294 Filed 5–19–08; 8:45 am]
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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 13 and 22

[FWS–R9–MB–2008–0057; 91200–1231–9BPP–L2]

RIN 1018–AV11

Authorizations Under the Bald and Golden Eagle Protection Act for Take of Eagles

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: These final regulations provide two mechanisms to authorize take under the Bald and Golden Eagle Protection Act (Eagle Act) by certain persons who have been authorized under the Endangered Species Act (ESA) to take bald eagles (*Haliaeetus leucocephalus*) and golden eagles (*Aquila chrysaetos*).

DATES: This rule goes into effect on June 19, 2008.

FOR FURTHER INFORMATION CONTACT: Eliza Savage, Division of Migratory Bird Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Mailstop 4107, Arlington, VA 22203–1610; or 703–358–2329.

SUPPLEMENTARY INFORMATION:

Background

The Bald and Golden Eagle Protection Act (16 U.S.C. 668–668d) (Eagle Act) prohibits the take of bald eagles and golden eagles unless pursuant to regulations (and in the case of bald eagles, take can be authorized only under a permit). While the bald eagle was listed under the ESA (16 U.S.C. 1531 et seq.), we authorized incidental take of bald eagles through take statements under ESA section 7 and through section 10 incidental take permits (50 CFR 402, Subparts A and B; 50 CFR 17.22(b) and 17.32(b)). Those authorizations were issued with assurances that the Service would exercise enforcement discretion in relation to violations of the Eagle Act (16 U.S.C. 668–668d) and the Migratory Bird Treaty Act (16 U.S.C. 703–712) (MBTA). Since the bald eagle has been removed from the ESA's List of Endangered and Threatened Wildlife throughout most of its range (see 72 FR 37345, July 9, 2007 and 73 FR 23966, May 1, 2008), the prohibitions of the ESA no longer apply except to the Sonoran Desert nesting bald eagle population. However, the potential for human activities to violate Federal law by taking bald eagles (and golden eagles) remains under the prohibitions of the Eagle Act and the MBTA. The Eagle Act defines the ''take'' of an eagle to include a broad range of actions: ''pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, or molest or disturb.'' ''Disturb'' is defined in our regulations at 50 CFR 22.3 as ''to agitate or bother a bald or golden eagle to a degree that causes, or is likely to cause, based on the best scientific information available, (1) injury to an eagle, (2) a decrease in its productivity, by substantially interfering with normal breeding, feeding, or sheltering behavior, or (3) nest abandonment, by substantially interfering with normal breeding, feeding, or sheltering behavior.'' Many actions that were considered likely to incidentally ''take'' (harm or harass) eagles under the ESA may also ''take'' eagles under the Eagle Act, as those terms have been defined by statute and regulation.

The ESA provides broad substantive and procedural protections for listed species but at the same time allows significant flexibility to permit activities that affect listed species. In particular, sections 7(b)(4) and 10(a)(1)(B) of the ESA provide that we may authorize the incidental take of listed wildlife in the course of otherwise lawful activities. Nationwide, since 2002, the Service issued an average of 52 incidental take statements per year that covered anticipated take of bald eagles under the ESA's section 7 (50 CFR 402, Subpart B). During that same 5-year period, we issued nine incidental take permits that included bald eagles under the ESA's section 10(a)(1)(B). A total of 126 such incidental take permits have been issued for bald eagles and 12 incidental take permits include golden eagles as covered, non-listed species (50 CFR 17.22(b) and 17.32(b)). The statutory and regulatory criteria for issuing those ESA authorizations included minimization, mitigation, or other conservation measures that also satisfied the statutory mandate under that Eagle Act that authorized take must be compatible with the preservation of the bald or golden eagle. Our practice was to provide assurances in each section 7 incidental take statement and section 10 permit that we would not refer the incidental take of a bald eagle for prosecution under the Eagle Act, if the take was in compliance with the terms and conditions of a section 7(b)(4) incidental take statement or the conditions of a section 10(a)(1)(B) incidental take permit. [1] Now that the

[1] Compliance with the conditions of a section 10(a)(1)(B) permit entails compliance with the terms of the associated Habitat Conservation Plan and Implementing Agreement (if applicable).

bald eagle is delisted in most of the U.S., new mechanisms are needed to address take pursuant to the Eagle Act.

The Eagle Act provides that the Secretary of the Interior may authorize certain otherwise-prohibited take of eagles through promulgation of regulations. The Secretary is authorized to prescribe regulations permitting the ''taking, possession, and transportation of [bald or golden eagles] * * * for the scientific or exhibition purposes of public museums, scientific societies, and zoological parks, or for the religious purposes of Indian tribes, or * * * for the protection of wildlife or of agricultural or other interests in any particular locality,'' provided such permits are ''compatible with the preservation of the bald eagle or the golden eagle'' (16 U.S.C. 668a). In accordance with this authority, the Secretary has previously promulgated Eagle Act permit regulations for scientific and exhibition purposes (50 CFR 22.21), for Indian religious purposes (50 CFR 22.22), for take of depredating eagles (50 CFR 22.23), for possession of golden eagles for falconry purposes (50 CFR 22.24), and for take of golden eagle nests that interfere with resource development or recovery operations (50 CFR 22.25).

We have not previously promulgated permit regulations to implement the statutory provision which allows the Secretary to authorize take ''for the protection of * * * other interests in any particular locality.'' This statutory authority accommodates the spectrum of public and private interests (such as utility infrastructure development and maintenance, road construction, operation of airports, commercial or residential construction, resource recovery, recreational use, etc.) that have received authorization to take eagles under the ESA.

Shortly before delisting the bald eagle, we proposed regulations to permit take under the Eagle Act where the take is associated with otherwise lawful activities, and to permit removal of eagle nests for emergency safety needs (see 72 FR 31141, June 5, 2007). That proposed rule also included provisions we are finalizing today under this rule to extend Eagle Act take authorizations to persons previously authorized to take eagles under the ESA, provided the take occurs in compliance with the terms of that ESA authorization. Because the authorizations associated with this final rulemaking are categorically excluded from the requirement to prepare an environmental assessment under the National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) under Departmental procedures and we find it is appropriate to have these authorizations available at the earliest practical date, we have bifurcated the proposed rule and are finalizing the ESA-related provisions ahead of the remainder of the proposal. That remainder is currently undergoing a NEPA analysis which we intend to complete later this year.

Summary of the Rulemaking

Eagle take that was prohibited under the ESA is, in many instances, also prohibited under the Eagle Act. Both statutes define take to prohibit killing, wounding, pursuing, shooting, capturing, and collecting the species they protect (16 U.S.C. 668c; 16 U.S.C. 1532(19)). The ESA definition of ''take'' additionally includes the terms ''harm'' and ''harass,'' while the Eagle Act includes ''molest or disturb'' in its definition of ''take.'' The regulatory definitions of ''harm,'' ''harass,'' and ''disturb'' differ; however they do overlap in several ways, with the result that an action considered likely to incidentally take eagles under the ESA may also take eagles under the Eagle Act.

Under this final rule, we extend Eagle Act authorizations to holders of existing ESA authorizations as seamlessly as is possible under the applicable laws. There are two mechanisms through which these new regulations provide Eagle Act authorization. First, the rule establishes regulatory provisions under 50 CFR 22.11 to provide take authorization under the Eagle Act to ESA section 10(a)(1)(B) permittees where the bald eagle is covered in a Habitat Conservation Plan (HCP) or the golden eagle is covered as a non-listed species, as long as the permittee is in full compliance with the terms and conditions of the ESA permit. This provision will also apply to the take of bald eagles and golden eagles specifically authorized in any future HCPs, whether or not eagles are then listed under the ESA. This provision also extends Eagle Act take authorization to ESA permits for Scientific Purposes and permits for Enhancement of Propagation or Survival (i.e., Recovery permits) issued under ESA section 10(a)(1)(A).

Second, the rule establishes a new permit category to provide expedited Eagle Act permits to entities authorized to take bald eagles through section 7 incidental take statements. Permits are not available under this new permit for golden eagles because as a non-listed species no take of golden eagles was previously authorized under the ESA's section 7.

Theoretically, this new permit category also may be used to extend Eagle Act take authorization to take exempted under section 7 of the ESA in the future where the bald eagle or golden eagle is protected under the ESA (e.g., for take of Sonoran Desert nesting bald eagles, or if bald eagles or golden eagles become ESA-listed in any portion of their respective ranges). However, in addition to the regulations being finalized herein, we intend to finalize regulations later this year to establish a new permit that will authorize take that is associated with, but not the purpose of, an action (proposed 50 CFR 22.26) (see 72 FR 31141, June 5, 2007). As part of that subsequent rule, we intend to amend the regulations we are promulgating today in a manner to restrict their use to section 7 incidental take statements issued prior to the date this later rule becomes effective. For any incidental take exempted under ESA section 7 that is authorized after the date § 22.26 becomes effective and that also constitutes take under the Eagle Act, the only permit that would be available to provide Eagle Act take authorization would be the new permit to be created by a final version of 50 CFR 22.26. Although the reasonable and prudent measures and associated terms and conditions of section 7 incidental take statements satisfy the statutory mandate of the Eagle Act, once a permit becomes available to authorize eagle take that is not associated with an ESA take authorization, for purposes of accountability and consistency, the same process and procedures should be used to authorize take under the Eagle Act regardless of whether it was also exempted under ESA section 7. Therefore, except for take authorized through ESA section 10 permits (which will confer authority to take under both the ESA and the Eagle Act under the new provision at 50 CFR 22.11), any take we authorize that is associated with, but not the purpose of an activity, would be provided under a single regulatory authority, 50 CFR 22.26, once it becomes available, rather than 50 CFR 22.28. Persons and entities permitted under § 22.28 may apply for a permit under § 22.26 when it becomes available.

The reason why different authorizing mechanisms are needed to extend Eagle Act take authorization to take authorized under ESA section 10 versus take exempted under ESA section 7 is that the Eagle Act requires that any bald eagle take to be authorized must be (1) pursuant to regulations, (2) authorized upon procurement of a permit from the Secretary of the Interior, and (3)

compatible with the preservation of the bald eagle. We now find that the previously issued ESA take authorizations are compatible with the preservation of the eagle, and we are able to extend Eagle Act take authorization to holders of ESA permits through this regulation without the need for an additional permit because (1) this regulation satisfies the Eagle Act statutory mandate that take be authorized by regulation, *and* (2) a permit to take eagles has been procured from the Secretary of the Interior. In contrast, the take authorizations provided under section 7 of the ESA were not provided through a permit, and so the holders of those authorizations cannot be extended an Eagle Act authorization without a permit being procured prior to such taking.

Description of the Rulemaking

New Provisions at 50 CFR 22.11 To Extend Eagle Act Take Authorization to Permittees Authorized To Take Eagles Under the ESA

Section 10(a)(1)(B) of the ESA authorizes incidental take permits for activities included in an HCP. One-hundred and twenty-six such permits cover bald eagles. Twelve permits authorize incidental take of golden eagles for ESA purposes (should the golden eagle be listed in the future) by their inclusion as covered non-listed species. Our practice was to issue these permits with a statement of enforcement discretion from the Service that provided assurances that the Service would not refer any take of bald or golden eagles for prosecution under the Eagle Act, as long as the take was in full compliance with the terms and conditions of the permit and HCP. While the bald eagle was protected under the ESA, these assurances also conveyed the Federal Government's commitment to make no additional conservation demands of permittees who were fully implementing the conservation measures within their HCPs.

Now that the bald eagle has been delisted in most portions of its range, all of these ESA permits will continue to provide viable authorizations under the ESA, should the affected eagle population become listed under the ESA in the future. The only change is that the bald eagle became a covered non-listed species under HCPs where it was delisted. However, none of these incidental take permits provided explicit authorization for take under the Eagle Act.

The conservation measures required to cover the bald eagle and the golden eagle under previously issued ESA incidental take permits (which were crafted to safeguard federally listed species, including those that may be listed in the future) are ''compatible with the preservation of the bald eagle and the golden eagle'' as required by the Eagle Act. Therefore, a separate Eagle Act permit is not required under this final rule. This rule amends the Eagle Act regulations at 50 CFR 22.11 to extend Eagle Act authorization for the take authorized under the ESA to entities who continue to operate in full compliance with the terms and conditions of permits issued under ESA section 10. Failure to abide by the section 10 permit requirements that pertain to eagles may, however, potentially void the Eagle Act authorization for these permits and result in permit revocation.

This final regulation diverges moderately from what we proposed in our June 2007 proposed rule (72 FR 31141). In the proposed rule, we suggested that section 10 incidental take permittees whose permits covered bald eagles as the only ESA-listed species would need to follow the same procedures as persons authorized under section 7 and apply for an expedited Eagle Act permit, rather than be covered by the new provision we are adding to 50 CFR 22.11. Although more cumbersome, we proposed that a new permit would be necessary because we thought that the ESA permit might be effectively ''null and void,'' since it no longer covered any species listed under the ESA.

However, after further consideration, we now conclude that a single-species HCP does not become null and void if the species is delisted, but instead is ineffective for purposes of providing ESA authorization as long as the species remains off the List of Endangered and Threatened Wildlife. However, should the species be re-listed within the tenure of the permit, the authorization would become effective (in much the same way that a permit under 50 CFR 17.22(d) that covers a Candidate species included in a Candidate Conservation Agreement becomes valid if the species becomes listed). Based on this approach, the seven section 10 permits that covered bald eagles as the only ESA-listed species are not null and void and are eligible to be treated in the same manner as section 10 incidental take permits that cover bald eagles among additional listed species, because both satisfy the Eagle Act permit requirement that a permit be procured before a bald eagle may be taken. Therefore the new provision at 50 CFR 22.11 will cover ESA section 10 incidental take permits that included eagles as the only ESA-listed species without the need for issuance of an additional Eagle Act permit.

The new provision at 50 CFR 22.11 also applies to take covered under *future* ESA section 10 permits associated with HCPs for multiple species that include bald eagles or golden eagles as covered species, whether or not eagles are listed under the ESA.

ESA Section 10(a)(1)(A) Permits

Take of bald eagles also was authorized under the ESA's section 10(a)(1)(A) permits for Scientific Purposes and permits for Enhancement of Propagation or Survival (i.e., Recovery permits). Many of these permits specifically provided take authorization under the Eagle Act in addition to the ESA authorization, and those permits will continue to serve as valid take authorizations under the Eagle Act. However, some section 10(a)(1)(A) permits provided take authority only under the ESA and these permits became inactive when the bald eagle was delisted. The new provision at § 22.11 will extend Eagle Act take authorization to the holders of those permits for the duration of the term of the section 10(a)(1)(A) permit, or until the amount or level of take authorized has been met.

New Permit Provisions Under 50 CFR 22.28

As discussed above, the Eagle Act provides that bald eagles may not be taken unless a permit is first procured from the Secretary of the Interior. The new provisions at § 22.11 that extend Eagle Act coverage to holders of section 10 permits do not apply to section 7 incidental take statements, since those authorizations were not provided via issuance of a permit. This final rule establishes a process to issue Eagle Act permits to entities that were subject to ESA section 7 incidental take authorizations and for which there may continue to be a need to take eagles in the future.

Through the ESA section 7 process, when the Service concludes that the agency action will not cause jeopardy or adverse modification, we include an incidental take statement that specifies the amount or extent of incidental take that will be caused by the agency's action and which is exempted from the ESA's take prohibitions. The incidental take statement includes reasonable and prudent measures and associated terms and conditions to which the agency (or

any applicant or grantee of the agency) must adhere in order for the take exception to apply (see 16 U.S.C. 1536(o)(2)). Those reasonable and prudent measures and associated terms and conditions in the incidental take statement also satisfy the statutory mandate of the Eagle Act that authorized take must be compatible with the preservation of the eagle. Therefore, criteria for issuing these expedited permits are limited to (1) whether the action agency (or any applicant or grantee of the agency) is implementing the action in full compliance with the terms and conditions of the ESA section 7 incidental take statement with respect to the take of eagles, and (2) whether new information is available to indicate that such take is not compatible with the preservation of the eagle (e.g., that take was or will be exceeded, or the activity will affect eagles in a manner or to an extent not previously considered, or the activity will be modified).

For ESA section 7 take statements issued before the date this rule takes effect, we will not refer such take for prosecution under the Eagle Act during an interim period that will afford the holders of the section 7 take statements a reasonable opportunity to obtain an Eagle Act permit, contingent on their remaining in full compliance with the terms and conditions of their take statements. For these purposes, ''reasonable opportunity'' means 1 year after the effective date of this rule, i.e., 13 months from the date of publication of this rule in the **Federal Register**. By that date, such applicants need to submit a completed application under these regulations. For ESA section 7 take statements issued before the date this rule takes effect, only those permittees whose activities will continue to take eagles *after* this 1-year period need to apply for an Eagle Act permit under these new regulations (as long as any take that occurs between August 8, 2007 (the effective date of the delisting of most bald eagles in the coterminous United States), through the end of this 1-year period is in accordance with the terms and conditions of the previously granted ESA incidental take statement).

For ESA section 7 incidental take statements issued on or after the date this rule takes effect, there will be no conversion period. At the present time, this applies only to the population of eagles found in the Sonoran Desert region of Arizona. Our aforementioned assurances that we will not refer take under the Eagle Act do not apply to take statements issued on or after the date this rule takes effect. If take of eagles is proposed within an ESA-listed population that we could authorize in accordance with the statutory and regulatory requirements of both laws, the Service's Migratory Bird and Endangered Species programs will coordinate the authorization processes with the goal of issuing the Eagle Act and ESA authorizations in a synchronized manner.

A separate authorization under the Migratory Bird Treaty Act is not required. Many impacts authorized under the ESA that will require Eagle Act authorization will not ''take'' eagles under the MBTA because that statute does not contain a prohibition against harassment or disturbance (without injury) of the birds it protects. Therefore, activities that harass or disturb an eagle would not require MBTA authorization unless the activity also results in injury or some other impact prohibited by the MBTA. Even where MBTA take will occur, a separate MBTA authorization in addition to the Eagle Act authorization is not required because 50 CFR 22.11(a) exempts those who hold Eagle Act permits from the requirement to obtain an MBTA permit.

In extending Eagle Act authorizations to entities authorized to take bald eagles under ESA section 7, we will make the permit available to either the action agency or the agency's grantee or permittee, or both. Either or both the action agency or the third party can request an Eagle Act permit under this section.

In applying for the permit, the applicant must include a written certification that he or she is in full compliance with all terms and conditions of the ESA incidental take statement. In making our determination, we will also review other any other relevant information available to us, including, but not limited to, any monitoring and progress reports required and submitted in furtherance of the ESA incidental take statement.

We anticipate that most permits will be issued with terms and conditions identical to those of the ESA incidental take statement. However, based on comments received on the proposed rule, we added provisions to the final regulation to address re-evaluation of terms and conditions, either at the request of the applicant, or initiated by the Service. Persons previously covered under an ESA incidental take statement, who apply for take authority under the Eagle Act through these regulations, may request a reevaluation from the Service to determine whether the conservation measures required under the ESA authorization are still necessary to satisfy the Eagle Act standard of compatibility with preservation of the bald eagle, or because of proposed modifications to the planned activity. However, if the ESA incidental take statement applies to eagles that are listed under the ESA, the Eagle Act permit cannot and will not remove or annul any terms and conditions contained in the ESA incidental take statement. Re-evaluation of the terms and conditions will likely require more time to process the application than when the applicant seeks to continue the past terms and conditions. Following issuance of the Eagle Act permit (as under most types of permits the Service administers) at any time during the permit tenure, the permittee may request amendment of his or her permit subject to general permit regulations at 50 CFR part 13.

We may initiate re-evaluation of terms and conditions under this rule if certain criteria that previously would have triggered reinitiation of formal consultation are present (see 50 CFR 402.16). Those criteria are any of the following: (1) The amount or extent of incidental take authorized under the take statement is exceeded; (2) new information reveals effects of the action that may affect eagles in a manner or to an extent not previously considered; or (3) the activity will be modified in a manner that causes effects to eagles not previously considered. If any of these factors is extant, depending on the specific circumstances, the Service may modify the terms and conditions as necessary to ensure that the authorized take is compatible with the preservation of the bald eagle or the golden eagle. The Service may re-evaluate the terms and conditions either before issuing the Eagle Act permit, or at any time during the permit tenure that one of the three ''reinitiation criteria'' triggers such re-evaluation, just as would be the case for the section 7 authorization. We do not anticipate that any such review under the Eagle Act would result in terms and conditions substantially different from those that would result under section 7 of the ESA.

The permit will be valid until the action that will take eagles, as described in the ITS or modified to condition the permit issued under this section, is completed, as long as the permittee complies with the terms and conditions of the permit, including any modified terms and conditions.

There is no permit application form or processing fee for this permit. To apply for a permit under this section, the applicant must send to his or her Regional Migratory Bird Permit Office a signed statement requesting an Eagle Act permit under this section and

certifying that he or she is in full compliance with the terms and conditions of his or her ESA incidental take statement. If needed and applicable, the permit office may request the applicant submit copies of any monitoring and progress reports required under the take statement.

Revisions to General Permit Conditions at 50 CFR Part 13

As part of establishing the new permit authorizations under 50 CFR 22.28, we are amending the list of permits at 50 CFR 13.12 to add this new permit type. We are also amending 50 CFR 13.11(d), the nonstandard fee schedule, to include this new permit and provide that no processing fee will be charged.

Response to Public Comments

The comments addressed below include only those that pertain to the provisions being finalized in this rule. These include comments from two national environmental advocacy organizations, two industry associations, two law firms on behalf of real estate developers, one consultant, two committees representing multiple State natural resource agencies, and one Federal reclamation project. The remainder of the substantive comments we received in response to the June 5, 2007, proposed rule will be addressed in a subsequent rulemaking.

Comment 1: The criteria for permit issuance should be more stringent. Rather than give these ''grandfathering'' authorizations the barest of reviews, the Service must establish a system to assess these actions in light of the unique requirements of the Eagle Act. Language should be added to the sections on ''Applying for a Permit'' and ''Required Determinations'' to clarify that, before extending Eagle Act authorization, the Service will review whether the taking is necessary to protect an interest in a particular locality and whether the take is compatible with the preservation of the eagle. Before issuing these permits, the Service should also consider whether additional permit conditions or conservation measures are needed.

Service response: The take that will be authorized under the Eagle Act through these permits has been (or will be) reviewed at least twice by the Service. First, at the time the original ESA authorization was issued, the Service reviewed the take under either section 7 or section 10 of the ESA. Prior to issuing a section 7 incidental take statement, the Service assesses the effects of the action and issues the take statement only if we conclude the take would not jeopardize the continued existence of bald eagles. For section 10 permits, the Service determines that the taking will not appreciably reduce the likelihood of survival or recovery of the species. For each of the ESA authorizations we issued, we included a statement that we did not intend to bring enforcement action under either the Eagle Act or the MBTA for the ESA-authorized take. Though the take was not technically authorized under the MBTA or the Eagle Act through the ESA authorization, we determined that the ESA conservation goal was compatible with the statutory mandate of both Acts. We carefully considered the consequences of extending Eagle Act authorization to these actions before proposing to do so in our June 5, 2007, proposed rule (see 72 FR 31141) and since then, as we examined public input on that rule. Our conclusion is that the taking authorized by the ESA authorizations is compatible with the preservation of the bald eagle, individually and cumulatively.

However, the authorizations granted under the ESA were themselves subject to re-evaluation by the Service under certain limited circumstances, and through this final rule, we are extending the same criteria that allowed us to revise terms and conditions under the ESA authorizations to the Eagle Act authorizations granted herein. For section 10 permits, we do this by adding language to the new provision at § 22.11 to clarify that the same regulatory provisions that applied to section 10(a)(1)(B) permits continue to apply, except that the revocation criterion is based on the Eagle Act mandate of compatibility with the preservation of the bald eagle or the golden eagle, rather than the ESA standard of inconsistency with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv). Accordingly, the Service cannot require any additional conservation measure for changed or unforeseen circumstances than we could have required under the ESA permit, but if mutually agreed upon conservation measures cannot assure compatibility with the preservation of the bald eagle or the golden eagle, the Service may revoke a permit that is determined to be incompatible with the preservation of the bald eagle or the golden eagle.

To provide for Service-initiated re-evaluation of the terms and conditions of section 7 authorizations, we have added language to the final regulations that mirrors the criteria for reinitiation of formal consultation under section 7, but is based on the Eagle Act standard of compatibility with the preservation of the bald eagle or the golden eagle.

Regarding whether the Service, before issuing each permit, must make the determination that take is necessary to protect an interest in a particular locality, we believe that extending Eagle Act authorization to take that was previously exempted under the ESA is necessary to protect the legitimate interests of those members of the public, in particular localities, who were proceeding in good faith under previously issued ESA authorizations and were complying with all required conservation measures of their take statements.

Comment 2: The regulations should contain an explicit finding that issuing Eagle Act permits for previously issued ESA authorizations is consistent with the Eagle Act's take authorization provisions at 16 U.S.C. 668a.

Service response: We found above that the permits issued under this rulemaking are consistent with the Eagle Act. Additionally, based on this finding, the final regulations continue to use as the sole criterion for permit issuance whether the applicant is implementing the action as analyzed in the formal consultation and continues to fully comply with the terms and conditions of the previously issued ESA authorization.

Comment 3: The scope of ''take'' under the Eagle Act is far narrower than under the ESA. Therefore, the expedited permit processing criteria are appropriate.

Service response: Our conclusion that take previously authorized under the ESA is compatible with the preservation of the bald eagle is not based on a relative comparison of the two statutes' definitions of ''take.'' Rather, it is based on the adequacy of the issuance criteria for ESA authorizations, including minimization, mitigation, and other conservation measures, designed to protect a species classified as threatened under the ESA, that would remain as terms and conditions under the Eagle Act authorization.

Comment 4: In the preamble to the proposed rule, the Service stated that persons applying under this permit would be given the opportunity to ask for a re-evaluation of permit conditions, to ensure that permittees are not compelled to undertake measures that would not otherwise be required to offset take under the Eagle Act. However, no such provisions were included within the proposed regulation itself.

Service response: We have added specific provisions for requesting a re-evaluation of permit conditions to the final rule in two places: In § 22.28(c),

Permit conditions; and in § 22.28(e)(2), Applying for an eagle take permit.

Comment 5: The Service should enact a general permit process similar to the U.S. Army Corps of Engineers' section 404(e) permit program under the Clean Water Act. The Eagle Act requirement that a permit must first be procured before bald eagle take can be authorized does not necessarily mean an individual permit is required. Without being automatically authorized via a general permit, some people may be subjected to criminal and civil penalties because they do not realize they need an Eagle Act permit.

Service response: The general permit program administered by the U.S. Army Corps of Engineers (Corps) provides authorization for certain types of activities without the landowner or developer having to obtain an individual site-specific permit in advance. The Clean Water Act specifically authorizes the Corps to issue general permits that are exempt from individual, case-by-case review (33 U.S.C. 1344(e)). No such provision exists within the Eagle Act, which states that ''bald eagles may not be taken for any purpose unless, prior to such taking, a permit to do so is procured from the Secretary of the Interior'' (16 U.S.C 668a). Because of that provision, we can promulgate regulations that authorize take of golden eagles without a permit, but not bald eagles; a regulation is not sufficient authorization, absent a permit from the Department of the Interior to take bald eagles.

The U.S. Court of Appeals for the District of Columbia Circuit has held that the Corps' nationwide general permits meet the statutory definition of rules because they are ''legal prescription[s] of general and prospective applicability'' *Natl. Assn. of Home Builders* vs. *U.S. Army Corps of Engineers*, 417 F. 3d 1272, 1284, D.C. Cir. 2005. Thus, if we attempted to authorize take of bald eagles with a ''prescription of general and prospective applicability'' and without individual permits, a reviewing court might find this to be inconsistent with the Eagle Act's requirement that a permit be procured prior to taking bald eagles. Consequently this final rule continues to require an application process, review, and issuance of a permit before take of bald eagles may be authorized under the Eagle Act for ESA section 7 authorizations because they were not provided via a permit from the Secretary of the Interior.

Regarding the issue of liability for unauthorized take, we believe that persons who were previously authorized to take eagles under the ESA should be at least as aware that most bald eagles were delisted and of the need to gain take authorization under the Eagle Act as the average citizen who has never had occasion to consider his legal responsibilities with regard to eagles.

Comment 6: There need to be timelines for issuance of the expedited permits, i.e., if no action is taken by the Service within 45 days, the applicant can conclusively presume that the permit is granted.

Service response: Regardless of any presumption on the part of the applicant, the activity is not authorized under the Eagle Act without a permit. We intend to issue these permits expeditiously, and we may include permit processing targets for these types of permits in forthcoming implementation guidance. However, due to factors not always under our control, such as the volume of requests, incomplete information provided by applicants, etc., we cannot always meet desired targets.

Comment 7: There should be a finite period of time during which people with previously issued incidental take statements must seek their conversion to an Eagle Act permit.

Service response: Elsewhere in the preamble, we have clarified that we expect those persons who wish to be able to continue to rely on the assurances provided in past ESA section 7 incidental take statements to apply for permits under this section within 1 year after this rule takes effect (thirteen months from the date of publication in the **Federal Register**). For ESA section 7 take statements issued on or after the date this rule takes effect, there will be no conversion period: The recipient of the take statement needs immediately, or concurrent with the related ESA consultation, to seek a permit under this section (until such time as a permit is available under § 22.26). An Eagle Act permit is required to authorize take under the Eagle Act regardless of whether the take has been exempted under section 7, and our aforementioned assurances that we will not refer take under the Eagle Act will not be included in incidental take statements issued on or after the date this rule is finalized.

Comment 8: The Service needs to issue an Enforcement Directive from the Director to the field providing assurances during the interim period that it will not exercise any enforcement. The directive should be similar to the February 9, 1996, memorandum from the Director to the Regional Directors, which suggested that the Regions include statements in ESA incidental take authorizations they issue to the effect that the Service would not initiate enforcement actions under the Eagle Act and MBTA for the ESA-authorized take of migratory birds and eagles.

Service response: This comment loses some of its urgency with the release of these final regulations. Even so, an ''enforcement directive'' that would apply for the next year while applicants undergo the Eagle Act permitting process may still be desired. However, we do not agree that an internal memorandum wherein the Director transmits ''recommendations to the Regions as interim guidance,'' as was the case with the February 9, 1996, memorandum, would provide greater assurances than we have already provided through language contained in four separate rulemaking actions (including this one) published in the **Federal Register**.

Comment 9: Recipients of technical assistance letters that authorized activities under the ESA that are inconsistent with the National Bald Eagle Management Guidelines (see 72 FR 31156, June 5, 2007) may be subject to Eagle Act prosecution. Eagle Act permits should be expedited for recipients of such technical assistance letters.

Service response: Technical assistance letters could not and did not provide any authorization to take eagles. The only means available to gain authorization to take eagles under the ESA was by means of a permit issued under section 10 or an incidental take statement issued under section 7. The role of technical assistance letters was to inform the landowner or project proponent that the Service did not consider take likely to occur. Generally we issued these letters after providing technical assistance to the project proponent that included recommended modifications to the planned activity to minimize the possibility of take, and after the project proponent agreed to incorporate the measures. Technical assistance letters do not authorize take should it occur despite the recommended measures; only a permit or incidental take statement could absolve a person of liability for take of eagles. In situations where these letters were issued and the activity proceeds, there is no Eagle Act violation unless an eagle is disturbed or otherwise taken, regardless of whether the activity was consistent or not with the National Bald Eagle Management Guidelines.

If take does occur, the Service is unlikely to prioritize enforcement actions against a party that followed the

Service's written advice (in the form of the technical assistance letter) regarding what steps were necessary to avoid taking eagles. Furthermore, although take of bald eagles under the Eagle Act can be authorized only by permit, it is not our goal to encourage applications for permits to cover take of eagles that is in fact very unlikely to occur. We believe our conservation mission is best served by helping the public reduce the likelihood of take, and to provide permits in appropriate circumstances where take is likely (and cannot practicably be avoided).

Comment 10: The Service should issue immediate guidance regarding prospective applicants who were in the midst of the HCP process when the bald eagle was delisted. The guidance should provide methods and standards for applicants to follow pending adoption of final take permit rules. Applicants who conform to the process should be given written assurances that the Service will not prosecute for eagle take, and the final rule should provide a means to convert that assurance into a permit.

Service response: This final rule provides a resolution of the issue raised by the commenter for most situations where project proponents were in the midst of developing an HCP that covered eagles when the bald eagle was delisted. The rule provides Eagle Act authorization for eagle take authorized under the ESA, including under future ESA section 10 permits.

However, there are some parties whose uncompleted HCPs were going to cover bald eagles but no other ESA-listed species, and they are no longer able to obtain a section 10 permit under the ESA for delisted eagles and cannot apply for take authorization under the Eagle Act until we finalize our proposed Eagle act take permit regulations. We recognize the difficult position in which these parties find themselves, having expended some effort towards development of HCPs and permit conditions for purposes of obtaining take authorization for bald eagles under the ESA. The best solution is that we expeditiously complete the new permit rule discussed above.

The difficulty with issuing the type of guidance the commenter suggests is that the handful of applicants in this position had reached different stages of the process at the time of bald eagle delisting. A few had nearly finalized development of appropriate minimization, mitigation, and conservation measures, but others had not. Because specific measures are needed in each particular situation to ensure impacts to eagles will be adequately mitigated, general guidance—other than what we provide in the National Bald Eagle Management Guidelines (e.g., how to avoid take)—would not be appropriate. For the handful of applicants who were engaged in the HCP process *and cannot avoid taking eagles*, we recommend that each such party continue working with our Ecological Services Field Office to implement measures that will minimize take until a means of Eagle Act authorization becomes available. The Service focuses its enforcement resources on investigating and prosecuting individuals and companies that take migratory birds without regard for the consequences of their actions and the law, especially when available conservation measures have not been implemented.

Comment 11: The statement that certain section 10 permits are ''null and void'' upon delisting should be struck because the minimization and mitigation measures are still required. Also, some of these permits contain the provision that the bald eagle will be covered if re-listed in the future.

Service response: We addressed this issue in the preamble discussion above: We do not consider certain section 10 permits to be ''null and void'' because eagles were the only listed species they covered. Rather, those permits are ''ineffective for purposes of providing ESA authorization.'' The commenter is technically incorrect in saying that HCPs that covered bald eagles as the only ESA-listed species contain the provision that the bald eagle will be covered if (delisted and) re-listed in the future. Neither the HCP, nor the permit, nor any implementing agreement included that specific provision. However, even without such a provision, the result is the same: If the bald eagle is re-listed for any reason in the future, we would recognize those permits as valid (within the timeframe for which the original permit was valid). Therefore, the single-species section 10 permit is not null and void, and can be treated under this rulemaking in the same manner as a section 10 permit associated with a multi-species HCP. The validity of the permit for both Eagle Act authorization and for future authorization under the ESA continues to be predicated on the permittee's compliance with the terms and conditions of the ESA permit.

Furthermore, the commenter is correct in noting that, even while the bald eagle remains off the List of Endangered and Threatened Wildlife and the single-species permit is ''inactive'' or ''quiescent'' for ESA purposes, if post-delisting take of bald eagles occurs, the permittee remains responsible for required minimization or mitigation measures that pertain to bald eagles in order to avoid liability under the Eagle Act.

Required Determinations

Energy Supply, Distribution or Use (E.O. 13211)

On May 18, 2001, the President issued Executive Order 13211, which addresses regulations that affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions.

This rule is not expected to significantly affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Regulatory Planning and Review (E.O. 12866)

The Office of Management and Budget (OMB) has determined that this rule is not significant under Executive Order 12866 (E.O. 12866). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever a Federal agency publishes 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) (5 U.S.C. 601 *et seq.*). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a

threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities.

This rule may benefit a variety of small businesses, including real estate developers and brokers; construction companies; forestry and logging, farming, and ranching operations; tourism companies; utility companies; and others who were previously granted authorization to incidentally take eagles under the ESA. However, the benefits are more legal in nature than economic because this rule provides legal coverage under the Eagle Act for activities that are underway and proceeding under assurances provided by the Service that it would use enforcement discretion with regard to the Eagle Act as long as the activities are conducted under the terms and conditions of ESA authorizations. The Eagle Act authorizations will apply to the same activities for which these assurances had been provided a connection with an ESA authorization. Thus, additional economic benefits will not be significant.

The Department of the Interior certifies that this rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Will not have an annual effect on the economy of $100 million or more. The principal economic effect of the rule would be to remove uncertainty and facilitate transactions related to activities that may incidentally take bald eagles, where the take had been authorized until the bald eagle was delisted under the ESA. Small entities that benefited from the issuance of permits under the ESA will continue to benefit from permits issued under this rule.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The permits issued under this regulation will not significantly affect costs or prices in any sector of the economy. The rule provides regulatory assurances under the Eagle Act for take that had previously been authorized under the ESA.

c. Will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This regulation establishes a mechanism to permit effects from activities within the United States that were already authorized under a different statute. Therefore, there is no anticipated negative economic effect to small businesses resulting from this rule.

Unfunded Mandates Reform Act

A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.) is not required.

a. This rule is not a significant regulatory action under the Unfunded Mandates Reform Act. A Small Government Agency Plan is not required. The permit regulations that are established through this rulemaking will not require actions on the part of small governments.

b. This rule is not a significant regulatory action under the Unfunded Mandates Reform Act. This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year.

Takings (E.O. 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. This rule will affect some private property insofar as it provides some land owners Eagle Act authorization for activities on their property that might incidentally take bald eagles, where the take was or is authorized under the ESA. A takings implication assessment is not required.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This rule will not interfere with the States' ability to manage themselves or their funds. Changes in the regulations governing the take of eagles should not result in significant economic impacts because this rule allows for the continuation of a current activity (take of eagles) albeit under a different statute (shifting from the ESA to the Eagle Act). A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

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) and 512 DM 2, we have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects. This rule will not interfere with Tribes' ability to manage themselves or their funds. This rule will not affect the process by which members of federally recognized tribes apply for and receive permits to possess eagle parts from the National Eagle Repository or permits to take eagles from the wild for religious purposes.

Paperwork Reduction Act

This rule does not contain new information collection under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). Any information we collect will be in the form of a certification and is therefore exempt from Paperwork Reduction Act requirements. We may not collect, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

National Environmental Policy Act

We have considered this action and determined that we do not need to prepare an environmental assessment (EA) or environmental impact statement (EIS) in association with the National Environmental Policy Act of 1969 because this action is categorically excluded from such analysis under the Department of the Interior's NEPA procedures at 516 DM 8.5(A)(1), which covers changes or amendments to an approved action when such changes have no or minor potential environmental impact. The authorizations provided under these regulations are ''approved actions'' and are being extended with no changes in most cases. If any permits are issued under these regulations with changed permit conditions (at the request of the holder of an ESA authorization) and the changed conditions have the potential for a more than minor impact, the permits will be subject to the NEPA assessment on a case-by-case basis before they are issued. Therefore, relative to those permits, this action is

categorically excluded under 516 DM 2, Appendix 1.1.

Endangered Species Act Considerations

Section 7(a)(2) of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 et seq.), requires all Federal agencies to ''insure that any action authorized, funded, or carried out * * * is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat.'' This rule provides authorizations for impacts that were already assessed under section 7 of the ESA and maintains the requirement to comply with the conservation measures prescribed under those assessments for listed species. This rule has no impact on endangered or threatened species.

List of Subjects

50 CFR Part 13

Administrative practice and procedure, Exports, Fish, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

50 CFR Part 22

Birds, Exports, Imports, Migratory birds, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

■ For the reasons described in the preamble, we amend subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 13—[AMENDED]

■ 1. The authority citation for part 13 continues to read as follows:

Authority: 16 U.S.C. 668a, 704, 712, 742j–1, 1374(g), 1382, 1538(d), 1539, 1540(f), 3374, 4901–4916; 18 U.S.C. 42; 19 U.S.C. 1202; 31 U.S.C. 9701.

■ 2. Amend § 13.11(d)(4) by adding an entry in the table as the last entry under ''Bald and Golden Eagle Protection Act'', to read as follows:

§ 13.11 Application procedures.

* * * * *

(d) * * *

(4) *User fees.* * * *

Type of permit	CFR citation	Fee	Amendment fee
* * * * *		*	*
Bald and Golden Eagle Protection Act			
* * * * *		*	*
Eagle Take—Exempted under ESA	50 CFR 22.		
* * * * *		*	*

* * * * *

■ 3. Amend § 13.12(b) by adding to the table the following entry in numerical order by section number under ''Eagle permits'' to read as follows:

§ 13.12 General information requirements on applications for permits.

* * * * *

(b) * * *

Type of permit	Section
* * * * *	
Eagle permits:	
* * * * *	
Eagle Take—Exempted under ESA	22.28
* * * * *	

PART 22—[AMENDED]

■ 4. The authority citation for part 22 is revised to read as follows:

Authority: 16 U.S.C. 668–668d; 16 U.S.C. 703–712; 16 U.S.C. 1531–1544.

■ 5. Amend § 22.1 by revising the first sentence to read as follows:

§ 22.1 What is the purpose of this part?

This part controls the taking, possession, and transportation within the United States of bald eagles (*Haliaeetus leucocephalus*) and golden eagles (*Aquila chrysaetos*) and their parts, nests, and eggs for scientific, educational, and depredation control purposes; for the religious purposes of American Indian tribes; and to protect other interests in a particular locality. * * *

■ 6. Amend § 22.11 as follows:

■ a. By revising the first sentence of the introductory text to read as set forth below;

■ b. By redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d); and

■ c. By adding a new paragraph (a) to read as set forth below.

§ 22.11 What is the relationship to other permit requirements?

You may not take, possess, or transport any bald eagle (*Haliaeetus leucocephalus*) or any golden eagle (*Aquila chrysaetos*), or the parts, nests, or eggs of such birds, except as allowed by a valid permit issued under this part, 50 CFR part 13, 50 CFR part 17, and/or 50 CFR part 21 as provided by § 21.2, or authorized under a depredation order issued under subpart D of this part. * * *

(a) A permit that covers take of bald eagles or golden eagles under 50 CFR part 17 for purposes of providing prospective or current ESA authorization constitutes a valid permit issued under this part for any take authorized under the permit issued under part 17 as long as the permittee is in full compliance with the terms and conditions of the permit issued under part 17. The provisions of part 17 that originally applied will apply for purposes of the Eagle Act authorization, except that the criterion for revocation of the permit is that the activity is incompatible with the preservation of the bald eagle or the golden eagle rather than inconsistent with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv).

* * * * *

■ 7. Amend part 22, subpart C, by adding new § 22.26, § 22.27 and § 22.28 to read as follows:

Subpart C—Eagle Permits

* * * * *

§ 22.26 [Reserved]

§ 22.27 [Reserved]

§ 22.28 Permits for bald eagle take exempted under the Endangered Species Act.

(a) *Purpose and scope.* This permit authorizes take of bald eagles (*Haliaeetus leucocephalus*) in compliance with the terms and conditions of a section 7 incidental take statement under the Endangered Species Act of 1973, as amended (ESA) (16 U.S.C. 1531 et seq.; 50 CFR 402, Subpart B).

(b) *Issuance Criteria.* Before issuing you a permit under this section, we must find that you are in full compliance with the terms and conditions contained in the applicable ESA incidental take statement for take of eagles, based on your certification and any other relevant information available to us, including, but not limited to, monitoring or progress reports required pursuant to your incidental take statement. The terms and conditions of the Eagle Act permit under this section, including any modified terms and conditions, must be compatible with the preservation of the bald eagle.

(c) *Permit conditions.* (1) You must comply with all terms and conditions of the incidental take statement issued under section 7 of the ESA, or modified measures specified in the terms of your permit issued under this section. At permit issuance or at any time during its tenure, the Service may modify the terms and conditions that were included in your ESA incidental take statement, based on one or more of the following factors:

(i) You requested and received modified measures because some of the requirements for take authorization under the ESA were not necessary for take authorization under the Eagle Act;

(ii) The amount or extent of incidental take authorized under the take statement is exceeded;

(iii) New information reveals effects of the action that may affect eagles in a manner or to an extent not previously considered, and requires modification of the terms and conditions to ensure the preservation of the bald eagle or the golden eagle; or

(iv) The activity will be modified by the permittee in a manner that causes effects to eagles that were not previously considered and which requires modification of the terms and conditions in the incidental take statement in order to ensure the preservation of the bald eagle or the golden eagle.

(2) During any period when the eagles covered by your incidental take statement are listed under the ESA, you must comply with the terms and conditions of both the incidental take statement and the permit issued under this section.

(d) *Permit duration.* The permit will be valid until the action that will take eagles, as described in the incidental take statement or modified to condition the permit issued under this section, is completed, as long as the permittee complies with the terms and conditions of the permit, including any modified terms and conditions.

(e) *Applying for an eagle take permit.* (1) Your application must consist of a copy of the applicable section 7 incidental take statement issued pursuant to the Endangered Species Act (ESA), and a signed certification that you are in full compliance with all terms and conditions of the ESA incidental take statement.

(2) If you request reevaluation of the terms and conditions required under your previously granted ESA incidental take statement for eagles, you must include a description of the modifications you request, and an explanation for why you believe the original conditions or measures are not reasonably justified to offset the detrimental impact of the permitted activity on eagles.

(3) Send completed permit applications to the Regional Director of the Region in which the disturbance would occur—Attention: Migratory Bird Permit Office. You can find the current addresses for the Regional Directors in § 2.2 of subchapter A of this chapter.

Dated: April 22, 2008.

Lyle Laverty,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–11091 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–P

Proposed Rules

Federal Register
Vol. 73, No. 98
Tuesday, May 20, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0562; Directorate Identifier 2008–NM–010–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been found cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by June 19, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal: Go to http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kenny Kaulia, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2848; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0562; Directorate Identifier 2008–NM–010–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directives 2007–11–01 and 2007–11–02, both dated December 12, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

It has been found cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

Corrective actions include inspecting for the presence of and, if necessary, installing pressure equalization valves. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Embraer has issued Service Bulletins 170–21–0032 and 190–21–0019, both dated August 10, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a **NOTE** within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 101 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to

comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $8,080, or $80 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA–2008–0562; Directorate Identifier 2008–NM–010–AD.

Comments Due Date

(a) We must receive comments by June 19, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Embraer Model ERJ 170–100 LR, –100 STD, –100 SE, and –100 SU, –200 LR, –200 STD, and –200 SU airplanes, having serial numbers (S/N) 17000002, 17000004 through 17000013, and 17000015 through 17000154; and Model ERJ 190–100 STD, –100 LR, –100 IGW, –100 ECJ, –200 STD, –200 LR, and –200 IGW airplanes, having S/N 19000002, 19000004, and 19000006 through 19000060; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 21: Air Conditioning.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

It has been found in cases where the pressure equalization valve was not installed in the left-hand bulkhead blowout panel, on the forward and/or aft cargo compartments, thus affecting the effectiveness of fire detection, containment and suppression.

Corrective actions include inspecting for the presence of and, if necessary, installing pressure equalization valves.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within 500 flight hours after the effective date of this AD, perform a general visual inspection on the left-hand bulkhead blowout panel of both the forward and aft cargo compartments to determine whether the pressure equalization valves, part number (P/N) 120–48865–003, are installed. If both pressure equalization valves are installed in their respective blowout panels, no additional action is required by this AD.

(2) If any valve is not installed, within 700 flight hours after the effective date of this AD, install valve P/N 120–48865–003, in accordance with the Accomplishment Instructions of Embraer Service Bulletin 170–21–0032 or 190–21–0019, both dated August 10, 2007; as applicable.

Note 1: For the purpose of this AD, a general visual inspection (GVI) is: ''A visual examination of an interior or exterior area, installation or assembly to detect obvious damage, failure or irregularity. This level of inspection is made from within touching distance, unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight or drop-light, and may require removal or opening of access panels or doors. Stands, ladders or platforms may be required to gain proximity to the area being checked.''

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Kenny Kaulia, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2848; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Brazilian Airworthiness Directives 2007–11–01 and 2007–11–02, both dated December 12, 2007; and Embraer Service Bulletins 170–21–0032 and 190–21–0019, both dated August 10, 2007; for related information.

Issued in Renton, Washington, on May 7, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11289 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0561; Directorate Identifier 2007–NM–223–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757–200 and –200PF Series Airplanes, and Model 767–200 and –300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 757–200 and –200PF series airplanes; and Model 767–200 and –300 series airplanes. This proposed AD would require doing an inspection to determine the part number and serial number of the hub assembly of the ram air turbine (RAT), and replacing the hub assembly of the RAT with a new, serviceable, or reworked and re-identified hub assembly if necessary. This proposed AD results from reports indicating that the counterweights in some hub assemblies of the RATs could be under strength and fracture when they are extended in flight. We are proposing this AD to prevent a fractured counterweight on the hub assembly of the RAT, which will cause an overspeed condition, and consequent turbine blade separation, possible injury to passengers, possible airplane structural damage, and an inoperative RAT. An inoperative RAT will cause the loss of hydraulic power to the primary flight controls in cases where both engines are shut down in flight, resulting in subsequent loss of control of the airplane.

DATES: We must receive comments on this proposed AD by July 7, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kenneth Frey, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6468; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0561; Directorate Identifier 2007–NM–223–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received reports indicating that the counterweights in some hub assemblies of the ram air turbine (RAT) could be under strength and fracture when they are extended in flight, on certain Boeing Model 757–200 and –200PF series airplanes and Model 767–200 and –300 series airplanes. The cause of the fractures has been attributed to a manufacturing process error. A fractured counterweight on the hub assembly of the RAT, if not corrected, will cause an overspeed condition, and consequent turbine blade separation, possible injury to passengers, possible airplane structural damage, and an inoperative RAT. An inoperative RAT will cause the loss of hydraulic power to the primary flight controls in cases where both engines are shut down in flight, resulting in subsequent loss of control of the airplane.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 757–29A0066, dated January 2, 2007 (for Model 757–200 and –200PF series airplanes); and Boeing Alert Service Bulletin 767–29A0110, dated January 2, 2007 (for Model 767–200 and –300 series airplanes). The service bulletins describe procedures for doing an inspection to determine the part number and serial number on the hub assembly of the RAT, replacing the hub assembly of the RAT with a new, serviceable, or reworked and re-identified hub assembly if necessary, and submitting a report to the manufacturer. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

Boeing Alert Service Bulletin 757–29A0066, refers to the Hamilton Sundstrand Service Bulletin 730814–29–12, dated November 30, 2005; and Boeing Alert Service Bulletin 767–29A0110, refers to the Hamilton Sundstrand Service Bulletin 729548–29–15, dated November 30, 2005; as additional sources of service information for accomplishing the inspection and replacement of the hub assembly of the RAT.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. For this reason, we are proposing this AD, which would require accomplishing the actions specified in the Boeing service information described previously, except as discussed under ''Difference between the Proposed Rule and Referenced Service Bulletin.''

Difference Between Proposed Rule and Referenced Service Bulletin

Operators should note that, although the Accomplishment Instructions of the referenced Boeing service bulletins describe procedures for submitting a feedback form related to the service bulletins, this proposed AD would not require those actions.

Costs of Compliance

There are about 60 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 43 airplanes of U.S. registry. The proposed inspection would take about 1 work hour per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $3,440, or $80 per airplane.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Boeing: Docket No. FAA–2008–0561; Directorate Identifier 2007–NM–223–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by July 7, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing airplanes identified in Table 1 of this AD, certified in any category.

TABLE 1.—APPLICABILITY

For model—	As identified in—
(1) 757–200 and –200PF series airplanes	Boeing Alert Service Bulletin 757–29A0066, dated January 2, 2007.
(2) 767–200 and –300 series airplanes	Boeing Alert Service Bulletin 767–29A0110, dated January 2, 2007.

Unsafe Condition

(d) This AD results from reports indicating that the counterweights in some hub assemblies of the ram air turbines (RAT) could be under strength and fracture when they are extended in flight. We are issuing this AD to prevent a fractured counterweight on the hub assembly of the RAT, which will cause an overspeed condition, and consequent turbine blade separation, possible injury to passengers, possible airplane structural damage, and an inoperative RAT. An inoperative RAT will cause the loss of hydraulic power to the primary flight controls in cases where both engines are shut down in flight, resulting in subsequent loss of control of the airplane.

Compliance

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

Inspection and Replacement

(f) Within 24 months after the effective date of this AD, do an inspection to determine the part number and serial number on the hub assembly of the RAT in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 757–29A0066, dated January 2, 2007 (for Model 757–200 and –200PF series airplanes); or Boeing Alert Service Bulletin 767–29A0110, dated January 2, 2007 (for Model 767–200 and –300 series airplanes); as applicable. If the part number and serial number on the hub assembly of the RAT are listed in Table 2 of this AD, within 24 months after the effective date of this AD, replace the hub assembly of the RAT with a new, serviceable, or reworked and re-identified hub assembly, in accordance with the Accomplishment Instructions of the service bulletin.

Parts Installation

(g) As of the effective date of this AD, no person may install a hub assembly of the RAT having any applicable part number and serial number listed in Table 2 of this AD, on any airplane, unless it has been reworked and re-identified in accordance with paragraph (f) of this AD.

TABLE 2.—RAT HUB ASSEMBLY PART NUMBERS

For model—	Part No.—	Serial No.—
(1) 757–200 and –200PF series airplanes	733785A or 733785B	0410 through 0413 inclusive, 0415, 0417 through 0430, 0432, or 0434.
(2) 767–200 and –300 series airplanes	734350A, 734350B, 734350C, or 734350D	0666, 0673 through 0684 inclusive, 0686, 0687, or 0689.

No Information Submission

(h) Although Boeing Alert Service Bulletin 757–29A0066, dated January 2, 2007 (for Model 757–200 and –200PF series airplanes); and Boeing Alert Service Bulletin 767–29A0110, dated January 2, 2007 (for Model 767–200 and –300 series airplanes); specify to submit information to the manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

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

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

Issued in Renton, Washington, on May 7, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11286 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0558; Directorate Identifier 2007–NM–365–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Some operators have reported occurrences of loss of the AC BUS 1 with subsequent loss of the AC ESS BUS and DC ESS BUS, resulting in the loss of 5 upper Display Units and the loss of integral lighting. In this situation, flight crew[s] have reported concerns in reading the standby instruments when the DOME lights were selected to OFF.

This situation, if not corrected, could increase the workload of the flight crew * * *.

* * * * *

The unsafe condition is reduced ability of the flightcrew to maintain the safe flight and landing of the airplane in adverse operating conditions. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by June 19, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0558; Directorate Identifier 2007–NM–365–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued Airworthiness Directive 2007–0286, dated November 14, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

Some operators have reported occurrences of loss of the AC BUS 1 with subsequent loss of the AC ESS BUS and DC ESS BUS, resulting in the loss of 5 upper Display Units and the loss of integral lighting. In this situation, flight crews[s] have reported concerns in reading the standby instruments when the DOME lights were selected to OFF.

This situation, if not corrected, could increase the workload of the flight crew * * *.

This Airworthiness Directive (AD) mandates the modification of the electrical supply logic by adding a back-up supply on the battery hot bus for the under glare shield flood lighting.

The unsafe condition is reduced ability of the flightcrew to maintain the safe flight and landing of the airplane in adverse operating conditions. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued Service Bulletin A320–33–1057, dated May 11, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 550 products of U.S. registry. We also estimate that it would take about 30 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $1,320,000, or $2,400 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Airbus: Docket No. FAA–2008–0558; Directorate Identifier 2007–NM–365–AD.

Comments Due Date

(a) We must receive comments by June 19, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A318, A319, A320, and A321 airplanes, certificated in any category; all certified models; all serial numbers; on which classical standby instruments have been installed per AIRBUS Modification 20011 or 21999 in production, or per Airbus Service Bulletin A320–34–1280 in service; excluding airplanes identified in paragraphs (c)(1) or (c)(2) of this AD.

(1) Airplanes on which ISIS equipment was installed per AIRBUS Modification 27620 in production or per Airbus Service Bulletin A320–34–1261 or Airbus Service Bulletin A320–34–1372 in service.

(2) Airplanes on which AIRBUS Modification 37329 or 37330 was installed in production or per Airbus Service Bulletin A320–33–1057 in service.

Subject

(d) Air Transport Association (ATA) of America Code 33: Lights.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Some operators have reported occurrences of loss of the AC BUS 1 with subsequent loss of the AC ESS BUS and DC ESS BUS, resulting in the loss of 5 upper Display Units and the loss of integral lighting. In this situation, flight crews[s] have reported concerns in reading the standby instruments when the DOME lights were selected to OFF.

This situation, if not corrected, could increase the workload of the flight crew * * *.

This Airworthiness Directive (AD) mandates the modification of the electrical supply logic by adding a back-up supply on the battery hot bus for the under glare shield flood lighting.

The unsafe condition is reduced ability of the flightcrew to maintain the safe flight and landing of the airplane in adverse operating conditions.

Actions and Compliance

(f) Within 42 months after the effective date of this AD, unless already done: Modify the electrical supply logic of the under glare shield flood lighting in accordance with the instructions given in Airbus Service Bulletin A320–33–1057, dated May 11, 2007.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2007–0286, dated November 14, 2007, and Airbus Service Bulletin A320–33–1057, dated May 11, 2007, for related information.

Issued in Renton, Washington, on May 9, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11284 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0557; Directorate Identifier 2007–NM–364–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Falcon 2000EX Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During approach, a Falcon 2000EX operator experienced a temporary loss of the 4 Electronic Flight Instrumentation System (EFIS) display units followed by a consecutive restart of the avionics. During initial investigation, a loose connection on the DC load distribution system was discovered and determined to be the root cause of this event. However, further analysis pointed out that large electrical transients on the essential bus bar may possibly cause simultaneous and temporary power shortage on both sides of the electrical system.

This Airworthiness Directive (AD) * * * action is necessary to prevent a momentary loss of data on the EFIS screens, which could lead to the pilot's loss of situational awareness during initial climb or approach/landing, and possibly result in reduced control of the airplane. * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by June 19, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal*: Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0557; Directorate Identifier 2007–NM–364–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2007–0290, dated November 26, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

During approach, a Falcon 2000EX operator experienced a temporary loss of the 4 Electronic Flight Instrumentation System (EFIS) display units followed by a consecutive restart of the avionics. During initial investigation, a loose connection on the DC load distribution system was discovered and determined to be the root cause of this event. However, further analysis pointed out that large electrical transients on the essential bus bar may possibly cause simultaneous and temporary power shortage on both sides of the electrical system.

This Airworthiness Directive (AD) requires a wiring modification of the GCUs (Generator Control Units) to increase the electrical system robustness. This action is necessary to prevent a momentary loss of data on the EFIS screens, which could lead to the pilot's loss of situational awareness during initial climb or approach/landing, and possibly result in reduced control of the airplane. This action is intended to address the identified unsafe condition.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Dassault has issued Service Bulletin F2000EX–141, Revision 1, dated November 26, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use

different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect 57 products of U.S. registry. We also estimate that it would take 8 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $36,480, or $640 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Dassault Aviation: Docket No. FAA–2008–0557; Directorate Identifier 2007–NM–364–AD.

Comments Due Date

(a) We must receive comments by June 19, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Dassault Model Falcon 2000EX airplanes from serial number 1 to 107 inclusive, certificated in any category; which have not been modified by Dassault Service Bulletin (SB) F2000EX–141.

Subject

(d) Air Transport Association (ATA) of America Code 24: Electrical Power

Reason

(e) The mandatory continuing airworthiness information (MCAI) states: During approach, a Falcon 2000EX operator experienced a temporary loss of the 4 Electronic Flight Instrumentation System (EFIS) display units followed by a consecutive restart of the avionics. During initial investigation, a loose connection on the DC load distribution system was discovered and determined to be the root cause of this event. However, further analysis pointed out that large electrical transients on the essential bus bar may possibly cause simultaneous and temporary power shortage on both sides of the electrical system.

This Airworthiness Directive (AD) requires a wiring modification of the GCUs (Generator Control Units) to increase the electrical system robustness. This action is necessary to prevent a momentary loss of data on the EFIS screens, which could lead to the pilot's loss of situational awareness during initial climb or approach/landing, and possibly result in reduced control of the airplane. This action is intended to address the identified unsafe condition.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within 13 months after the effective date of this AD, modify the GCU electrical wiring as instructed in the Accomplishment Instructions of Dassault Service Bulletin F2000EX–141, Revision 1, dated November 26, 2007.

(2) Actions done prior to the effective date of this AD according to Dassault Service Bulletin F2000EX–141, dated February 16, 2007, are acceptable for compliance with the corresponding requirements of this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2007–

0290, dated November 26, 2007, and Dassault Service Bulletin F2000EX–141, Revision 1, dated November 26, 2007, for related information.

Issued in Renton, Washington, on May 8, 2008.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–11282 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic Atmospheric Administration

15 CFR Part 923

[Docket No. 080416573–8574–01]

RIN 0648–AW74

Changes to the Coastal Zone Management Act Program Change Procedures

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic Atmospheric Administration (NOAA), Department of Commerce (Commerce).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: NOAA intends to replace the Coastal Zone Management Act (CZMA) program change regulations (15 CFR part 923, subpart H) and associated guidance (OCRM's Program Change Guidance (July 1996)) with new regulations at 15 CFR part 923, subpart H. This notice requests public comment on the CZMA program change process that NOAA should consider when developing a proposed rule to replace 15 CFR part 923, subpart H.

DATES: Comments on this notice must be received by August 18, 2008.

ADDRESSES: Please send comments as an attachment to an e-mail in MS Word (WordPerfect is also acceptable), or in the body of an e-mail, to *CZMA.ProgramChanges.ANPR@noaa.gov.* Address all comments regarding this notice to Mr. Kerry Kehoe, Federal Consistency Specialist, Coastal Programs Division, Office of Ocean and Coastal Resource Management, NOAA, 1305 East-West Highway, 11th Floor, Silver Spring, MD 20910. Attention: CZMA Program Change Comments. Written comments may also be sent to this address.

All comments received by the comment deadline and this **Federal Register** notice will be posted at OCRM's federal consistency Web page at: *http://coastalmanagement.noaa.gov/consistency/rule.html.*

FOR FURTHER INFORMATION CONTACT: Kerry Kehoe, Federal Consistency Specialist, 301–713–3155 ext. 151, Office of Ocean and Coastal Resource Management, NOAA.

SUPPLEMENTARY INFORMATION:

I. Background

The CZMA (16 U.S.C. 1451–1465) was enacted on October 27, 1972, to encourage coastal States, Great Lake States, and United States Territories and Commonwealths (collectively referred to as ''coastal States'' or ''States'') to be proactive in managing the uses and resources of the coastal zone for their benefit and the benefit of the Nation. The CZMA recognizes a national interest in the uses and resources of the coastal zone and in the importance of balancing the competing uses of coastal resources. The CZMA is a voluntary program for States. If a State elects to participate it must develop and implement a coastal management program (CMP) pursuant to federal requirements. See CZMA section 306(d)(16 U.S.C. 1455(d)); 15 CFR part 923. State CMPs are comprehensive management plans that describe the uses subject to the management program, the authorities and enforceable policies of the management program, the boundaries of the State's coastal zone, the organization of the management program, and related State coastal management concerns. Thirty-five coastal States are eligible to participate in the federal coastal management program. Thirty-four of the eligible States have federally approved CMPs.

An important component of the CZMA program is that State CMPs are developed with the full participation of state and local agencies, industry, the public, other interested groups and Federal agencies. See *e.g.*, 16 U.S.C. 145 1(i) and (m), 1452(2)(H) and (I), 1452(4) and (5), 1455(d)(1) and (3)(B), and 1456. Program changes are changes to NOAA-approved components of State CZMA programs and new program components. There are five program approval areas (includes related changes to, or new, enforceable policies related to the five areas).

The five areas are:

1. Uses subject to program;
2. Coastal zone boundaries;
3. National interest;
4. Special Area Management Plans; and
5. Authorities & Organization.

Program changes are important for several reasons. The statute requires submission to NOAA and NOAA approval (16 U.S.C. 1455(e)); state programs are not static; laws and issues change requiring continual operation of the CZMA State-Federal partnership. The State-Federal partnership is a cornerstone of the CZMA. The primacy of state CZMA decisions and the CZMA federal consistency requirement is balanced with adequate consideration national interest components, Federal agency input into the content of State programs, and NOAA approval.

In their federally approved CMPs and state CZMA decisions states must consider national interest areas of the CZMA to benefit national, not just local interests. In addition to the national interest in comprehensive coastal management by states, states must give priority consideration to coastal dependant national interest activities: Defense, energy, ports, transportation. For example, some of the more important issues NOAA must consider when evaluating program changes include whether the proposed change would: Affect CZMA national interest areas; seek to regulate federal agencies or areas outside state jurisdiction; be preempted by federal law; discriminate against particular coastal users or federal agencies; be enforceable under State law; raise issues under the National Environmental Policy Act (NEPA), Endangered Species Act (ESA), National Historic Preservation Act (NHPA), etc.

Program changes are also important because the CZMA has a strong public participation role, combined with the State-Federal partnership. NOAA can only approve CMPs and changes to CMPs after Federal agencies and the public have an opportunity to comment on whether proposed new or revised ''enforceable policies'' are appropriate under the CZMA authority and other federal and state legal requirements. An enforceable policy is a State policy that is legally binding under State law (*e.g.*, through constitutional provisions, laws, regulations, land use plans, ordinances, or judicial or administrative decisions) and by which a State exerts control over private and public coastal uses and resources, and which are incorporated in a State's federally approved CMP. See 16 U.S.C. 1453(6a). This means that enforceable policies must be given legal effect by State law and cannot apply to Federal lands, Federal waters, Federal agencies or other areas or entities outside a State's jurisdiction, unless authorized by Federal law. Also, the CZMA section 307 federal consistency provision requires that state enforceable policies are the standards that apply to Federal agency activities, federal license

or permit activities, outer continental shelf plans and federal financial assistance activities. 16 U.S.C. 1456. Therefore, Federal agencies and the public must have an opportunity to review proposed changes to a State's enforceable policies.

Program changes are also important because the CZMA federal consistency provision is triggered only if the federal action has reasonably foreseeable coastal effects and a State has applicable policies approved by NOAA that are legally enforceable under state law. It is therefore important for states to submit to NOAA for approval timely updates to CZMA enforceable policies.

II. Need for Revised Program Change Regulations

The current program change regulations, 15 CFR part 923, subpart H, have been in place since the late 1970's. In 1996, NOAA made minor revisions to the regulations and also issued program change guidance that further elaborated on program change requirements. Over the years, states and NOAA have, at times, found the regulations difficult to interpret. For example, determining: When a program change is ''routine'' or an ''amendment;'' when a program change is ''substantial;'' what level of state analysis is required; when preliminary approval can be granted by NOAA.

In addition, the CZMA was revised in 1990, in part, to place greater emphasis on state CMP enforceable policies. This has led to the submission to NOAA of many more updates to CMPs. This increase in program change submissions has furthered the complexities of the current program change regulations. States and NOAA have, therefore, recognized the need to clarify the program change procedures and to provide a more administratively efficient submission and review process, while still addressing the importance of program changes, as discussed above.

III. Action Requested From the Public

NOAA requests input from states, federal agencies and the public on revised program change regulations. Some of NOAA's goals in revising the program change regulations that reviewers should consider are:

1. Establishing a clearer and more efficient and transparent process for program change review;

2. Describing clearer approval/disapproval criteria and how these apply;

3. Using the statutory language of the CZMA, including time lines, extensions, and preliminary approval;

4. Keeping the ''routine'' concept to streamline the process for truly routine changes, but do away with ''routine program changes (RPCs)'' and ''Amendments'' and replace with just ''program changes;''

5. Removing the ''substantial'' evaluations currently done by states and replace with just describing what the change is to the program. Further evaluations (by states or NOAA) would be for specific CZMA, NEPA, ESA, NHPA, etc., purposes, *e.g.*, is a NEPA Environmental Assessment or Environmental Impact Statement, or ESA consultation needed;

6. Establishing use of NEPA categorical exclusions;

7. Submitting underline/strikeout documents showing changes to previously approved policies; and

8. Creating a program change checklist that states would submit to ease state and NOAA paperwork burdens and promote consistent submissions and NOAA analyses.

Comments received by NOAA will help to develop a proposed rule for 15 CFR part 923, subpart H. Any proposed changes to the CZMA program change regulations would be published in the **Federal Register** following compliance with the Administrative Procedure Act and other relevant statutes and executive orders.

Dated: May 13, 2008.

John H. Dunnigan,

Assistant Administrator for Oceans and Coastal Zone Management.

[FR Doc. E8–11064 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

33 CFR Part 385

Programmatic Regulations for the Comprehensive Everglades Restoration Plan

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of initiation of rule review.

SUMMARY: The Army has initiated a review of the programmatic regulations for the Comprehensive Everglades Restoration Plan required by section 601(h)(3)(E) of the Water Resources Development Act of 2000. As part of scoping the review for the regulations, the public is invited to provide comments on this review. Specifically, we welcome your comments on issues concerning the programmatic regulations, any items in the regulations that should be reviewed, or suggestions to improve the programmatic regulations.

DATES: We will accept comments until August 18, 2008.

ADDRESSES: If you wish to comment on the review of the programmatic regulations, you may submit your comments by either of these methods:

1. You may submit written comments to: U.S. Army Corps of Engineers, ATTN: Stu Appelbaum, P.O. Box 4970, Jacksonville, FL 32232–0019.

2. You may send comments by electronic mail (e-mail) to: *ProRegs@usace.army.mil.*

If submitting comments by electronic format, please submit them in ASCII file format or Word file format and avoid the use of special characters and any form of encryption. Please include your name and return e-mail address in your e-mail message. Please note that your e-mail address will not be retained at the termination of the public comment period.

FOR FURTHER INFORMATION CONTACT: Stu Appelbaum, Corps of Engineers, Jacksonville District, P.O. Box 4970, Jacksonville, FL 32232–0019, phone (904) 232–2584; fax (904) 232–1251.

SUPPLEMENTARY INFORMATION: On November 12, 2003 the Department of the Army published the final rule in the **Federal Register** that established the programmatic regulations required by the Water Resources Development Act of 2000 as 33 CFR Part 385. Section 601(h)(3)(E) of the Water Resources Development Act of 2000 requires that the Secretary of the Army review the programmatic regulations whenever necessary, but at least every five years. Section 385.6 of the programmatic regulations requires that upon completing the review of the regulations, the Secretary of the Army will promulgate any revisions to the regulations after notice and opportunity for public comment in accordance with applicable law, with the concurrence of the Secretary of the Interior and the Governor, and in consultation with the Seminole Tribe of Florida, the Miccosukee Tribe of Indians of Florida, the Administrator of the Environmental Protection Agency, the Secretary of Commerce, and other Federal, State, and local agencies.

The first step of the review process is to scope out issues and concerns. The public is invited to provide comments on the review of the programmatic regulations. We welcome the public to tell us about specific issues that should

be addressed or suggestions to improve the programmatic regulations. We will be providing additional opportunities for public involvement throughout the review process. An electronic copy of the current programmatic regulations is available at: *http://www.evergladesplan.org/pm/progr_regs_final_rule.aspx*.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–11250 Filed 5–19–08; 8:45 am]

BILLING CODE 3710–AJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA–HQ–OAR–2006–0735; FRL–8563–7]

RIN 2060–AN83

Public Hearings for National Ambient Air Quality Standards for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public hearings.

SUMMARY: The EPA is announcing two public hearings to be held for the proposed rule ''National Ambient Air Quality Standards for Lead'' which is published elsewhere in this **Federal Register**. The hearings will be held concurrently in Baltimore, Maryland and St. Louis, Missouri on Thursday, June 12, 2008.

In the notice of proposed rulemaking, EPA describes making revisions to the primary and secondary national ambient air quality standards (NAAQS) for lead to provide requisite protection of public health and welfare, respectively, to make corresponding revisions in data handling procedures and ambient air monitoring and reporting requirements for lead, and to provide guidance on its proposed approach for implementing the proposed revised primary and secondary standards for lead.

DATES: The public hearings will be held on June 12, 2008. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the public hearings.

ADDRESSES: The hearings will be held at the following locations:

1. *Baltimore:* Tremont Grand Historic Venue, 225 North Charles Street, Baltimore, Maryland 21201, telephone (443) 573–8444. The hearing will be held in The Marble Room on the First Floor of the hotel.

2. *St. Louis:* Omni Majestic Hotel, 1019 Pine Street, St. Louis, Missouri 63101, telephone (314) 436–2355. The hearing will be held in Salon A and B.

Written comments on this proposed rule may also be submitted to EPA electronically, by mail, by facsimile, or through hand delivery/courier. Please refer to the notice of proposed rulemaking for the addresses and detailed instructions for submitting written comments.

A complete set of documents related to the proposal is available for public inspection at the EPA Docket Center, located at 1301 Constitution Avenue, NW., Room 3334, Washington, DC between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying. Documents are also available through the electronic docket system at *http://www.regulations.gov*.

The EPA Web site for the rulemaking, which includes the proposal and information about the public hearings can be found at: *http://www.epa.gov/air/lead/actions.html.*

FOR FURTHER INFORMATION CONTACT: If you would like to speak at the public hearings or have questions concerning the public hearings, please contact Ms. Tricia Crabtree at the address given below under **SUPPLEMENTARY INFORMATION.**

Questions concerning the ''National Ambient Air Quality Standards for Lead'' proposed rule should be addressed to Dr. Deirdre Murphy, U.S. EPA, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division (C504–06), Research Triangle Park, NC 27711, telephone (919) 541–0729, e-mail: *Murphy.deirdre@epa.gov*.

SUPPLEMENTARY INFORMATION: The proposal for which EPA is holding the public hearings is published elsewhere in this **Federal Register** and is also available on the following Web site: *http://www.epa.gov/air/lead/actions.html.*

The public hearings will provide interested parties the opportunity to present data, views, or arguments concerning the proposed rules. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearings. Written comments must be received by the last day of the comment period, as specified in the proposal.

The two public hearings will be held concurrently in Baltimore, Maryland and St. Louis, Missouri on June 12, 2008. The public hearings will begin each day at 9 a.m. and continue into the evening until 9 p.m. (local time) or later, if necessary, depending on the number of speakers wishing to participate. The EPA will make every effort to accommodate all speakers that arrive and register before 9 p.m. The EPA is scheduling lunch breaks from 12:30 p.m. until 2 p.m. and dinner breaks from 6 p.m. until 7:30 p.m. If you would like to present oral testimony at the hearings, please notify Ms. Tricia Crabtree (C504–02), U.S. EPA, Research Triangle Park, NC 27711. The preferred method for registering is by e-mail (*crabtree.tricia@epa.gov*). Ms. Crabtree may be reached by telephone at (919) 541–5688. She will arrange a general time slot for you to speak. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearings.

Oral testimony will be limited to five (5) minutes for each commenter to address the proposal. We will not be providing equipment for commenters to show overhead slides or make computerized slide presentations unless we receive special requests in advance. Commenters should notify Ms. Crabtree if they will need specific audiovisual (AV) equipment. Commenters should also notify Ms. Crabtree if they need specific translation services for non-English speaking commenters. The EPA encourages commenters to provide written versions of their oral testimonies either electronically on computer disk or CD ROM or in paper copy.

The hearing schedules, including lists of speakers, will be posted on EPA's Web site for the proposal at *http://www.epa.gov/air/lead/actions.html* prior to the hearings. Verbatim transcripts of the hearings and written statements will be included in the rulemaking dockets.

How Can I Get Copies Of This Document and Other Related Information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2006–0735. The EPA has also developed a Web site for lead NAAQS materials, including the notice of proposed rulemaking, at the address given above. Please refer to the notice of proposed rulemaking for detailed information on accessing information related to the proposal.

Dated: April 29, 2008.

Jennifer Edmonds,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. E8–10812 Filed 5–19–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 88

RIN 0991–AB46

Office of Global Health Affairs; Regulation on the Organizational Integrity of Entities Implementing Leadership Act Programs and Activities

AGENCY: Department of Health and Human Services.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a technical error that appeared in the Notice of Proposed Rulemaking (NPRM) on April 17, 2008, entitled ''Organizational Integrity of Entities Implementing Leadership Act Programs and Activities.''

FOR FURTHER INFORMATION CONTACT: William R. Steiger, PhD, Office of Global Health Affairs, Hubert H. Humphrey Building, Room 639H, 200 Independence Avenue, SW., Washington, DC 20201.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 08–1147 of April 17, 2008 (73 FR 20900), there was a technical error that is identified and corrected in the Correction of Errors section below. The provisions in this correction notice are applicable as if they had been included in the document published April 17, 2008. Accordingly, the corrections are applicable May 20, 2008.

We inadvertently omitted the words ''has objective integrity and independence'' from section 88.3(d)(1), which describes the required certification that recipients must submit. We are also correcting the Executive Order 12866—Regulatory Planning and Review section beginning with the second paragraph to read ''the'' instead of ''this''. We are correcting the errors by republishing the corrected paragraph in this section of the proposed rule.

II. Correction of Errors

In FR Doc. 08–1147 of April 17, 2008 (73 FR 20900), make the following corrections:

On Page 20902, in the last column; second paragraph of the Executive Order 12866—Regulatory Planning and Review section, replace the word ''This'' with ''The''. The corrected paragraph should read:

''The benefits of this rule are to ensure that an appropriate separation exists. * * * ''

On page 20904, in the second column; in the last paragraph, insert ''has objective integrity and independence'' before ''as defined in 45 CFR part 88, from any * * *'' The corrected paragraph should read:

(1) Organizational Integrity Certification: ''I hereby certify that [name of recipient], a recipient of the funds made available through this [grant, cooperative agreement, contract, or other funding instrument], has objective integrity and independence as defined in 45 CFR part 88, from any affiliated organization that engages in activities inconsistent with a policy opposing prostitution and sex trafficking.''

Dated: May 8, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E8–10890 Filed 5–19–08; 8:45 am]

BILLING CODE 4150–38–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R2–ES–2008–0059; 1111 FY07 MO–B2]

Endangered and Threatened Wildlife and Plants; Initiation of Status Review for the Bald Eagle (Haliaeetus leucocephalus) in the Sonoran Desert Area of Central Arizona and Northwestern Mexico

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; initiation of status review and solicitation of new information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the initiation of a status review for the bald eagle (*Haliaeetus leucocephalus*) in the Sonoran Desert area of central Arizona and northwestern Mexico, hereafter referred to as the ''Sonoran Desert area bald eagle.'' Through this action, we encourage all interested parties to provide us with information regarding the status of, and any potential threats to, the Sonoran Desert area bald eagle.

DATES: To allow us adequate time to conduct this review, we request that information be submitted on or before July 7, 2008.

ADDRESSES: You may submit information by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R2–ES–2008–0059; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Information Solicited section below for more information).

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor, Arizona Ecological Services Office, 2321 West Royal Palm Road, Suite 103, Phoenix, AZ 85021–4951; telephone 602–242–0210; facsimile 602–242–2513. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Information Solicited

To ensure that the status review is complete and based on the best available scientific and commercial information, we are soliciting information concerning the status of the Sonoran Desert area bald eagle (*Haliaeetus leucocephalus*). Information gained during this process will be used to evaluate whether the Sonoran Desert area bald eagle is a Distinct Population Segment (DPS) as described in our policy on determining a DPS (61 FR 4722, February 7, 1996) (DPS), and if listing as threatened or endangered is warranted under the Endangered Species Act of 1973, as amended (Act). If we determine that listing the Sonoran Desert area bald eagle is warranted, we intend to propose critical habitat to the maximum extent prudent and determinable at the time we prepare a proposed listing rule.

At this time, we request any additional information from the public, other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties on the status of the Sonoran Desert area bald eagle, including:

(1) Information regarding Sonoran Desert area bald eagles' historical and current population status, distribution, and trends; biology and ecology; and habitat selection. We also solicit information of this type on adjacent populations and geographic areas for use in evaluating discreteness and significance of the Sonoran Desert area bald eagle.

(2) Information that supports or refutes the appropriateness of

considering the Sonoran Desert area bald eagle to be discrete, as defined in the Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722, February 7, 1996), including, but not limited to:

(a) Information indicating that Sonoran Desert area bald eagles are markedly separated from other populations of bald eagles due to physical, physiological, ecological, or behavioral factors. This may include information regarding bald eagles of Sonoran Desert area natal origin breeding with bald eagles from populations of different natal origin, and information regarding the Sonoran Desert area bald eagles' isolation from other breeding populations of eagles.

(b) Information indicating whether or not the Sonoran Desert area bald eagle is delimited by international governmental boundaries within which significant differences in control of exploitation, management of habitat, conservation status, or regulatory mechanisms exist.

(3) Information that supports or refutes the appropriateness of considering the Sonoran Desert area bald eagle to be significant, as defined in the Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (61 FR 4722, February 7, 1996) including, but not limited to:

(a) Information indicating that the ecological setting, including such factors as temperature, moisture, weather patterns, plant communities, etc., in which the Sonoran Desert area bald eagle persists is unusual or unique when compared to that of bald eagles found elsewhere in the United States or Mexico. This may also include information indicating that the Sonoran Desert area bald eagle has or has not developed adaptations to that unique environment, such as breeding behavior, morphological characteristics, egg development and characteristics, or nest types.

(b) Information indicating that loss of Sonoran Desert area bald eagle would or would not result in a significant gap in the range of the taxon.

(c) Information indicating that the Sonoran Desert area bald eagle differs markedly from other populations of bald eagles in its genetic characteristics.

(4) Information regarding the availability of suitable, but unoccupied, breeding habitat that might allow for expansion of the Sonoran Desert area bald eagle populations. This may include information on areas outside of the boundaries delineated for the Sonoran Desert area bald eagle in our May 1, 2008, final listing rule (73 FR 23966).

(5) Information on the effects of potential threat factors that are the basis for a listing determination under section 4(a) of the Act, which are:

(a) The present or threatened destruction, modification, or curtailment of the Sonoran Desert area bald eagle's breeding habitat or range, including but not limited to the effects on habitat from: Water management (river diversions, dams, dam operations, surface and groundwater withdrawals); human population growth and accompanying increases in water demands; human recreation; reduced riparian health and regrowth of streamside trees for nesting, foraging, and roosting; urban development; and climate change;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation, including but not limited to the effects of avian pox or West Nile virus, Mexican chicken bugs, or ticks;

(d) The inadequacy of existing regulatory mechanisms, including but not limited to adequacy or inadequacy of funding for ongoing management; appropriateness and effect of incidental take permitted for Sonoran Desert area bald eagles while listed under the Act; impacts of low-flying aircraft and effectiveness of flight advisories; and the adequacy or inadequacy of protections under the Bald and Golden Eagle Protection Act and the Migratory Bird Treaty Act; and

(e) Other natural or manmade factors affecting its continued existence, including but not limited to information on: Productivity, survival, and mortality rates of this population; the occurrence and effect of inbreeding; effects to Sonoran Desert area bald eagles while outside the Sonoran Desert area; effects to Sonoran Desert area bald eagles' prey base and productivity, including effects of nonnative predatory fish and native fish restoration; the presence and abundance of pesticides and contaminants such as lead, mercury, or dichlorodiphenyldichloroethylene (DDE); the effects of climate change; and the effects from eggshell thinning.

(6) Information supporting the existing boundary developed in our May 1, 2008, final listing rule (73 FR 23966) for Sonoran Desert area bald eagles under consideration in this status review, or information indicating that the boundary should be modified to include other areas.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, because section 4(b)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) directs that determinations as to whether any species is a threatened or endangered species shall be made ''solely on the basis of the best scientific and commercial data available.'' At the conclusion of the status review, we will determine whether listing is warranted, not warranted, or warranted but precluded.

You may submit your information concerning this status review by one of the methods listed in the **ADDRESSES** section. We will not consider submissions sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Information and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

Section 4(b)(3)(A) of the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 et seq.), requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. We are to base this finding on information provided in the petition, supporting information submitted with the petition, and information otherwise available in our files at the time we make the determination. To the maximum extent practicable, we are to make this finding within 90 days of our receipt of the petition and publish our notice of the finding promptly in the **Federal Register**. Section 4(b)(3)(B) also requires that, for any petition to revise the Lists of Threatened and Endangered Wildlife and Plants that contains substantial scientific or commercial information that the action may be warranted, we make a finding within 12

months of the date of the receipt of the petition on whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted but precluded by other pending proposals. Such 12-month findings are to be published promptly in the **Federal Register**.

On October 6, 2004, we received a petition, dated October 6, 2004, from the Center for Biological Diversity (CBD), the Maricopa Audubon Society, and the Arizona Audubon Council requesting that the ''Southwestern desert nesting bald eagle population'' be classified as a DPS, that this DPS be reclassified from a threatened species to an endangered species, and that we concurrently designate critical habitat for the DPS under the Act.

On March 27, 2006, the CBD and the Maricopa Audubon Society filed a lawsuit against the U.S. Department of the Interior and the Service for failing to make a timely finding on the petition. The parties reached a settlement, and the Service agreed to complete its petition finding by August 2006. On August 30, 2006 (71 FR 51549), we announced our 90-day finding that the petition did not present substantial scientific or commercial information indicating that the petitioned action may be warranted.

On January 5, 2007, the CBD and the Maricopa Audubon Society filed a lawsuit challenging the Service's 90-day finding that the ''Sonoran Desert population'' of the bald eagle did not qualify as a DPS, and further challenging the Service's 90-day finding that the population should not be up-listed to endangered status.

On July 9, 2007 (72 FR 37346), we published the final delisting rule for bald eagles in the lower 48 States. In that final delisting rule, we stated that our findings on the status of the Sonoran Desert population of bald eagles superseded our 90-day petition finding because the final delisting rule constituted a final decision on whether the Sonoran Desert population of bald eagles qualified for listing as a DPS under the Act.

On March 5, 2008, the U.S. District Court for the District of Arizona ruled in favor of the CBD and the Maricopa Audubon Society. The court order (*Center for Biological Diversity* v. *Kempthorne,* CV 07–0038–PHX–MHM (D. Ariz)) was filed on March 6, 2008.

The court ruled for the plaintiffs and ordered the Service to:

(1) Conduct a status review of the Sonoran Desert area bald eagle population pursuant to the Act to determine whether listing that population as a DPS is warranted, and if so, whether listing that DPS as threatened or endangered pursuant to the Act is warranted;

(2) Issue a 12-month finding on whether listing the Sonoran Desert area bald eagle population as a DPS is warranted, and if so, whether listing that DPS as threatened or endangered is warranted; and

(3) Issue the 12-month finding within 9 months of the court order pursuant to 16 U.S.C. 1533(b)(3)(B), which translates to on or before December 5, 2008.

Further, the court enjoined the Service's application of the July 9, 2007 (72 FR 37346), final delisting rule to the Sonoran Desert population of bald eagles pending the outcome of our status review and 12-month petition finding. The court order was effective as of March 6, 2008, the date it was filed. On May 1, 2008, we published a final rule (73 FR 23966) listing the potential Sonoran Desert area bald eagle DPS as threatened under the Act in response to the court order. Please refer to the map and final rule published on May 1, 2008 (73 FR 23966) for details of the geographic area affected by this action.

At this time, we are soliciting new information on the status of and potential threats to the Sonoran Desert population of bald eagles. We will base our new determination as to whether listing is warranted on a review of the best scientific and commercial information available, including all such information received as a result of this notice. For more information on the biology, habitat, and range of the Sonoran Desert population of bald eagles, please refer to our previous 90-day finding published in the **Federal Register** on August 30, 2006 (71 FR 51549), and our final delisting rule for the bald eagle published in the **Federal Register** on July 9, 2007 (72 FR 37346).

Author

The primary author of this notice is the staff of the Arizona Ecological Services Office.

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: May 8, 2008.

Kenneth Stansell,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. E8–11052 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 080306389–8391–01]

RIN 0648–AW53

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Allowance of New Gear (Eliminator Trawl) in Specific Special Management Programs

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes approval for using another type of trawl gear known as the ''eliminator trawl'' in the Regular B Days-at-Sea (DAS) Program and the Eastern U.S./Canada Haddock Special Access Program (SAP). Vessels fishing in the Regular B DAS Program and the Eastern U.S./Canada Haddock SAP must use approved trawl gear in order to reduce the catch of multispecies (groundfish) stocks of concern. The Northeast (NE) Regional Administrator, NMFS, may approve additional gears for use in these programs if research demonstrates that the gear meets specific standards for the reduction of catch of stocks of concern. The intent of this action is to reduce catch of stocks of concern in the NE multispecies fishery.

DATES: Comments must be received by June 4, 2008.

ADDRESSES: You may submit comments, identified by 0648–AW53, by any one of the following methods:

• Electronic Submissions: Submit all electronic public comments via the Federal e-rulemaking portal: *http://www.regulations.gov.*

• Mail: Paper, disk, or CD-ROM comments should be sent to Patricia A. Kurkul, Regional Administrator, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the eliminator trawl.''

• Fax: (978) 281–9135.

Instructions: All comments received are part of the public record and will generally be posted to http://www.regulations.gov without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publically accessible. Do not submit Confidential Business

Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF formats only.

Copies of the Technical Report ''Bycatch Reduction in the Directed Haddock Bottom Trawl Fishery'' and a diagram of the eliminator trawl may be obtained from NMFS at the mailing address specified above; telephone (978) 281–9315. NMFS prepared an Initial Regulatory Flexiblity Analysis (IRFA), which is contained in the Classification section of this proposed rule.

FOR FURTHER INFORMATION CONTACT: Thomas Warren, Fishery Policy Analyst, (978) 281–9347, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION: The NE Multispecies Fishery Management Plan (FMP) contains broadly applied input control regulations that are designed to protect stocks that need reductions in fishing mortality. Because such regulations apply in a broad manner, they not only restrict fishing effort on stocks of concern, but also restrict fishing effort on stocks that do not need reductions in fishing mortality. Therefore, SAPs were implemented in the FMP to increase access to stocks that do not need reductions in fishing mortality. A SAP authorizes additional fishing effort in order to allow an increased yield in specific stocks without undermining the achievement of the goals of the FMP. For example, SAPs may allow the use of Category B DAS or allow temporary access to a closed area to increase access to particular stocks. To help ensure that catch of stocks of concern is reduced to acceptable levels, vessels fishing in a SAP are subject to additional fishing restrictions than those that apply to vessels fishing in the NE multispecies fishery at large. Framework Adjustment (FW) 40–A (69 FR 67780; November 19, 2004) implemented the Regular B DAS Program and the Eastern U.S./Canada Haddock special management programs that currently include gear restrictions designed to substantially reduce the catch of stocks of concern.

The Regular B DAS Program, which initially did not contain any gear restrictions, was later modified under FW 42 (71 FR 62156; October 23, 2006) to require trawl vessels to use a haddock separator trawl in order to further reduce the potential for vessels to catch stocks of concern-- notably, cod, yellowtail flounder, and winter flounder. The Eastern U.S./Canada Haddock SAP, from its inception, contained a more restrictive requirement specifying that any vessel fishing in the program must use a haddock separator trawl. FW 42 also authorized the Regional Administrator to approve other gear types for use in the Regular B DAS Program and the Eastern U.S./Canada Haddock SAP to reduce catch of stocks of concern, based upon approved gear standards, but did not contain any standards for evaluating proposed additional gear types. On December 26, 2007, based upon recommendations of the New England Fishery Management Council (Council), NMFS implemented specific gear standards that could be used to evaluate additional gear proposed for use in these programs to reduce catch of stocks of concern and clarified the process by which new gear would be considered (72 FR 72965).

The December 26, 2007 rule specified that, to be approved, new gear must first be compared to an appropriately selected control gear. Based on this comparison, new gear can be approved if it meets one of the following two standards: (1) Use of the gear must result in a statistically significant reduction, compared to the control gear, of at least 50 percent (by weight, on a trip-by-trip basis) in catch of each regulated species stock of concern, or other non-groundfish stocks that are overfished or subject to overfishing identified by the Council; or (2) the use of the gear must result in a catch of each regulated NE multispecies stock of concern, or other non-groundfish stocks that are overfished or subject to overfishing identified by the Council, that is less than 5 percent of the total catch of regulated groundfish (by weight, on a trip-by-trip basis). Neither of these requirements apply to regulated species identified by the Council as not being subject to gear performance standards. Because many species in the fishery are caught together, and the dynamic nature of the status of stocks, the performance standard must have a reasonable amount of flexibility in order to be practical.

One of these standards must be met in a completed experiment, where comparisons of new gear are made to an appropriately selected control gear that has been reviewed according to the standards established by the Council's research policy, before the gear can be considered and approved by the Regional Administrator. In addition, a request for approval of the use of additional gear in the Regular B DAS Program and the Eastern U.S./Canada Haddock SAP must be made by either the Council or the Council's Executive Committee.

Regarding the proposal to approve the gear specified in this action, an experiment was conducted by the University of Rhode Island, Rhode Island Sea Grant Program, in conjunction with members of the fishing industry, from September 2004 through July 2006, to investigate a large-mesh experimental net known as the ''eliminator trawl'', designed to capture haddock while reducing the catch of cod and other species. Two fishing vessels with equivalent length, horsepower, and fishing capacity participated in the study, and compared the eliminator trawl with a control net (constructed with currently legal specifications) using side-by-side tows. Four trips, conducted in the months of June, November, December, and April, resulted in 107 comparison tows, 100 of which were analyzed. The final report, ''Bycatch Reduction in the Directed Haddock Bottom Trawl Fishery'' (URI Fisheries Center Technical Report: 01–06; October 2006) included the following results and conclusions: Haddock was the dominant species caught in the experimental net, and represented 77 percent of the total catch. The overall rounded ratio of haddock to cod in the experimental and control nets was 20:1 and 3:1, respectively. A statistical comparison by tow indicated that there was a significant difference in the catch weights between the control and the experimental nets for cod, yellowtail flounder, winter flounder, witch flounder, American plaice, white hake, monkfish, skates, and other non-groundfish species. The eliminator trawl caught less of these species than the control net, whereas there was no statistical difference in the weight of haddock caught between the two nets.

A February 5, 2007, review by the Northeast Fisheries Science Center, NMFS's NE State, Federal, and Constituent Programs Office noted the successful conclusion of the research project, and the Council's Research Steering Committee reviewed the research on March 29, 2007. Both reviews agreed that the experiment successfully demonstrated that the net design allowed the harvest of haddock, while reducing catches of cod and other stocks of concern. Although the NE Multispecies Plan Development Team did not review the experimental results, a February 8, 2008, memorandum from the Council's Executive Director to the Council indicated that the Council staff had reviewed the experimental data and concluded that the eliminator trawl clearly met the first regulatory standard for approval of new gear requiring a

showing of more than a 50- percent reduction compared to the control gear of catch of regulated species stocks of concern. On February 13, 2008, the Council passed a motion that the haddock eliminator trawl be recommended to the Regional Administrator for use in the Eastern U.S./Canada Haddock SAP and the Regular B DAS Program, and on February 19, 2008, the Council sent the Regional Administrator a letter requesting approval of this gear.

Based upon the final report, ''Bycatch Reduction in the Directed Haddock Bottom Trawl Fishery,'' and the Council's February 19, 2008, letter, NMFS is proposing approval of the eliminator trawl. The pertinent information indicates that the catch of each regulated species stock of concern, as well as other species, declined by more than 50 percent with use of the eliminator trawl, which complies with the first standard for approval of additional gear. The proposed eliminator trawl net specifications are based upon input from the individuals involved in the eliminator trawl research, and NMFS gear experts. Approval of the eliminator trawl would allow trawl vessels fishing in the Regular B DAS Program or the Eastern U.S./Canada Haddock SAP a choice of whether to use the haddock separator trawl or the eliminator trawl. The size of the eliminator trawl specified would be appropriate for fishing vessels with engines of at least 600 horsepower. The results of the experiment cannot be used to extrapolate to smaller scale eliminator trawl gear that could be readily used by smaller horsepower vessels.

The Council identified that the gear performance standards do not apply to haddock, pollock, and redfish. Haddock, pollock, and redfish are target stocks for which no reductions in fishing mortality are required. The researchers could not conduct statistical tests on Atlantic halibut because the species was not present in sufficient numbers (defined by the researchers as present in at least 10 paired tows), and therefore the gear standard could not be applied in a meaningful way to Atlantic halibut. Because Atlantic halibut is caught in very low numbers by the trawl fishery, and is subject to a possession limit of one fish per trip, NMFS has determined that the lack of information on the compliance of Atlantic halibut with gear standards is not sufficient justification for disapproval of the eliminator trawl. Furthermore, it is likely that the selectivity of the eliminator trawl for Atlantic halibut is low, given the similarity in body shape and ecology of the Atlantic halibut to the other flatfishes, which were less numerous in the eliminator trawl. This application of the gear standard is consistent with the intent of the Council (i.e., reasonable flexibility in application of the gear standards) and the goal of providing opportunities and incentives for the fishing industry to utilize gear that results in substantial reductions in bycatch.

NMFS is not proposing that vessels must have their eliminator trawl net inspected and certified by a net manufacturer, as suggested by Council staff in the attachment to the Council's February 19, 2008, letter to NMFS. The stated concern is that slight modifications in the net configuration could alter the effectiveness of the net in reducing catches of species of concern. Inspection by a net manufacturer would not prevent a vessel operator from modifying his/her net after such an inspection occurred, would impose additional costs to the industry, would be difficult to enforce, and would be redundant, because the net manufacturer can verify to the net purchaser what he/she is purchasing at the time of purchase. The fisherman is responsible for the compliance of his/her gear with the regulations, and NMFS and the United States Coast Guard enforce the gear regulations. Furthermore, this requirement was not proposed by the Council (based on the Council's pertinent motion).

Classification

NMFS has determined that the proposed rule is consistent with the FMP and has preliminarily determined that this rule is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

An initial regulatory flexibility analysis (IRFA) has been prepared, as required by section 603 of the Regulatory Flexibility Act (RFA), consisting of this proposed rule, the following analysis, and the Categorical Exclusion prepared for this action. The IRFA below describes the economic impact this proposed rule, if adopted, would have on small entities.

Allowing the use of the eliminator trawl in the Regular B DAS Program and the Eastern U.S./Canada Haddock SAP would provide the fishing industry more flexibility in the use of trawl gear that minimizes catch of stocks of concern by providing them with a choice of whether to use the haddock separator trawl or the eliminator trawl. Vessels fishing under a Regular B DAS in these programs must comply with restrictive landing limits of various species. The choice of two nets would enable a vessel owner to decide which net is the most cost effective means of targeting haddock and complying with the landing restrictions. A description of the objectives and legal basis for the proposed eliminator trawl is contained in the **SUMMARY** of this proposed rule.

Under the Small Business Administration (SBA) size standards for small fishing entities ($ 4.0 million in annual gross sales), all permitted and participating vessels in the groundfish fishery are considered to be small entities and, therefore, there are no disproportionate impacts between large and small entities. Gross sales by any one entity (vessel) do not exceed this threshold. The maximum number of small entities that could be affected by the proposed approval of the eliminator trawl are approximately 1,200 vessels; i.e., those issued limited access NE multispecies DAS permits that have an allocation of Category A or B DAS. Realistically, however, the number of vessels that choose to fish in either of these programs, and that would therefore be subject to the associated restrictions, including the use of either the haddock separator trawl or the eliminator trawl, would be substantially smaller. For example, in fishing year (FY) 2005, 132 vessels fished in either the Regular B DAS Program or the Eastern U.S./Canada Haddock SAP. In FY 2006, there were only 45 vessels that fished in either program. Although it is possible that, under future circumstances, more vessels may elect to participate in these programs, a large increase in the numbers of participants is unlikely. Furthermore, some participants in the Regular B DAS Program and in the SAP may not have sufficient engine horsepower to use the eliminator trawl, and, therefore, may not be able to use the trawl.

Based on information from a commercial net manufacturer, the cost of purchasing a new eliminator trawl net is approximately $ 13,000. A squid trawl net could be modified into an eliminator trawl for approximately $ 1,000, by replacing the last belly portion of the net and putting in a rockhopper sweep. If 130 vessels fished in either of the special management programs that require the use of a specialized trawl, and the vessel operators decided to purchase the eliminator trawl net, the total cost to the industry would be approximately $1,690,000. It is likely that many vessels that have fished in these programs in the past using a separator trawl may choose not to purchase an eliminator trawl. Vessels choosing to use the eliminator trawl would incur the purchase cost and other

adjustment costs. The decision to do so, and to thereby fish in a special management program offering additional revenue opportunities is a voluntary decision based on the individual vessel's assessment of profitability.

Because of the context in which this action is proposed, there are only two alternatives under consideration: The no action alternative and approval of the eliminator trawl. Consideration of another trawl gear (i.e., a third alternative) in addition to the eliminator trawl is not proposed at this time. The process of conducting gear research and reviewing such research is time consuming and costly, and the standards for approval must be met. Although other trawl gear research is either underway or proposed, the eliminator trawl is the only gear that has been vetted through the review process and recommended by the Council. Additional research is being proposed by two of the co-authors of ''Bycatch Reduction in the Directed Haddock Bottom Trawl Fishery'' that will investigate the use of an eliminator trawl net designed for smaller vessels with 250 to 550 horsepower engines.

Performance standards rather than design standards are utilized for the evaluation of new trawl gear, in order to provide conservation engineers flexibility in design and a meaningful standard for the achievement of the goal of bycatch reduction. The performance standards under § 648.85(b)(6)(iv)(J)(*2*) were developed for the specific purpose of evaluating additional fishing gear for these special management programs.

The proposed action would not modify any collection of information, reporting, or recordkeeping requirements. The proposed net does not duplicate, overlap, or conflict with any other Federal rules.

Dated: May 14, 2008.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 648.2, new definitions for ''fishing circle,'' ''stretched mesh,'' and ''sweep'' are added in alphabetical order, to read as follows:

§ 648.2 Definitions.

* * * * *

Fishing circle, with respect to the NE multispecies limited access fishery, means the calculated circumference of a bottom trawl based on the number of meshes and stretched mesh length at the narrow, aft end of the square of the net.

* * * * *

Stretched mesh, with respect to the NE multispecies eliminator trawl, means mesh that is pulled so that slack in the mesh is eliminated and the mesh opening is closed.

* * * * *

Sweep, with respect to the NE multispecies limited access fishery, means the part of a bottom trawl that, during normal use, is in contact with the sea floor along the outer edges of the lower webbing of the net.

* * * * *

3. In § 648.14, paragraphs (a)(132) and (b)(81) are revised to read as follows:

§ 648.14 Prohibitions.

(a) * * *

(132) If fishing with trawl gear under a NE multispecies DAS in the Eastern U.S./Canada defined in § 648.85(a)(1)(ii), fail to fish with a haddock separator trawl or a flounder trawl net, as specified in § 648.85(a)(3)(iii), unless otherwise allowed under the Eastern U.S./Canada Haddock SAP rules in § 648.85(b)(8)(v)(E).

* * * * *

(b) * * *

(81) If fishing in the Regular B DAS Program specified in § 648.85(b)(6), fail to use a haddock separator trawl as described under § 648.85(a)(3)(iii)(A), or other approved gear as described under § 648.85(b)(6)(iv)(J).

* * * * *

4. In § 648.85, paragraphs (b)(6)(iv)(J)(*1*) and (b)(8)(v)(E) introductory heading and (b)(8)(v)(E)(*1*) are revised, and paragraph (b)(6)(iv)(J)(*3*) is added to read as follows:

§ 648.85 Special management programs.

* * * * *

(b) * * *

(6) * * *

(iv) * * *

(J) * * *

(*1*) Vessels fishing with trawl gear in the Regular B DAS Program must use the haddock separator trawl or eliminator trawl net, as described under paragraphs (a)(3)(iii)(A) and (b)(6)(iv)(J)(*3*) of this section, respectively, or other type of gear if approved as described under this paragraph (b)(6)(iv)(J). Other gear may be on board the vessel, provided it is stowed when the vessel is fishing under the Regular B DAS Program.

* * * * *

(*3*) *Eliminator Trawl.* The eliminator trawl is a four-seam bottom groundfish trawl designed to reduce the bycatch of cod while retaining or increasing the catch of haddock, when compared to traditional groundfish trawls. An eliminator trawl must be constructed in accordance with the following standards:

(*i*) The net must be constructed with four seams (i.e., a net with a top and bottom panel and two side panels), and include at least the following net sections as depicted in Figure 1 of this part ''Nomenclature for 4–seam eliminator trawl'' (this figure is also available from the Administrator, Northeast Region): Top jib, bottom jib, jib side panels (x 2), top wing, bottom wing, wing side panels (x 2), square, bunt, square side panels (x 2), first top belly, first bottom belly, first belly side panels (x 2), second top belly, second bottom belly, second belly side panels (x 2), and third bottom belly.

(*ii*) The first bottom belly, bunt, the top and bottom wings, and the top and bottom jibs, jib side panels, and wing side panels (the first bottom belly and all portions of the net in front of the first bottom belly, with the exception of the square and the square side panels) must be at least two meshes long in the fore and aft direction. For these net sections the stretched length of any single mesh must be at least 7.9 ft (240 cm).

(*iii*) Mesh size in all other sections must be consistent with mesh size requirements specified under § 648.80 and meet the following minimum specifications: Each mesh in the square, square side panels, and second bottom belly must be 31.5 inches (80 cm); each mesh in the first and second top belly, the first belly side panels, and the third bottom belly must be at least 7.9 inches (20 cm); and 6 inches or larger in sections following the second top belly and third bottom belly sections, all the way to the codend. The mesh size requirements of the top sections apply to the side panel sections.

(*iv*) The trawl must have a fishing circle of at least 398 ft (121.4 m). This number is calculated by separately counting the number of meshes for each section of the net at the wide, fore end of the first bottom belly, and then calculating a stretched length as follows: For each section of the net (first bottom belly, two belly side panels and first top belly) multiply the number of meshes times the length of each stretched mesh to get the stretched mesh length for that section, and then add the sections

together. For example, if the wide, fore end of the bottom belly of the eliminator trawl is 22 meshes (and the mesh is at least 7.9 ft (240 cm)), the stretched mesh length for that section of the net is derived by multiplying 22 times 7.9 ft (240 cm) and equals 173.2 ft (52.8 m). The top and sides (x 2) of the net at this point in the trawl are 343 meshes (221 + 61 + 61, respectively) (each 7.9 inches (20 cm)), which equals 225.1 ft (68.6 m) stretched length. The stretched lengths for the different sections of mesh are added together (173.2 ft + 225.1 ft (52.8 + 68.6 m)) and result in the length of the fishing circle, in this case 398.3 ft (121.4 m).

(*v*) The trawl must have at least three 1–square meter or larger kite panels on the forward end of the square to help maximize headrope height, for the purpose of capturing rising fish. A kite panel is a flat structure, usually semi-flexible used to modify the shape of trawl and mesh openings by providing lift when a trawl is moving through the water.

(*vi*) The sweep must consist of rockhoppers, which are graduated from 16–inch (40–cm) diameter in the center down to 12–inch (30–cm) diameter at the wing ends. There must be six or fewer 12 to16–inch (30 to 40–cm) rockhopper discs over any 10–ft (3.0 m) length of the sweep. The 12 to16 inch (30 to 40–cm) discs must be spaced evenly, with one disc placed approximately every 2 ft (60 cm) along the sweep. The 12 to 16–inch (30 to 40–cm) discs must be separated by smaller discs, no larger than 3.5 inches (8.8 cm) in diameter.

* * * * *

(8) * * *

(v) * * *

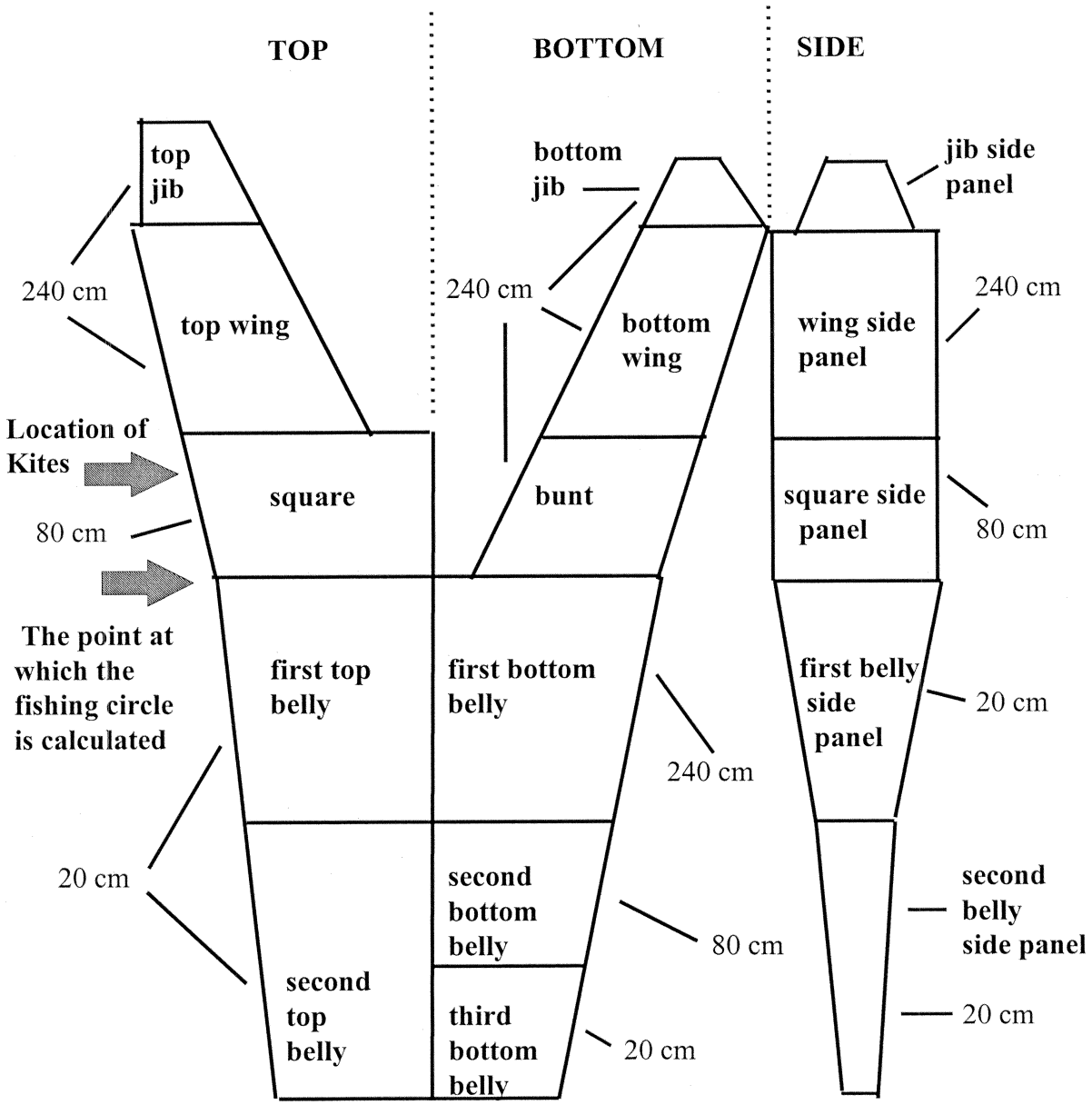
(E) Gear requirement (*1*) A NE multispecies vessel fishing in the Eastern U.S./Canada Haddock SAP must use the haddock separator trawl or eliminator trawl net, as described under paragraphs (a)(3)(iii)(A) and (b)(6)(iv)(J)(*3*) of this section, respectively, or other type of gear, if approved as described under this paragraph (b)(8)(v)(E). No other type of fishing gear may be on the vessel when on a trip in the Eastern U.S./Canada Haddock SAP, with the exception of a flounder net, as described in paragraph (a)(3)(iii) of this section, provided that the flounder net is stowed in accordance with § 648.23(b).

* * * * *

5. In part 648, add Figure 1 as follows:

BILLING CODE 3510–22–S

Figure 1 to Part 648



Nomenclature for 4 Seam, Eliminator Trawl and Minimum Mesh Size by Section

20 cm = 7.9 inches;
80 cm = 31.5 inches;
240 cm = 7.9 ft

[FR Doc. E8–11303 Filed 5–19–08; 8:45 am]
BILLING CODE 3510–22–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 071106669–7824–02]

RIN 0648–AU26

Fisheries Off West Coast States; Coastal Pelagic Species Fishery; Amendment 12 to the Coastal Pelagic Species Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 12 to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP) which would provide protection for all species of krill off the West Coast (i.e., California, Oregon and Washington). This rule would prohibit the harvest of all species of krill by any fishing vessel operating in the Exclusive Economic Zone (EEZ) off the West Coast, and would also deny the use of exempted fishing permits to allow krill fishing.

DATES: Comments must be received by June 19, 2008.

ADDRESSES: You may submit comments on this proposed rule identified by ''I.D. 012607A-PR'' by any of the following methods:

- Federal e-Rulemaking portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- E-mail: *0648–AU26.SWR@noaa.gov*. Include the I.D. number in the subject line of the message.
- Mail: Rodney R. McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802.
- Fax: (562)980–4047

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of Amendment 12, which includes an Environmental Assessment/Initial Regulatory Flexibility Analysis/Regulatory Impact Review, are available from Donald O. McIssac, Executive Director, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Joshua B. Lindsay, Sustainable Fisheries Division, NMFS, at 562–980–4034 or Mike Burner, Pacific Fishery Management Council, at 503–820–2280.

SUPPLEMENTARY INFORMATION: The CPS fishery in the EEZ off the West Coast is managed under the CPS FMP, which was developed by the Council pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The CPS FMP was approved by the Secretary of Commerce and was implemented by regulations that can be found at 50 CFR part 660, subpart I.

Amendment 12 would add all species of krill as a management unit species under the CPS FMP and would place krill under a newly established ''prohibited harvest species'' category. This new category would differ from the existing ''prohibited species'' definition in the FMP because ''prohibited harvest species'' may not be taken by any fishery or gear type in the U.S. EEZ. In contrast, ''prohibited species'' may not be taken and retained incidentally by CPS fishery participants, but are legally harvested under provisions in Federal regulations implementing other Pacific Fishery Management Council (Council) FMPs.

As the principal food source for many fish and non-fish species, krill are a critical component of the marine ecosystem. Off the West Coast krill are important prey for a variety of fish species, including many Council managed stocks. Krill are also a principal food source for many species of marine mammals and seabirds; some of which are listed as threatened or endangered and warrant special efforts for protection and recovery. Protecting krill will likely minimize adverse impacts on these fish stocks and living marine resources and in turn, help to maintain ecological relationships and ensure the long-term health and productivity of the West Coast ecosystem. Amendment 12 is an attempt to incorporate ecosystem conservation principles into fishery management programs by protecting, to the extent practicable, krill resources, which are an integral part of that ecosystem.

At this time, there are no Federal regulations that limit fishing for krill in the EEZ. While a krill fishery off the U.S. West Coast does not currently exist, NMFS is concerned such a fishery could develop and have an adverse impact on other West Coast fish stocks, marine mammals, and the ecosystem generally.

The states of Washington, Oregon, and California prohibit their vessels from fishing for krill and prohibit landings of krill into their respective ports. However, these prohibitions would not prevent a fishery from developing in the West Coast EEZ by vessels from outside of the region, as long as landings were not made into a West Coast port. A market for krill currently exists in Washington and Oregon, where salmon farms use krill products as a supplemental feed. Federal (EEZ) waters which lie outside of the state prohibitions on krill harvest, may in the future be used for fish farming. These operations will likely demand krill as feed stock, and a fishery could develop around the needs of these aquaculture facilities. Local krill would be an obvious food source, which may significantly increase the likelihood of a krill fishery developing within West Coast EEZ waters.

NMFS is concerned about the impacts of a krill fishery based in part on information regarding large-scale krill fishing methods and the impacts of existing krill fisheries in other areas. Krill concentrations attract marine mammal, bird, and fish predators, and due to the trawl-type gear used to catch krill, bycatch and/or disturbance of these predators could occur. In the Antarctic krill fishery, there is known bycatch of fur seals as well as various sea birds. In British Columbia a krill fishery began in 1970 and in 1976 quotas were established due to concerns for harvesting a forage species upon which salmon and other commercially important finfish depend. An annual catch was set at 500 tons with an open season from November to March to minimize the incidental catch of larval and juvenile fish.

In the Antarctic, although krill catches are currently well below catch limits, some have questioned whether there is a risk that localized, excessive fishing effort might have an impact on land-based predators that depend on krill for food. This could be of particular concern during the breeding season considering the considerable overlap between the krill fishery and breeding areas for penguins and seals in the South Atlantic Ocean. Some believe that demand for krill has begun to exceed supply in areas of the southwest Atlantic and as a result penguins and

albatrosses might be having difficulties in rearing offspring successfully on South Georgia due to this competition for resources.

NMFS' examination of this action began in September 2004, when managers of the Cordell Bank, Monterey Bay, and Gulf of the Farallones National Marine Sanctuaries (Sanctuaries) requested that the Council consider prohibiting krill fishing in the federal waters portion of the three sanctuaries. The Council moved forward with the request recognizing the need for a more substantive analysis of the krill resource - including an analysis of possible controls that would meet the objectives of the requested action. The analysis also considered the total distribution and importance of krill throughout waters off the West Coast EEZ, not just in sanctuary waters.

At the November 2004 Council meeting, NMFS presented the Council with advice on alternative approaches by which krill fishery controls could be implemented. NMFS subsequently prepared an Alternatives Analysis that presented information on the various species of krill that occur off the West Coast, their productivity (as well as the uncertainty of the information available), and the relationship between krill and other fish and non-fish species. The analysis also provided information on potential mechanisms for achieving control over krill fishing in the EEZ as well as evaluated different conservation and management measures that could be applied if krill fishing were to be permitted.

The Council discussed the content of the Alternatives Analysis at its October 31, 2005, meeting and after receiving recommendations from its advisory groups and the public, directed that a draft CPS FMP amendment be prepared presenting a preliminary preferred alternative for public review and comment. Once completed, the document was circulated for public review and comment. Following public testimony at its March 2006 meeting the Council adopted Amendment 12 to the CPS FMP.

The three alternatives that were analyzed for this amendment are as follows:

Alternative 1: No Action

Every assessment of potential management strategies by the Council for consideration of implementation by Federal regulation includes a ''no action'' alternative, as required by National Environmental Policy Act (NEPA) implementing regulations and against which other alternatives are compared. Under this alternative, NMFS would not take action at this time. This would mean that the states' prohibitions on landing krill by their vessels would remain in place (see section 3.5 of Environmental Assessment (EA)), but that a fishery by vessels from outside of the region could develop in the EEZ if landings were not made into a West Coast port. If a krill fishery developed, the Council would have an opportunity to develop conservation and management measures in the future.

Alternative 2: Manage Krill Fishing Through Amendment of the CPS FMP (Proposed Action)

Under this alternative, krill (all species) would be added to the management unit species of the CPS FMP. Further, a new category of management unit species - ''prohibited harvest'' - would be established under the FMP. Krill would be placed in that category. This means that optimum yield (OY) for krill would be zero, and the target, harvest and transhipment of krill would be prohibited. Also, exempted fishing permits (EFPs) would not be issued under the EFP procedures of the CPS FMP to allow individuals to harvest krill as an exception to the prohibition of harvest. These actions would fully achieve the objectives of the amendment to the extent practicable, but would not account for environmental conditions and the responses of krill and other resources to changes in environmental conditions. NMFS recognizes that *de minimis* or trace amounts of krill may be retained by fishermen while targeting other species; such inadvertent action is not intended to be the subject of this prohibition.

Alternative 3: Prohibit Krill Fishing but Establish a Process for Allowing Future Fishing

This alternative would add krill to the management unit species group contained within the CPS FMP as well as initially prohibit fishing for krill in the West Coast EEZ (i.e., OY would have been zero), but a procedure would be established by which krill fishing in the future could be permitted (subject to conditions). That procedure would involve such steps as completing the modeling described in section 3.1.3.5 of the EA, establishing a firm Maximum Sustainable Yield estimate(s), prohibiting the direct harvest of krill but possibly setting an initial low harvest allowance for EFPs with a complete monitoring and evaluation program.

NMFS has considered the potential for development of a krill fishery and the potentially drastic effects a fishery could have on krill resources and on the fish and other species, such as birds and mammals, that are dependent on, or that are sensitive to, the abundance and availability of krill. NMFS believes it is critical to take preventive action at this time to ensure that a krill fishery will not develop that could potentially harm krill stocks, and in turn harm other fish and non-fish stocks. Therefore, NMFS proposes to Alternative 2 prohibit krill fishing in the EEZ off the West Coast.

Classification

Pursuant to section 304 (b)(1)(A) of the Magnuson-Stevens Act, I have determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

The Council and NMFS has prepared an EA for this amendment that discusses the impact on the environment as a result of this rule. A copy of the EA is available from the Council or NMFS (see **ADDRESSES**).

This proposed rule has been determined to be significant for the purposes of Executive Order 12866.

There are no reporting, recordkeeping, or other compliance requirements of the proposed rule.

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, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

A fishing vessel is considered a ''small'' business by the U.S. Small Business Administration (SBA) if its annual receipts are not in excess of $4.0 million. Since all of the vessels fishing for CPS have annual receipts below $4.0 million they would all be considered small businesses under the SBA standards. Therefore this rule will not create disproportionate costs between small and large vessels/businesses.

No small entities would be directly affected if this action were taken. There are currently no entities engaged in fishing for krill off the West Coast. It is possible that, in the absence of this action, a krill fishery could develop, but it is not possible to estimate the number of entities (large or small) that might engage in such fishing in the future. No criteria for such an evaluation were used as no entities (large or small) will be directly affected by the proposed action. No entities now fish for krill so no entities would be disproportionately affected or suffer reductions in profits. No entities now fish for krill so a ''substantial number'' of small entities would not be affected.

NMFS has determined that there will not be a significant economic impact to a substantial number of small entities.

As a result, a regulatory flexibility analysis is not required.

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.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 14, 2008.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 660.502 the definitions of ''Krill'' and ''Prohibited harvest species'' are added in alphabetical order to read as follows:

§ 660.502 Definitions.

* * * * *

Krill means all species of euphausiids that occur in the EEZ off the West Coast.

* * * * *

Prohibited harvest species means all krill species in the EEZ off the West Coast.

* * * * *

3. In § 660.505, add paragraph (o) as follows:

§ 660.505 Prohibitions.

* * * * *

(o) Fish for, target, harvest or land a prohibited harvest species in any fishery within the EEZ off the West Coast.

[FR Doc. E8–11253 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 73, No. 98
Tuesday, May 20, 2008

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

Commodity Credit Corporation

Public Hearing on New Entrant's 2008—Crop Cane Sugar Marketing Allocation

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice of invitation to request a public hearing.

SUMMARY: The Commodity Credit Corporation (CCC) issues this notice to advise sugarcane processors and growers that they may request a public hearing as a result of an application made by a new sugarcane processor, Andino Energy Enterprises, L.L.C., for a cane sugar allocation starting with the 2008 crop year. Andino Energy Enterprises, L.L.C., is requesting a 2008-crop year allocation of 50,000 short tons, raw value (STRV), with annual increases in its allocation to 60,000, 80,000, 100,000 and 120,000 STRV, for crop years 2009, 2010, 2011 and 2012, respectively. The new processor will be located in Louisiana, an existing mainland State in the CCC sugar marketing allotment program. If CCC receives a request for a hearing, CCC will conduct a hearing.

DATES: Send requests for hearings by June 3, 2008.

ADDRESSES: Please send hearing requests to Barbara Fecso, Farm Service Agency, United States Department of Agriculture (USDA), Stop 0516, 1400 Independence Ave, SW., Washington, DC 20250–0540, fax: (202) 690–1480, e-mail: *barbara.fecso@wdc.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Barbara Fecso Farm Service Agency, telephone: (202) 720–4146, fax: (202) 690–1480, e-mail: *barbara.fecso@wdc.usda.gov.* To view original application, go to *http://www.fsa.usda.gov/FSA/webapp?area=home&subject=ecpa&topic=dsa.* Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Section 359d(b)(1)(E) of the Agricultural Adjustment Act of 1938, as amended, authorizes CCC to provide a sugarcane processor, who begins processing after May 13, 2002, with an allocation that provides a fair, efficient, and equitable distribution of the allocations from the allotment for the State in which the processor is located. CCC is also required to establish proportionate shares in a quantity sufficient to produce the sugarcane required to satisfy the new allocation. If an allocation is provided by CCC to the new applicant, that processor's allocation will be subtracted, on a pro rata basis, from the allocations otherwise provided to each sugarcane processor in Louisiana.

CCC will publicly announce the hearing if one is requested.

Signed in Washington, DC on May 13, 2008.

Teresa C. Lasseter,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. E8–11213 Filed 5–19–08; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Request for Public Comments for Use in Preparing for 2009 Reauthorization of the Child Nutrition Programs and the Special Supplemental Nutrition Program for Women, Infants and Children

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice of request for comments.

SUMMARY: This notice announces a request for public comments to help senior officials of the United States Department of Agriculture (USDA) prepare for the 2009 Reauthorization of the Child Nutrition Programs and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). USDA believes that public input and assessment of the performance of current programs—including WIC, National School Lunch Program, School Breakfast Program, Child and Adult Care Food Program, Summer Food Service Program, WIC Farmers Market Nutrition Program, Fresh Fruit and Vegetable Program, and Special Milk Program—are essential to help the Department plan for reauthorization.

SUPPLEMENTARY INFORMATION:

Background

The nutrition assistance programs administered by USDA work together to ensure a nutrition safety net for the Nation's children, elderly, and low-income families. These programs help protect children and low-income households from hunger. They inform all of us about the importance of healthful diets and active lifestyles. They help to prevent the health problems associated with poor nutrition and physical inactivity for all Americans.

While these programs are designed to meet the needs of people of all ages who may require assistance, they focus most strongly on the needs of children. The Child Nutrition Programs include the school meal programs (National School Lunch Program and School Breakfast Program) and the Child and Adult Care Food Program, which support nutritious meals and snacks served to children in schools, child care institutions, and afterschool care programs. In addition, the Summer Food Service Program and the Seamless Summer component of the National School Lunch Program provide nutritious food to children in programs in the summer months, when school is not in session.

WIC addresses the special needs of at-risk, low-income pregnant, breastfeeding, and postpartum women, infants, and children up to five years of age. It provides participants with monthly supplemental food packages targeted to their dietary needs, nutrition education, and referrals to a range of health and social services—benefits that promote a healthy pregnancy for mothers and a healthy start for their children.

Public Comment Submission

The reauthorization process provides Congress with a regular opportunity to examine the operation and effectiveness of the Federal nutrition assistance programs, and consider making improvements to their statutory structure under the Richard B. Russell

National School Lunch Act (42 U.S.C. 1751–1769i) and the Child Nutrition Act of 1966 (42 U.S.C. 1771–1791). In anticipation of these discussions, USDA intends to gather input that will help the Department better understand the needs and concerns of program cooperators and participants at the State and local levels, including representatives from State agencies, local program offices, industry, and State and local advocacy groups.

This notice provides the public the opportunity to comment in writing on the issues that USDA expects to address in preparing for this reauthorization process. USDA has developed a framework of three themes to help focus the discussion of reauthorization issues. Commenters will be asked to address, but not be limited to, issues related to specific aspects of WIC, the WIC Farmers' Market Nutrition Program, National School Lunch Program, School Breakfast Program, Child and Adult Care Food Program, Summer Food Service Program, Fresh Fruit and Vegetable Program, and Special Milk Program. Key among these are:

- Strengthening program management and improving nutrition services,
- Ensuring that all eligible persons have access to program benefits, and
- Advancing technology and innovation.

Electronic Access and Filing Addresses

USDA invites interested persons to submit written comments electronically or by postal mail. To be assured of consideration, written comments must be received on or before October 15, 2008. Comments may be submitted by any of the following methods:

Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments electronically.

Mail: Address comments to Mr. Robert M. Eadie, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594.

Fax: Submit comments by facsimile transmission to: 703–305–2879, attention Mr. Robert M. Eadie.

Hand Delivery or Courier: Deliver comments to 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594, during normal business hours of 8:30 a.m. to 5 p.m.

All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that comments, as well as the identity of the individuals or entities submitting the comments, will be subject to public disclosure. All submissions will be available for public inspection at the address noted above, Monday through Friday, 8:30 a.m. to 5 p.m. USDA may also make the comments available on the Federal eRulemaking portal.

Dated: May 14, 2008.

Eric Steiner,

Acting Administrator, Food and Nutrition Service.

[FR Doc. E8–11236 Filed 5–19–08; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 080512652–8653–01]

Reporting on Offsets Agreements in Sales of Weapon Systems or Defense-Related Items to Foreign Countries or Foreign Firms for Calendar Year 2007

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Notice.

SUMMARY: This notice is to remind the public that U.S. firms are required to report annually to the Department of Commerce (Commerce) on contracts for the sale of defense-related items or defense-related services to foreign countries or foreign firms that are subject to offsets agreements exceeding $5,000,000 in value. U.S. firms are also required to report annually to Commerce on offsets transactions completed in performance of existing offsets commitments for which offsets credit of $250,000 or more has been claimed from the foreign representative. Such reports must be submitted to Commerce no later than June 15, 2008.

ADDRESSES: Reports should be addressed to ''Offsets Program Manager, U.S. Department of Commerce, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, Room 3878, Washington, DC 20230.''

FOR FURTHER INFORMATION CONTACT: Ronald DeMarines, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce, telephone: 202–482–3755; fax: 202–482–5650; e-mail: *rdemarin@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

In 1984, the Congress enacted amendments to the Defense Production Act (DPA), including the addition of Section 309, which addresses offsets in defense trade (*See* 50 U.S.C. app. § 2099). Offsets are compensation practices required as a condition of purchase in either government-to-government or commercial sales of defense articles and/or services, as defined by the Arms Export Control Act and the International Traffic in Arms Regulations.

Section 309(a)(1) requires the President to submit an annual report to the Congress on the impact of offsets on the U.S. defense industrial base. In 1992, section 309 was amended to direct the Secretary of Commerce (Secretary) to function as the President's executive agent for carrying out the responsibilities set forth in that section. Specifically, section 309 authorizes the Secretary to develop and administer the regulations necessary to collect offsets data from U.S. defense exporters.

The authorities of the Secretary regarding offsets have been redelegated to the Under Secretary of the Bureau of Industry and Security (BIS). The regulations associated with offsets reporting are set forth in Part 701 of title 15 of the Code of Federal Regulations. The offsets regulations of Part 701 set forth the obligations of U.S. industry to report to the Bureau of Industry and Security, no later than June 15 of each year, offsets agreement and transaction data for the previous calendar year.

As described in section 701.1 of the regulations, U.S. firms are required to report on contracts for the sale of defense-related items or defense-related services to foreign countries or foreign firms that are subject to offsets agreements exceeding $5,000,000 in value. U.S. firms are also required to report annually on offsets transactions completed in performance of existing offsets commitments for which offsets credit of $250,000 or more has been claimed from the foreign representative. The required data elements and filing procedures for such reports are outlined in section 701.4 of title 15, Code of Federal Regulations.

The Department's annual report to Congress includes an aggregated summary of the data reported by industry in accordance with the offsets regulation and the DPA. As provided by section 309(c) of the DPA, BIS will not publicly disclose the information it receives through offsets reporting unless the firm furnishing the information specifically authorizes public disclosure. The information collected is sorted and organized into an aggregate report of national offsets data, and therefore does not identify company-specific information.

Required information must be submitted to BIS no later than June 15, 2008.

Dated: May 13, 2008.

Matthew S. Borman,

Acting Assistant Secretary for Export Administration.

[FR Doc. E8–11208 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–588–847

Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act Regarding the Antidumping Duty Order on Certain Cut–to-Length Carbon–Quality Steel Plate Products from Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On April 8, 2008, the U.S. Trade Representative instructed the Department of Commerce (the Department) to implement its determination under section 129 of the Uruguay Round Agreements Act (URAA) regarding the investigation of certain cut–to-length carbon–quality steel plate products from Japan. The Department issued its final results on December 21, 2007, regarding the offsetting of dumped comparisons with non–dumped comparisons when making average–to-average comparisons of export price and normal value in the investigation challenged by Japan before the World Trade Organization in *United States - Measures Relating to Zeroing and Sunset Reviews*. The Department is now implementing this determination.

DATES: The effective date of this determination is April 8, 2008.

FOR FURTHER INFORMATION CONTACT: Maisha Cryor or Mark Manning, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW, Washington, DC 20230; telephone: (202) 482–5831, or (202) 482–5253, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 19, 2007, the Department advised interested parties that it was initiating a proceeding under section 129 of the URAA to issue a determination that would implement the findings of the World Trade Organization (WTO) dispute settlement panel in United States - Measures Relating to Zeroing and Sunset Reviews (WT/DS322) (September 20, 2006). On November 26, 2007, the Department issued its preliminary results, in which it recalculated the weighted–average dumping margins from the antidumping investigation of certain cut–to-length carbon–quality steel plate products from Japan[1] by applying the calculation methodology described in *Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin During an Antidumping Investigation; Final Modification*, 71 FR 77722 (December 27, 2006). The Department also invited interested parties to comment on the preliminary results. On December 3, 2007, we received a case brief from IPSCO Steel Inc. (IPSCO), a domestic interested party. We received no other case briefs. After receiving comments from IPSCO, the Department issued its final results for the section 129 determination on December 21, 2007.

On January 11 and 14, 2008, consistent with section 129(b)(3) of the URAA, the U.S. Trade Representative held consultations with the Department and the appropriate congressional committees with respect to this determination. On April 8, 2008, in accordance with sections 129(b)(4) and 129(c)(1)(B) of the URAA, the U.S. Trade Representative directed the Department to implement this determination.

Nature of the Proceedings

Section 129 of the URAA governs the nature and effect of determinations issued by the Department to implement findings by WTO dispute settlement panels and the Appellate Body. Specifically, section 129(b)(2) provides that ''notwithstanding any provision of the Tariff Act of 1930,'' within 180 days of a written request from the U.S. Trade Representative, the Department shall issue a determination that would render its actions not inconsistent with an adverse finding of a WTO panel or the Appellate Body. *See* 19 USC 3538(b)(2). The Statement of Administrative Action, URAA, H. Doc. 316, Vol. 1, 103d Cong. (1994) (SAA), variously refers to such a determination by the Department as a ''new,'' ''second,'' and ''different'' determination. See SAA at 1025, 1027. After consulting with the Department and the appropriate congressional committees, the U.S. Trade Representative may direct the Department to implement, in whole or in part, the new determination made under section 129. *See* 19 USC 3538(b)(4). Pursuant to section 129(c), the new determination shall apply with respect to unliquidated entries of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the date on which the U.S. Trade Representative directs the Department to implement the new determination. *See* 19 USC 3538(c). The new determination is subject to judicial review separate and apart from judicial review of the Department's original determination. *See* 19 USC 1516a(a)(2)(B)(vii).

Analysis of Comments Received

The issues raised in the case brief submitted by an interested party to this proceeding are addressed in the Issues and Decision Memorandum for the Final Results of Proceeding Under Section 129 of the Uruguay Round Agreements Act: Antidumping Measures on Certain Cut–to-Length Carbon–Quality Steel Plate Products from Japan from Stephen J. Claeys to David M. Spooner, dated December 21, 2007 (Issues and Decision Memorandum), which is hereby adopted by this notice. The Issues and Decision Memorandum is on file in the Central Records Unit (CRU), room B–099 of the Department of Commerce main building. A list of the issues addressed in the Issues and Decision Memorandum is appended to this notice.

Final Antidumping Margins

The recalculated margins, unchanged from the preliminary decision in this 129 proceeding, are as follows:

- The margin for Kawasaki Steel Corporation decreases from 10.78 percent to 9.46 percent.
- The all–others rate decreases from 10.78 percent to 9.46 percent.

On April 8, 2008, in accordance with sections 129(b)(4) and 129(c)(1)(B) of the URAA, the U.S. Trade Representative, after consulting with the Department and Congress, directed the Department to implement this determination. Therefore, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of the subject merchandise from all exporters or producers, entered, or withdrawn from warehouse, for consumption on or after April 8, 2008 (the effective date). CBP shall continue to require cash deposit equal to the estimated amount by which normal value exceeds the U.S. price. The suspension of liquidation will remain in effect until further notice. The Section

[1] *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-To-Length Carbon-Quality Steel Plate Products from Japan*, 64 FR 73215 (December 29, 1999).

129 Determination ''all others'' rate will be the new cash deposit rate for all exporters of subject merchandise for whom the Department has not assigned an individual rate, which is 9.46 percent.

This determination is issued and published in accordance with section 129(c)(2)(A) of the URAA.

Dated: May 13, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix I

Issued Raised in the Issues and Decision Memorandum

Comment 1: Whether Customs Instructions Should Be Clarified to Retain the Deposit Rates for Producers Whose Margins Were Not Recalculated
Comment 2: Whether the Preliminary Results Are Consistent with U.S. Law
Comment 3: Whether the Statute Equates the Dumping Margin with the Antidumping Duty Assessment
Comment 4: Whether the Department's Interpretation of the Term Dumping Margin' is Inconsistently Applied to Antidumping Investigations and Administrative Reviews

[FR Doc. E8–11299 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 08–00002]

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Export Trade Certificate of Review to Wilco Machine & Fab, Inc. (Application No. 08–00002).

SUMMARY: On May 12, 2008, the U.S. Department of Commerce issued an Export Trade Certificate of Review to Wilco Machine & Fab, Inc. (''WILCO''). This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT: Jeffrey Anspacher, Director, Export Trading Company Affairs, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number), or by E-mail at *oetca@ita.doc.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (2006).

Export Trading Company Affairs (''ETCA'') is issuing this notice pursuant to 15 CFR section 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR section 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct: WILCO is certified to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets.

I. Export Trade

Products

All Products manufactured by WILCO, including all fabricated, machined, or assembled pressure vessels, tanks, bulk transport trailers, bulk storage trailers, bulk plants or any components of or tools for the aforementioned items (North American Industry Classification System codes: 333132; 332313; 332420; and 332439).

II. Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

III. Export Trade Activities and Methods of Operation

1. WILCO, on its own behalf, may:

a. *Sales Price:* Establish sale prices, minimum sales prices, target sale prices and/or minimum target sales prices, and other terms of sale in Export Markets.

b. *Marketing and Distribution:* Conduct marketing and distribution of Products in Export Markets.

c. *Promotion:* Conduct promotion of Products in Export Markets.

d. *Quantities:* Determine quantities of Products to be sold in Export Markets.

e. *Market and Customer Allocation:* Allocate geographic areas or countries in the Export Markets and/or customers in the Export Markets to Export Intermediaries.

f. *Refusals to Deal:* Refuse to quote prices for Products, or to market or sell Products, to or for any customers in the Export Markets, or any countries or geographical areas in the Export Markets.

g. *Exclusive and Nonexclusive Export Intermediaries:* Enter into exclusive and nonexclusive agreements appointing one or more Export Intermediaries for the sale of Products in Export Markets with price, quantity, territorial, and/or customer restrictions as provided above.

WILCO may meet with customers or Export Intermediaries to discuss or engage in the activities described above.

2. WILCO may, on a one-to-one basis, meet with, exchange, and discuss the following information with its customers and its Export Intermediaries:

a. Information about sale and marketing efforts for the export markets, activities and opportunities for sales of Products in the Export Markets, selling strategies for the Export Markets, sales for the Export Markets, contracts and pricing in the Export Markets, project demands in the Export Markets for Products, customary terms of sale in the Export Markets, price and availability of Products from competitors for sale in Export Markets, and specifications for Products by customers in the Export Markets.

b. Information about its price, quality, quantity, source, and delivery dates of Products for Export Markets.

c. Information about terms and conditions of contracts for sale in the Export Markets to be considered and/or bid on by WILCO.

d. Information about bidding, selling, or sales arrangements for the Export Markets.

e. Information about expenses specific to exporting to and within the Export Markets, including without limitation, transportation, shipments, insurance, inland freight to port, port storage, commissions, export sales, documentation, financing, customs, duties, and taxes.

f. Information about U.S. and foreign legislation and regulations relating to sales in the Export Markets.

g. Information about WILCO's export operations, including without limitation, sales and prior export sales information and prior export price information.

h. Information about export customer credit terms and credit history.

V. Definition

• ''Export Intermediary'' means a person who acts as a distributor, sales representative, sales or marketing agent, import agent, broker, or a person who performs similar functions including providing or arranging for the provision of export trade facilitation services.

A copy of the Certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility,

Room 4100, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Dated: May 14, 2008.

Jeffrey Anspacher,

Director Export Trading Company Affairs.

[FR Doc. E8–11262 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

A–552–801

Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Extension of Time Limit for Final Results of the New Shipper Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: May 20, 2008.

FOR FURTHER INFORMATION CONTACT: Julia Hancock, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–1394.

SUPPLEMENTARY INFORMATION:

Background

On February 1, 2008, the Department of Commerce (''Department'') issued the preliminary results of the shipper reviews for Vinh Quang Fisheries Corporation (''Vinh Quang''), Ngoc Thai Company (''Ngoc Thai''), and Anvifish Co., Ltd. (''Anvifish''). *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Partial Rescission and Preliminary Results of the First New Shipper Review*, 73 FR 6125 (February 1, 2008) (''*Preliminary Results*''). The Department extended the final results 30 days until May 21, 2008. *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: extension of time Limit for Final Results of the New Shipper Reviews*, 73 FR 15478 (March 24, 2008).

Extension of Time Limits for Final Results

Section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the ''Act''), and 19 CFR 351.214(i)(1) require the Department to issue the preliminary results of a new shipper review within 180 days after the date on which the new shipper review was initiated and final results of a review within 90 days after the date on which the preliminary results were issued. The Department may, however, extend the deadline for completion of the final results of a new shipper review to 150 days if it determines that the case is extraordinarily complicated. *See* section 751(a)(2)(B)(iv) of the Act, and 19 CFR 351.214(i)(2).

The Department is extending the deadline for the completion of the final results of these new shipper reviews of the antidumping duty order on certain frozen fish fillets from Vietnam because the case is extraordinarily complicated. The Department preliminarily rescinded the new shipper review with respect to Vinh Quang, however, the Department resumed the review of Vinh Quang based on additional analysis and party comments. In addition, the Department has received additional surrogate value information and case and rebuttal briefs concerning complicated issues. The Department needs additional time to properly consider this information for the final results. Therefore, the completion of the final results of these new shipper reviews is extended by an additional 30 days to June 20, 2008.

We are issuing and publishing this notice in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act.

Dated: May 13, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration,

[FR Doc. E8–11298 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XI01

File No. 13388

Marine Mammals; Receipt of Application to Import One Beluga Whale

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Sea World, Inc., 7007 Sea World Drive, Orlando, FL 32821, has applied in due form for a permit to import one beluga whale (Delphinapterus leucas) for the purposes of public display.

DATES: Written or telefaxed comments must be received on or before June 19, 2008.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 427–2521; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Written comments or requests for a public hearing on this application should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

Comments may also be submitted by facsimile at (301)427–2521, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Comments may also be submitted by e-mail. The mailbox address for providing e-mail comments is *NMFS.Pr1Comments@noaa.gov*. Include in the subject line of the e-mail comment the following document identifier: File No. 13388.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Kate Swails, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant requests authorization to import one male adult beluga whale from the Vancouver Aquarium Marine Science Center, British Columbia, Canada to Sea World of Texas. The applicant requests this import for the purpose of public display. The receiving facility, Sea World of Texas, 10500 SeaWorld Drive, San Antonio, TX 78251 is: (1) open to the public on regularly scheduled basis with access that is not limited or restricted other than by charging for an admission fee; (2) offers an educational program based on professionally accepted standards of the AZA and the Alliance for Marine Mammal Parks and Aquariums; and (3) holds an Exhibitor's License, number 58–C–0077, issued by the U.S. Department of Agriculture under the Animal Welfare Act (7 U.S.C. §§ 2131 - 59).

In addition to determining whether the applicant meets the three public display criteria, NMFS must determine

whether the applicant has demonstrated that the proposed activity is humane and does not represent any unnecessary risks to the health and welfare of marine mammals; that the proposed activity by itself, or in combination with other activities, will not likely have a significant adverse impact on the species or stock; and that the applicant's expertise, facilities and resources are adequate to accomplish successfully the objectives and activities stated in the application.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: May 14, 2008.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E8–11300 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG74

Permits; Foreign Fishing

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; denial of permit.

SUMMARY: Notice is hereby given that a request for five transshipment permits regarding a foreign fishing application submitted under provisions of the Magnuson-Stevens Fishery Conservation and Management Act has been denied.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office:

Office of International Affairs, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Jennifer Olson, Office of International Affairs, (301) 713–2276.

SUPPLEMENTARY INFORMATION: NMFS received an application requesting authorization for five Mexican vessels to receive, within the Pacific waters of the U.S. EEZ south of 34000'N. lat. and east of 121000'W.long., transfers of live tuna from U.S. purse seiners for the purpose of transporting the tuna alive to an aquaculture facility located in Baja California, Mexico. On April 1, 2008 (73 FR 11327), NMFS published a notice of receipt for the application. Because the transshipment of purse seine-caught tuna is prohibited in the Eastern Pacific Ocean under 50 CFR 300.24(d) and 50 CFR 300.25(d), the application has been denied.

Dated: May 15, 2008.

Jean-Pierre Ple,

Acting Director, Office of International Affairs, National Marine Fisheries Service.

[FR Doc. E8–11251 Filed 5–19–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. [Transmittal Nos. 08–31]]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency

ACTION: Notice

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 08–31 with attached transmittal, policy justification, and Sensitivity of Technology.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY
WASHINGTON, DC 20301-2800

MAY 05 2008

In reply refer to:
USP001113-08

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 08-31, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Australia for defense articles and services estimated to cost $450 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

Richard J. Millies
Deputy Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Same ltr to:

House
Committee on Foreign Affairs
Committee on Armed Services
Committee on Appropriations

Senate
Committee on Foreign Relations
Committee on Armed Services
Committee on Appropriations

Transmittal No. 08-31

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) **Prospective Purchaser:** Australia

(ii) **Total Estimated Value:**

Major Defense Equipment*	$ 100 million
Other	$ 350 million
TOTAL	$ 450 million

(iii) **Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:** AEGIS Combat System and select combat system and communication components consisting of 3 AN/SPQ-9B Horizon Search Radars, 3 Cooperative Engagement Capability Systems, 3 Naval Fire Control Systems, 3 Multi-Functional Information Distribution Systems, AN/SLQ-25A Nixie Countermeasure Suite, MK160 Gun Computer System, AIMS MK XII Identification Friend or Foe (IFF) system for the Air Warfare Destroyer platform, communication and information distribution systems, U.S. Government and contractor engineering and logistics personnel services, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, and other related elements of logistics support.

(iv) **Military Department:** Navy (LCQ, Amendment 3)

(v) **Prior Related Cases, if any:**
FMS case LCQ - $489 million - 31Oct05
FMS case LCQ(A01) - $196 million - 04Apr06
FMS case LCQ(A02) - $ 489 million - 31Jul06

(vi) **Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:** none

(vii) **Sensitivity of Technology Contained in the Defense Articles or Defense Services Proposed to be Sold:** See Annex attached

(viii) **Date Report Delivered to Congress:** MAY 05 2008

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia – AEGIS Combat System Components for Air Warfare Destroyer Program

The Government of Australia requested a possible sale of the AEGIS Combat System and select combat system and communication components consisting of 3 AN/SPQ-9B Horizon Search Radars, 3 Cooperative Engagement Capability Systems, 3 Naval Fire Control Systems, 3 Multi-Functional Information Distribution Systems, AN/SLQ-25A Nixie Countermeasure Suite, MK160 Gun Computer System, AIMS MK XII Identification Friend or Foe (IFF) for the Air Warfare Destroyer platform, communication and information distribution systems, U.S. Government and contractor engineering and logistics personnel services, personnel training and training equipment, support and test equipment, spare and repair parts, publications and technical documentation, and other related elements of logistics support. The estimated cost is $450 million.

Australia is one of our most important allies in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region. Australia's efforts in peacekeeping and humanitarian operations in Iraq and in Afghanistan have had a significant impact on regional political and economic stability and have served U.S. national security interests. This proposed sale is consistent with those objectives and facilitates burden sharing with our allies.

The proposed sale of the AEGIS Combat System and components to Australia will contribute to U.S. security objectives by providing a coalition partner with significantly improved Air Warfare capability. This will improve the Royal Australian Navy's ability to participate in coalition operations, will enhance the lethality of its Air Warfare Destroyer platform, and will provide common logistical support with the U.S. Navy. The Royal Australian Navy can easily integrate the capabilities of the AEGIS Weapons Systems into its concept of operations. Australia will have no difficulty absorbing these systems into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractors will be:

Lockheed Martin Maritime Systems and Sensors (two locations)	**Moorestown, New Jersey**
	Eagan, Minnesota
Raytheon Systems Company	**St. Petersburg, Florida**
Northrop Grumman Corporation	**Melville, New York**

There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of three contractor representatives in Australia for approximately 3 months during the preparation, equipment installations, and equipment test and checkout of Cooperative Engagement Capability systems and the AN/SPQ-9B radar.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 08-31

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act

Annex
Item No. vii

(vii) Sensitivity of Technology:

1. The Cooperative Engagement Capability (CEC) is a system that fuses tracking data from shipboard sensors and distributes radar measurement data to other platforms with CEC capability. This data is filtered and combined to create a common tactical picture, based on available sensor data from all platforms netted through the CEC system. The hardware is Unclassified with the exception of a Communications Security (COMSEC) card which is classified Secret. The software and documentation is classified Secret.

2. The Multi-Functional Information Distribution System (MIDS) Terminal is a secure data and voice communication network using the Link 16 architecture. The system provides enhanced situational awareness, positive identification of participants within the network, secure connectivity and secure voice capability. The MIDS Terminal is classified Confidential. The MIDS software and documentation are Unclassified. MIDS has been previously purchased by Australia and the appropriate safeguards are in place to accept delivery and integrate it into the Air Warfare Destroyer.

3. The AN/SPQ-9B radar is a high resolution, three dimensional, rotating phased array, X-band narrow beam radar, providing both air and surface tracking data. The radar will become a component of the AEGIS Combat System on the Australia Air Warfare Destroyer, to serve as a complement to the Aegis SPY-1D (V) radar, providing additional capability to detect and engage surface and low altitude air targets. The AN/SPQ-9B Radar hardware and documentation is Unclassified. The software is classified Secret.

4. The Naval Fire Control System (NFCS) is an automated mission planning system for Naval surface fire support, designed to coordinate and execute fire support weapons engagements. NFCS receives targeting data, generates a coordinated land tactical picture, and prepares fire plans. The NFCS hardware, software, and documentation are Unclassified.

5. All manuals and technical documentation disclosure will be limited to those necessary for operational use and organizational maintenance. No special tooling and/or manufacturing equipment will be sold in connection with this sale.

6. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

Dated: May 7, 2008.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–11142 Filed 5–19–08; 8:45 am]

BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0153]

Federal Acquisition Regulation; Submission for OMB Review; OMB Circular A–119

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (9000–0153).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning OMB Circular A–119. A request for public comments was published at 73 FR 4188, January 24, 2008. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before June 19, 2008.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (VPR), 1800 F Streets, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT Ms. Cecelia Davis, Contract Policy Division, GSA (202) 219–0202.

SUPPLEMENTARY INFORMATION:

A. Purpose

On February 19, 1998, a revised OMB Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' was published in the **Federal Register** at 63 FR 8545, February 19, 1998. FAR Subparts 11.1 and 11.2 were revised and a solicitation provision was added at 52.211–7, Alternatives to Government-Unique Standards, to implement the requirements of the revised OMB circular. If an alternative standard is proposed, the offeror must furnish data and/or information regarding the alternative in sufficient detail for the Government to determine if it meets the Government's requirements.

B. Annual Reporting Burden

Respondents: 100.
Responses Per Respondent: 1.
Total Responses: 100.
Hours Per Response: 1.
Total Burden Hours: 100.
OBTAINING COPIES OF PROPOSALS: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VPR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0153, OMB Circular A–119, in all correspondence.

Dated: May 13, 2008.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E8–11233 Filed 5–19–08; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent to Grant Exclusive Patent License; Vytral Systems Co. Ltd, LLC

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Vytral Systems Co. Ltd, LLC a revocable, nonassignable, partially exclusive license to practice throughout the United States the Government-owned inventions described in U.S. Patent No. 7,281,482: SIDE THRUSTER PERFORMANCE IMPROVEMENT WITH POWER OPTIMIZATION CONTROLLER; U.S. Patent No. 7,277,573: ENHANCED RANDOMNESS ASSESSMENT METHOD FOR THREE-DIMENSIONS; U.S. Patent No. 7,272,072: METHOD OF CONVERTING RECEIVED DATA TO A TWO-DIMENSIONAL COLOR MAP; U.S. Patent No. 7,269,538: METHOD FOR SPARSE DATA TWO-STAGE STOCHASTIC MENSURATION; U.S. Patent No. 7,259,637: DELAY LOOP CORRECTION FOR A PROCESSOR; U.S. Patent No. 7,251,605: SPEECH TO TOUCH TRANSLATOR ASSEMBLY AND METHOD; U.S. Patent No. 7,236,252: SYSTEM AND APPARATUS FOR MEASURING DISPLACEMENTS IN ELECTRO-ACTIVE MATERIALS; U.S. Patent No. 7,212,652: METHOD FOR TRACKING TARGETS WITH HYPER-SPECTRAL DATA; U.S. Patent No. 7,209,240: SYSTEM AND APPARATUS FOR MEASURING DISPLACEMENTS IN ELECTRO-ACTIVE MATERIALS; U.S. Patent No. 7,180,416: TIME KEYED INFORMATION TRANSMISSION; U.S. Patent No. 7,177,232: WIRELESS RADIO FREQUENCY HYDROPHONE SYSTEM; U.S. Patent No. 7,155,389: DISCRIMINATING SPEECH TO TOUCH TRANSLATOR ASSEMBLY AND METHOD; U.S. Patent No. 7,143,033: AUTOMATIC MULTI-LANGUAGE PHONETIC TRANSCRIBING SYSTEM; U.S. Patent No. 7,120,089: SELF-CONTAINED AMBIENT NOISE RECORDER; U.S. Patent No. 7,111,577: ELECTROMAGNETIC WAVE PROPAGATION SCHEME; U.S. Patent No. 7,110,946: SPEECH TO VISUAL AID TRANSLATOR ASSEMBLY AND METHOD; U.S. Patent No. 7,106,658: NAVIGATION SYSTEM AND METHOD USING DIRECTIONAL SENSOR; U.S. Patent No. 7,106,269: OMNI-AZIMUTHAL PATTERN GENERATOR FOR VLF AND LF COMMUNICATION; U.S. Patent No. 7,103,502: ENHANCED SYSTEM FOR DETECTION OF RANDOMNESS IN SPARSE TIME SERIES DISTRIBUTIONS; U.S. Patent No. 7,062,386: METHOD TO ESTIMATE THE MECHANICAL PROPERTIES OF A SOLID MATERIAL SUBJECTED TO INSONIFICATION; U.S. Patent No. 7,061,431: SEGMENTED MICROSTRIP PATCH ANTENNA WITH EXPONENTIAL CAPACITIVE LOADING; U.S. patent No. 7,032,456: ISOSTATIC PIEZORESISTIVE PRESSURE TRANSDUCER WITH TEMPERATURE OUTPUT; U.S. Patent No. 7,027,211: FIBER OPTIC SWITCH EMPLOYING OPTICAL AMPLIFIERS; U.S Patent No. 7,020,046: SYSTEM

AND METHOD FOR TARGET MOTION ANALYSIS WITH INTELLIGENT PARAMETER EVALUATION PLOT; U.S. Patent No. 7,016,563: FIBER OPTIC SWITCH; U. S. Patent No. 7,013,808: METHOD AND SYSTEM FOR DETERMINING A BOUNDING REGION; U.S. Patent No. 7,010,981: INVERSE METHOD FOR ESTIMATING THE WAVE PROPAGATION PARAMETERS OF TWO DISSIMILAR WAVE TYPES; U.S Patent No. 6,984,899: WIND DAM ELECTRIC GENERATOR & METHOD; U.S. Patent No. 6,983,222: MULTI-STAGE PLANAR STOCHASTIC MENSURATION; U.S. Patent No. 6,980,926: DETECTION OF RANDOMNESS IN SPARSE DATA SET OF THREE DIMENSIONAL TIME SERIES DISTRIBUTIONS; U.S Patent No. 6,967,899: METHOD FOR CLASSIFYING A RANDOM PROCESS FOR DATA SETS IN ARBITRARY DIMENSIONS; U.S. Patent No. 6,963,690: TERMINATION CLAMP ASSEMBLY FOR A HYBRID ELECTRICAL/FIBER OPTIC CABLE; U.S. Patent No. 6,940,986: APPARATUS AND METHOD FOR REMOTELY AND AUTOMATICALLY CONTROLLING THE VOLUME OF AUDIO SIGNALS PRODUCED BY A REMOTELY CONTROLLED AUDIO DEVICE; U.S. Patent No. 6,921,990: ELECTRONIC STATUS MONITORING SYSTEM FOR SECURITY CONTAINERS; U.S. Patent No. 6,674,406: MICROSTRIP PATCH ANTENNA WITH PROGRESSIVE SLOT LOADING; U.S. Patent No. 6,611,824: SYSTEM FOR BEARING-ONLY CONTACT STATE ESTIMATION USING RECURRENT NEURAL NETWORKS; U.S. Patent No. 6,564,169: METHOD FOR WIRE GUIDANCE TONE CERTIFICATION; U.S. Patent No. 6,469,666: DIGITAL ANTENNA GONIOMETER AND METHOD; U.S. Patent No. 6,385,130: DUAL CHANNEL SWITCH WITH FREQUENCY BAND LIMITING; U.S. Patent No. 6,374,197: FUZZY LOGIC BASED MODEL ASSESSMENT SYSTEM AND METHOD FOR CONTACT TRACKING; U.S. Patent No. 6,356,600: NON-PARAMETRIC ADAPTIVE POWER LAW DETECTOR; U.S. Patent No. 6,137,909: SYSTEM AND METHOD FOR FEATURE SET REDUCTION; U.S. Patent No. 5,787,408: SYSTEM AND METHOD FOR DETERMINING NODE FUNCTIONALITY IN ARTIFICIAL NEURAL NETWORKS; U.S Patent No. 5,751,260: SENSORY INTEGRATED DATA INTERFACE; U.S. Patent No. 5,727,561: METHOD AND APPARATUS FOR NON-INVASIVE DETECTION AND ANALYSIS OF TURBULENT FLOW IN A PATIENT'S BLOOD VESSELS; and, U.S. Patent No. 5,617,869: DEVICE AND METHOD FOR LOCATING FLOW BLOCKAGE IN A THREE-DIMENSIONAL OBJECT and all patents or patent applications: (i) To which any of the above mentioned patents directly claims priority, (ii) for which any of the above mentioned patents directly forms a basis for priority, (iii) that were co-owned applications that directly incorporate by reference, or are incorporated by reference into, any of the above mentioned patents; (iv) reissues, reexaminations, extensions, continuations, continuing prosecution applications, requests for continuing examinations, divisions, and registrations of any of the above mentioned patents; and (v) foreign patents, patent applications and counterparts relating to any of the above mentioned Patents, including, without limitation, certificates of invention, utility models, industrial design protection, design patent protection, and other governmental grants or issuances.

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with the Naval Undersea Warfare Center Division, Newport, 1176 Howell St., Bldg 990, Code 07TP, Newport, RI 02841.

FOR FURTHER INFORMATION CONTACT: Dr. Theresa A. Baus, Head, Technology Partnership Enterprise Office, Naval Undersea Warfare Center Division, Newport, 1176 Howell St., Bldg 990, Code 07TP, Newport, RI 02841, telephone: 401–832–8728, or e-mail: bausta@npt.nuwc.navy.mil.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: May 14, 2008.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–11241 Filed 5–19–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Partially Closed Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board shall deem necessary into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy. The meeting will include discussions of personnel issues at the Naval Academy, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. The executive session of this meeting will be closed to the public.

DATES: The open session of the meeting will be held on Tuesday, July 08, 2008, from 8 a.m. to 10:45 a.m. The closed Executive Session will be held from 10:45 a.m. to 12 p.m.

ADDRESSES: The meeting will be held in Alumni Hall at the United States Naval Academy, Annapolis, MD.

FOR FURTHER INFORMATION CONTACT: Lieutenant Andrew B. Koy, USN, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, telephone: 410–293–1503.

SUPPLEMENTARY INFORMATION: This notice of meeting is provided per the Federal Advisory Committee Act, as amended (5 U.S.C. App.). The executive session of the meeting will consist of discussions of personnel issues at the Naval Academy and internal Board of Visitors matters. The proposed closed session from 1045–1200 will include a discussion of new and pending courts-martial and state criminal proceedings involving the Midshipmen attending the Naval Academy to include an update on the pending/ongoing sexual assault cases, rape cases, etc. The proposed closed session from 10:45 a.m. to 12 p.m. will include a discussion of new and pending administrative/minor disciplinary infractions and nonjudicial punishments involving the Midshipmen attending the Naval Academy to include but not limited to individual honor/conduct violations within the Brigade. Discussion of such information cannot be adequately segregated from other topics, which precludes opening the executive session of this meeting to the public.

Accordingly, the Secretary of the Navy has determined in writing that the meeting shall be partially closed to the public because it will be concerned with matters listed in section 552b(c)(5), (6), and (7) of title 5, United States Code.

Dated: May 14, 2008.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–11223 Filed 5–19–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Nominations for Membership on Ocean Research and Resources Advisory Panel

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Ocean Research and Resources Advisory Panel (ORRAP) is soliciting nominations for new members.

DATES: Nominations should be submitted no later than June 30, 2008.

ADDRESSES: Nominations should be submitted via e-mail to Mr. John H. Beadling, at *john.beadling.ctr@navy.mil.* Contact Information: Office of Naval Research, 875 North Randolph Street, Suite 1425, ATTN: ONR Code 322B Room 1075, Arlington, VA 22203–1995, telephone: 703–696–4395.

FOR FURTHER INFORMATION CONTACT: Dr. Charles L. Vincent, Office of Naval Research, 875 North Randolph Street, Suite 1425, Arlington, VA 22203–1995, telephone 703–696–4118.

SUPPLEMENTARY INFORMATION: ORRAP, previously named the Ocean Research Advisory Panel, is a statutorily mandated federal advisory committee that provides senior scientific advice to the National Ocean Research Leadership Council (NORLC), the governing body of the National Oceanographic Partnership Program (NOPP). ORRAP advises the NORLC on policies, procedures, selection of projects and allocation of funds, as well as other responsibilities that NORLC considers appropriate.

Panel Member Duties and Responsibilities: Members of the panel represent the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, ocean industries, state governments, academia, and others including individuals who are eminent in the fields of marine science, marine policy, or related fields. Members are appointed for not more than four years, and are not normally compensated except for travel expenses and per diem while away from their homes in performance of services for the panel.

The panel meets for at least one two-day public meeting per year, but possibly meets three times per year, on dates agreed to by the panel members; attendance at meetings is expected. Intercessional activities may be carried out electronically, and the panel may establish sub-panels composed of less than full membership to carry out panel duties.

Nominations: Any interested person or organization may nominate qualified individuals for membership on the panel. Nominated individuals should have extended expertise and experience in the field of ocean science. Nominations should be identified by name, occupation, position, address, telephone number, e-mail address, and a brief paragraph describing their qualifications in the context of the ORRAP Charter (*http://www.nopp.org/Dev2Go.web?id=207773*). A resume or curriculum vitae should be included.

Process a Deadline for Submitting Nominations: Submit nominations via e-mail to *john.beadling.ctr@navy.mil* no later than June 30, 2008. Nominations will be acknowledged and nominators will be informed of the new panel members which are ultimately selected and approved. From the nominees identified by respondents to this **Federal Register** Notice, the ORRAP Nominations Committee will down-select to a short-list of available candidates (150% of the available open positions for consideration). These selected candidates will be required to fill out the ''Confidential Financial Disclosure Report'' OGE form 450. This confidential form will allow Government officials to determine whether there is a statutory conflict between the person's public responsibilities and private interests and activities, or the appearance of a lack of impartiality, as defined by federal regulation. The form and additional guidance may be viewed from the following URL address: *http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/forms/oge450_2006/oge450_automated_06.pdf.*

In accordance with section 7903 of title 10, United States Code, the short-list of candidates will then be submitted for approval by the Secretary of the Navy with concurrence by the Secretary of Defense. In order to have the collective breadth of experience in the panel and maintain full panel membership, six new candidates are expected to be selected with terms to begin in December 2008.

The selection of new panel members will be based on the nominees' qualifications to provide senior scientific advice to the NORLC; the availability of the potential panel member to fully participate in the panel meetings; absence of any conflict of interest or appearance of lack of impartiality, and lack of bias; the candidates' areas of expertise and professional qualifications; and achieving an overall balance of different scientific perspectives and expertise on the panel.

Dated: May 13, 2008.

T.M. Cruz,

Lieutenant, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–11243 Filed 5–19–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Office of Vocational and Adult Education; Overview Information; Promoting Rigorous Career and Technical Education Programs of Study Through Statewide or Multi-State Articulation Agreements

Notice Inviting Applications for New Awards Using Fiscal Year (FY) 2007 Funds.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.051C.

DATES:

Applications Available: May 20, 2008.

Deadline for Notice of Intent to Apply: May 30, 2008.

Deadline for Transmittal of Applications: July 7, 2008.

Deadline for Intergovernmental Review: September 2, 2008.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of the Program: Section 114(c)(1) of the Carl D. Perkins Career and Technical Education Act of 2006 (Act), 20 U.S.C. 2324(c)(1), authorizes the Secretary to carry out research, development, dissemination, evaluation and assessment, capacity building, and technical assistance with regard to the career and technical education (CTE) programs under the Act. Under that authority, the Secretary plans to support State efforts to offer rigorous CTE programs of study and to institutionalize those rigorous CTE programs of study using articulation agreements.

Background Information

The current Act continues the commitment to high-quality CTE embodied in the previous Perkins Act. The Act also continues the previous law's focus on developing challenging academic and technical standards and assisting students in meeting such standards, including through preparation for high-skill, high-wage, or high-demand occupations in current or emerging professions and in nontraditional fields.

Through this competition, the Department continues its efforts to

promote rigorous secondary and postsecondary CTE programs of study and to implement the reauthorized statute. The competition is intended to (1) build on the efforts of States and localities to develop challenging academic and technical standards and to assist students in meeting such standards, including through preparation for high-skill, high-wage, or high-demand occupations in current or emerging professions, and (2) promote the development of services and activities that integrate rigorous and challenging academic and career and technical instruction, and that link secondary education and postsecondary education for participating CTE students. Through this competition, we also intend to build States' capacities to offer rigorous CTE programs of study that are implemented through statewide or multi-State articulation agreements that will continue after Federal funding under this competition ends.

Definitions

The definitions in section 3 of the Act apply to this competition. (20 U.S.C. 2302)

Requirements and Priority

Required Cooperative Agreement: The Secretary will make awards to each grantee under the terms of a cooperative agreement. The Secretary expects to have substantial involvement with grantees during the performance period of funded projects. Substantial involvement on the part of the Department includes—

(a) Reviewing and approving project activities;

(b) Halting an activity immediately if detailed performance specifications or requirements are not met;

(c) Reviewing and approving one stage of work before the grantee can begin a subsequent stage during the project period;

(d) Collaborating or participating jointly in the assisted activities; and

(e) Reviewing and approving plans for developing a CTE program of study and statewide or multi-State articulation agreement.

Required Project Activities: Through this competition, the Secretary will award cooperative agreements to applicants that propose projects that will build a State's capacity, or the capacity of two or more States in the case of consortia, to promote rigorous CTE programs of study. A project must propose to incorporate all of the following elements.

(a) *Use of Partnership.* (1) Use a partnership to develop a new program of study, or adopt or adapt an existing program of study, that aligns secondary and postsecondary education courses that are needed to prepare students for further education and employment.

(2) Use a partnership to develop a statewide or multi-State articulation agreement that the grantee will use to implement the program of study. The statewide or multi-State articulation agreement developed under this competition must be designed to continue after Federal funding under this competition ends.

(b) *CTE programs of study.* (1) Develop a new CTE program of study, or adopt or adapt an existing CTE program of study, that—

(i) Incorporates secondary and postsecondary education elements;

(ii) Includes coherent and rigorous content aligned with challenging academic standards and relevant career and technical content in a coordinated, non-duplicative progression of courses that aligns secondary education with postsecondary education to adequately prepare students to succeed in postsecondary education; and

(iii) Leads to an industry-recognized credential or certificate at the postsecondary level or an associate or baccalaureate degree.

(2) In addition, each grantee's program of study must—

(i) At the secondary education level, align coherent and rigorous academic curriculum with challenging academic content standards and student academic achievement standards in reading/language arts, mathematics, and science that the State (or States) in a consortium in which the program of study will be implemented has (or have) established under Title I of the Elementary and Secondary Education Act of 1965, as amended (20 U.S.C. 6301 *et seq.*) (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB) (20 U.S.C. 6301 *et seq.*);

(ii) Enable secondary education students to meet State high school graduation requirements;

(iii) Offer the opportunity for CTE secondary education students to participate in dual or concurrent enrollment programs with postsecondary institutions or otherwise acquire postsecondary education credits;

(iv) Include either—

(A) One of the 16 career clusters recognized by the Department (on the Internet at: *http://www.careerclusters.org/16clusters.cfm)*;

(B) A career cluster approach previously developed by one or more States; or

(C) An approach that a State or a consortium of States wants to develop with funds awarded under this competition;

(v) Incorporate CTE content standards that have been validated by a State, regional, or national third-party entity that is qualified to assess and confirm the rigor of the program of study (e.g., the National Home Builders Association, Oklahoma General Contractor's Association, or NASDCTEc National Advisory Committees) in conjunction with employers and postsecondary institutions that are familiar with the elements of the program of study (*e.g.*, with the CTE courses, industry-recognized standards, or technical skill proficiencies that will be embedded in the program of study);

(vi) Ensure alignment between the State secondary CTE and postsecondary CTE referred to in paragraph (b)(1)(ii) of this section; and

(vii) Offer academic and career counseling.

(c) *Partnership Activities.* (1) Establish a partnership that, at a minimum, includes the State agencies responsible for the administration of CTE, secondary education, and postsecondary education (both two- and four-year institutions); at least one State workforce agency; and representatives of employers and of faculty and administrators from the State's or States' secondary and postsecondary education institutions who are familiar with elements of the program of study (e.g., with the CTE courses, industry-recognized standards, or technical skill proficiencies that will be embedded in the program of study).

(i) The partnership must—

(A) Ensure the rigor and quality of the CTE program of study to be developed under the cooperative agreement, as described in paragraph (b) of this section; and

(B) Develop a statewide or multi-State articulation agreement that will be used to implement the program of study within the State, or within the States within a consortium.

(ii) Ensure that the projects proposing to develop multi-State articulation agreements include each of the partners listed in paragraph (c)(1) of this section for each State participating in the project.

(2) Actively involve the partners in the project (i.e., each of the partners must have a clearly defined leadership role in planning, developing, and implementing the CTE program of study) as evidenced by clearly delineated responsibilities that are described in the application and by a letter from each State agency committing the agency to carry out the agreed upon partnership responsibilities.

(3) Include in the project representatives of partners who are able to answer questions and influence decisions, have excellent knowledge of the program of study to be developed, adapted, or adopted, and have the authority to communicate information to decision-makers.

(4) Develop a clear rationale for selecting the program of study (e.g., a program of study will provide training in a high-growth, high-demand, or high-wage occupation as reflected in the national, State, or regional labor market), including information about the number of students, schools, and institutions statewide (or within the consortium) that would implement the program of study.

(5) Identify or develop the academic and career content standards, validated by a qualified third-party as described in paragraph (b)(2)(v) of this section, that students would strive to meet under the program of study.

(6) For the program of study, identify the coherent and rigorous sequence of courses the State will require students to take at the secondary and postsecondary (at both two- and four-year institutions) levels.

(7) Perform a course-by-course analysis of the State's secondary and postsecondary CTE courses to identify courses that meet the requirements of the program of study and, if there are missing courses, design courses to complete the program of study.

(8) Identify or develop courses that provide opportunities for secondary education students to participate in dual or concurrent enrollment programs or otherwise acquire postsecondary education credits.

(9) Identify or develop postsecondary courses that, when successfully completed, allow students to transfer to another community college or institution of higher education without losing credit for courses already completed.

(10) Review State and local policies and issues in the following areas and determine how they enhance or inhibit the establishment of a statewide or multi-State articulation agreement for the program of study:

(i) Funding.

(ii) Faculty certification.

(iii) Assessments documenting student attainment of technical skills.

(iv) Credit transfer.

(v) Tracking student transitions.

(vi) Awarding of credit.

(vii) Statewide program of study availability.

(11) Develop and implement plans addressing issues that inhibit the establishment of a program of study and a statewide or multi-State articulation agreement.

(d) *Statewide or multi-State articulation agreement.*

(1) Prepare a written articulation agreement that is signed by the chief executive of each of the State agencies responsible for the administration of CTE, secondary, and postsecondary education (both two- and four-year institutions) agreeing to implement the program of study.

(2) The articulation agreement must—

(i) Describe the program of study, including—

(A) The specific coursework requirements at the secondary, two-year college, and four-year college levels, including pre-requisites;

(B) As appropriate, course grade requirements, end-of-course exams, certifications, or minimum grade-point average for each secondary and postsecondary level course;

(C) Options available for students to transfer credits to community colleges or four-year institutions; and

(D) The minimum qualifications for faculty teaching courses in the program of study;

(ii) Describe how the program of study meets the requirements in paragraph (b) of this section of the notice;

(iii) Describe plans for implementing the statewide or multi-State articulation agreement;

(iv) Describe plans for periodically reviewing and updating the program of study and statewide or multi-State articulation agreement and for maintaining the involvement of the partners;

(v) Identify the curriculum standards and admission requirements for two- and four-year postsecondary institutions for the program of study;

(vi) Describe the procedures and requirements for transferring secondary and community college coursework for credit;

(vii) Describe the procedures for secondary education students to participate in dual or concurrent enrollment programs or otherwise acquire postsecondary education credits;

(viii) Explain how credit is awarded to students under the program of study;

(ix) Describe the State's or States' plans for developing statewide or multi-State articulation agreements for additional CTE programs of study after the project ends; and

(x) Describe the State's or States' plans for providing, after Federal funding ends, professional development opportunities, including faculty certification training or in-service training designed to prepare staff for implementation of the program of study developed under the project.

(e) *Documentation.* (1) Document the process the grantee used to design, adapt, or adopt and reach agreement on the program of study, maintain the partnership, build collaborative relationships, develop the statewide or multi-State articulation agreement, and enhance students' ability to transition from secondary to postsecondary education, including how the grantee analyzed courses and reviewed and negotiated transfer and admissions requirements.

(2) Document the process the qualified third party used to assess and confirm the rigor of the content standards of the program of study, as described in paragraph (b)(2)(v) of this section.

(3) Document the State and local policies and issues that enhanced or inhibited the development of the program of study and the statewide or multi-State articulation agreement.

(4) Describe the methods the partnership used to incorporate into the program of study and the articulation agreement State and local policies that facilitated the development of a program of study and facilitated the development of the articulation agreement.

(5) Describe the methods the partnership used to address the obstacles in the following areas:

(i) Funding.

(ii) Faculty certification.

(iii) Assessments documenting student attainment of technical skills.

(iv) Credit transfer.

(v) Tracking student transitions.

(vi) Awarding of credit.

(vii) Statewide program of study availability.

(6) Prepare materials for dissemination that describe the process the grantee followed when designing, adapting, or adopting and reaching agreement on the program of study and developing the statewide or multi-State articulation agreement.

(f) *Dissemination.* Disseminate—

(1) Material on the process the grantee followed when designing, adapting, or adopting and reaching agreement on the program of study; and

(2) Program-specific material developed for the program of study.

(g) *Technical assistance.* Plan to participate in technical assistance activities sponsored by the Department, including two meetings in which grantees will describe their projects' progress, make connections with other projects, and discuss common issues, strategies, best practices, and actual or potential barriers to implementation.

Priority: We are establishing this priority for the FY 2007 funds grant

competition and any subsequent year in which we make awards from the list of unfunded applicants from this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232(d)(1).

Competitive Preference Priority: This priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i) we award an additional 10 points to an application that meets this priority.

The priority is:

Commitment to the project: In order to build States' capacities to offer rigorous CTE programs of study through statewide or multi-State articulation agreements that will continue after Federal funding ends under this competition, we award 10 points to an application that demonstrates commitment to the project funded under this competition and to enhancing project activities by providing 30 percent of the total cost of the proposed project using either State leadership funds awarded under the Act; or non-Federal contributions, including use of facilities, equipment, supplies, services, third-party in-kind contributions, and other resources; or a combination of both State leadership funds and non-Federal contributions.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed non-statutory requirements, priorities, and selection criteria. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements non-statutory requirements, priorities, and selection criteria governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 114 of the Act and, therefore, qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the non-statutory requirements, priority, and selection criteria under the authority of section 437(d)(1) of GEPA. The non-statutory requirements, priority, and selection criteria set forth in this notice will apply to the FY 2007 funds competition and any subsequent year in which we make awards from the list of unfunded applicants from this competition.

Program Authority: 20 U.S.C. 2324(c)(1).

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Cooperative agreements.

Estimated Available Funds: $750,000 is available from the FY 2007 appropriation for the first 12 months of the project period. $500,000 is available from the FY 2008 appropriation for the second 12 months and is subject to a grantee meeting the requirements of 34 CFR 75.253.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2009 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $120,000 to $130,000.

Estimated Average Size of Awards: $125,000.

Estimated Number of Awards: 6.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 24 months.

III. Eligibility Information

1. *Eligible Applicants:* The following entities are eligible to apply under this competition:

(a) A State board designated or created consistent with State law as the sole State agency responsible for the administration of CTE in the State or for the supervision of the administration of CTE in the State.

(b) A consortium of State boards identified in paragraph (a) of this section. Eligible applicants proposing to develop a multi-State articulation agreement must apply for funds as a consortium and must comply with the regulations in 34 CFR 75.127 through 75.129, which address group applications.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* Scott Hess, U.S. Department of Education, 400 Maryland Avenue, SW., room 11073, Potomac Center Plaza, Washington, DC 20202–7241. *Telephone:* (202) 245–7772 or by *e-mail: scott.hess@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Notice of Intent to Apply: The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department by sending a short e-mail message indicating the applicant's intent to submit an application for funding. The e-mail should include only the applicant's intent to submit an application; it does not need to include information regarding the content of the proposed application. This e-mail notification should be sent no later than May 30, 2008 to Scott Hess at: *scott.hess@ed.gov.*

We will consider an application submitted by the deadline date for transmittal of applications even if the applicant did not provide notice of its intent to apply.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 25 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is 12 point.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

We will reject your application if you apply these standards and exceed the page limit; or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: May 20, 2008.

Deadline for Notice of Intent to Apply: May 30, 2008.

Deadline for Transmittal of Applications: July 7, 2008.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: September 2, 2008.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section in this notice.

6. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications:* To comply with the President's Management Agenda, we are participating as a partner in the Governmentwide Grants.gov Apply site. Promoting Rigorous Career and Technical Education Programs of Study Through Statewide or Multi-State Articulation Agreements, CFDA Number 84.051C, is included in this project. We request your participation in Grants.gov.

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *http://www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

You may access the electronic grant application for the Promoting Rigorous Career and Technical Programs of Study Through Statewide Articulation Agreements competition at *http://www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.051, not 84.051C).

Please note the following:

- Your participation in Grants.gov is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date and time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf.*
- To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see *http://www.grants.gov/applicants/get_registered.jsp*). These steps include (1) registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf*). You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to submit successfully an application via Grants.gov. In addition, you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. Please note that two of these forms—the SF 424 and the Department of Education Supplemental Information for SF 424—have replaced the ED 424 (Application for Federal Education Assistance).
- If you submit your application electronically, you must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail.

This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail:* If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service:
U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.051C),
400 Maryland Avenue, SW.,
Washington, DC 20202–4260 or
By mail through a commercial carrier:
U.S. Department of Education,
Application Control Center, Stop 4260, Attention: (CFDA Number 84.051C), 7100 Old Landover Road,
Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery:* If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.051C), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The Secretary uses the following selection criteria to evaluate an application for this competition. The maximum score for each criterion is indicated in parentheses. The maximum score for all of these selection criteria is 150 points.

(a) *Project design (50 points).* In determining the quality of the design of the proposed project, the Assistant Secretary considers the extent to which the project design is an effective strategy for building a State's capacity, or the capacity of the States in the case of consortia, to promote a rigorous CTE program of study and developing a statewide or multi-State articulation agreement that will extend beyond the period of Federal financial assistance under this competition, including by—

(1) Carrying out the project using a partnership among State agencies responsible for the administration of CTE, secondary education, and postsecondary education (both two- and four-year institutions); at least one State workforce agency; representatives of employers and of faculty and administrators from the State's or States' secondary and postsecondary education institutions who are familiar with elements of the program of study (e.g., with CTE courses, industry-recognized standards, or technical skill proficiencies that will be embedded in the program of study);

(2) Making effective use of the partnership described in paragraph (a)(1) of this section and its individual members to reach agreement on the content standards for a State program of study that will improve the rigor and quality of CTE programs within the State or States within a consortium and to develop an articulation agreement for implementing the CTE program of study;

(3) For projects proposing to develop a multi-State articulation agreement, including the partners listed in paragraph (a)(1) of this section of the notice for each State participating in the project;

(4) Actively involving partners in the project (i.e., each partner will have a clearly defined leadership role in planning, developing, and implementing the program of study) as evidenced by clearly delineated responsibilities that are described in the application and by a letter from the State agency committing the agency to

carry out the agreed upon responsibilities; and

(5) Involving partners whose representatives are able to answer questions and influence decisions, have excellent knowledge of the program of study to be developed, and have the authority to communicate information to decision-makers.

(b) *Technical approach (45 points).* In determining the quality of the technical approach of the proposed project, the Assistant Secretary considers the following factors:

(1) The extent to which the application comprehensively addresses each required project activity, clearly defining the actions to be undertaken to accomplish each activity.

(2) The extent to which the applicant demonstrates a thorough understanding of effective practices in the development of articulation agreements and of CTE programs of study.

(3) The extent to which the applicant describes in a clear and sequential manner effective strategies for accomplishing the required project activities.

(c) *Project management (30 points).* In determining the quality of the management plan for the proposed project, the Assistant Secretary considers the following factors:

(1) The extent to which the Project Director has clearly identified and documented professional qualifications, competencies, and experience necessary to carry out project tasks. (10 points)

(2) The extent to which—

(i) The applicant includes a description, in a clear and sequential manner, of the plan for managing the project; and

(ii) The plan provides credible evidence that the management of personnel, physical resources, and activities will result in orderly and timely completion of work within the project performance period. (15 points)

(3) The extent to which the time commitments of the Project Director, key personnel, and partners are appropriate to the tasks assigned. (5 points)

(d) *Dissemination (15 points).* In determining the quality of the dissemination activities of the proposed project, the Assistant Secretary considers the following factors:

(1) The extent to which the proposed project will result in replicable strategies that are practical and can be packaged for dissemination nationally.

(2) The extent to which the proposed project will develop material that can be packaged for dissemination, particularly the extent to which such material will include a description of the procedure the grantee used to develop the statewide or multi-State articulation agreement and to develop, adapt, or adopt a program of study, including any specific material or curriculum developed for the program of study.

(e) *Adequacy of resources (10 points).* In determining the adequacy of resources for the proposed project, the Assistant Secretary considers the following factors:

(1) The adequacy of resources for the proposed project, including facilities, equipment, supplies, and other resources needed to carry out successfully the purpose and activities of the proposed project.

(2) The extent to which the budget is adequate to support the proposed project.

(3) The extent to which the costs are reasonable in relation to the technical approach and significance of the proposed project.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notice (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:*

We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section in this notice and include these and other specific conditions in the GAN. The GAN also incorporates the approved application as part of your binding commitments under the grant.

3. *Reporting.* (a) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(b) In addition, grantees under this competition must submit—

(1) An interim report six months after the grant is awarded; and

(2) An annual report on the GPRA measures identified in the *Performance Measures* section of this notice.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993, Federal departments and agencies must clearly describe the goals and objectives of programs, identify resources and actions needed to accomplish goals and objectives, develop a means of measuring progress made, and regularly report on achievement. In determining the overall effectiveness of projects funded under this competition, grantees must be prepared to measure and report on the following measures of effectiveness:

a. The percentage of the State's CTE secondary students in the career cluster for the program of study developed by the grantee who can participate in dual or concurrent enrollment programs with postsecondary institutions, or otherwise acquire postsecondary education credits, as determined by the number of CTE concentrators in the career cluster in those secondary schools that commit to implementing the articulation agreement developed by the grantee divided by the total number of CTE concentrators in the State in the career cluster for the program of study.

b. The percentage of the State's CTE postsecondary students in the career cluster for the program of study developed by the grantee who can transfer to another community college or four-year college without losing credit for courses already completed, as determined by the number of CTE concentrators in the career cluster in those postsecondary institutions that commit to implementing the articulation agreement developed by the grantee divided by the total number of CTE concentrators in the State's postsecondary institutions in the career cluster for the program of study.

c. The percentage of the State's secondary schools offering the career cluster for the grantee's program of study that commit to implementing the articulation agreement developed by the grantee.

d. The percentage of the State's postsecondary institutions offering the career cluster for the grantee's program of study that commit to implementing the articulation agreement developed by the grantee.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Scott Hess, U.S. Department of Education, 400 Maryland Avenue, SW., room 11073, Potomac Center Plaza, Washington, DC 20202–7241. Telephone: (202) 245–7772, or by e-mail: *scott.hess@ed.gov.*

If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: May 15, 2008

Troy R. Justesen,

Assistant Secretary for Vocational and Adult Education.

[FR Doc. E8–11271 Filed 5–19–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.133A]

Disability and Rehabilitation Research Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of intent to fund down the grant slate for the Disability and Rehabilitation Research Projects (DRRP) program for Traumatic Brain Injury Model Systems (TBIMS).

SUMMARY: The Secretary intends to use the grant slate developed for the TBIMS grant competition in fiscal year (FY) 2007 to make new grant awards for TBIMS centers in FY 2008. The Secretary takes this action because Congress requested that the Secretary fund two additional TBIMS centers in FY 2008.

FOR FURTHER INFORMATION CONTACT: Donna Nangle, U.S. Department of Education, 400 Maryland Avenue, SW., Room 6030, Potomac Center Plaza, Washington, DC 20202–2700. Telephone: (202) 245–7462 or via Internet: *donna.nangle@ed.gov*.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) upon request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: On February 14, 2007, we published a notice in the **Federal Register** (72 FR 7288) inviting applications for new awards under the TBIMS program for FY 2007. We received 23 applications for grants in response to that notice and funded 14 new grants.

The explanatory statement accompanying the Department of Education Fiscal Year 2008 Appropriations Act (Pub. L. 110–161) specifies that the Secretary reserve $8.3 million to carry out the TBIMS program and, more specifically, that in FY 2008 the Secretary fund two additional applicants from the list of unfunded applications for the last TBIMS grant competition. Consistent with the Congressional intent expressed in the explanatory statement, the Secretary intends to fund two additional TBIMS centers in FY 2008 by funding down the grant slate developed for the TBIMS program in FY 2007, which includes several high-quality applications that have not yet been funded.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: May 15, 2008.

William W. Knudsen,

Deputy Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E8–11269 Filed 5–19–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13130–000]

Dan River Hydropower LLC; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

May 13, 2008.

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–13130–000.

c. *Date Filed:* February 25, 2008.

d. *Applicant:* Dan River Hydropower, LLC.

e. *Name of the Project:* Danville Hydropower Project.

f. *Location:* The project would be located on the Dan River in Pittsylvania County, Virginia. The Union Street Dam is owned and maintained by Dan Rivers Properties.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

Applicant Contact: Mr. Kevin Edwards, P.O. Box 143, Mayodan, NC 27027, (336) 589–6138.

i. *FERC Contact:* Patricia W. Gillis, (202) 502–8735.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, 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–13130–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list

for the project. Further, if an intervenor 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 document on that resource agency.

k. *Description of Project:* The proposed project would utilize the existing U.S. Army Corps of Engineers' Coralville Lake Dam and would consist of: (1) Two 70-foot-long, 180-inch diameter proposed penstocks; (2) a proposed powerhouse containing two generating units with a total installed capacity of 5.7-megawatts; (3) a proposed transmission line; and (4) appurtenant facilities. The proposed project would have an estimated annual generation of 50-gigawatts and would be sold to a local utility.

l. *Location of Application:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30 and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30 and 4.36.

p. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *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.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', and ''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 the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *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.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–11198 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP08–389–000]

Coastal Bend Gas Storage, LLC; Notice of Application

May 13, 2008.

Take notice that on May 7, 2008, Coastal Bend Gas Storage, LLC (CBGS), 400, 607—8th Avenue, SW., Calgary, AB, T2P 0A7, Canada, filed in Docket No. CP08–389–000, a petition for Exemption of Temporary Acts and Operations from Certificate Requirements, pursuant to Rule 207(a)(5) of the Commission's Rules of Practice and Procedure, and section 7(c)(1)(B) of the Natural Gas Act, seeking approval of an exemption from certificate requirements to perform temporary activities designed to determine the feasibility of developing an underground natural gas storage facility in San Patricio and Refugio Counties, Texas, as more fully set forth in the petition which is open to the public for inspection. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits,

in the docket number field to access the document. For assistance, call (202) 502–8659 or TTY, (202) 208–3676.

Any questions regarding this application should be directed to counsel for CBGS, Douglas F. John, John & Hengerer, 1730 Rhode Island Avenue, NW., Suite 600, Washington, DC 20036, or via telephone at (202) 429–8800, facsimile number (202) 429–8805, or e-mail *djohn@jhenergy.com*.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: May 28, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–11201 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

May 14, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP08–372–000.

Applicants: Ozark Gas Transmission, L.L.C.

Description: Ozark Gas Transmission, LLC modifies its FERC Gas Tariff to permit Ozark and a firm transportation service customer to negotiate the fuel retention percentage that will be applicable to customers.

Filed Date: 05/12/2008.

Accession Number: 20080513–0195.

Comment Date: 5 p.m. Eastern Time on Tuesday, May 27, 2008

Docket Numbers: RP08–373–000.

Applicants: Wyoming Interstate Company, Ltd.

Description: Wyoming Interstate Co, Ltd submits Second Revised Sheet 6 et al. to FERC Gas Tariff, Second Revised Volume 2, to become effective 6/10/08.

Filed Date: 05/12/2008.

Accession Number: 20080513–0194.

Comment Date: 5 p.m. Eastern Time on Tuesday, May 27, 2008.

Docket Numbers: RP08–374–000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: Maritimes & Northeast Pipeline LLC submits First Revised Sheet 268 et al. to FERC Gas Tariff, First Revised Volume 1, to become effective 6/11/08.

Filed Date: 05/12/2008.

Accession Number: 20080513–0100.

Comment Date: 5 p.m. Eastern Time on Tuesday, May 27, 2008.

Docket Numbers: RP08–375–000.

Applicants: Energy West Development, Inc.

Description: Energy West Development, Inc submits First Revised Sheet 1 et al. to its FERC Gas Tariff, Volume 1, to become effective 6/12/08.

Filed Date: 05/12/2008.

Accession Number: 20080513–0196.

Comment Date: 5 p.m. Eastern Time on Tuesday, May 27, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously

intervened in the same docket. 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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–11252 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–256–000]

Algonquin Gas Transmission, LLC; Notice of Filing

May 13, 2008.

Take notice that on April 30, 2008, Algonquin Gas Transmission, LLC (Algonquin), 5400 Westheimer Court, Houston, Texas 77056–5310, filed an application, pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's Rules and Regulations, for a certificate of public convenience and necessity authorizing Algonquin to construct, own, operate and maintain an approximately 2.3 miles of 14-inch diameter pipeline loop from the head of the existing J–2 Lateral in Medford, Massachusetts (J–2 Loop). The application is on file with the Commission and open for public inspection. 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* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Pursuant to the settlement agreement between Algonquin and NSTAR Gas Company (NSTAR), in Docket No. RP07–395, Algonquin requests authorization to construct the J–2 Loop. The J–2 Loop will allow Algonquin to inspect and, if necessary, repair the existing J–2 Lateral while at the same time continuing to deliver gas to NSTAR. Also, the J–2 Loop will provide NSTAR additional capacity to meet increased demand and to ensure reliability of service. The J–2 Loop will have a total design capacity of 140,000 Dth/d, and a maximum allowable operating pressure of 433 psi. Algonquin proposes to implement initial Section 7(c) rates and related tariff provisions for services on the J–2 Loop pursuant to Rate Schedule AFT–CL and AIT–2. The entire capacity created by the J–2 Loop project has been subscribed by NSTAR under the J–2 Facility Firm Service Agreement, which specifies a long-term firm commitment for 20 years from the in-service date of the project. Algonquin proposes a service date of September 1, 2009.

Any questions regarding the application are to be directed to Garth Johnson, General Manager, Certificates and Reporting, Algonquin Gas Transmission, LLC, 5400 Westheimer Court, P.O. Box 1642, Houston, TX 77251–1642; phone number (713) 627–5415 or by e-mail at *gjohnson@spectraenergy.com.*

Any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the below listed comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Motions to intervene, protests and comments 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: June 3, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–11199 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12615–001]

Alaska Power & Telephone Company; Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Alternative Licensing Procedures

May 13, 2008.

a. *Type of Filing:* Notice of Intent to File License Application, Filing of Pre-Application Document, and Approving Use of the Alternative Licensing Procedures.

b. *Project No.:* 12615–001.

c. *Dated Filed:* March 10, 2008.

d. *Submitted by:* Alaska Power & Telephone Company.

e. *Name of Project:* Soule River Hydroelectric Project.

f. *Location:* On the Soule River, a tributary to the Portland Canal, approximately 9 miles south of Hyder, Alaska. The project would occupy 1,112 acres of United States lands administered by the U.S. Forest Service.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. *Applicant Contact:* Glen D. Martin, Project Manager, Alaska Power & Telephone Company, 193 Otto Street, P.O. Box 3222, Port Townsend, WA

98368; (360) 385–1733 extension 122; e-mail at *glen.m@aptalaska.com.*

i. *FERC Contact:* Matt Cutlip at (503) 552–2762; or e-mail at *matt.cutlip@ferc.gov.*

j. Alaska Power & Telephone Company filed its request to use the Alternative Licensing Procedures on March 10, 2008. Alaska Power & Telephone Company provided public notice of its request on March 7, 2008. In a letter dated May 5, 2008, the Director, Division of Hydropower Licensing approved Alaska Power & Telephone Company's request to use the Alternative Licensing Procedures.

k. With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402; (b) NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR section 600.920; and (c) the Alaska State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Alaska Power & Telephone Company as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act, section 305 of the Magnuson-Stevens Fishery Conservation and Management Act, and section 106 of the National Historic Preservation Act.

m. Alaska Power & Telephone Company filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD 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, contact FERC Online Support at *FERCONlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h.

o. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–11202 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–355–000]

East Tennessee Natural Gas, LLC; Notice of Request Under Blanket Authorization

May 13, 2008.

Take notice that on May 1, 2008, East Tennessee Natural Gas, LLC (East Tennessee), 5400 Westheimer Court, Houston, Texas 77056–5310, filed in Docket No. CP08–355–000, an application pursuant to sections 157.205, 157.208, and 157.210 of the Commission's Regulations under the Natural Gas Act (NGA) as amended, to remove and replace pipe, modify certain underground piping, and install a new inspection and cleaning pipeline pig launcher and appurtenant facilities on Line No. 3300–1 as part of the Greenway/Nora Expansion Project in Washington County, Virginia, under East Tennessee's blanket certificate issued in Docket No. CP82–412–000,[1] all as more fully set forth in the application which is on file with the Commission and open to the public for inspection.

East Tennessee proposes to (1) Remove and replace (relay) approximately 5.65 miles of 8-inch diameter pipe with 24-inch diameter pipe between Mileposts 9.30 and 14.95 on its Line No. 3300–1 between the Bristol and Glade Springs compressor stations in Washington County; (2) modify underground interconnecting piping at two existing meter stations located within the proposed relay section; and (3) install a new inspection and cleaning pipeline pig launcher and appurtenant facilities at the beginning of the proposed relay, all at an estimated cost of $18,900,000. East Tennessee states that it would finance this project with funds on hand. East Tennessee also states that the proposed Greenway/Nora Expansion Project facilities would allow East Tennessee to provide firm transportation service for 50,000 dekatherms (Dth) equivalent per day of natural gas into the growing North Carolina market and other upstream system locations by December 1, 2008.

Any questions concerning this application may be directed to Garth Johnson, General Manager, Certificates & Reporting, East Tennessee Natural Gas, LLC, P.O. Box 1642, Houston, Texas 77251–1642, or via telephone at (713) 627–5415, or facsimile number (713) 627–5947.

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'' link. Enter the docket number excluding the last three digits in the docket number filed to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or call toll-free at (866) 206–3676, or, for TTY, contact (202) 502–8659. 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 intervenors to file electronically.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–11200 Filed 5–19–08; 8:45 am]

BILLING CODE 6717–01–P

[1] 20 FERC ¶62,413(1982).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2008–0353; FRL–8568–1]

Agency Information Collection Activities; Proposed Collection; Comment Request; Motor Vehicle Emissions and Fuel Economy Compliance: Light Duty Vehicles, Light Duty Trucks, and Highway Motorcycles; EPA ICR No. 0783.54, OMB Control No. 2060–0104

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on November 30, 2008. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before July 21, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2008–0353, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Fax:* 202–566–9744.
- *Mail:* Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket, Mailcode 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* Docket Center, (EPA/DC), EPA, West Room B102, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2008–0353. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Lynn Sohacki, Compliance and Innovative Strategies Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan, 48105; telephone number: 734–214–4851; fax number: 734–214–4869; e-mail address: *sochacki.lynn@epa.gov.*

SUPPLEMENTARY INFORMATION:

How Can I Access the Docket and/or Submit Comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2008–0353, which is available for online viewing at *www.regulations.gov,* or in person viewing at the Air Docket in the Docket Center (EPA/DC), EPA West, EPA Headquarters Library, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 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 Docket is 202–566–1742.

Use *www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What Information is EPA Particularly Interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) 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;

(ii) 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;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What Should I Consider when I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under **DATES**.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What Information Collection Activity or ICR Does this Apply to?

Docket ID No. EPA–HQ–OAR–2008–0353

Affected entities: Entities potentially affected by this action are manufacturers

and independent commercial importers into the United States of light duty vehicles, light duty trucks and highway motorcycles.

Title: Motor Vehicle Emissions and Fuel Economy Compliance: Light Duty Vehicles, Light Duty Trucks, and Highway Motorcycles.

ICR numbers: EPA ICR No. 0783.54, OMB Control No. 2060–0104.

ICR status: This ICR is currently scheduled to expire on November 30, 2008. 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 title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Under the Clean Air Act (42 U.S.C. 7521 *et seq.*) manufacturers and importers of light duty vehicles (passenger cars), light trucks, and motorcycles must have a certificate of conformity issued by EPA covering any vehicle they intend to offer for sale. In addition, light duty vehicles and light truck manufacturers and importers must also submit fuel economy information and reports required by the Energy Policy and Conservation Act (49 U.S.C. 32901 *et seq.*). EPA reviews vehicle information and manufacturer test data to determine if the vehicle design conforms to applicable requirements and to verify that the required testing has been performed. After a certificate of conformity has been issued, subsequent audit and enforcement actions may be taken based on the initial information submitted as well as on information submitted while the vehicles are in service. Until a vehicle is available for purchase, information is confidential. Some proprietary information is permanently confidential.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 346.24 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; 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.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 173.

Frequency of response: Yearly and occasionally.

Estimated total average number of responses for each respondent: 10.82.

Estimated total annual burden hours: 647,100.

Estimated total annual costs: $58,343,913. This includes an estimated labor burden cost of $39,876,745 and an estimated cost of $18,467,168 for capital investment or maintenance and operational costs.

What is the Next Step in the Process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: May 14, 2008.

Karl J. Simon,

Director, Compliance and Innovative Strategies Division.

[FR Doc. E8–11296 Filed 5–19–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8567–7]

EPA's 2008 Report on the Environment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: EPA is announcing the availability of a final report titled, ''EPA's 2008 Report on the Environment'' (EPA/600/R–07/045F), which was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD) with significant input from partners across EPA and other federal agencies.

EPA's 2008 Report on the Environment (2008 EPA ROE) compiles the most reliable indicators available to help understand important trends in the environment and human health. The indicators are supported by data that are as current as possible (data included in the 2008 EPA ROE are as recent as October 2007). Additionally, the report identifies key limitations of these indicators and gaps where reliable indicators do not yet exist. These gaps and limitations highlight the disparity between the current state of knowledge and the goal of full, reliable, and insightful representation of environmental conditions and trends, and provide direction for future research and monitoring efforts.

DATES: This document will be available on or about May 20, 2008.

ADDRESSES: The document will be available electronically through the NCEA Web site at *http://www.epa.gov/ncea*. The main distribution method for this report will be via the Internet. A limited number of paper copies and compact disks, however, will be available from the EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1–800–490–9198; facsimile: 301–604–3408; e-mail: *nscep@bps-lmit.com.* Please provide your name, your mailing address, and the title and EPA number of the requested publication.

FOR FURTHER INFORMATION CONTACT: The Information Management Team, National Center for Environmental Assessment (8601P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone: 703–347–8561; fax: 703–347–8691; e-mail: *nceadc.comment@epa.gov.*

SUPPLEMENTARY INFORMATION:

To accomplish its mission to protect human health and the environment, the U.S. Environmental Protection Agency (EPA) must pay close attention to trends in the condition of the nation's air, water, and land, as well as related trends in human health and ecological systems. To meet this need, EPA embarked on a bold initiative in 2001 to assemble, for the first time, the most reliable available indicators of national environmental and health conditions and trends that are important to EPA's mission. EPA initially presented these

indicators in its *Draft Report on the Environment (ROE) Technical Document (TD), and its publicly oriented companion document, the Draft Report on the Environment (ROE),* both released in 2003. For the 2008 EPA ROE, both the proposed indicators included in the report and the complete draft document were subjected to rigorous, independent, and external peer review, as well as public comment. Complete documentation of the peer review process and responses are available at *http://www.epa.gov/ncea.roe.* Thus, EPA has revised, updated, and refined the 2003 draft ROE in response to scientific developments, as well as feedback from EPA's Science Advisory Board and stakeholders. As a result, the 2008 EPA ROE provides both an update and an improvement over the 2003 draft edition.

EPA is also producing a *Highlights of Conditions and Trends* document, which summarizes the findings of the 2008 EPA ROE in an easier-to-understand format. The Highlights Document is expected to be publicly available later in the year.

EPA is committed to releasing periodic updates of the ROE so that information on environmental conditions and trends can be provided to interested members of the public.

Dated: May 13, 2008.

George Gray,

Assistant Administrator, Office of Research and Development.

[FR Doc. E8–11132 Filed 5–19–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 4, 2008.

A. Federal Reserve Bank of Kansas City (Todd Offenbacker, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. Scott K. Martinsen, Overland Park, Kansas, and Dean A. Lanier, Leavenworth, Kansas, as co–trustees for the CCB Financial Corporation Voting Trust and the Thompson Family Trusts and as members of the Thompson Family Group, to acquire control of CCB Financial Corporation, Kansas City, Missouri, and thereby indirectly acquire control of Country Club Bank, National Association, Shawnee Mission, Kansas, and MidAmerican Bank and Trust Company, National Association, Leavenworth, Kansas.

2. Scott K. Martinsen, Overland Park, Kansas, and Dean A. Lanier, Leavenworth, Kansas, as co–trustees for the Thompson Family Trusts and as members of the Thompson Family Group, to acquire control of MidAmerican Bancshares, Inc., Kansas City, Missouri, and thereby indirectly acquire control of Allen Bank and Trust Company, Harrisonville, Missouri.

3. Platte County Bancshares Voting Trust and by Scott K. Martinsen, Overland Park, Kansas, and Dean A. Lanier, Leavenworth, Kansas, as co–trustees for the Platte County Bancshares Voting Trust and as members of the Thompson family group, to acquire control of Platte County Bancshares, Inc., and thereby indirectly acquire control of Platte Valley Bank of Missouri, both in Platte City, Missouri.

Board of Governors of the Federal Reserve System, May 15, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–11234 Filed 5–19–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/.*

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 13, 2008.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Charter Bankshares, Inc., Eau Claire, Wisconsin, to acquire 100 percent of the voting shares of Peregrine Corporation, and thereby indirectly acquire voting shares of Community Bank Corporation, both of Chaska, Minnesota.

Board of Governors of the Federal Reserve System, May 15, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–11235 Filed 5–19–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Consumer Advisory Council; Notice of Meeting of the Consumer Advisory Council

The Consumer Advisory Council will meet on Thursday, June 19, 2008. The meeting, which will be open to public observation, will take place at the Federal Reserve Board's offices in Washington, DC, in Dining Room E on the Terrace Level of the Martin Building. Anyone planning to attend the meeting should, for security purposes, register no later than Tuesday, June 17, by completing the form found online at: *https://www.federalreserve.gov/secure/forms/cacregistration.cfm.*

Additionally, attendees must present photo identification to enter the building.

The meeting will begin at 9 a.m. and is expected to conclude at 1 p.m. The

Martin Building is located on C Street, NW., between 20th and 21st Streets.

The Council's function is to advise the Board on the exercise of the Board's responsibilities under various consumer financial services laws and on other matters on which the Board seeks its advice. Time permitting, the Council will discuss the following topics:

• Proposed rules regarding credit cards and overdraft services.

Members will discuss the Board's proposal under the Federal Trade Commission Act to prohibit unfair or deceptive acts or practices by banks in connection with credit card accounts and overdraft services for deposit accounts. The proposed changes to the Board's Regulation AA (Unfair or Deceptive Acts or Practices) would be complemented by separate proposals under the Truth in Lending Act (Regulation Z) and the Truth in Savings Act (Regulation DD).

• Proposed rules on risk-based pricing notices.

Members will discuss proposed regulations that generally would require a creditor to provide a consumer with a risk-based pricing notice when, based in whole or in part on the consumer's credit report, the creditor offers or provides credit to the consumer on terms less favorable than those it offers or provides to other consumers. The proposal would implement section 311 of the Fair and Accurate Credit Transactions Act of 2003, which amends the Fair Credit Reporting Act.

Reports by committees and other matters initiated by Council members also may be discussed.

Persons wishing to submit views to the Council on any of the above topics may do so by sending written statements to Jennifer Kerslake, Secretary of the Consumer Advisory Council, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551. Information about this meeting may be obtained from Ms. Kerslake, 202–452–6470.

Board of Governors of the Federal Reserve System, May 14, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–11161 Filed 5–19–08; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Peer Review Panel Report on the Validation Status of New Versions and Applications of the Murine Local Lymph Node Assay (LLNA): A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals and Products: Notice of Availability and Request for Public Comments

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for comments.

SUMMARY: NICEATM, in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), convened an independent international scientific peer review panel on March 4–6, 2008 to evaluate new versions and applications of the LLNA for assessing the allergic contact dermatitis potential of chemicals and products. The peer review panel (''the Panel'') report from this meeting is now available. The report contains (1) the Panel's evaluation of the validation status of the methods and (2) the Panel's comments and conclusions on draft ICCVAM test method recommendations. NICEATM invites public comment on the Panel's report. The report is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm* or by contacting NICEATM at the address given below.

DATES: Written comments on the Panel report should be received by July 7, 2008.

ADDRESSES: Comments should be submitted preferably electronically via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm*. Comments can also be submitted by e-mail to *niceatm@niehs.nih.gov*. Written comments can be sent by mail or fax to Dr. William S. Stokes, Director, NICEATM, NIH/NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947. Courier address: NICEATM, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM (919–541–2384 or *niceatm@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Background

In January 2007, the Consumer Product Safety Commission submitted a nomination to NICEATM and ICCVAM to assess the validation status of (1) The use of the LLNA to determine potency for hazard classification purposes; (2) LLNA protocols using non-radioactive procedures; (3) the LLNA limit dose procedure; and (4) the use of the LLNA to test mixtures, aqueous solutions, and metals (*i.e.*, an updated assessment of the applicability domain of the LLNA). In June 2007, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) endorsed these activities as high priorities for ICCVAM. NICEATM, on behalf of ICCVAM, also sought input from the public on these activities and requested data from studies using the LLNA or modified versions of the LLNA (**Federal Register** Vol. 72, No. 95, pages 27815–27817, May 17, 2007). After considering all comments received, ICCVAM endorsed carrying out these activities as high priorities. ICCVAM also developed draft LLNA performance standards to facilitate evaluation of modified LLNA protocols that are functionally and mechanistically similar to the traditional LLNA. These draft LLNA performance standards were made public and comments were requested via the **Federal Register** (Vol. 72, No. 176, pages 52130–52131, Sept. 12, 2007).

ICCVAM and NICEATM prepared draft background review documents (BRDs) that provided comprehensive reviews of available data and relevant information for each of the modifications and new applications of the LLNA. ICCVAM also developed draft test method recommendations regarding the proposed usefulness and limitations, standardized protocols, and future studies. Both the draft BRDs and draft recommendations were made available for public comment, and a public peer review meeting was announced in the **Federal Register** (Vol. 73, No. 5, pages 1360–1362, Jan. 8, 2008).

The Panel met in public session on March 4–6, 2008. The Panel reviewed the draft ICCVAM BRDs for completeness, errors, and omissions of any existing relevant data or information. The Panel evaluated the information in the BRDs to determine the extent to which each of the applicable criteria for validation and acceptance of toxicological test methods (ICCVAM, 2003) had been appropriately addressed. The Panel then considered the ICCVAM draft test method

recommendations (*i.e.*, proposed test method uses, proposed recommended standardized protocol, proposed test method performance standards, and proposed additional studies) and commented on whether the recommendations were supported by the information provided in the draft BRDs.

The Panel's conclusions and recommendations are detailed in the *Peer Review Panel Final Report: Validation Status of New Versions and Applications of the Murine Local Lymph Node Assay (LLNA): A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals and Products* (available at *http://iccvam.niehs.nih.gov/methods/immunotox/llna_PeerPanel.htm*). The draft BRDs, draft ICCVAM test method recommendations, and the draft LLNA Performance Standards are available at *http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm*.

Request for Comments

NICEATM invites the submission of written comments on the Panel's report. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). All comments received will be made publicly available on the NICEATM–ICCVAM Web site at *http://ntp-apps.niehs.nih.gov/iccvampb/searchPubCom.cfm*. In addition, there will be an opportunity for oral public comments on the Panel's report during an upcoming meeting of SACATM scheduled for June 18–19, 2008. Information concerning the SACATM meeting will be published in a separate **Federal Register** notice and available on the SACATM Web site at *http://ntp.niehs.nih.gov/go/7441*.

ICCVAM will consider the Panel report along with SACATM and public comments when finalizing test method recommendations. An ICCVAM test method evaluation report, which will include the final ICCVAM recommendations, will be forwarded to relevant Federal agencies for their consideration. The evaluation report will also be available to the public on the NICEATM–ICCVAM Web site and by request from NICEATM (see **ADDRESSES** above).

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes scientific validation, regulatory acceptance, and national and international harmonization of toxicological test methods that more accurately assess safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*-3, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167*.

References

ICCVAM, 2003, ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No. 03–4508. Research Triangle Park, NC: NIEHS. Available at: *http://iccvam.niehs.nih.gov*.

Dated: May 8, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–11195 Filed 5–19–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0230]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays.'' This guidance document describes a means by which antigen detection assays for *Plasmodium* species may comply with the requirement of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify these device types into class II (special controls). This guidance document is immediately in effect as the special control for antigen detection assays for *Plasmodium* species, but it remains subject to comment in accordance with the agency's good guidance practices.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays'' 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 240–276–3151. 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Freddie Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration,2098 Gaither Rd., Rockville, MD 20850, 240–276–0712.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying *Plasmodium* species antigen detection assays into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(c)(f)(2)). This

guidance document will serve as the special control for *Plasmodium* species antigen detection assays. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on ''*Plasmodium* species antigen detection assays.'' 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: *Plasmodium* Species Antigen Detection Assays'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1646 to identify the guidance you are requesting.

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 at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 30, 3008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–11261 Filed 5–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 5, 2008, 12 p.m. to 5 p.m. EDT. June 6, 2008, 9 a.m. to 12:30 p.m. EDT.

Place: Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, June 5 from 1 p.m. to 5 p.m. (EDT) and Friday, June 6 from 9 a.m. to 12:30 p.m. (EDT). The public can join the meeting via audio conference call by dialing 1–888–593–8429 on June 5 & 6 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the June meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics Evaluation and Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Michelle Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: *mherzog@hrsa.gov.* Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Michelle Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593 or e-mail: *mherzog@hrsa.gov.*

Dated: May 14, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–11237 Filed 5–19–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the NTP Board of Scientific Counselors: Amended Notice

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Availability of a Public Telephone Call-In Line.

SUMMARY: This notice announces the availability of a public telephone call-in line for the June 11–12, 2008 meeting of the NTP Board of Scientific Counselors. The meeting will be held at the Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709 and videocast through the Internet at *http://www.niehs.nih.gov/news/video/live*. Information regarding the meeting was announced in the **Federal Register** (73FR20289) published on April 15, 2008. The guidelines published in the April 15 **Federal Register** notice for submitting written public comments or making an oral presentation at the meeting still apply. In response to the public interest in the peer review of the Draft NTP Brief on Bisphenol A, the NTP will provide a telephone call-in line for public comments. The line will be open from 8:30 a.m. until 3 p.m. on June 11, although public comments will be received only during the formal public comment period on the draft brief. The exact time for the presentation of public comments is not set, but will follow the overview presentation on the draft brief and the talk on biomonitoring of bisphenol A exposures (the preliminary agenda is available at (*http://ntp.niehs.nih.gov/go/165*) or by contacting Dr. Barbara Shane, see **FOR FURTHER INFORMATION CONTACT** below).

ADDRESSES: Public comments on all agenda topics and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–4253; fax: 919–541–0295; or e-mail: *shane@niehs.nih.gov*. Courier address: NIEHS, 111 T.W. Alexander Drive, Room A322, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Shane (telephone: 919–541–4253 or e-mail: *shane@niehs.nih.gov*).

Telephone Call-in Line

The following information is required for telephone access:

- USA Toll Free Number: 877–915–2768.
- Passcode: NTP.
- Leader Name: Barbara Shane.

The NTP has reserved 50 telephone lines for this call and access availability will be on a first come first served basis. Telephone comments should not exceed three minutes in length and each organization is allowed only one oral slot (in person at the meeting or by telephone) per agenda topic. Calls will be taken as time permits and at the discretion of the BSC chairperson. Every effort will be made to accommodate callers, but the total time allotted for comments and the time allotted per speaker via the telephone will depend on how many people register online to speak. Registration to present oral public comments or to submit written comments can be completed online at the BSC meeting site (*http://ntp.niehs.nih.gov/go/165*). Details about the meeting, Internet access, and telephone call-in are also available at this site. The public telephone call-in is a new remote access option for the BSC, thus its technical quality cannot be guaranteed.

Persons who register online to make oral comments by telephone are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by June 4, 2008, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation.

Dated: May 8, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–11206 Filed 5–19–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Report on Carcinogens (RoC); Availability of the Draft Background Document for Styrene; Request for Comments on the Draft Background Document for Styrene; Announcement of the Styrene Expert Panel Meeting

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Availability of Background Documents; Request for Comments; and Announcement of a Meeting.

SUMMARY: The NTP announces the availability of the draft background document for styrene on May 22, 2008, on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*) or in printed text from the RoC (see **ADDRESSES** below). The NTP invites the submission of public comments on the draft background document for styrene. The expert panel will meet on July 21–22, 2008, at the Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709 to peer review the draft background document for styrene and, once completed, make a recommendation regarding the listing status for styrene (i.e., *known to be a human carcinogen, reasonably anticipated to be a human carcinogen*, or not to list) in the 12th Edition of the RoC (12th RoC). The RoC expert panel meeting is open to the public with time scheduled for oral public comments. Attendance is limited only by the available meeting room space. Following the expert panel meeting and completion of the expert panel report, the NTP will post the final version of the background document and the expert-panel peer review report on the RoC Web site.

DATES: The expert panel meeting for styrene will be held on July 21–22, 2008. The draft background document for styrene will be available for public comment on May 22, 2008. The deadline to submit written comments is July 07, 2008, for pre-registration to attend the meeting is July 14, 2008, and for pre-registration to provide oral comments at the meeting is July 14, 2008.

ADDRESSES: The RoC expert panel meeting on styrene will be held at Radisson Hotel Research Triangle Park, 150 Park Drive, Research Triangle Park, NC 27709. Access to on-line registration and materials for the meeting are available on the RoC Web site (*http://ntp.niehs.nih.gov/go/29679*). Comments

on the draft background document should be sent to Dr. Ruth M. Lunn, NIEHS, P.O. Box 12233, MD EC–14, Research Triangle Park, NC 27709, FAX: (919) 316–4637, or *lunn@niehs.nih.gov*. Courier address: Report on Carcinogens Office, 79 T.W. Alexander Drive, Building 4401, Room 3118, Research Triangle Park, NC 27709. Persons needing interpreting services in order to attend should contact 301–402–8180 (voice) or 301–435–1908 (TTY). Requests should be made at least seven business days in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Ruth M. Lunn (telephone: 919–316–4637, or *lunn@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Background

The NTP announced the RoC review process for the 12th RoC on April 16, 2007, in the **Federal Register** (72 FR 18999 available at *http://ntp.niehs.nih.gov/go/15208*). An expert panel meeting is being convened on July 21–22, 2008, to review styrene for possible listing in the 12th RoC. The draft background document for styrene will be available on the RoC Web site on May 22, 2008, in printed text from the RoC Office (see **ADDRESSES** above). Persons can register free-of-charge with the NTP listserv to receive notification when draft RoC background documents for other candidate substances for the 12th RoC are made available on the RoC Web site *(http://ntp.niehs.nih.gov/go/231)*.

Styrene is a very important monomer used worldwide in the production of polymers, which are incorporated into products such as rubber, plastic, insulation, fiberglass, pipes, automobile parts, food containers, and carpet backing. Most of these products contain both free styrene monomer and styrene polymerized in long chains (polystyrene). Sources of exposure to the general public include inhalation of indoor and outdoor ambient air, smoking, and ingestion of foods. Occupational exposure occurs mainly in the reinforced plastics, styrene-butadiene rubber, and styrene monomer and polymer industries.

Preliminary Agenda, Availability of Meeting Topics and Registration

Preliminary agenda topics include:

- Oral public comments on styrene.
- Peer review of the draft background document on styrene.
- Recommendation for listing status for styrene in the 12th RoC.

The meeting is schedule for July 21–22, 2008, from 8:30 a.m. to adjournment each day. A copy of the preliminary agenda, expert panel roster, and any additional information, when available, will be posted on the RoC Web site or may be requested from the Director of the RoC Office (see **ADDRESSES** above). Individuals who plan to attend the meeting are encouraged to register on-line by July 14, 2008, to facilitate planning for the meeting.

Request for Comments

The NTP invites both written and oral public comments on the draft background document on styrene. All written comments received will be posted on the RoC website prior to the meeting and distributed to the expert panel and RoC staff for their consideration in the peer review of the draft background document and/or preparation for the expert panel meeting. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Lunn (see **ADDRESSES** above) for receipt by July 07, 2008. Time will be set-aside at the expert panel meeting for the presentation of oral public comments. Seven minutes will be available for each speaker (one speaker per organization). Persons can register on-line to present oral comments or contact Dr. Lunn (see **ADDRESSES** above). When registering to comment orally, please provide your name, affiliation, mailing address, telephone and facsimile numbers, e-mail and sponsoring organization (if any). If possible, send a copy of the statement or talking points to Dr. Lunn by July 14, 2008. This statement will be provided to the expert panel to assist them in identifying issues for discussion and will be noted in the meeting record. Registration for presentation of oral comments will also be available at the meeting on July 21–22, 2008, from 7:30–8:30 a.m. Time allowed for comments by on-site registrants may be less than for pre-registered speakers and will be determined by the number of persons who register at the meeting. Persons registering at the meeting are asked to bring 25 copies of their statement or talking points for distribution to the expert panel and for the record.

Background Information on the RoC

The RoC is a congressionally mandated document [Section 301(b)(4) of the Public Health Services Act, 42 U.S.C. 241(b)(4)] that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as ''substances'') that may pose a hazard to human health by virtue of their carcinogenicity. Substances are listed in the report as either *known or reasonably anticipated to be human carcinogens*. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services. Information about the RoC and the nomination process can be obtained from its homepage (*http://ntp.niehs.nih.gov/go/roc*) or by contacting Dr. Lunn (see **FOR FURTHER INFORMATION CONTACT** above). The NTP follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process is available on the RoC Web site (*http://ntp.niehs.nih.gov/go/15208*) or in printed copy from the RoC Office.

Dated: May 8, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–11207 Filed 5–19–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

ODS Analytical Methods and Reference Materials Program—Vitamin Methodology Workshop; Notice

Notice is hereby given of the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) Analytical Methods and Reference Materials Program, Vitamin Methodology Workshop to be held Monday, July 7th and Tuesday, July 8th, 2008 at the Marriott Gaithersburg Washingtonian Center Hotel in Gaithersburg, Maryland, 20878.

Summary

In FY 2002, Congress addressed the need for support of analytical methods and reference materials development related to dietary supplements. The congressional appropriation language supported an increased ODS budget for several topics, including analytical methods and reference materials. The Senate language called for: ''ODS to allocate sufficient funds to speed up an ongoing collaborative effort to develop and disseminate validated analytical methods and reference materials for the most commonly used botanicals and other dietary supplements.''

On February 8, 2002, ODS held a public meeting to solicit comments to assist ODS in designing an overall strategy for implementing the Congressional mandate to foster development and validation of

analytical methods and reference materials for dietary supplements.

In FY 2004 and 2005, Congress again used similar language supporting the Analytical Methods and Reference Materials program in the ODS appropriations.

On September 10, 2007 ODS held a Stakeholders' Meeting to state the progress that had been made by the Analytical Methods and Reference Materials program since its inception in 2002 and to receive comments on the future directions for the next five years. The Vitamin Methodology Workshop is a follow-up to the recommendations from the stakeholders. The purpose of the workshop is to evaluate the state of analytical methodology on vitamins suitable for dietary supplements and identify gaps in the analytical science for the purpose of meeting future methods needs of stakeholders.

The sponsor of this meeting is the NIH Office of Dietary Supplements.

Registration

Seating at this workshop is very limited. To register please forward your name and complete mailing addresses including phone number via e-mail to Mr. Mike Bykowski at *mbyskowski@csion.com*. Mr. Bykowski will be coordinating the registration for this meeting. If you wish to make an oral presentation during the meeting, you must indicate this when you register and submit the following information: (1) A brief written statement of the general nature of the statement that you wish to present, (2) the names and addresses of the person(s) who will give the presentation, and (3) the approximate length of time that you are requesting for your presentation. Depending on the number of people who register to make presentations, we may have to limit the time allotted for each presentation. If you don't have access to e-mail please call Mr. Bykowski at 301–670–0270.

Dated: May 12, 2008.

Paul Coates,

Director, Office of Dietary Supplements, National Institutes of Health.

[FR Doc. E8–11192 Filed 5–19–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0383]

Information Collection Request to Office of Management and Budget; OMB Control Numbers: 1625–0028, 1625–0034, and 1625–0043

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Requests (ICRs) and Analyses to the Office of Management and Budget (OMB) requesting an extension of their approval for the following collections of information: (1) 1625–0028, Course Approvals for Merchant Marine Training Schools; (2) 1625–0034, Ships' Stores Certification for Hazardous Materials Aboard Ships, and (3) 1625–0043, Ports and Waterways Safety—Title 33 CFR Subchapter P. Before submitting these ICRs to OMB, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 21, 2008.

ADDRESSES: To avoid duplicate submissions to the docket [USCG–2008–0383], please use only one of the following means:

(1) Online: *http://www.regulations.gov.*

(2) Mail: Docket Management Facility (DMF) (M–30), U.S. Department of Transportation (DOT), West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) Hand deliver between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) Fax: 202–493–2251.

The DMF 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 W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., 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://www.regulations.gov.*

Copies of the completed ICRs are available through this docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from Commandant (CG–611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593–0001. The telephone number is 202–475–3523.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, telephone 202–475–3523, or fax 202–475–3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

The Coast Guard invites comments on whether this information collection request should be granted based on it being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of information subject to the collections; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology.

We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the paragraph on DOT's ''Privacy Act Policy'' below.

Submitting comments: If you submit a comment, please include the docket number [USCG–2008–0383], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the DMF 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: Go to *http://www.regulations.gov* to view documents mentioned in this notice as being available in the docket. Enter the docket number [USCG–2008–0383] in the Search box, and click, ''Go>>.'' You may also visit the DMF in room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., 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 by visiting *http://DocketsInfo.dot.gov.*

Information Collection Request

1. *Title:* Course Approval and Records for Merchant Marine Training Schools.

OMB Control Number: 1625–0028.

Summary: The information is needed to ensure that merchant marine training schools meet minimal statutory requirements. The information is used to approve the curriculum, facility and faculty for these schools.

Need: 46 U.S.C. 7315 authorizes an applicant for a license or document to substitute the completion of an approved course for a portion of the required sea service. 46 CFR 10.302 prescribes the Coast Guard regulations for course approval.

Respondents: Merchant marine training schools.

Frequency: Five years for reporting; one year for recordkeeping.

Burden Estimate: The estimated burden has increased from 27,675 hours to 97,260 hours a year.

2. *Title:* Ships' Stores Certification for Hazardous Materials Aboard Ships.

OMB Control Number: 1625–0034.

Summary: The information is needed to ensure that personnel aboard ships are made aware of the proper usage and stowage instructions for certain hazardous materials. Provisions are made for waivers of products in special DOT hazard classes.

Need: 46 U.S.C. 3306 authorizes the Coast Guard to prescribe regulations for the transportation, stowage, and use of ships' stores and supplies of a dangerous nature. 46 CFR Part 147 prescribes the regulations for hazardous ships' stores.

Respondents: Suppliers and manufacturers of hazardous products used on ships.

Frequency: On occasion.

Burden Estimate: The estimated burden has increased from 9 hours to 12 hours a year.

3. Title: Ports and Waterways Safety—Title 33 CFR Subchapter P.

Summary: This collection of information allows the master, owner, or agent of a vessel affected by these rules to request a deviation from the requirements governing navigation safety equipment to the extent that there is no reduction in safety.

Need: Provisions in 33 CFR chapter I, subchapter P, allow any person directly affected by the rules in that subchapter to request a deviation from any of the requirements as long as it does not compromise safety. This collection enables the Coast Guard to evaluate the information the respondent supplies, to determine whether it justifies the request for a deviation.

Respondents: Master, owner, or agent of a vessel.

Frequency: On occasion.

Burden Estimate: The estimated burden has decreased from 3,171 hours to 2,865 hours a year.

Dated: May 13, 2008.

D.T. Glenn,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. E8–11231 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2008–N0107; 96300–1671–0000–P5]

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits for marine mammals.

SUMMARY: The following permits were issued.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 212, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Fish and Wildlife Service issued the requested permits subject to certain conditions set forth therein.

MARINE MAMMALS

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
773494	Florida Fish and Wildlife Conservation Commission, Fish ad Wildlife Research Institute.	72 FR 68176; Decemer 4, 2007	April 22, 2008.
165727	Niladri Basu, University of Michigan	73 FR 10282; February 26, 2008	April 21, 2008.
166346	Matson's Laboratory	73 FR 14266; March 17, 2008	April 21, 2008.

Dated: April 25, 2008.

Lisa J. Lierheimer,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E8–11259 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2008–N0123; 40120–1112–0000-F5]

Receipt of Applications for Endangered Species Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with threatened and endangered species.

DATES: We must receive written data or comments on the applications at the address given below, by *June 19, 2008.*

ADDRESSES: Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: David Dell, HCP Coordinator).

FOR FURTHER INFORMATION CONTACT: David Dell, telephone 404/679–7313; facsimile 404/679–7081.

SUPPLEMENTARY INFORMATION: The public is invited to comment on the following applications for permits to conduct certain activities with endangered and threatened species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). This notice is provided under section 10(c) of the Act. If you wish to comment, you may submit comments by any one of the following methods. You may mail comments to the Fish and Wildlife Service's Regional Office (see **ADDRESSES** section) or via electronic mail (e-mail) to *david_dell@fws.gov*. Please include your name and return address in your e-mail message. If you do not receive a confirmation from the Fish and Wildlife Service that we have received your e-mail message, contact us directly at the telephone number listed above (see **FOR FURTHER INFORMATION CONTACT** section). Finally, you may hand deliver comments to the Fish and Wildlife Service office listed above (see **ADDRESSES** section).

Before including your address, telephone number, e-mail address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comments to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. We will not, however, 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.

Applicant: Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, Southeast Region, TE697819

The applicant requests renewal of existing authorization to take or remove and reduce to possession listed species occurring in the U.S. Fish and Wildlife Service's Southeast Region for scientific purposes, the enhancement of propagation or survival, and for approved recovery activities. The applicant also requests amendment of their existing permit to add or remove all newly listed or de-listed species since the last permit renewal, as well as to add candidate species expected to be listed in the near future.

Applicant: Harold Schramm, USGS, Mississippi Cooperative Fish and Wildlife Research Unit, Mississippi State, Mississippi, TE178448

The applicant requests authorization to capture, implant acoustic transmitters into, and release pallid sturgeon (*Scaphirhynchus albus*) for tracking purposes in the Mississippi and Atchafalaya Rivers in Mississippi and Louisiana.

Applicant: Scott Slankard, Eco-Tech Consultants, Inc., Frankfort, Kentucky, TE810274

The applicant requests authorization to amend an existing permit to capture, handle, radio-tag, and release Indiana bats (*Myotis sodalis*) and gray bats (*Myotis grisescen*) for presence/absence surveys and scientific research aimed at recovery of the species throughout the states of New Jersey, West Virginia, Kentucky, Georgia, North Carolina, South Carolina, Tennessee, Missouri, Ohio, Indiana, and Illinois.

Applicant: Peggy Measel, Round Mountain Biological and Environmental Studies, Inc., Nicholasville, Kentucky, TE121059

The applicant requests authorization to amend an existing permit to capture, identify, measure, sex, and release Indiana bats and gray bats while conducting presence/absence surveys throughout the species ranges in Tennessee.

Applicant: Norman Wagoner, Forest Supervisor, Ouachita National Forest, Hot Springs, Arkansas, TE125605

The applicant requests renewal of existing authorization to capture, handle, band, and release the Indiana bat while conducting inventory and monitoring surveys within the boundaries of Ouachita National Forest, Arkansas and Oklahoma.

Applicant: Chris Fleming, BDY Environmental, LLC, Nashville, Tennessee, TE111326

The applicant requests renewal of existing authorization to capture, identify, sex, photograph, temporarily hold, release, and relocate the Nashville crayfish (*Orconectes shoupi*) while conducting presence/absence surveys and translocation activities in Mill Creek Watershed, Davidson and Williamson Counties, Tennessee.

Applicant: Robert Oney, Palmer Engineering, Winchester, Kentucky, TE178524

The applicant requests authorization to capture, identify, temporarily hold, and release Indiana bats, gray bats, and Virginia big-eared bats (*Corynorhinus townsendii virginianus*); cumberlandian combshell (*Epioblasma brevidens*), Cumberland elktoe (*Alasmidonta atropurpurea*), Cumberland bean (*Villosa trabalis*), fanshell (*Cyprogenia stegaria*), ring pink (*Obovaria retusa*), orangefoot pimpleback (*Plethobasus cooperianus*), rough pigtoe (*Pleurobema plenum*), pink mucket (*Lampsilis abrupta*), clubshell (*Pleurobema clava*), and fat pocketbook (*Potamilus capax*); and locate white-haired goldenrod (*Solidago albopilosa*), running buffalo clover (*Trifolium stoloniferum*), and Virginia spiraea (*Spiraea virginiana*) while conducting presence/absence surveys throughout the range of the species.

Applicant: Paul Stone, Crosby Resource Management, LLC, DeRidder, Louisiana, TE179330

The applicant requests authorization to harass the red-cockaded woodpecker (*Picoides borealis*) while surveying population occurrence and conducting management activities for this species throughout Louisiana, Mississippi, and Texas.

Applicant: Jeffrey Walters, Department of Biological Sciences, Virginia Tech, Blacksburg, Virginia, TE070846

The applicant requests renewal of existing authorization to monitor nests, capture, band, radio-tag, collect blood, construct cavities, and translocate red-cockaded woodpeckers for the purposes of banding juveniles and adults, monitoring populations and nest cavities, and various research projects throughout the species range in Florida, South Carolina, and North Carolina.

Applicant: Michael Keys, North Florida Wildlife, Crawfordville, Florida, TE834056

The applicant requests renewal of existing authorization to capture, band, and release red-cockaded woodpeckers for the purposes of banding juveniles and adults and monitoring populations and nest cavities throughout the species range in Arkansas, Florida, Georgia, South Carolina, North Carolina, Alabama, Louisiana, Mississippi, Virginia, Oklahoma, and Texas.

Applicant: Shaun Williamson, Forest Supervisor, National Forests in Mississippi, Jackson, Mississippi, TE020890

The applicant requests renewal of existing authorization to harass red-cockaded woodpeckers for the purposes of constructing and monitoring artificial nest cavities and restrictors; for capturing, banding, and translocation of birds; and for monitoring populations and nest cavities throughout the species range in Mississippi.

Applicant: Charles Rabolli, CCR Environmental, Inc., Atlanta, Georgia, TE096132

The applicant requests renewal of existing authorization to harass red-cockaded woodpeckers while conducting presence/absence surveys, constructing artificial nest cavities, controlling vegetation, and monitoring activities in clusters throughout the species range in Virginia, Arkansas, Florida, Georgia, South Carolina, North Carolina, Alabama, Louisiana, Mississippi, and Tennessee.

Applicant: Curtis Garriock, Pittsboro, North Carolina, TE179329

The applicant requests authorization to capture, identify, photograph, temporarily hold, and release the Saint Francis Satyr butterfly (*Neonympha mitchellii francisci*) while conducting presence/absence surveys for this species throughout North Carolina and Virginia.

Applicant: Eric Hoffman, Department of Biology, University of Central Florida, Orlando, Florida, TE179312

The applicant requests authorization to capture, examine, draw blood, collect hairs, and release the Lower Keys marsh rabbit (*Sylvilagus palustris hefneri*) to assess genetic diversity in Monroe County, Florida.

Applicant: Chris Isaac, Appalachian Technical Services, Inc., Wise, Virginia, TE009638

The applicant requests authorization to amend an existing permit to capture, handle, radio-tag, and release Indiana bats, gray bats, Virginia big-eared bats, and blackside dace (*Phoxinus cumberlandensis*) for presence/absence surveys and scientific research aimed at recovery of the species throughout the species ranges in Georgia, North Carolina, Alabama, Mississippi, Kentucky, Tennessee, Ohio, Indiana, Pennsylvania, Virginia, and West Virginia.

Applicant: Brian Estes, Jordan, Jones, and Goulding, Inc., Norcross, Georgia, TE087127

The applicant requests renewal of existing authorization to capture, identify, and release blue shiner (*Cyprinella caerulea*), Etowah darter (*Etheostoma etowahae*), Cherokee darter (*Etheostoma scotti*), amber darter (*Percina antesella*), goldline darter (*Percina aurolineata*), snail darter (*Percina tanasi*), Conasauga logperch (*Percina jenkinsi*), and the eastern indigo snake (*Drymarchon corais couperi*) for presence/absence surveys throughout the species ranges in Georgia.

Applicant: Jeffrey West, Columbia, South Carolina, TE178643

The applicant requests authorization to harass the Carolina heelsplitter (*Lasmigona decorate*) for presence/absence surveys throughout the species range in North Carolina and South Carolina.

Applicant: John Alford, Ecological Solution, Inc., Roswell, Georgia, TE070800

The applicant requests authorization to amend an existing permit to harass all threatened and endangered fish, mussel, and snail species native to Georgia and Alabama for presence/absence surveys.

Applicant: Julie Lockwood, North Brunswick, New Jersey, TE075916

The applicant requests authorization to amend an existing permit to capture, band, collect blood samples, release, and monitor nests of the Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*) while conducting demographic studies in Everglades National Park and Big Cypress National Preserve, Monroe and Miami-Dade Counties, Florida.

Dated: May 5, 2008.

Cynthia K. Dohner,

Acting Regional Director.

[FR Doc. E8–11292 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–IA–2008–N0119; 96300–1671–0000–P5]

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by June 19, 2008.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 212, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (**ADDRESSES** above).

Applicant: Dr. M.K. Gonder, University at Albany, SUNY, Albany, NY, PRT–180709

The applicant requests a permit to import hair and fecal samples collected from chimpanzee (*Pan troglodytes*) sleep nests in the wild in Cameroon for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 3-year period.

Applicant: James M. Falco, Phoenixville, PA, PRT–179951

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Tyler D. Hutt, Dallas, TX, PRT–162777

The applicant requests a permit to import the sport-hunted trophy of one scimitar-horned oryx (*Oryx dammah*) culled from a captive herd in the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Earl D. Robinson, Rancho Santa Fe, CA, PRT–161751

The applicant requests a permit to import the sport-hunted trophy of one male scimitar-horned oryx (*Oryx dammah*) culled from a captive herd in the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: John S. MacDonnell, Arcadia, CA, PRT–181059.

The applicant requests a permit to import the sport-hunted trophy of one female scimitar-horned oryx (*Oryx dammah*) culled from a captive herd in the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Timothy D. Akers, Richmond, KY, PRT–182065

The applicant requests a permit to import the sport-hunted trophy of one male scimitar-horned oryx (*Oryx dammah*) culled from a captive herd in the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Endangered Marine Mammals

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered marine mammals. The applications were submitted to satisfy requirements of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing endangered species (50 CFR part 17) and marine mammals (50 CFR part 18). Written data, comments, or requests for copies of the complete applications or requests for a public hearing on these applications should be submitted to the Director (address above). Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Applicant: Terrie M. Williams, Center for Ocean Health, University of California, Santa Cruz, CA, PRT–045447

The applicant requests a permit to take up to 24 captive-held southern sea otters (*Enhydra lutris nereis*) annually for the purpose of scientific research on the physiology of and metabolic demands on southern sea otters related to energetics, diving, and thermoregulation. This notification covers activities to be conducted by the applicant over a five-year period.

Concurrent with the publication of this notice in the **Federal Register**, the Division of Management Authority is forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Lisa J. Lierheimer,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E8–11260 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–922–08–1310–FI–P; NDM 95197]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease NDM 95197

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Per 30 U.S.C. 188(d), LoneTree Energy & Associates, LLC timely filed a petition for reinstatement of oil and gas lease NDM 95197, Divide County, North Dakota. The lessee paid the required rental accruing from the date of termination.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals and royalties of $10 per acre and 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee paid the $500 administration fee for the reinstatement of the lease and $163 cost for publishing this Notice.

The lessee met the requirements for reinstatement of the lease per Sec. 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10 per acre;
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate; and
- The $163 cost of publishing this Notice.

FOR FURTHER INFORMATION CONTACT: Karen L. Johnson, Chief, Fluids Adjudication Section, BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101–4669, 406–896–5098.

Dated: May 14, 2008.

Karen L. Johnson,

Chief, Fluids Adjudication Section.

[FR Doc. E8–11220 Filed 5–19–08; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

[Docket No. MMS–2007–OMM–0063]

MMS Information Collection Activity: 1010–0151 (30 CFR 250, Subpart B) Plans and Information, Extension of a Collection; Submitted for Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of extension of an information collection (1010–0151).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements in the regulations under 30 CFR 250, Subpart B, Plans and Information, and related documents. This notice also provides the public a second opportunity to comment on the paperwork burden of these regulatory requirements.

DATE: Submit written comments by June 19, 2008.

ADDRESSES: You should submit comments directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (1010–0141), either by fax (202) 395–6566 or e-mail (*OIRA_DOCKET@omb.eop.gov*).

Please also send a copy to MMS by either of the following methods:

- *http://www.regulations.gov.* Under the tab ''More Search Options,'' click ''click Advanced Docket Search'', then select ''Minerals Management Service'' from the agency drop-down menu, then click ''submit.'' In the Docket ID column, select MMS–2008–OMM–xxxx to submit public comments and to view supporting and related materials available for this rulemaking. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link. The MMS will post all comments.
- Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Attention: Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ''Information Collection 1010–0151'' in your subject line and mark your message for return receipt. Include your name and return address in your message text.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch, (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulations and forms that require the subject collection of information.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart B, Plans and Information.

Forms: MMS–137, MMS–138, MMS–139, MMS–141, and MMS–142.

OMB Control Number: 1010–0151.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.*, 31 U.S.C. 9701), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. Sections 11 and 25 of the amended OCS Lands Act require the holders of OCS oil and gas or sulphur leases to submit exploration plans (EPs) or development and production plans (DPPs) to the Secretary for approval prior to commencing these activities. As a Federal agency, we have a continuing affirmative duty to comply with the Endangered Species Act (ESA). This includes a substantive duty to carry out any agency action in a manner that is not likely to jeopardize protected species as well as a procedural duty to consult with the Fish and Wildlife Service (FWS) and National Oceanic and Atmospheric Administration Fisheries (NOAA Fisheries) before engaging in a discretionary action that may affect a protected species.

To provide supplementary guidance and procedures, MMS issues Notices to Lessees and Operators (NTLs) on a regional or national basis. Regulation 30 CFR 250.103 allows MMS to issue NTLs to clarify, supplement, or provide more detail about certain requirements.

Regulations at 30 CFR part 250 subpart B, implement these statutory requirements. The MMS engineers, geologists, geophysicists, environmental scientists, and other Federal agencies analyze and evaluate the information and data collected under subpart B to ensure that planned operations are safe; will not adversely affect the marine, coastal, or human environment; and will conserve the resources of the OCS. We use the information to: (a) Report annually to NOAA Fisheries the effectiveness of mitigation, any adverse effects of the proposed action, and any incidental take, in accordance with 50 CFR 402.14(i)(3), and (b) allow the Regional Supervisor to make an informed decision on whether to approve the proposed exploration or development and production plans as submitted, or whether modifications are necessary without the analysis and evaluation of the required information. The affected States also review the information collected for consistency with approved Coastal Zone Management (CZM) plans.

Specifically, MMS uses the information to evaluate, analyze, determine, or ensure that:

- Ancillary activities comply with appropriate laws or regulations and are conducted safely, protect the environment, and do not interfere or conflict with the other uses of the OCS (*i.e.*, military use, subsistence activity).
- Points of contact and responsible parties are designated for proposed activities.
- Surveying, monitoring, or other activities do not interfere or conflict with preexisting and other uses of the area.
- Plans or actions meet or implement lease stipulation requirements.
- Proposed exploration, drilling, production, and pipeline activities are conducted in a safe and acceptable manner for the location and water depth proposed and conserve reservoir energy to allow enhanced recovery operations in later stages of lease development.
- Unnecessary or incompatible facilities are not installed on the OCS.
- Shallow drilling hazards (such as shallow gas accumulations or mudslide areas) are avoided.
- Areas are properly classified for H^2S, and appropriate procedures are in place.
- Appropriate oil spill planning measures and procedures are implemented.
- Expected meteorological conditions at the activity site are accommodated.
- Environmentally sensitive areas are identified, and the direct and cumulative effects of the activities are minimized.
- Offshore and onshore air quality is not significantly affected by the proposed activities.
- Waste disposal methods and pollution mitigation techniques are appropriate for local conditions.

• State CZM requirements have been met.

• Archaeological or cultural resources are identified and protected from unreasonable disturbances.

• Socioeconomic effects of the proposed project on the local community and associated services have been determined.

• Support infrastructures and associated traffic are adequately covered in plans.

The following forms used in the Gulf of Mexico Region (GOMR) are also submitted to MMS.

• Form MMS–137 (Plan Information Form) is submitted to summarize plan information.

• Forms MMS–138 (GOM Air Emission Calculations for Exploration Plans) and MMS–139 (GOM Air Emission Calculations for Development Operations Coordination Documents (DOCDs)) are submitted to standardize the way potential air emissions are estimated and approved as part of the OCS plan.

• MMS–141 (ROV Survey Report) is submitted to report the observations and information recorded from 2 sets of ROV monitoring surveys to identify high-density biological communities that may occur on the seafloor in deep water. We also use the information to help assess the effectiveness of avoidance criteria and expand the knowledge base regarding the benthic habitats of the deep water seafloor.

• MMS–142 (Environmental Impact Analysis Worksheet) is a fill in the blank form that is submitted to identify the environmental impact-producing factors (IPFs) for the listed environmental resources. We use the information to assess impact and determine compliance with the National Environmental Policy Act.

We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2) and under regulations at 30 CFR 250.197, ''Data and information to be made available to the public or for limited inspection.'' No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion.

Estimated Number and Description of Respondents: Approximately 130 Federal OCS oil and gas lessees and operators.

Estimated Reporting and Recordkeeping ''Hour'' Burden: The estimated annual ''hour'' burden for this information collection is a total of 291,414 hours. The following chart details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

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Citation 30 CFR 250 Subpart B and NTLs	Reporting &Recordkeeping Requirement	Hour Burden	Average No. of Annual Responses Annual	Burden Hours
		Non-Hour Costs		
200 thru 206	General requirements for plans and information.	Burden included with specific requirements below.		0
Ancillary Activities				
208	Notify MMS and other users of the OCS before conducting ancillary activities.	10	23 notices	230
210(a)	Submit report summarizing & analyzing data/ information obtained or derived from ancillary activities.	1	25 reports	25
210(b)	Retain ancillary activities data/information.	2	130 recordkeepers	260
Subtotal			**178 responses**	**515 hours**
Contents of Exploration Plans (EP)				
211 thru 228	Submit EP and accompanying information (including forms MMS-137, MMS 138, MMS-142 used in GOMR) and provide notifications.	640	200 plans	128,000
		$3,250 x 454* EP surface locations = $1,475,500		
		AKOCS – 1,000	1 plan	1,000
		201 responses		**129,000 hours**
		$1,475,500 Non-Hour Costs		
Seismic Survey Mitigation Measures and Protected Species Observer Program				
211 thru 228: 241 thru 262; NTLs	Submit to MMS observer training requirement materials and information.	½ hour	24 reports x 4 vessels = 96	48
	Training certification and recordkeeping.	½ hour	20	10
	If used, submit to MMS information on any passive acoustic monitoring system prior to placing it in service.	1 hour	3	3
	Submit to MMS marine mammal observation report(s) (This includes observer duty and training and are the occasional activities done in-house and not subcontracted out.)	345 hours**	2 reports	690
	Observer training*** (in-house training is in hours – contracted out training is in non-hour cost burdens).	8	3	24
		8 hours x 72 observers = 576 hours x $37.50/hr = $21,600.		
	Observation Report/Form.	1 hour x 200 reports/forms = 200 x $52/hr = $10,400.		
	Observation Duty (3 observers fulfilling an 8 hour shift ea for 365 calendar days x 4 vessels = 35,040 man-hours).	3 observers x 8 hrs x 365 days = 8,760 hours x 4 vessels observing = 35,040 man-hours x $52/hr = $1,822,080.		
			124 responses	**775 hours**
		$1,854,080 Non-Hour Costs		
Protected Species Report				

Citation 30 CFR 250 Subpart B and NTLs	Reporting &Recordkeeping Requirement	Hour Burden	Average No. of Annual Responses Annual	Burden Hours
		Non-Hour Costs		
211 thru 228: 241 thru 262; NTLs	Submit injured/dead protected species report.	½ hour	2 reports	1
			2 responses	**1**
Trash and Debris Awareness/Elimination				
211 thru 228: 241 thru 262; NTLs	Submit request for training video.	½ hour	100 requests	50
	Submit annual report to MMS on training process and certification.	½ hour	200 records	100
	Training recordkeeping.	½ hour	200 records	100
	Post placards on vessels and structures. (Exempt from information collection burden because MMS is providing exact language for the trash and debris warning, similar to the "Surgeon General's Warning" exemption.)		Exempt	0
			500 responses	**250**
Subtotal			**827 responses**	**130,026 hours**
			$3,329,580 Non-Hour Costs	
Review and Decision Process for the EP				
231(b); 232(d); 234; 235(a); 281(d)(3); 283; 284; 285; 209	Submit amended, modified, revised, or supplemental EP, or resubmit disapproved EP.	120	224 changed plans	26,880
235(b); 272(b); 281(d)(3)(ii)	Appeal State's objection.	Burden exempt as defined in 5 CFR 1320.4(a)(2), (c)		0
Subtotal			**224 responses**	**26,880 hours**
Contents of Development and Production Plans (DPP) and Development Operations Coordination Documents (DOCD)				
241 thru 262; 209	Submit DPP or DOCD and accompanying information (including forms MMS-137, MMS 139, MMS-142 used in GOMR) and provide notifications.	690	110 plans	75,900
		$3,750 x 306* DPP/DOCD wells = $1,147,500		
		AKOCS – 1,700	1 plan	1,700
Subtotal			**111 responses**	**77,600 hours**
			$1,147,500 Non-Hour Costs	
Review and Decision Process for the DPP or DOCD				
266(b); 267(d);	Submit amended, modified, revised, or supplemental DPP or DOCD, or resubmit	95	250 changed plans	23,750

Citation 30 CFR 250 Subpart B and NTLs	Reporting &Recordkeeping Requirement	Hour Burden	Average No. of Annual Responses Annual	Burden Hours
		Non-Hour Costs		
272(a); 273, 283; 284; 285; 209	disapproved DPP or DOCD.	POCS - 680	1 changed plan	680
269(b)	Submit information on preliminary plans for leases or units in vicinity of proposed development and production activities.	2	1 response	2
Subtotal			**252 responses**	**24,432 hours**
Post-Approval Requirements for the EP, DPP, and DOCD				
281(a)	Submit various applications.	Burdens included under appropriate subpart or form (1010-0050; 1010-0059; 1010-0141; 1010-0149).		0
282	Retain monitoring data/information.	2	313 records	626
	Submit monitoring plans.	1	30 plans	30
282(b)	Submit monitoring reports and data (including form MMS-141 used in GOMR).	2	2 each for 33 wells = 66	132
Subtotal			**409 responses**	**788 hours**
Submit DWOPs, CIDs, and Departure/Alternative Compliance Requests				
287 thru 295	Submit DWOP.	750	35 plans	26,250
		$3,150 x 35 = $110,250		
296 thru 298	Submit CID.	443	11 documents	4,873
		$24,200 x 11 = $266,200		
200 thru 299	General departure and alternative compliance requests not specifically covered elsewhere in subpart B regulations.	2	25 requests	50
Subtotal			**71 responses**	**31,173 hours**
			$376,450 Non-Hour Costs	
TOTAL BURDEN			**2,072 Responses**	**291,414 Hours**
			$4,853,530 Non-Hour Costs	

* You may have multiple locations and/or wells for each EP, EPP, or DOCD.

** Hours are based on 14 days of observing, attending a training session, and writing report(s).

***Allowed minimal hour burden for in-house training.

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Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We have identified seven non-hour costs associated with this information collection. Four of these non-hour cost burdens are cost recovery fees. They consist of fees being submitted with EP's, DPP's or DOCD's, DWOP's, and CID's. There are also three non-hour cost burdens that are associated with the Protected Species Observer Program. The costs associated with this program are due to activities that are, for the most part, subcontracted to other service companies with expertise in these areas. To allow for in-house training by lessees/operators, we have retained a minimal hour burden in the burden table for the Protected Species Observer Program training requirement. Since all the observation duty and reporting would be done while on the vessel and by contractors, these requirements were calculated as non-hour burden costs. See the hours, fees, and costs in the burden table.

We estimate that the annual non-hour cost burden is $4,853,530. We have not identified any other ''non-hour cost'' burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501, *et seq.*) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *'' *Agencies must specifically solicit comments to:* (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

To comply with the public consultation process, on November 15, 2007, we published a **Federal Register** notice (72 FR 64238) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. In addition, 250.199 provides the OMB control number for the information collection requirements imposed by the 30 CFR 250 regulations and forms. The regulation also informs the public that they may comment at any time on the collections of information and provides the address to which they should send comments. We have received no comments in response to these efforts.

If you wish to comment in response to this notice, you may send your comments to the offices listed under the **ADDRESSES** section of this notice. The OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, to ensure maximum consideration, OMB should receive public comments by June 19, 2008.

Public Availability of Comments: Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

MMS Information Collection Clearance Officer: Arlene Bajusz, (202) 208–7744.

Dated: March 21, 2008.

E.P. Danenberger,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. E8–11287 Filed 5–19–08; 8:45 am]

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INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–588]

In the Matter of Certain Digital Multimeters, and Products With Multimeter Functionality; Issuance of General Exclusion Order and Cease and Desist Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued a general exclusion order and cease and desist orders directed to two defaulting domestic respondents in the above-identified investigation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Michael K. Haldenstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3041. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 13, 2006, based on a complaint filed on October 6, 2006, and supplemented on October 27 and 30, 2006, by Fluke Corp. of Everett, Washington, alleging violations of section 337 of the Tariff Act of 1930 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital multimeters and products with multimeter functionality by reason of infringement of United States Trademark Registration No. 2,796,480 (''the '480 mark'') and also by reason of infringement of trade dress, the threat or effect of which is to destroy or substantially injure an industry in the United States. 71 FR 661940 (November 13, 2006). Complainant requested that the Commission issue a general exclusion order and cease and desist orders. The complaint named eighteen respondents in China, Hong Kong, and the United States. Fourteen respondents were terminated from the investigation by settlement agreement, consent order, or both. The four remaining respondents were found in default.

On July 3, 2007, complainant filed a motion seeking summary determination of violation of section 337. On January 14, 2008, the presiding administrative law judge (''ALJ'') issued an initial determination (''ID'') granting complainant's motion for summary determination of violation of section 337 as to the four defaulting respondents. He recommended issuance of a general exclusion order, issuance of cease and desist orders against respondents Electronix Express and HandsOnTools, and that the amount of bond for temporary importation during

the Presidential review period be set at 100 percent of the entered value of the articles concerned. No petitions for review were filed.

On February 12, 2008, the Commission determined not to review the ID and requested written submissions on the issues of remedy, the public interest, and bonding. On February 28 and March 6, 2008, respectively, the complainant Fluke and the Investigative Attorney (''IA'') filed briefs and the IA filed a reply brief on these issues.

Having reviewed the record in this investigation, including the ALJ's recommended determination and the parties' written submissions, the Commission has determined that the appropriate form of relief is a general exclusion order prohibiting the unlicensed entry of digital multimeters that infringe the '480 mark or Fluke's protected trade dress and cease and desist orders directed to Electronix Express and HandsOnTools.

The Commission has further determined that the public interest factors enumerated in section 337(d)(1) (19 U.S.C. 1337(d)(1)) do not preclude issuance of the general exclusion order. Finally, the Commission determined that the amount of bond to permit temporary importation during the Presidential review period (19 U.S.C. *1337(j)) shall be in the amount of 100 percent of the value of the digital multimeters that are subject to the order. The Commission's order and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in sections 210.42–46 of the Commission's Rules of Practice and Procedure, 19 CFR 210.42–46.

Issued: May 14, 2008.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–11196 Filed 5–19–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–595]

In the Matter of Certain Dynamic Random Access Memory Devices and Products Containing Same; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of a Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 19) granting the joint motion to terminate the captioned investigation based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on March 1, 2007, based on a complaint filed by Renesas. The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dynamic random access memory devices and products containing the same by reason of infringement of certain claims of U.S. Patent Nos. 7,115,344 and 7,116,128. The complaint named as respondents Samsung Electronics Co., Ltd., of Seoul, Korea, and Samsung Electronics America, Inc., of Ridgefield Park, New Jersey (collectively, ''Samsung'').

On April 25, 2008, Renesas and Samsung jointly moved to terminate the investigation on the basis of a settlement agreement. On April 28, 2008, the Commission investigative attorney filed a response supporting the motion.

On April 29, 2008, the ALJ issued the subject ID granting the joint motion to terminate the investigation based on a settlement agreement. The ALJ found that the motion complied with the requirements of Commission Rule 210.21 (19 CFR 210.21). The ALJ also concluded that, pursuant to Commission Rule 210.50(b)(2) (19 CFR 210.50(b)(2)), there is no evidence that termination of this investigation will prejudice the public interest. No petitions for review of this ID were filed.

The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

By order of the Commission.

Issued: May 13, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–11197 Filed 5–19–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on May 14, 2008, a proposed consent decree in *United States* v. *Waste Management of Illinois, Inc. et al.*, Civil Action No. 06cv6880, was lodged with the United States District Court for the Northern District of Illinois.

In this cost recovery action brought pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9607, the United States sought recovery of approximately $1.15 million in unreimbursed past response costs and prejudgment interest incurred by the United States Environmental Protection Agency at the H.O.D. Landfill Superfund Site located near Antioch in Lake County, Illinois. Under the proposed consent decree, Waste Management of Illinois, Inc., on behalf of itself, Morton International, Inc., and Rohm and Haas Chemicals, LLC will

pay a total of $900,000 to the Hazardous Substance Superfund.

The Department of Justice will accept comments relating to the proposed consent decree for a period of thirty (30) days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and mailed either electronically to *pubcomment-ees.enrd@usdoj.gov* or in hard copy to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. Comments should refer to *United States* v. *Waste Management of Illinois, Inc., et al.*, Civil No. 06cv6880 (N.D. Ill.) and D.J. Reference No. 90–11–3–1006/1.

The proposed consent decree may be examined at: (1) The Office of the United States Attorney for the Northern District of Illinois, 219 South Dearborn Street, Suite 500, Chicago, Illinois 60604, (312) 353–5300; and (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact Jeffrey A. Cahn (312–886–6670)). During the comment period, the proposed consent decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decree.html*. A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please refer to the referenced case and D.J. Reference No. 90–11–3–1006/1, and enclose a check in the amount of $60.75 for the consent decree (243 pages at 25 cents per page reproduction costs), made payable to the U.S. Treasury.

William D. Brighton,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. E8–11204 Filed 5–19–08; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (08–046)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Dr. Walter Kit, National Aeronautics and Space Administration, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Dr. Walter Kit, NASA Clearance Officer, NASA Headquarters, 300 E Street, SW., JE0000, Washington, DC 20546, (202) 358–1350, *Walter.Kit-1@nasa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The information submitted by recipients is to provide a tracking mechanism for property on an annual basis, at the end of the grant, or on the occurrence of certain event. This information is used by NASA to effectively maintain an appropriate internal control system for equipment and property provided or acquired under grants and cooperative agreements with institutions of higher education and other non-profit organizations, and to comply with statutory requirements.

II. Method of Collection

NASA is participating in Federal efforts to extend the use of information technology to more Government processes via Internet.

III. Data

Title: NASA Inventory Report: Property Management & Control, Grants.

OMB Number: 2700–0047.

Type of review: Revision of currently approved collection.

Affected Public: Not-for-profit institutions and State, Local or Tribal. Government

Estimated Number of Respondents: 141.

Estimated Time per Response: 12.28 hours.

Estimated Total Annual Burden Hours: 1732 hours.

Estimated Total Annual Cost: $0.00.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Gary Cox,

Associate Chief Information Officer (Acting).

[FR Doc. E8–11193 Filed 5–19–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (08–047)]

NASA Advisory Council; Science Committee; Heliophysics Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: The National Aeronautics and Space Administration (NASA) announces a meeting of the Heliophysics Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

DATES: Thursday, June 12, 2008, 8:30 a.m. to 5:30 p.m., and Friday, June 13, 2008, 8:30 a.m. to 5:30 p.m.

ADDRESSES: NASA Headquarters, 300 E Street, SW., room 3H46, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up

to the capacity of the room. The agenda for the meeting includes the following topics:

—Heliophysics Division Overview and Program Status.
—Report of the Mission Planning Working Group.
—Assessment of Heliophysic Scientific Progress for Fiscal Year 2008.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information no less than 5 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at *mnorris@nasa.gov* or by telephone at (202) 358–4452.

Dated: May 12, 2008.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. E8–11194 Filed 5–19–08; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of the Federal Register

Agreements In Force as of December 31, 2007, Between the American Institute in Taiwan and the Taipei Economic and Cultural Representative Office in the United States

AGENCY: Office of the Federal Register, NARA.

ACTION: Notice of availability of agreements.

SUMMARY: The American Institute in Taiwan has concluded a number of agreements with the Taipei Economic and Cultural Representative Office in the United States (formerly the Coordination Council for North American Affairs) in order to maintain cultural, commercial and other unofficial relations between the American people and the people of Taiwan. The Director of the Federal Register is publishing the list of these agreements on behalf of The American Institute in Taiwan in the public interest.

SUPPLEMENTARY INFORMATION: Cultural, commercial and other unofficial relations between the American people and the people of Taiwan are maintained on a non-governmental basis through the American Institute in Taiwan (AIT), a private nonprofit corporation created under the Taiwan Relations Act (Pub. L. 96–8; 93 Stat. 14). The Coordination Council for North American Affairs (CCNAA) was established as the nongovernmental Taiwan counterpart to AIT. On October 10, 1995, the CCNAA was renamed the Taipei Economic and Cultural Representative Office in the United States (TECRO).

Under section 12 of the Act, agreements concluded between AIT and TECRO (CCNAA) are transmitted to the Congress, and according to sections 6 and 10(a) of the Act, such agreements have full force and effect under the law of the United States.

The texts of the agreements are available from the American Institute in Taiwan, 1700 North Moore Street, Suite 1700, Arlington, Virginia 22209. For further information, please telephone (703) 525–8474, or fax (703) 841–1385.

Following is a list of agreements between AIT and TECRO (CCNAA) which were in force as of December 31, 2007.

Barbara J. Schrage,

Managing Director, American Institute in Taiwan

Dated: May 15, 2008.

Raymond A. Mosley,

Director of the Federal Register.

AIT–TECRO Agreements In Force as of December 31, 2007

Status of TECRO

The Exchange of Letters concerning the change in the name of the Coordination Council for North American Affairs (CCNAA) to the Taipei Economic and Cultural Representative Office in the United States (TECRO). Signed December 27, 1994 and January 3, 1995. Entered into force January 3, 1995.

Agriculture

1. Guidelines for a cooperative program in the agriculture sciences. Signed January 15 and 28, 1986. Entered into force January 28, 1986.

2. Amendment amending the 1986 guidelines for a cooperative program in the agricultural sciences. Effected by exchange of letters September 1 and 11, 1989. Entered into force September 11, 1989.

3. Cooperative service agreement to facilitate fruit and vegetable inspection through their designated representatives, the United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) and the Taiwan Provincial Fruit Marketing Cooperative (TPFMC) supervised by the Taiwan Council of Agriculture (COA). Signed April 28, 1993. Entered into force April 28, 1993.

4. Memorandum of agreement concerning sanitary/phytosanitary and agricultural standards. Signed November 4, 1993. Entered into force November 4, 1993.

5. Agreement amending the guidelines for the cooperative program in agricultural sciences. Signed October 30, 2001. Entered into force October 30, 2001.

6. Memorandum of Understanding Establishing Consultative Committee on Agriculture Terms of Reference. Signed July 10, 2007. Entered into force July 10, 2007.

7. Consultative Committee on Agriculture Terms of Reference. Signed July 10, 2007. Entered into force July 10, 2007.

Aviation

1. Memorandum of agreement concerning the arrangement for certain aeronautical equipment and services relating to civil aviation (NAT–I–845), with annexes. Signed September 24 and October 23, 1981. Entered into force October 23, 1981.

2. Amendment amending the memorandum of agreement concerning aeronautical equipment and services of September 24 and October 23, 1981. Signed September 18 and 23, 1985. Entered into force September 3, 1985.

3. Agreement amending the memorandum of agreement of September 24 and October 23, 1981, concerning aeronautical equipment and services. Signed September 23 and October 17, 1991. Entered into force October 17, 1991.

4. Air transport agreement, with annexes. Signed at Washington March 18, 1998. Entered into force March 18, 1998.

5. Agreement for promotion of aviation safety. Signed June 30, 2003. Entered into force June 30, 2003.

6. Exchange of Letters concerning removal from the agreement of provisions relating to regulations of computer reservation systems in Annex III to the Air Transport Agreement signed March 18, 1998. Signed

December 11, 2006 and January 2, 2007. Entered into force January 2, 2007.

Conservation

1. Memorandum on cooperation in forestry and natural resources conservation. Signed May 23 and July 4, 1991. Entered into force July 4, 1991.

2. Memorandum on cooperation in soil and water conservation under the guidelines for a cooperative program in the agricultural sciences. Signed at Washington October 5, 1992. Entered into force October 5, 1992.

3. Agreement on technical cooperation in forest management and nature conservation. Signed October 24, 2003 and February 27, 2004. Entered into force February 27, 2004.

Consular

1. Agreement regarding passport validity. Effected by exchange of letters of August 26 and November 13, 1998. Entered into force December 10, 1998.

Consumer Product Safety

1. Memorandum of Understanding for cooperation associated with consumer product safety matters. Signed April 29 and July 27, 2004. Entered into force July 27, 2004.

Customs

1. Agreement for technical assistance in customs operations and management, with attachment. Signed May 14 and June 4, 1991. Entered into force June 4, 1991.

2. Agreement on TECRO/AIT carnet for the temporary admission of goods. Signed June 25, 1996. Entered into force June 25, 1996.

3. Agreement regarding mutual assistance between their designated representatives, the United States Customs Administration and the Taiwan Customs Administration. Signed January 17, 2001. Entered into force January 17, 2001.

Education and Culture

1. Agreement amending the agreement for financing certain educational and cultural exchange programs of April 23, 1964. Effected by exchange of letters at Taipei April 14 and June 4, 1979. Entered into force June 4, 1979.

2. Agreement concerning the Taipei American School, with annex. Signed at Taipei February 3, 1983. Entered into force February 3, 1983.

Energy

1. Agreement relating to the establishment of a joint standing committee on civil nuclear cooperation. Signed at Taipei October 3, 1984. Entered into force October 3, 1984.

2. Agreement amending and extending the agreement of October 3, 1984, relating to the establishment of a joint standing committee on civil nuclear cooperation. Signed October 19, 1989. Entered into force October 19, 1989.

3. Agreement abandoning in place in Taiwan the Argonaut Research Reactor loaned to National Tsing Hua University. Signed November 28, 1990.

4. Agreement Amending and Extending the Agreement of October 3, 1984, as amended and extended, relating to the establishment of a joint standing committee on civil nuclear cooperation. Signed October 3, 1994. Entered into force October 3, 1994.

5. Agreement concerning safeguards arrangements for nuclear materials transferred from France to Taiwan. Effected by exchange of letters February 12 and May 13, 1993. Entered into force May 13, 1993.

6. Memorandum of Agreement for release of an Energy and Power Evaluation Program (ENPEP) computer software package. Signed January 25 and February 27, 1995. Entered into force February 27, 1995.

7. Agreement regarding terms and conditions for the acceptance of foreign research reactor spent nuclear fuel at the Department of Energy's Savannah River site. Signed December 28, 1998 and February 25, 1999. Entered into force February 25, 1999.

8. Agreement in the area of probabilistic risk assessment research. Signed July 20 and December 27, 1998. Entered into force January 1, 1999.

9. Agreement for technical cooperation in clean coal and advanced power systems technologies. Signed October 31, 2003 and January 20, 2004. Entered into force January 20, 2004.

10. Agreement in the area of probabilistic risk assessment research. Signed October 18 and December 29, 2004. Entered into force December 29, 2004, effective January 1, 2005.

11. Agreement relating to participation in the USNRC program of thermal-hydraulic code applications and maintenance research. Signed December 13, 2004 and December 13, 2004. Entered into force December 13, 2004.

12. Joint determination of safeguard ability for alteration in form or content of irradiated fuel elements pursuant to article VIII.C of the agreement for cooperation concerning civil uses of atomic energy signed April 4, 1972. Signed May 17, 2006 and May 17, 2006. Entered into force May 17, 2006.

Environment

1. Agreement for technical cooperation in the field of environmental protection, with implementing arrangement. Signed June 21, 1993. Entered into force June 21, 1993.

2. Agreement extending the agreement of June 21, 1993 for technical cooperation in the field of environmental protection. Effected by exchanges of letters June 30 and July 20 and 30, 1998. Entered into force July 30, 1998, effective June 21, 1998.

3. Agreement extending the agreement for technical cooperation in the field of environmental protection. Signed September 23, 2003. Entered into force September 23, 2003.

Health

1. Guidelines for a cooperative program in the biomedical sciences. Signed May 21, 1984. Entered into force May 21, 1984.

2. Guidelines for a cooperative program in food hygiene. Signed January 15 and 28, 1985. Entered into force January 28, 1985.

3. Agreement amending the 1984 guidelines for a cooperative program in the biomedical sciences, with attachment. Signed April 20, 1989. Entered into force April 20, 1989.

4. Agreement amending the 1984 guidelines for a cooperative program in the biomedical sciences, as amended, with attachment. Signed August 24, 1989. Entered into force August 24, 1989.

5. Guidelines for a cooperative program in public health and preventive medicine. Signed at Arlington and Washington June 30 and July 19, 1994. Entered into force July 19, 1994.

6. Agreement for technical cooperation in vaccine and immunization-related activities, with implementing arrangement. Signed at Washington October 6 and 7, 1994. Entered into force October 7, 1994.

7. Agreement regarding the mutual exchange of information on medical devices, including quality systems requirements inspectional information. Effected by exchange of letters January 9, 1998. Entered into force January 9, 1998.

Homeland Security

1. Declaration of Principles for governing cooperation, on the basis of reciprocity, including the posting of AIT Representatives at the Port of Kaohsiung, and the posting of TECRO Representatives at certain U.S. seaports. Signed August 18, 2004 and August 18, 2004. Entered into force August 18, 2004.

2. Memorandum of understanding concerning cooperation to prevent the illicit trafficking in nuclear and other radioactive material. Signed May 25, 2006 and May 25, 2006. Entered into force May 25, 2006.

3. Declaration of Principles for governing cooperation, on the basis of reciprocity, including the posting of AIT Representatives at seaports in Taiwan. Signed September 22, 2006 and September 22, 2006. Entered into force September 22, 2006.

4. Exchange of Letters to facilitate the implementation of the MOU concerning cooperation to prevent the illicit trafficking in nuclear and other radioactive material signed May 25, 2006. Signed April 30, 2007 and July 5, 2007. Entered into force July 5, 2007.

Intellectual Property

1. Agreement concerning the protection and enforcement of rights in audiovisual works. Effected by exchange of letters at Arlington and Washington June 6 and 27, 1989. Entered into force June 27, 1989.

2. Understanding concerning the protection of intellectual property rights. Signed at Washington June 5, 1992. Entered into force June 5, 1992.

3. Agreement for the protection of copyrights, with appendix. Signed July 16, 1993. Entered into force July 16, 1993.

4. Memorandum of understanding regarding the extension of priority filing rights for patent and trademark applications. Signed April 10, 1996. Entered into force April 10, 1996.

Judicial Assistance

1. Memorandum of understanding on cooperation in the field of criminal investigations and prosecutions. Signed at Taipei October 5, 1992. Entered into force October 5, 1992.

2. Agreement on mutual legal assistance in criminal matters. Signed March 26, 2002. Entered into force March 26, 2002.

Labor

1. Guidelines for a cooperative program in labor affairs. Signed December 6, 1991. Entered into force December 6, 1991.

Mapping

1. Agreement concerning mapping, charting, and geodesy cooperation. Signed November 28, 1995. Entered into force November 28, 1995.

Maritime

1. Agreement concerning mutual implementation of the 1974 Convention for the safety of life at sea. Effected by exchange of letters at Arlington and Washington August 17 and September 7, 1982. Entered into force September 7, 1982.

2. Agreement concerning mutual implementation of the 1969 international convention on tonnage measurement. Effected by exchange of letters at Arlington and Washington May 13 and 26, 1983. Entered into force May 26, 1983.

3. Agreement concerning mutual implementation of the protocol of 1978 relating to the 1974 international convention for the safety of life at sea. Effected by exchange of letters at Arlington and Washington January 22 and 31, 1985. Entered into force January 31, 1985.

4. Agreement concerning mutual implementation of the protocol of 1978 relating to the international convention for the prevention of pollution from ships, 1973. Effected by exchange of letters at Arlington and Washington January 22 and 31, 1985. Entered into force January 31, 1985.

5. Agreement concerning mutual implementation of the 1966 international convention on load lines. Effected by exchange of letters at Arlington and Washington March 26 and April 10, 1985. Entered into force April 10, 1985.

6. Agreement concerning the operating environment for ocean carriers. Effected by exchange of letters at Washington and Arlington October 25 and 27, 1989. Entered into force October 27, 1989.

Military

1. Agreement for foreign military sales financing by the authorities on Taiwan. Signed January 4 and July 12, 1999. Entered into force July 12, 1999.

2. Letter of Agreement concerning exchange of research and development information. Signed August 4, 2004 and August 4, 2004. Entered into force August 4, 2004.

3. Master Information Exchange Agreement Information Exchange Annex AF–05–TW–9301 Concerning Nanoscience and Nanotechnology. Signed December 15, 2005 and December 15, 2005. Entered into force December 15, 2005.

4. Information and communication technologies (ICT) forum terms of reference. Signed October 31, 2007 and October 31, 2007. Entered into force October 31, 2007.

Postal

1. Agreement concerning establishment of INTELPOST service. Effected by exchange of letters at Arlington and Washington April 19 and November 26, 1990. Entered into force November 26, 1990.

2. International business reply service agreement, with detailed regulations. Signed at Washington February 7, 1992. Entered into force February 7, 1992.

3. Agreement on the application of an EMS (express mail service) pay-for-performance plan. Signed March 5, 2004 and August 25, 2004. Entered into force January 1, 2005.

Privileges and Immunities

1. Agreement on privileges, exemptions and immunities, with addendum. Signed at Washington October 2, 1980. Entered into force October 2, 1980.

2. Agreement governing the use and disposal of vehicles imported by the American Institute in Taiwan and its personnel. Signed at Taipei April 21, 1986. Entered into force April 21, 1986.

Scientific & Technical Cooperation

1. Agreement on scientific cooperation. Effected by exchange of letters at Arlington and Washington on September 4, 1980. Entered into force September 4, 1980.

2. Agreement concerning renewal and extension of the 1980 agreement on scientific cooperation. Signed March 10, 1987. Entered into force March 10, 1987.

3. Guidelines for a cooperative program in atmospheric research. Signed May 4, 1987. Entered into force May 4, 1987.

4. Agreement for technical assistance in dam design and construction, with appendices. Signed August 24, 1987. Entered into force August 24, 1987.

5. Agreement for a cooperative program in the sale and exchange of technical, scientific, and engineering information. Signed November 17, 1987. Entered into force November 17, 1987.

6. Agreement extending the agreement of November 17, 1987, for a cooperative program in the sale and exchange of technical, scientific and engineering information. Signed August 8, 1990. Entered into force August 8, 1990.

7. Cooperative program on Hualien soil-structure interaction experiment. Signed September 28, 1990. Entered into force September 28, 1990.

8. Agreement for technical cooperation in geodetic research and use of advanced geodetic technology, with implementing arrangement. Signed January 11 and February 21, 1991. Entered into force February 21, 1991.

9. Agreement amending and extending the agreement of August 24, 1987, for technical assistance in dam design and construction. *Name changed to Agreement for Technical Assistance in Areas of Water Resource

Development. Signed May 11 and June 9, 1992. Entered into force June 9, 1992.

10. Agreement for technical cooperation in seismology and earthquake monitoring systems development, with implementing arrangement. Signed July 22 and 24, 1992. Entered into force July 24, 1992.

11. Agreement amending the Agreement of August 24, 1987 for technical assistance in areas of water resource development. Signed August 30 and September 3, 1996. Entered into force September 3, 1996.

12. Agreement concerning joint studies on reservoir sedimentation and sluicing, including computer modeling. Signed February 14 and March 8, 1996. Entered into force March 8, 1996.

13. Guidelines for a cooperative program in physical sciences. Signed January 2 and 10, 1997. Entered into force January 10, 1997.

14. Agreement for scientific and technical cooperation in ocean climate research. Signed February 18, 1997. Entered into force February 18, 1997.

15. Agreement amending the agreement of August 24, 1987 for technical assistance in areas of water resource development. Signed October 14, 1997. Entered into force October 14, 1997.

16. Agreement for technical cooperation in scientific and weather technology systems support. Signed October 22 and November 5, 1997. Entered into force November 5, 1997.

17. Agreement for technical cooperation associated with establishment of advanced operational aviation weather systems. Signed February 10 and 13, 1998. Entered into force February 13, 1998.

18. Agreement for technical cooperation associated with development, launch and operation of a constellation observing system for meteorology, ionosphere and climate. Signed May 29 and June 30, 1999. Entered into force June 30, 1999.

19. Agreement for technical cooperation associated with establishment of advanced data assimilation and modeling systems. Signed December 20, 2004 and January 12, 2005. Entered into force January 12, 2005.

20. Agreement for cooperation in the micro pulse lidar network and the aerosol robotic network. Signed July 13, 2007 and April 17, 2007. Entered into force July 13, 2007.

21. Agreement for technical cooperation in meteorology and forecast systems development. Signed September 5, 2007 and June 25, 2007. Entered into force September 5, 2007.

Security of Information

1. Protection of information agreement. Signed September 15, 1981. Entered into force September 15, 1981.

Taxation

1. Agreement concerning the reciprocal exemption from income tax of income derived from the international operation of ships and aircraft. Effected by exchange of letters at Taipei May 31, 1988. Entered into force May 31, 1988.

2. Agreement for technical assistance in tax administration, with appendices. Signed August 1, 1989. Entered into force August 1, 1989.

Trade

1. Agreement concerning trade matters, with annexes. Effected by exchange of letters at Arlington and Washington October 24, 1979. Entered into force October 24, 1979; effective January 1, 1980.

2. Agreement concerning trade matters. Effected by exchange of letters at Arlington and Washington December 31, 1981. Entered into force December 31, 1981.

3. Agreement concerning measures that the CCNAA will undertake in connection with implementation of the GATT Customs Valuation Code. Effected by exchange of letters at Bethesda and Arlington August 22, 1986. Entered into force August 22, 1986.

4. Agreement concerning the export performance requirement affecting investment in the automotive sector. Effected by exchange of letters at Washington and Arlington October 9, 1986. Entered into force October 9, 1986.

5. Agreement concerning beer, wine and cigarettes. Signed at Washington December 12, 1986. Entered into force December 12, 1986, effective January 1, 1987.

6. Agreement implementing the agreement of December 12, 1986 concerning beer, wine and cigarettes. Effected by exchange of letters at Taipei April 29, 1987. Entered into force April 29, 1987, effective January 1, 1987.

7. Agreement concerning trade in whole turkeys, turkey parts, processed turkey products and whole ducks, with memorandum of understanding. Effected by exchange of letters at Arlington and Washington March 16, 1989. Entered into force March 16, 1989.

8. Agreement concerning the protection of trade in strategic commodities and technical data, with memorandum of understanding. Effected by exchange of letters at Arlington and Washington December 4, 1990 and April 8, 1991. Entered into force April 8, 1991.

9. Administrative arrangement concerning the textile visa system. Effected by exchange of letters at Arlington and Washington April 18 and May 1, 1991. Entered into force May 1, 1991.

10. Agreement regarding new requirements for health warning legends on cigarettes sold in the territory represented by CCNAA. Effected by exchange of letters at Washington and Arlington October 7 and 16, 1991. Entered into force October 16, 1991.

11. Memorandum of understanding concerning a new quota arrangement for cotton and man-made fiber trousers. Signed at Washington December 18, 1992. Entered into force December 18, 1992.

12. Memorandum of understanding on the exchange of information concerning commodity futures and options matters, with appendix. Signed January 11, 1993. Entered into force January 11, 1993.

13. Agreement concerning a framework of principles and procedures for consultations regarding trade and investment, with annex. Signed at Washington September 19, 1994. Entered into force September 19, 1994.

14. Visa arrangement concerning textiles and textile products. Effected by exchange of letters of April 30 and September 3 and 23, 1997. Entered into force September 23, 1997.

15. Agreement concerning trade in cotton, wool, man-made fiber, silk blend and other non-cotton vegetable fiber textile products, with attachment. Effected by exchange of letters December 10, 1997. Entered into force December 10, 1997, effective January 1, 1998.

16. Agreed minutes on government procurement issues. Signed December 17, 1997. Entered into force December 17, 1997.

17. Understanding concerning bilateral negotiations on the WTO accession of the separate customs territory of Taiwan, Penghu, Kinmen and Matsu (Chinese Taipei) and the United States. Signed February 20, 1998. Entered into force February 20, 1998.

18. Agreement on mutual recognition for equipment subject to electro-magnetic compatibility (EMC) regulations. Signed March 16, 1999. Entered into force March 16, 1999.

19. Agreement concerning the Asia Pacific Economic Cooperation mutual recognition arrangement for conformity assessment of telecommunications equipment (APEC Telecon MRA).

Signed March 16, 1999. Entered into force March 16, 1999.

20. Memorandum of understanding on the extension of trade in textile and apparel products. Signed February 9, 2001. Entered into force February 9, 2001.

[FR Doc. E8–11316 Filed 5–19–08; 8:45 am]

BILLING CODE 4710–49–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On April 8, 2008, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A permit was issued on May 14, 2008 to: Peter West; Permit No. 2009–002.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. E8–11189 Filed 5–19–08; 8:45 am]

BILLING CODE 7555–01–P

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 April 24 to May 7, 2008. The last biweekly notice was published on May 6, 2008 (73 FR 25034).

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.

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, Rulemaking, Directives and Editing 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 T6–D44, 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 O1–F21, 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, person(s) 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 via electronic submission through the NRC E-Filing system 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 person(s) 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 O1–F21, 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 hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated in August 28, 2007 (72 FR 49139). The E–Filing process requires participants to submit and serve documents over the Internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least five (5) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at *hearingdocket@nrc.gov*, or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E–Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html*. Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html*.

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E–Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E–Filing system.

A person filing electronically may seek assistance through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737.

Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted 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; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely 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 and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this amendment 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 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 PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

AmerGen Energy Company, LLC, Docket No. 50–461, Clinton Power Station (CPS), Unit No.1, DeWitt County, Illinois

Date of amendment request: January 26, 2007.

Description of amendment request: The proposed amendment would revise Technical Specification 3.3.1.1, ''Reactor Protection System (RPS) Instrumentation,'' Table 3.3.1.1–1, ''Reactor Protection System Instrumentation,'' Function 8, ''Scram Discharge Volume Water Level—High,'' item b, ''Float Switch,'' by replacing Surveillance Requirement (SR) 3.3.1.1.9 with SR 3.3.1.1.12. This change will effectively revise the surveillance frequency for the scram discharge volume level float switch from every 92 days to every 24 months.

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 proposed TS change involves a change in the surveillance frequency for the SDV water level float switch channel functional test. The proposed TS change does not physically impact the plant. The proposed change does not affect the design of the SDV water level instruments, the operational characteristics or function of the instruments, the interfaces between the instruments and the RPS, or the reliability of the SDV water level instruments. The proposed TS change does not degrade the performance of, or increase the challenges to, any safety systems assumed to function in the accident analysis. As noted in the Bases to TS 3.3.1.1, even though the two types of SDV Water Level—High Functions are an input to the RPS logic, no credit is taken for a scram initiated from these functions for any of the design basis accidents or transients evaluated in the CPS Updated Safety Analysis Report (USAR). An inoperable SDV water level instrument is not considered as an initiator of any analyzed event. The proposed TS change does not impact the usefulness of the SRs in evaluating the operability of required systems and components, or the way in which the surveillances are performed. In addition, the frequency of surveillance testing is not considered an initiator of any analyzed accident, nor does a revision to the frequency introduce any accident initiators. Therefore, the proposed change does not involve a significant increase in the probability of an accident previously evaluated.

The consequences of a previously analyzed event are dependent on the initial conditions assumed in the analysis, the availability and successful functioning of equipment assumed to operate in response to the analyzed event, and the setpoints at which these actions are initiated. The consequences of a previously evaluated accident are not significantly increased by the proposed change. The proposed change does not affect the performance of any equipment credited to mitigate the radiological consequences of an accident. The risk assessment of the proposed changes has concluded that there is an insignificant increase in the core damage frequency as well as the total population dose rate. Historical review of surveillance test results and associated maintenance records did not find evidence of failures that would invalidate the above conclusions.

Therefore, the proposed change does not alter the ability to detect and mitigate events and, as such, does not involve a significant increase in the 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 proposed TS change does not introduce any failure mechanisms of a different type than those previously evaluated, since there are no physical changes being made to the facility. No new or different equipment is being installed. No installed equipment is being operated in a different manner. There is no change being made to the parameters within which CPS is operated. There are no setpoints at which protective or mitigative actions are initiated that are affected by this proposed action. The change does not alter assumptions made in the safety analysis. 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 alteration in the procedures, which ensure the unit remains within analyzed limits, is proposed, and no change is being made to procedures relied upon to respond to an off-normal event. As a result, no new failure modes are being introduced. The way surveillance tests are performed remains unchanged. A historical review of surveillance test results and associated maintenance records indicated there was no evidence of any failures that would invalidate the above conclusions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any [accident] previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Margins of safety are established in the design of components, the configuration of components to meet certain performance parameters, and in the establishment of setpoints to initiate alarms or actions. The proposed TS change involves a change in the surveillance frequency for the SDV water level float switch channel functional test. There is no change in the design of the affected systems, no alteration of the setpoints at which alarms or actions are initiated, and no change in plant configuration from original design. The proposed change does not significantly impact the condition or performance of structures, systems, and components relied upon for accident mitigation. The proposed change does not result in any hardware changes or in any changes to the analytical limits assumed in accident analyses. Existing operating margin between plant conditions and actual plant setpoints is not significantly reduced due to these changes. The proposed change does not significantly impact any safety analysis assumptions or results.

AmerGen has conducted a risk assessment to determine the impact of a change to the SDV water level instrument surveillance frequency from the current once every 92 days to once every 24 months for the risk measures of Core Damage Frequency (CDF) and Large Early Release Frequency (LERF). This assessment indicated that the proposed CPS surveillance frequency extension has a very small change in risk to the public and is an acceptable plant change from a risk perspective.

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: Mr. Bradley J. Fewell, Associate General Counsel,

Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Russell Gibbs.

Carolina Power & Light Company, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of amendments request: July 17, 2007.

Description of amendment request: The proposed amendment would modify Brunswick Steam Electric Plant, Units 1 and 2, technical specifications (TS) requirements regarding control room envelope habitability in TS 3.7.3, ''Control Room Emergency Ventilation (CREV) System,'' and TS Section 5.5, ''Programs and Manuals.'' The changes would be consistent with NRC-approved industry Technical Specifications Task Force (TSTF) standard TS change traveler, TSTF–448, Revision 3. The NRC staff issued a ''Notice of Availability of Technical Specification Improvement to Modify Requirements Regarding Control Room Envelope Habitability Using the Consolidated Line Item Improvement Process,'' associated with TSTF–448, Revision 3, in the **Federal Register** on January 17, 2007 (72 FR 2022). The notice included a model safety evaluation, a model no significant hazards consideration (NSHC) determination, and a model license amendment request. In its application dated July 17, 2007, Carolina Power and Light Company (the licensee) affirmed the applicability of the model NSHC determination.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of NSHC 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 does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change revises the TS for the control room envelope (CRE) emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of the CRE emergency ventilation system is the CRE boundary. The CRE emergency ventilation system is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased. 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 does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation. The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice. 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 alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee 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: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: Thomas H. Boyce.

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 amendment request: January 4, 2008.

Description of amendment request: The proposed amendments would modify technical specification (TS) requirements related to control room envelope (CRE) habitability in accordance with the U.S. Nuclear Regulatory Commission (NRC)-approved Revision 3 of Technical Specification Task Force (TSTF) Standard Technical Specifications (STS) Change Traveler TSTF–448, ''Control Room Habitability.''

The NRC staff published a notice of opportunity for comment in the **Federal Register** on October 17, 2006 (71 FR 61075), on possible license amendments adopting TSTF–448, which included a model safety evaluation (SE) and model no significant hazards consideration (NSHC) determination. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on January 17, 2007 (72 FR 2022), which included the resolution of public comments on the model SE and model NSHC determination. The licensee affirmed the applicability of the following NSHC determination in its application dated January 4, 2008.

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 does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change revises the TS for the CRE emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of the CRE emergency ventilation system is the CRE boundary. The CRE emergency

ventilation system is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased. 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 does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation. The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice. 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 alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation as determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. 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: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: Thomas H. Boyce.

Exelon Generation Company, LLC, Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Units 1 and 2, Will County, Illinois

Exelon Generation Company, LLC, Docket Nos. STN 50–454 and STN 50–455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois

AmerGen Energy Company, LLC, Docket No. 50–461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Exelon Generation Company, LLC, Docket Nos. 50–237 and 50–249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois

Exelon Generation Company, LLC, Docket Nos. 50–373 and 50–374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Exelon Generation Company, LLC, Docket No. 50–352 and No. 50–353, Limerick Generating Station, Unit 1 and 2, Montgomery County, Pennsylvania

AmerGen Energy Company, LLC, et al., Docket No. 50–219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey

Exelon Generation Company, LLC, and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3,York and Lancaster Counties, Pennsylvania

Exelon Generation Company, LLC, Docket Nos. 50–254 and 50–265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois

AmerGen Energy Company, LLC, Docket No. 50–289, Three Mile Island Nuclear Station, Unit 1 (TMI–1), Dauphin County, Pennsylvania

Date of amendment request: February 28, 2008.

Description of amendment request: The proposed amendment would clarify the wording of the Radioactive Effluent Controls Program (RECP) administrative technical specifications to reflect the intent of Generic Letter 89–01, ''Implementation of Programmatic Controls for Radiological Effluent Technical Specifications [TS] in the Administrative Controls Section of the Technical Specifications and the Relocation of Procedural Details of RETS to the Offsite Dose Calculation Manual or to the Process Control Program,'' regarding the determination requirements for cumulative and projected dose contributions. The proposed change will address ambiguity in the current TS where the program element could be interpreted to require determining projected dose contributions for the calendar quarter and current calendar year every 31 days.

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 change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the applicable TS Section to conform to TSTF–308–A, Revision 1[, ''Determination of Cumulative and Projected Dose Contributions in RECP.'']

The proposed change is administrative and simply provides enhanced clarity of current requirements. Therefore, this change does not affect any accident initiators, does not affect the ability to successfully respond to previously evaluated accidents, and does not affect radiological assumptions used in the evaluations. This change will not alter the operation of process variables, structures, systems, or components as described in the affected stations' Updated Final Safety Analysis Report (UFSAR). As such, the probability of occurrence for a previously evaluated accident is not increased.

The consequences of a previously analyzed event are dependent on the initial conditions assumed in the analysis, the availability and successful functioning of equipment assumed to operate in response to the analyzed event, and the setpoints at which these actions are initiated. The consequences of a previously evaluated accident are not increased by the proposed change. The proposed change does not affect the performance of any equipment credited to mitigate 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. 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 (i.e., no new or different type of equipment will be installed) or changes in methods governing normal plant operation. No system or component setpoints will be changed, and the proposed change will not impose any new or eliminate any old requirements. There are no new accident initiators or equipment failure modes resulting from the proposed changes. The proposed changes are administrative in nature and support the implementation of common programs.

Thus, this proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

Response: No.

The proposed change revises the applicable TS Section for the affected EGC and AmerGen stations to provide clarity concerning the determination requirements

for cumulative and projected dose contributions.

The proposed change is administrative in nature and does not modify the safety limits or setpoints at which protective actions are initiated, and does not change the requirements governing operation or availability of safety equipment assumed to operate to preserve the margin of safety. In addition, there are no changes proposed to equipment operability requirements, setpoints, or limiting parameters specified in the stations' Technical Specifications.

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. Bradley Fewell, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Russell Gibbs.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant, Citrus County, Florida

Date of amendment request: July 12, 2007.

Description of amendment request: The proposed amendment would modify Crystal River Unit 3 Improved Technical Specifications (ITS) requirements related to control room envelope habitability in ITS Section 3.7.12, ''Control Room Emergency Ventilation System (CREVS),'' and ITS Section 5.6.2.21, ''Control Complex Habitability Envelope Integrity Program.'' The changes would be consistent with the NRC-approved industry Technical Specifications Task Force (TSTF) standard TS change traveler, TSTF–448, Revision 3. The NRC staff issued a ''Notice of Availability of Technical Specification Improvement to Modify Requirements Regarding Control Room Envelope Habitability Using the Consolidated Line Item Improvement Process,'' associated with TSTF–448, Revision 3, in the **Federal Register** on January 17, 2007 (72 FR 2022). The notice included a model safety evaluation, a model no significant hazards consideration (NSHC) determination, and a model license amendment request. In its application dated July 12, 2007, Florida Power Corporation (the licensee) affirmed the applicability of the model NSHC determination.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), an analysis of the issue of NSHC 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 does not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed change revises the TS for the control room envelope (CRE) emergency ventilation system, which is a mitigation system designed to minimize unfiltered air leakage into the CRE and to filter the CRE atmosphere to protect the CRE occupants in the event of accidents previously analyzed. An important part of the CRE emergency ventilation system is the CRE boundary. The CRE emergency ventilation system is not an initiator or precursor to any accident previously evaluated. Therefore, the probability of any accident previously evaluated is not increased. Performing tests to verify the operability of the CRE boundary and implementing a program to assess and maintain CRE habitability ensure that the CRE emergency ventilation system is capable of adequately mitigating radiological consequences to CRE occupants during accident conditions, and that the CRE emergency ventilation system will perform as assumed in the consequence analyses of design basis accidents. Thus, the consequences of any accident previously evaluated are not increased. 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 does not impact the accident analysis. The proposed change does not alter the required mitigation capability of the CRE emergency ventilation system, or its functioning during accident conditions as assumed in the licensing basis analyses of design basis accident radiological consequences to CRE occupants. No new or different accidents result from performing the new surveillance or following the new program. The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a significant change in the methods governing normal plant operation. The proposed change does not alter any safety analysis assumptions and is consistent with current plant operating practice. 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 alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change does not affect safety analysis acceptance criteria. The proposed change will not result in plant operation in a configuration outside the design basis for an unacceptable period of time without compensatory measures. The proposed change does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the analysis adopted by the licensee 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: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: Thomas H. Boyce.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit 3 Nuclear Generating Plant, Citrus County, Florida

Date of amendment request: January 17, 2008.

Description of amendment request: The proposed amendment would revise the Crystal River Unit 3 (CR3) Improved Technical Specification SR [surveillance requirement] 3.7.5.2, ''Emergency Feedwater System,'' and would align the text for the surveillance test frequency with the text in the NRC technical report, NUREG–1430, Volume 1, Revision 3, ''Standard Technical Specifications Babcock and Wilcox Plants-Specifications.''

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 not involve a significant increase in the probability or consequences of an accident previously evaluated.

Changing the test frequency of SR 3.7.5.2 from ''45 days on a STAGGERED TEST BASIS'' to ''In accordance with the Inservice Testing Program'' will not affect any CR3 structure, system or component (SSC). As such, there will be no effect on plant operation, to any design function or analysis that verifies the capability of a SSC to perform a design function, or to any of the

previously evaluated accidents in the CR3 Final Safety Analysis Report (FSAR). The proposed amendment will not change any operating procedure or administrative control.

Since the proposed amendment does not involve a change to any SSC, their operation or design, and since the proposed amendment will not change any of the previously evaluated accident in the CR3 FSAR, the probability and consequences of any accident or operating scenario will be unchanged by its implementation.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change will not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. The proposed change will not alter any assumptions made in the safety analysis.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does not involve a significant reduction in a margin on safety.

The proposed change will 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 affected by this change. The proposed change will not result in plant operation in a configuration outside of the accepted design basis. As such, 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: David T. Conley, Associate General Counsel II—Legal Department, Progress Energy Service Company, LLC, Post Office Box 1551, Raleigh, North Carolina 27602.

NRC Branch Chief: Thomas H. Boyce.

Tennessee Valley Authority (TVA), Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: April 15, 2008.

Description of amendment request: The proposed amendment would change and realign several containment isolation subject matter Technical Specifications to the Nuclear Regulatory Commission Regulation (NUREG)—1431, Revision 3, ''Standard Technical Specifications Westinghouse Plants.''

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.

TVA's proposed change that involves administrative changes, including relocation of actions or SRs [surveillance requirements] to another LCO [limiting condition of operation] or to the TS administrative controls section; revision of text to conform with NUREG–1431 and add clarity; minor revision to definitions and other LCOs for fidelity; and deletion of Type A leakage test performance deferral information, do not result in technical changes to requirements currently present in the TS. These changes are administrative in nature and do not impact initiators of analyzed events.

They also do not impact the assumed mitigation of accidents or transients events. Therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

TVA's proposed change eliminates an hourly time limit for operation of the containment purge supply and exhaust isolation valves. This change also eliminates associated actions and SRs. The containment purge and ventilation system is qualified and designed to isolate in the event of a design basis accident (DBA). The probability of occurrence of an accident is not increased by deletion of the time limit nor will it affect the system's capability for purge valve closure or containment isolation. This change does not result in a modification of the reactor building purge ventilation (RBPV) system. Consequently, the 10 CFR 100 limits for site boundary dose will not be exceeded in the event of an accident during containment purge operation. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

TVA proposes to implement a new required action for systems that meet the criteria of general design requirement (GDC) 57 for closed system. The change would provide relaxation of the completion time for isolation of a penetration flow path for the identified systems. This change does not result in any plant modification and therefore the systems will continue to mitigate the consequences of a DBA. The proposed completion time is reasonable and is consistent with standard industry guidelines to ensure the accident mitigation equipment will be restored in a timely manner. The allow[ed] completion time for isolation is not a precursor to any DBE [Design Basis Event]; thus, no increase in the probability of accident previously evaluated is considered. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

TVA's proposed change reduces the amount of technical details of an SR and relocates it to a licensee controlled document under the control of 10 CFR 50.59. The reduction in information is consistent with NUREG–1431. This change does not result in any hardware or operating procedure changes. Requirements to perform surveillances of the systems detailed in the information are not eliminated. The details being removed from the TSs are not assumed to be an initiator of any analyzed event and therefore would not involve a significant increase in the probability of an accident. This information also does not impact the assumed mitigation of accidents or transient events. Therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

TVA's proposed change adds a more restrictive requirement to conform to NUREG–1431 in support of eliminating the hourly time limit for the operation of the containment purge isolation valves. This change will require a verification that open travel restrictors are in the containment purge valves during modes of applicability. The change will also require conditional leakage testing of a containment purge valve used to isolate a penetration.

This change does not result in a modification of the RBPV system as the restrictors were installed during initial plant licensing. Leakage testing is not a new requirement for these valves. These changes provide a more stringent requirement that previously existed in the TSs. These more stringent requirements do not result in operation that will increase the probability of initiating an analyzed event. This change assists in the operability of the containment purge supply and exhaust isolation valves.

Therefore, the proposed change 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.

TVA's proposed changes that involve administrative change, including relocation of actions or SRs to another LCO or to the TS administrative controls section; revision of text to conform with NUREG–1431 and add clarity; minor revision to definitions and other LCOs for fidelity; and deletion of Type A leakage test performance deferral information, do not result in technical changes to requirements currently present in the TS. These changes do not involve a physical alteration of the plant (no new or different type of equipment will be installed) or changes in the methods governing normal plant operations. These changes will not impose any new or different requirements or eliminate any existing requirements. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

TVA's proposed change eliminates an hourly time limit for operation of the containment purge supply and exhaust

isolation valves. This change also eliminates associated actions and SRs. This change does not involve a change to plant systems, components, or operating practices that could result in a change in accident generation potential. The containment purge supply and exhaust valves are utilized for the isolation of flow paths to the environs and are not a feature that could generate a postulated accident. Elimination of the operational time restriction of the containment purge supply and exhaust isolation valves will not impact the potential for accidents. Therefore, this proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

TVA proposes to implement a new required action for systems that meet the closed system design. The change would provide relaxation of the completion time for isolation of a penetration flow path for the identified systems. This change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or require any unusual operator actions. The proposed change will not alter the way any structure, system, or component functions, and will not alter the manner the plant is operated. The response of the plant and the operators following an accident will not be different. The change does not introduce any new failure modes.

Therefore, this proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

TVA's proposed change reduces the amount of technical details of an SR and relocates it to a licensee controlled document under the control of 10 CFR 50.59.

The reduction in information is consistent with NUREG–1431 and adequate control of the information will be maintained. This change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or changes in testing requirements of these systems. This change will not alter assumptions made in the safety analysis and licensing basis. Therefore, this proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

TVA's proposed change adds a more restrictive requirement to conform to NUREG–1431 in support of eliminating the hourly time limit for the operation of the containment purge isolation valves. This change will require a verification that open travel restrictors are in the containment purge valves during modes of applicability. The change will also require conditional leakage testing of a containment purge valve used to isolate a penetration. This change does not result in a modification of the RBPV system as the restrictors were installed during initial plant licensing. Leakage testing is not a new requirement for these valves. Verification of restrictors does not modify normal plant operations, but does impose different administrative requirements. Action required leakage rate testing of an isolated containment purge valve does create new requirements. However, these changes will maintain the assumptions in the safety analyses and licensing basis. Therefore, this proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

TVA's proposed changes that involve administrative change, including relocation of actions or SRs to another LCO or to the TS administrative controls section; revision of text to conform with NUREG–1431 and add clarity; minor revision to definitions and other LCO for fidelity; and deletion of Type A leakage test performance deferral information, do not result in technical changes to requirements currently present in the TS. These changes will not reduce a margin of safety because it has no impact on any safety analysis assumptions. Also, since these changes are administrative in nature, no question of safety is involved. Therefore, these changes do not involve a significant reduction in a margin of safety.

TVA's proposed change eliminates an hourly time limit for operation of the containment purge supply and exhaust isolation valves. This change also eliminates associated actions and SRs. The proposed change does not alter plant systems or their setpoints that are used to maintain the margin of safety. Operability will continue to be maintained by testing and verification requirements on the containment purge valves. Therefore, the proposed change does not involve a reduction in a margin of safety.

TVA proposes to implement a new required action for systems that meet the closed system design. The change would provide relaxation of the completion time for isolation of a penetration flow path for the identified systems. This change does not result in any plant modification, testing requirements to ensure operability, or a change in safety limits or safety system settings. The proposed completion time is reasonable and is consistent with standard industry guidelines to ensure the accident mitigation equipment will be restored in a timely manner. Therefore, the proposed change does not involve a reduction in a margin of safety.

TVA's proposed change reduces the amount of technical details of an SR and relocates it to a licensee controlled document under the control of 10 CFR 50.59. This change does not reduce the margin of safety since the location of the details has no impact on any safety assumptions. Therefore, the proposed change does not involve a reduction in a margin of safety.

TVA's proposed change adds a more restrictive requirement to conform to NUREG–1431 in support of eliminating the hourly time limit for the operation of the containment purge isolation valves. This change will require a verification that open travel restrictors are in the containment purge valves during modes of applicability. The change will also require conditional leakage testing of a containment purge valve used to isolate a penetration. Adding more stringent requirements, by definition, provides additional restrictions to enhance plant safety. As such, no question of safety is involved. Therefore, the proposed changes do 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: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Branch Chief: Thomas H. Boyce.

Virginia Electric and Power Company, Docket Nos. 50–280 and 50–281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of amendment request: April 2, 2008.

Description of amendment request: The proposed change revises Technical Specification (TS) Section 5.0, ''Design Features,'' to delete certain design details and descriptions included in TS 5.0 that are already contained in the Updated Final Safety Analysis Report (UFSAR), or are redundant to existing TS requirements, and are not required to be included in the TSs pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Section 50.36(c)(4). The proposed change also revises the format of, and incorporates design descriptions into, TS 5.0 consistent with Nuclear Regulatory Commission (NRC) policy and NUREG–1431, Standard Technical Specifications, Westinghouse Plants, Revision 3.0, to the extent practical. An editorial change is also proposed to address a minor TS discrepancy introduced by a previous license amendment.

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 change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to Section 5.0, ''Design Features,'' deletes certain details from the TS that are not required to be maintained in the TS by 10 CFR 50.36(c)(4), adds new TS limits that meet the 10 CFR 50.36(c)(4) inclusion criteria and revises the TS for consistency with NUREG–1431, Revision 3.0. The remaining change addresses a minor editorial discrepancy.

The proposed change does not add or modify any plant system, structures or component and has no impact on plant equipment operation. Thus, the proposed change is administrative in nature and does

not affect initiators of analyzed events or assumed mitigation of accident or transient events. 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.

Since the proposed change is administrative in nature, it 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 not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility. The proposed change does not alter or prevent the ability of structures, systems, and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. 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 TS change is administrative in nature and as such does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined, and the dose analysis acceptance criteria are not affected. The proposed change does not result in plant operation in a configuration outside the analyses or design basis and does not adversely affect systems that respond to safely shut down the plant and to maintain the plant in a safe shutdown condition. Therefore, the proposed TS 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: Lillian M. Cuoco, Esq., Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2 Richmond, VA 23219.

NRC Branch Chief: Melanie C. Wong.

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 51.22(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 (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 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 PDR Reference staff at 1 (800) 397–4209, (301) 415–4737 or by e-mail to *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: April 12, 2007.

Brief description of amendment: The amendment establishes more effective and appropriate action, surveillance, and administrative requirements related to ensuring the habitability of the control room envelope in accordance with Nuclear Regulatory Commission approved Technical Specification Task Force (TSTF) Standard Technical Specification change traveler TSTF–448, Revision 3, ''Control Room Habitability.''

Date of Issuance: April 30, 2008.

Effective date: As of its date of issuance and shall be implemented within 180 days of issuance.

Amendment No.: 265.

Facility Operating License No. DPR–16: Amendment revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** The January 23, 2008, 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 dated June 5, 2007 (72 FR 31100). The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated April 30, 2008.

No significant hazards consideration comments received: No.

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 amendments: November 8, 2007, as supplemented by letter dated March 11, 2008.

Brief description of amendments: The amendments modify Technical Specification (TS) 1.1, ''Definitions,'' to clarify the definitions of Channel Calibration and Channel Functional Test. The amendments incorporate TS Task Force (TSTF) Standard TS Change Traveler TSTF–205–A, ''Revision of Channel Calibration, Channel Functional Test, and Related Definitions,'' Revision 3, dated July 31, 2003.

Date of issuance: April 23, 2008.

Effective date: As of the date of issuance to be implemented within 60 days.

Amendment Nos.: 286 and 263.

Renewed Facility Operating License Nos. DPR–53 and DPR–69: Amendments revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** December 18, 2007 (72 FR 71705).

The letter dated March 11, 2008, 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 as published in the **Federal Register**. The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated April 23, 2008.

No significant hazards consideration comments received: No.

Carolina Power & Light Company, Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of application for amendments: September 26, 2007, as supplemented by letter dated December 7, 2007.

Brief description of amendments: The amendments revise Technical Specification (TS) 5.5.6, ''Inservice Testing Program,'' to reflect changes to the American Society of Mechanical Engineers Boiler and Pressure Vessel Code requirements for inservice testing of pumps and valves, and corresponding changes to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.55a, ''Codes and standards.'' The changes are based on Technical Specification Task Force (TSTF) Traveler TSTF–479, ''Changes to Reflect Revision of 10 CFR 50.55a,'' as modified by TSTF–497, ''Limit Inservice Testing Program SR [Surveillance Requirement] 3.0.2 Application to Frequencies of 2 Years or Less.''

Date of issuance: April 23, 2008.

Effective date: Date of issuance, to be implemented within 60 days.

Amendment Nos.: 247 and 275.

Facility Operating License Nos. DPR–71 and DPR–62: Amendments change the TSs and licenses.

Date of initial notice in ***Federal Register:*** January 29, 2008 (73 FR 5217). The staff's proposed no significant hazards consideration determination, as published in the **Federal Register** was based on the letter dated December 7, 2007. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 23, 2008.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of application for amendment: September 18, 2007.

Brief description of amendment: This amendment would modify Technical Specification (TS) requirements related to control room envelope habitability in accordance with Technical Specification Task Force (TSTF) Traveler TSTF–448, Revision 3.

Date of issuance: April 25, 2008.

Effective date: As of the date of issuance and shall be implemented within 120 days.

Amendment No.: 148.

Facility Operating License No. NPF–58: This amendment revised the Technical Specifications and License.

Date of initial notice in ***Federal Register:*** January 29, 2008 (73 FR 5221). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 25, 2008.

No significant hazards consideration comments received: No.

Florida Power Corporation, et al., Docket No. 50–302, Crystal River Unit No. 3 Nuclear Generating Plant, Citrus County, Florida

Date of application for amendment: April 13, 2007, as supplemented by letters dated September 4 and 13, 2007, and February 25, 2008.

Brief description of amendment: The amendment changes the technical specifications (TSs) to extend the completion time associated with an inoperable low pressure injection train, reactor building spray train, decay heat closed cycle cooling water train, and decay heat seawater train, from 72 hours to 7 days. The change has been requested consistent with NRC-approved T–S Task Force (TSTF) traveler TSTF–430 Revision 2. Additional changes to the TSs implement TSTF–439 Revision 2, to eliminate second completion times.

Date of issuance: April 30, 2008.

Effective date: Date of issuance, to be implemented within 60 days.

Amendment No.: 229.

Facility Operating License No. DPR–72: Amendment revises the technical specifications.

Date of initial notice in ***Federal Register:*** September 12, 2007 (72 FR 52167). The supplements dated September 4 and 13, 2007, and February 25, 2008, 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 as published in the **Federal Register**. The Commission's related evaluation of the amendment is contained in a safety evaluation dated April 30, 2008.

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: March 7, 2008, as supplemented by letter dated March 26, 2008.

Description of amendment request: The amendment revises the Seabrook Technical Specifications to extend the time allowed to collect initial plateau curves for the intermediate and power range neutron detectors to 24 hours after reaching 100 percent of rated thermal power.

Date of issuance: April 29, 2008.

Effective date: As of its date of issuance, and shall be implemented within 5 days.

Amendment No.: 118.

Facility Operating License No. NPF–86: The amendment revised the License and Technical Specifications.

Date of initial notice in ***Federal Register:*** March 19, 2008 (73 FR 14850). A correction to the notice was published on March 27, 2008 (73 FR 16327) and a duplicate, bi-weekly notice was published on April 8, 2008 (73 FR 19111). The licensee's March 26, 2008, supplement 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 April 29, 2008.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2 (DCCNP–1 and DCCNP–2), Berrien County, Michigan

Date of application for amendments: July 30, 2007, as supplemented by letter dated February 13, 2008.

Brief description of amendments: The amendments added a Surveillance Requirement, SR 3.8.2.2, that is applicable when offsite electrical power is supplied to a unit via backfeed through the main transformer and the unit is in either MODE 5, MODE 6, or during movement of irradiated fuel.

Date of issuance: April 28, 2008.

Effective date: As of the date of issuance, and shall be implemented within 45 days.

Amendment No.: 304 (for DCCNP–1) and 287 (for DCCNP–2).

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revised the Renewed Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** September 25, 2007 (72 FR 54475).

The supplemental letter contained clarifying information, 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 amendment is contained in a safety evaluation dated April 28, 2008.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2 (DCCNP–1 and DCCNP–2), Berrien County, Michigan

Date of application for amendments: June 13, 2007, as supplemented by letter dated February 13, 2008.

Brief description of amendments: The amendments revised Section 5.5.9, ''Ventilation Filter Testing Program (VFTP),'' changing the specified pressure drop values for the combined high efficient particulate air filters and charcoal adsorbers for three engineered safety feature ventilation systems from less than 6 inches water gauge to less than 4 inches water gauge at the specified flow rates.

Date of issuance: April 28, 2008.

Effective date: As of the date of issuance, and shall be implemented within 45 days.

Amendment No.: 305 (for DCCNP–1) and 288 (for DCCNP–2).

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revised the Renewed Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register:*** August 14, 2007 (72 FR 45458). The supplemental letter contained clarifying information, 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 amendment is contained in a safety evaluation dated April 28, 2008.

No significant hazards consideration comments received: No.

Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment requests: July 30 and October 19, 2007, as supplemented by letters dated August 31 and December 12, 2007, and February 21, March 28, and April 4 and 10, 2008.

Brief description of amendment: The amendment revised Technical Specification (TS) Limiting Condition for Operation (LCO) 2.4, ''Containment Cooling,'' LCO 2.14, ''Engineered Safety Features System Initiation Instrumentation Settings,'' and LCO 2.15, ''Instrumentation and Control Systems''; TS Surveillance Requirement (SR) 3.1, ''Instrumentation and Control,'' SR 3.5(4), ''Containment Isolation Valves Leak Rate Tests (Type C Tests),'' and SR 3.6(3), ''Containment Recirculating Air Cooling and Filtering System''; and associated TS Basis documents and Updated Safety Analysis Report sections to modify the containment spray system actuation logic to preclude automatic start of the containment spray pumps for a loss-of-coolant accident. The amendment also revised TS SR 3.6(3)a. to delete SRs for testing of the containment air cooling and filtering system emergency mode dampers and replace it with a surveillance to verify that the dampers are in the accident positions in all operating plant modes and deletes the requirement in TS SR 3.6(3)b. to remotely operate dampers. The amendment added license conditions related to the replacement and testing of containment air cleaning and filtering (CACF) unit HEPA (high-efficiency particulate air) filters and surveillance testing of the CACF unit relief ports. The license conditions require administrative controls pending the completion of detailed analysis and confirm commitments for the licensee to submit TS amendments by October 31, 2008.

Date of issuance: May 2, 2008.

Effective date: The license amendment is effective as of its date of issuance and shall be implemented prior to startup from the 2008 refueling outage.

Amendment No.: 255.

Renewed Facility Operating License No. DPR–40: The amendment revised the Technical Specifications and added additional conditions to the Renewed Facility Operating License.

Date of initial notice in ***Federal Register:*** August 28, 2007 (72 FR 49581), and January 29, 2008 (73 FR 5227). The supplemental letters dated August 31 and December 12, 2007, and February 21, March 28, and April 4 and 10, 2008, provided additional information that clarified the applications, did not expand the scope of the applications as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**. The Commission's related evaluation of the amendment is contained in a safety evaluation dated May 2, 2008.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 9th day of May 2008.

For the Nuclear Regulatory Commission.

Catherine Haney,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E8–11246 Filed 5–19–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the Subcommittee on Economic Simplified Boiling Water Reactor (ESBWR); Notice of Meeting

The ACRS Subcommittee on ESBWR will hold a meeting on June 3, 2008, Room T2 B3, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to protect information that is proprietary to General Electric-Hitachi (GEH) Nuclear Energy and its contractors pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Tuesday June 3, 2008—9 a.m. Until 5:30 p.m.

The Subcommittee will review several chapters of the Safety Evaluation Report with Open Items associated with the Economic Simplified Boiling Water Reactor (ESBWR) Design Certification Application. The Subcommittee will hear presentations by and hold discussions with representatives of the NRC staff, GEH, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official, Mr. David Bessette (telephone 301/415–8065) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695).

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 7:45 a.m. and 4:30 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes to the agenda.

Dated: May 9, 2008.

Cayetano Santos,

Branch Chief, ACRS.

[FR Doc. E8–11228 Filed 5–19–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Subcommittee Meeting on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on June 3, 2008, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b (c) (2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Tuesday, June 3, 2008, 8 a.m. Until 9 a.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Officer, Mr. Sam Duraiswamy (telephone: 301–415–7364) between 7:30 a.m. and 4 p.m. (ET) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695).

Further information regarding this meeting can be obtained by contacting the Designated Federal Officer between 7:30 a.m. and 4 p.m. (ET). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes in the agenda.

Dated: May 13, 2008.

Cayetano Santos,

Chief, Reactor Safety Branch.

[FR Doc. E8–11230 Filed 5–19–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on June 4–6, 2008, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Monday, October 22, 2007 (72 FR 59574).

Wednesday, June 4, 2008, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10 a.m.: ARTIST Test Program (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the findings from the ARTIST Tests on aerosol retention in the secondary side of a steam generator, and related matters.

10:15 a.m.–11:45 a.m.: Risk Assessment Standardization Project (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the Risk Assessment Standardization Project (RASP) and related matters.

1:45 p.m.–3:45 p.m.: Overview of the U.S. Evolutionary Power Reactor (EPR) Design (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and AREVA Nuclear Power Inc., regarding design features of the EPR and related matters.

4 p.m.–5 p.m.: Status of the Development of Rules and Regulatory Guidance in the areas of Safeguards and Security (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the status of activities associated with the development of rules and regulatory guidance in the safeguards and security areas.

5 p.m.–5:30 p.m.: Status of the Quality Assessment of Selected Research Projects (Open)—The Committee will hold discussions with the Chairmen of the ACRS Panels regarding the status of the quality assessment of the research projects on: FRAPCON/FRAPTRAN Code work at the Pacific Northwest National Laboratory; and NUREG–6943, ''Study of Remote Visual Methods to Detect Cracking in Reactor Components.''

5:45 p.m.–7 p.m.: Preparation of ACRS Report (Open)—The Committee will prepare and discuss the proposed ACRS report on the ARTIST Test Program.

Thursday, June 5, 2008, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–9:30 a.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future ACRS meetings. It will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, including anticipated workload and member assignments.

9:30 a.m.–9:45 a.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

10 a.m.–11:15 a.m.: Preparation for Meeting with the Commission (Open)—The Committee will hold discussions in preparation for their meeting with the Commission on the following topics: Safety Research Program Report, Digital I&C Matters, State-of-the-Art Reactor Consequence Analysis Program, ESBWR Design Certification, and Extended Power Uprates and related Technical Issues.

1:30 p.m.–3:30 p.m.: Meeting with the Commission (Open)—The Committee will meet with the Commission to discuss topics noted above.

3:45 p.m.–6 p.m.: Preparation of ACRS Report (Open)—The Committee will continue its discussion of a proposed ACRS report on the ARTIST Test Program.

Friday June 6, 2008, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:30 a.m.: Overview of the US-Advanced Pressurized Water Reactor (US-APWR) Design (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and Mitsubishi Heavy Industries, Ltd., regarding design features of the US-APWR and related matters.

10:45 a.m.–11:45 a.m.: Status of NRC Staff Activities Associated with the Resolution of Generic Safety Issue (GSI)-191, ''Assessment of Debris Accumulation on Pressurized-Water Reactor (PWR) Sump Performance'' (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the status of NRC staff activities associated with the resolution of GSI–191.

1:15 p.m.–1:30 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 26, 2007 (72 FR 54695). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Girija S. Shukla, Cognizant ACRS staff (301–415–6855), between 7:30 a.m. and 4 p.m., (ET). ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html or http://www.nrc.gov/reading-rm/doc-collections/ACRS/.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: May 14, 2008.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. E8–11232 Filed 5–19–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Weeks of May 19, 26, June 2, 9, 16, 23, 2008.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of May 19, 2008

There are no meetings scheduled for the Week of May 19, 2008.

Week of May 26, 2008—Tentative

Tuesday, May 27, 2008

1:30 p.m.—NRC All Hands Meeting (Public Meeting), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852.

Wednesday, May 28, 2008

9:30 a.m.—Briefing on Equal Employment Opportunity (EEO) and Workforce Planning (Public Meeting) (Contact: Kristin Davis, 301–492–2266).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

Week of June 2, 2008—Tentative

Wednesday, June 4, 2008

9 a.m.—Briefing on Results of the Agency Action Review Meeting (AARM) (Public Meeting) (Contact: Shaun Anderson, 301–415–2039).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

Thursday, June 5, 2008

1:30 p.m.—Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: Tanny Santos, 301–415–7270).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

Week of June 9, 2008—Tentative

There are no meetings scheduled for the Week of June 9, 2008.

Week of June 16, 2008—Tentative

There are no meetings scheduled for the Week of June 16, 2008.

Week of June 23, 2008—Tentative

Friday, June 27, 2008

9:30 a.m.—Periodic Briefing on New Reactor Issues (Public Meeting) (Contact: Donna Williams, 301–415–1322).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

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* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Michelle Schroll, 301–415–1662.

* * * * *

Additional Information

The start time for the Briefing on Results of the Agency Action Review Meeting (AARM) (Public Meeting) on Wednesday, June 4, 2008, has been changed from 9:30 a.m. to 9 a.m.

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The NRC Commission Meeting Schedule can be found on the Internet

at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: May 15, 2008.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. 08–1281 Filed 5–16–08; 11:40 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on May 22, 2008 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3) (5), (7), (9)(B), and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Casey, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting scheduled for May 22, 2008 will be: Formal orders of investigation; institution and settlement of injunctive actions; institution and settlement of administrative proceedings of an enforcement nature; resolution of litigation claims; adjudicatory matters; and post-argument discussions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: May 15, 2008.

Nancy M. Morris.

Secretary.

[FR Doc. E8–11277 Filed 5–19–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57817; File No. SR–SCCP–2008–01]

Self-Regulatory Organizations; Stock Clearing Corporation of Philadelphia; Notice of Filing of a Proposed Rule Change To Amend and Restate Its Articles of Incorporation

May 14, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on April 24, 2008, Stock Clearing Corporation of Philadelphia (''SCCP'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by SCCP. The Commission is publishing this notice to solicit comments from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

SCCP proposes to amend its current Articles of Incorporation (''Articles'') to more clearly state that all of the authorized shares of common stock of SCCP are issued and outstanding and are held by the Philadelphia Stock Exchange, Inc., (''Phlx''), a Delaware corporation. In addition, SCCP proposes to add language to its Articles relating to transfers and assignments of SCCP shares of stock. The proposed language would state that Phlx may not transfer or assign any SCCP shares, in whole or in part, unless such transfer or assignment is filed with and approved by the Commission under Section 19 of the Act and the rules promulgated thereunder. Additionally, SCCP proposes to restate its Articles to consolidate previous amendments and make other technical amendments to modernize the existing language in the Articles.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, SCCP 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. SCCP has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to ensure that any future change in ownership of SCCP stock, whether transferred or assigned, in whole or in part, would be filed with the Commission under Section 19 of the Act and the rules promulgated thereunder. This language is consistent with language recently proposed by the Phlx in connection with amending its Certificate of Incorporation and By-Laws[4] as a result of the proposed acquisition of Phlx by The NASDAQ OMX Group, Inc. (''NASDAQ OMX'').[5]

[1] 15 U.S.C. 78s(b)(1).

[2] The specific amendments proposed for SCCP's Articles can be viewed at *http://www.phlx.com/SCCP/sccp_rules/SR–SCCP–2008–01.pdf.*

[3] The Commission has modified the text of the summaries prepared by SCCP.

[4] On April 21, 2008, Phlx filed a proposed rule change to amend its Certificate of Incorporation, By-Laws, and rules in connection with the NASDAQ OMX Merger, as defined in footnote 4 below. Securities Exchange Act Release No. 57703 (April 23, 2008), 73 FR 23293, (April 29, 2008) [File No. SR–Phlx–2008–31].

[5] On November 7, 2007, NASDAQ OMX announced that it had entered into an agreement with Phlx pursuant to which NASDAQ OMX would acquire all of the outstanding capital stock of Phlx. In connection with this acquisition, Pinnacle Merger Corp., a Delaware corporation and wholly owned subsidiary of NASDAQ OMX, would be merged with and into Phlx with Phlx surviving the merger (''NASDAQ OMX Merger''). As a result of the NASDAQ OMX Merger, all of Phlx's common stock would be owned by NASDAQ OMX. Thereafter, NASDAQ OMX would operate Phlx as a wholly-owned subsidiary. Phlx would continue to be a separate self-regulatory organization.

In addition, the language in the proposed Articles would be amended to modernize the existing language. Also, previous amendments to the Articles would be consolidated into the proposed restated Articles for ease of reference.

SCCP believes that the proposed rule change is consistent with Section 17A of the Act,[6] in general, and with Section 17A(b)(3)(A) of the Act,[7] in particular, in that it is designed to ensure that SCCP is so organized and has the capacity to be able to facilitate the prompt and accurate clearance and settlement of securities transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

SCCP does not believe that the proposed rule change will impose any burden on competition 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

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period: (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–SCCP–2008–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–SCCP–2008–01. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of SCCP and on Phlx's Web site at *http://www.phlx.com/SCCP/sccp_rules/SR–SCCP–2008–01.pdf.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–SCCP–2008–01 and should be submitted on or before June 4, 2008.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–11205 Filed 5–19–08; 8:45 am]

BILLING CODE 8010–01–P

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78q–1(b)(3)(A).

[8] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 6232]

Determination and Certification Under Section 40A of the Arms Export Control Act

Pursuant to Section 40A of the Arms Export Control Act (22 U.S.C. 2781), and Executive Order 11958, as amended, I hereby determine and certify to the Congress that the following countries are not cooperating fully with United States antiterrorism efforts: Cuba; Eritrea; Iran; North Korea; Syria; Venezuela.

I hereby notify that the decision to retain the certification of North Korea pursuant to Section 40A of the Arms Export Control Act comes during an ongoing review of the designation of North Korea as a state sponsor of terrorism. The outcome of this review may warrant a re-assessment of whether North Korea should be included among the Countries certified as not cooperating fully with United States antiterrorism efforts.

This determination and certification shall be transmitted to the Congress and published in the **Federal Register**.

Dated: May 14, 2008.

John D. Negroponte,

Deputy Secretary of State, Department of State.

[FR Doc. E8–11255 Filed 5–19–08; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

[Docket No. OST–2007–27407]

National Surface Transportation Infrastructure Financing Commission

AGENCY: Department of Transportation (DOT).

ACTION: Notice of meeting location and time.

SUMMARY: This notice lists the location and time of the twelfth and thirteenth meetings of the National Surface Transportation Infrastructure Financing Commission.

FOR FURTHER INFORMATION CONTACT: John V. Wells, Chief Economist, U.S. Department of Transportation, (202) 366–9224, *jack.wells@dot.gov.*

SUPPLEMENTARY INFORMATION:

By **Federal Register** Notice dated March 12, 2007, and in accordance with the requirements of the Federal Advisory Committee Act (''FACA'') (5 U.S.C. App. 2) and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for

Users (''SAFETEA–LU'') (Pub. L. 109–59, 119 Stat. 1144), the U.S. Department of Transportation (the ''Department'') issued a notice of intent to form the National Surface Transportation Infrastructure Financing Commission (the ''Financing Commission''). Section 11142(a) of SAFETEA–LU established the National Surface Transportation Infrastructure Financing Commission and charged it with analyzing future highway and transit needs and the finances of the Highway Trust Fund and with making recommendations regarding alternative approaches to financing surface transportation infrastructure.

Notice of Meeting Location and Time

The Commissioners have agreed to hold their twelfth meeting from 8:30 a.m. to 4 p.m. on Thursday, June 5, 2008, and their thirteenth meeting from 8:30 a.m. to 4 p.m. on Tuesday, July 22, 2008. Each of the meetings will be open to the public and is scheduled to take place at the offices of the Information Technology and Innovation Foundation, 1250 I (''Eye'') Street, NW., Suite 200, Washington, DC 20005.

If you need accommodations because of a disability or require additional information to attend this meeting, please contact John V. Wells, Chief Economist, U.S. Department of Transportation, (202) 366–9224, *jack.wells@dot.gov.*

Issued on this 14th day of May, 2008.

John V. Wells,

Chief Economist, U.S. Department of Transportation, Designated Federal Official.

[FR Doc. E8–11185 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on a Proposed U.S. Highway Project in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). These actions relate to a proposed highway project to add a standard northbound HOV Lane and standardized Northbound Mixed-Flow Lanes, Median and Shoulder Alternative.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the project will be barred unless the claim is filed on or before November 17, 2008. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Ron Kosinski, Deputy District Director, Division of Environmental Planning, California Department of Transportation, District 7, 100 S. Main Street, Los Angeles, CA 90012, Telephone: 213–897–0703 or *Ron.Kosinski@dot.ca.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the FHWA assigned, and the California Department of Transportation (Caltrans) assumed environmental responsibilities for this project pursuant to 23 U.S.C. 327. Caltrans prepared an Environmental Impact Statement on a proposal for a highway widening improvement project in Los Angeles County, California.

The proposed project would widen I–405 to add a northbound HOV lane between National Boulevard and Ventura Boulevard, connecting with existing HOV lanes. The northbound roadway would meet current design standards for lane, median, and shoulder widths except at the I–10/I–405 interchange area and between Moraga Dr. and Sunset Blvd. interchanges. Standard lanes consist of an 11-foot half median, a 12-foot HOV lane, a 1-foot HOV buffer, five 12-foot mixed-flow lanes, and a 10-foot outside shoulder. The selected alternative would also widen the southbound I–405 to meet current design standards for lane, median, and shoulder widths at certain sections. Southbound standardization would be within the following segments: Between Olympic Blvd. and Waterford Street and between Bel Air Crest to the north end of the project (just south of Ventura Boulevard). Local interchanges within the project limits would be reconstructed and improved notably at Wilshire Boulevard, Sunset Boulevard, and Skirball Center Drive.

The anticipated permits include:

- 401 Water Quality Certification (from the Regional Water Quality Control Board) under Section 401 of the Clean Water Act).
- 404 Individual Permit (from the U. S. Army Corps of Engineers) under Section 404 of the Clean Water Act).

A Public meeting was held at the Skirball Cultural Center in Los Angeles on August 22, 2007. The Environmental Impact Statement, which was approved on February 29, 2008, and other documents are available for public and agency review at Caltrans, District 7 office provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal Aid-Highway Act [23 U.S.C. 109].

Land: Landscape and Scenic Enhancement (Wildflowers) [23 U.S.C. 219].

Air: Clean Air Act 42 U.S.C. 7401–7671(q).

Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and section 1536], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712]. Section 4(f) of the U.S. Department of Transportation Act of 1966 [49 U.S.C. 303].

Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(aa)-11]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209]; The Uniform Relocation Assistance Act and Real Property Acquisition Policies Act of 1970, as amended.

Hazardous Materials: Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601–9675; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901–6992(k).

Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of

Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: May 12, 2008.

Shawn E. Oliver,

South Team Leader.

[FR Doc. E8–11209 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2000–7257; Notice No. 46]

Railroad Safety Advisory Committee (RSAC); Notice of Meeting

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Announcement of Railroad Safety Advisory Committee Meeting.

SUMMARY: FRA announces the 35th meeting of the RSAC, a federal advisory committee that develops railroad safety regulations through a consensus process. The RSAC meeting topics will include opening remarks from the FRA Administrator, presentations on the Volpe Final Report on Private Crossings and the Pressure Tank Car Proposed Rule, and an update on the FRA Risk Reduction Program. Status reports will be provided by the Passenger Safety, Locomotive Safety Standards, Railroad Bridge Safety, Medical Standards, Railroad Operating Rules, and Track Safety Standards Working Groups. This agenda is subject to change.

DATES: The RSAC meeting will be held on Wednesday, June 11, 2008, from 9:30 a.m. to 4:30 p.m.

ADDRESSES: The RSAC meeting will be held at the National Housing Center, 1201 15th Street, NW., Washington, DC 20005. The meeting is open to the public on a first-come, first-serve basis, and is accessible to individuals with disabilities. Sign and oral interpretation can be made available if requested 10 calendar days before the meeting.

FOR FURTHER INFORMATION CONTACT: Larry Woolverton, RSAC Coordinator, FRA, 1200 New Jersey Avenue, SE., Mailstop 25, Washington, DC 20590, (202) 493–6212; or Grady Cothen, Deputy Associate Administrator for Safety, FRA, 1200 New Jersey Avenue, SE., Mailstop 25, Washington, DC 20590, (202) 493–6302.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), FRA is giving notice of a meeting of the Railroad Safety Advisory Committee. The RSAC was established to provide advice and recommendations to FRA on railroad safety matters. The RSAC comprises 54 voting representatives from 31 member organizations, representing various rail industry perspectives. In addition, there are nonvoting advisory representatives from agencies with railroad safety regulatory responsibility in Canada and Mexico, the National Transportation Safety Board, and the Federal Transit Administration. The diversity of the Committee ensures the requisite range of views and expertise necessary to discharge its responsibilities. See the RSAC Web site for details on pending tasks at: *http://rsac.fra.dot.gov.* Please refer to the notice published in the **Federal Register** on March 11, 1996, (61 FR 9740) for additional information about the RSAC.

Issued in Washington, DC, on May 14, 2008.

Michael J. Logue,

Deputy Associate Administrator for Safety Compliance and Program Implementation.

[FR Doc. E8–11239 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2008–0044]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel LIBERTY 55.

SUMMARY: As authorized by Pub. L. 105–383 and Pub. L. 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2008–0044 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Pub. L. 105–383 and MARAD's regulations at 46 CFR part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before June 19, 2008.

ADDRESSES: Comments should refer to docket number MARAD–2008–0044. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LIBERTY 55 is:

Intended Use: ''Private Passenger Charter''.

Geographic Region: ''Florida''.

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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: May 13, 2008.

By order of the Maritime Administrator.

Murray Bloom,

Acting Secretary, Maritime Administration.

[FR Doc. E8–11242 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2008–0042]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel CANYON CRUSHER.

SUMMARY: As authorized by Pub. L. 105–383 and Pub. L. 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2008–0042 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Pub. L. 105–383 and MARAD's regulations at 46 CFR part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before June 19, 2008.

ADDRESSES: Comments should refer to docket number MARAD–2008–0042. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CANYON CRUSHER is:

Intended Use: ''Coastwise Trade—Mid Atlantic Area predominately six pack charter operation from Ocean City, MD''.

Geographic Region: ''Mid Atlantic and Delmarva Region—Delaware, Maryland, Virginia areas. Some tournament fishing in North Carolina''.

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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: May 13, 2008.

By order of the Maritime Administrator.

Murray Bloom,

Acting Secretary, Maritime Administration.

[FR Doc. E8–11244 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2008–0043]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel TYCHE II.

SUMMARY: As authorized by Pub. L. 105–383 and Pub. L. 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2008–0043 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Pub. L. 105–383 and MARAD's regulations at 46 CFR part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before June 19, 2008.

ADDRESSES: Comments should refer to docket number MARAD–2008–0043. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TYCHE II is:

Intended Use: ''Passenger charter''.

Geographic Region: ''RI, MA, CT''.

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 DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Dated: May 13, 2008.

By order of the Maritime Administrator.

Murray Bloom,

Acting Secretary, Maritime Administration.

[FR Doc. E8–11245 Filed 5–19–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–762X]

Middletown and New Jersey Railway Company, Inc.—Abandonment Exemption—in Orange County, NY

Middletown and New Jersey Railway Company, Inc. (M&NJ) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 7.50+/-mile line of railroad between milepost 6.50 +/-in Slate Hill and milepost 14.00+/-in the Village of Unionville, in Orange County, NY. The line traverses United States Postal Service Zip Codes 10973, 10933, 10998, and 10988.

M&NJ has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on June 19, 2008, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by May 30, 2008. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 9, 2008, with: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to M&NJ's representative: Imre Eszenyi, 140 East Main Street, Middletown, NY 10940.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

M&NJ has filed a combined environmental and historic report addressing the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by May 23, 2008. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), M&NJ shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by M&NJ's filing of a notice of consummation by May 20, 2009, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: May 14, 2008.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–11131 Filed 5–19–08; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,300. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 14, 2008.

The Department of Treasury will submit the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. 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 June 19, 2008 to be assured of consideration.

Financial Crimes Enforcement Network (FinCEN)

OMB Number: 1506–0009.

Type of Review: Extension.

Title: Financial Record-keeping and Reporting and Report of Foreign Bank and Financial Accounts.

Description: The Bank Secrecy Act authorizes Treasury to require financial institutions and individuals to keep records and file reports that the Treasury determines have a high degree of usefulness in criminal, tax, or regulatory matters, or to protect against international terrorism.

Respondents: Individuals or households.

Estimated Total Reporting Burden: 10,942,392 hours.

OMB Number: 1506–0043.

Type of Review: Extension.

Title: Correspondent Accounts for Foreign Shell Banks; Record keeping and Termination of Correspondent Accounts.

Description: These rules prohibit domestic financial institutions from

maintaining correspondent accounts with foreign shell banks and require such institutions to maintain records of the owners, and agents, for service of legal process of foreign banks.

Respondents: Businesses and other for-profit institutions, and not-for-profit institutions.

Estimated Total Reporting Burden: 306,000 hours.

Clearance Officer: Russell Stephenson, (202) 354–6012, Department of the Treasury, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E8–11211 Filed 5–19–08; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

May 14, 2008.

The Department of Treasury will submit the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the publication date of this notice. 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 June 19, 2008 to be assured of consideration.

Bureau of Public Debt (BPD)

OMB Number: 1535–0113.

Type of Review: Revision.

Title: Disclaimer and Consent with Respect to United States Savings Bond/ Notes.

Forms: PD F 1849.

Description: This form is used to obtain a disclaimer and consent as the result of an error in registration or otherwise the payment, refund of the purchase price, or reissue as requested by one person would appear to affect the right, title or interest of some other person.

Respondents: Individuals or households.

Estimated Total Burden Hours: 700 hours.

OMB Number: 1535–0059.

Type of Review: Revision.

Title: Special Form of Assignment for U.S. Registered Definitive Securities and U.S. Bearer Securities for Conversion to BECCS or CUBES.

Forms: PD F 1832.

Description: This form is used to certify assignments of U.S. Registered and Bearer Securities.

Respondents: Individuals or households.

Estimated Total Burden Hours: 1,250 hours.

Clearance Officer: Brian Lallemont, (304) 480–8150, Bureau of the Public Debt, 200 Third Street, Parkersburg, West Virginia 26106.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E8–11212 Filed 5–19–08; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–122450–98, REG–100276–97]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning existing proposed and final regulations; Financial Asset Securitization Investment Trust; Real Estate Mortgage Investment Conduits [REG–100276–97; REG–122450–98]; Real Estate Mortgage Investment Conduits (TD 9004 (final)) Sections 1.860E–1(c)(4)–(10).

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3634, or through the Internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Financial Asset Securitization Investment Trusts; Real Estate Mortgage Investment Conduits.

OMB Number: 1545–1675.

Regulation Project Number: [REG–100276–97; REG–122450–98]; TD 9004 (final).

Abstract: REG–122450–98 Sections 1.860E–1(c)(4)–(10) of the Treasury Regulations provide circumstances under which a transferor of a noneconomic residual interest in a Real Estate Mortgage Investment Conduit (REMIC) meeting the investigation, and two representation requirements may avail itself of the safe harbor by satisfying either the formula test or asset test. REG–100276–97; REG–122450–98. This regulation provides start-up and transitional rules applicable to financial asset securitization investment trust. TD 9004 contains final regulations relating to safe harbor transfers of noneconomic residual interests in real estate mortgage investment conduits (REMICs). The final regulations provide additional limitations on the circumstances under which transferors may claim safe harbor treatment.

Current Actions: There are no changes being made to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit.

Estimated Total Annual Reporting and/or Recordkeeping Burden: 1,220.

Estimated Average Annual Burden Hours per Respondent and/or Recordkeeping: 1 hour 58 minutes.

Estimated Number of Respondents and/or Recordkeeping: 620. The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal

revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 6, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11178 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 6765

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning Form 6765, Credit for Increasing Research Activities.

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland Internal Revenue Service, room 6512, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–3634, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Credit for Increasing Research Activities.

OMB Number: 1545–0619.

Form Number: 6765.

Abstract: IRC section 38 allows a credit against income tax (Determined under IRC section 41) for an increase in research activities in a trade or business. Form 6765 is used by businesses and individuals engaged in a trade or business to figure and report the credit. The data is used to verify that the credit claimed is correct.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 15,805.

Estimated Time per Respondent: 21 hours, 24 minutes.

Estimated Total Annual Burden Hours: 338,227.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 6, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11179 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8804–C and TD 9394

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning Form 8804–C, Certificate of Partner-Level Items to Reduce Section 1446 Withholding and TD 9394, Special Rules to Reduce Section 1446 Withholding.

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 622–3634, at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificate of Partner-Level Items to Reduce Section 1446 Withholding.

OMB Number: 1545–1934.

Form Number: Form 8804–C.

Abstract: Form 8804–C will be a form a foreign partner would voluntary submit to the partnership if it chooses

to provide a certification that could reduce or eliminate the partnership's need to withhold 1446 tax.

Title: Special Rules to Reduce Section 1446 Withholding.

OMB Number: 1545–1934.

Form Number: TD 9394.

Abstract: This document contains final regulations regarding when a partnership may consider certain deductions and losses of a foreign partner to reduce or eliminate the partnership's obligation to pay withholding tax under section 1446 on effectively connected taxable income allocable under section 704 to such partner.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or Households, and Not-for-Profit Organizations.

Estimated Number of Respondents: 17,775.

Estimated Time per Respondent: 1 hour 2 minutes.

Estimated Total Annual Burden Hours: 18,168.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 7, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11180 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8801

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning Form 8801, Credit for Prior Year Minimum Tax—Individuals, Estates and Trusts.

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 622–3634, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Credit for Prior Year Minimum Tax—Individuals, Estates and Trusts.

OMB Number: 1545–1073.

Form Number: 8801.

Abstract: Form 8801 is used by individuals, estates, and trusts to compute the minimum tax credit, if any, available from a tax year beginning after 1986 to be used in the current year or to be carried forward for use in a future year.

Current Actions: There are no changes being made to Form 8801 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 12,914.

Estimated Time per Respondent: 6 hr., 54 min.

Estimated Total Annual Burden Hours: 89,107.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 6, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11182 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form W–2G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning Form W–2G, Certain Gambling Winnings.

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carolyn N. Brown, at (202) 622–6688, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certain Gambling Winnings.

OMB Number: 1545–0238.

Form Number: Form W–2G.

Abstract: Internal Revenue Code sections 6041, 3402(q), and 3406 require payers of certain gambling winnings to withhold tax and to report the winnings to the IRS. IRS uses the information to verify compliance with the reporting rules and to verify that the winnings are properly reported on the recipient's tax return.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, state or local governments, and non-profit institutions.

Estimated Number of Responses: 4,104,771.

Estimated Time per Response: 19 min.

Estimated Total Annual Burden Hours: 1,272,479.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11266 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–124667–02, EE–35–85]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the IRS is soliciting comments concerning existing final regulation, REG–124667–02 (NPRM) Disclosure of Relative Values of Optional Forms of Benefit; and EE–35–85 (Final) Income Tax: Taxable Years Beginning After December 31, 1953; OMB Control Number Under The Paperwork Reduction Act; Survivor Benefits, Distribution Restriction and Various Other Issues Under the Retirement Equity Act of 1984.

DATES: Written comments should be received on or before July 21, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Carolyn N. Brown at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6688, or through the Internet at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Disclosure of Relative Values of Optional Forms of Benefit; and Income Tax: Taxable Years Beginning After December 31, 1953; OMB Control Number Under The Paperwork Reduction Act; Survivor Benefits, Distribution Restriction and Various Other Issues Under the Retirement Equity Act of 1984.

OMB Number: 1545–0928.

Regulation Project Number: REG–124667–02.

Abstract: The notices referred to in this NPRM are required by statute and by state and must be provided by employers to retirement plan participants to inform participants of their rights under the plan or under the law. Failure to timely notify participants of their rights may result in loss of plan benefits.

Current Actions: There are no changes to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit.

Estimated Total Annual Reporting Burden: 385,000.

Estimated Average Annual Burden per Respondent: 1 hour, 57 minutes.

Estimated Number of Respondents: 750,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the

request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: May 9, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–11288 Filed 5–19–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974

AGENCY: Department of Veterans Affairs.

ACTION: Notice of amendment to system name and addition of routine uses.

SUMMARY: As required by the Privacy Act of 1974, 5 U.S.C. 552a(e)(4), notice is hereby given that the Department of Veterans Affairs (VA) is amending the system name of the system of records currently identified as ''Compensation, Pension, Education, and Rehabilitation Records—VA'' (58VA21/22/28) to be identified as ''Compensation, Pension, Education, and Vocational Rehabilitation Records—VA'' (58VA21/22/28). The system of records is also amended by adding new routine uses for disclosure of identifying information on VA beneficiaries.

DATES: The proposed routine uses will be effective June 19, 2008 unless comments are received before this date that would result in a contrary determination.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand delivery to the Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 273–9515 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System.

FOR FURTHER INFORMATION CONTACT: Brandye R. Terrell, Management and Program Analyst, Education Service (225C), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 461–9822. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA proposes to amend the system name of the system of records identified by system number 58VA21/22/28 to better identify the business lines covered by the system of records. The current name ''Compensation, Pension, Education, and Rehabilitation Records-VA'' is amended to read ''Compensation, Pension, Education, and Vocational Rehabilitation Records-VA''.

VA also proposes to add additional routine use disclosures to release identifying information on VA beneficiaries to:

1. The National Archives and Records Administration to perform records management inspections under title 44 U.S.C.

2. The Department of Justice (DoJ), court, or other administrative body if the information is relevant to DoJ's representation of the United States in any legal proceedings or if the use of the information is compatible with the purpose for which it was collected.

3. Individuals, organizations, private or public agencies, or other entities with whom VA has a contract, agreement, or subcontract to perform services as VA determines useful for the purposes of laws administered by VA.

4. Federal agencies to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

5. Appropriate agencies, entities, and persons VA determines are reasonably necessary to assist VA in preventing, minimizing, or remedying a suspected or confirmed compromise of information that may result in embarrassment or harm to the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of systems maintained by VA, other agencies, or entities that also rely on the potentially compromised information. This routine use will allow VA to provide necessary information in response to a suspected or confirmed data breach, including conducting a risk analysis or other provision of credit protection as provided in 38 U.S.C. 5724.

The Privacy Act permits VA to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which the information was collected. In all of the proposed routine use disclosures, either the recipient of the information will use the information in connection with a matter relating to one of VA's programs, or will use the information to provide a benefit to VA, or disclosure is required by law.

VA has determined that release of information under circumstances such as those described above is a necessary and proper use of the information in this system of records and that the specific routine uses proposed for the transfer of this information are appropriate.

An altered system of records report and a copy of the revised system notice have been sent to the House of Representatives Committee on Government Reform and Oversight, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB), as required by 5 U.S.C. 552a(r) and guidelines issued by OMB (65 FR 77677, December 12, 2000).

The proposed new routine uses 65 through 69 will be added to the system of records entitled ''Compensation, Pension, Education, and Rehabilitation Records—VA'' (58VA21/22/28), as published in the **Federal Register** at 41 FR 9294 (3/3/76), and amended at 63 FR 37941 (7/14/98), 65 FR 37605 (6/15/00), 66 FR 47725 (9/13/01), and last amended at 70 FR 34186 (6/13/05), with other amendments as cited therein.

Approved: May 2, 2008.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

Notice of Amendment of System of Records

The system identified as 58VA21/22/28 ''Compensation, Pension, Education and Rehabilitation Records-VA'' published in the **Federal Register** at 41 FR 9294 (3/3/76), amended at 63 FR 37941 (7/14/98), 65 FR 37605 (6/15/00), 66 FR 47725 (9/13/01), and last amended at 70 FR 34186 (6/13/05), with other amendments as cited therein, is revised to amend the system name and add new routine uses numbered 65 through 69 as follows:

58VA21/22/28

SYSTEM NAME:

Compensation, Pension, Education, and Vocational Rehabilitation Records-VA.

* * * * *

65. Disclosure may be made to the National Archives and Records Administration in record management inspections conducted under Authority of Title 44 U.S.C.

66. VA may disclose information from this system of records to the Department of Justice (DoJ), either on VA's initiative or in response to DoJ's request for the information, after either VA or DoJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DoJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its on initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

67. Disclosure of relevant information may be made to individuals, organizations, public or private agencies, or other entities with whom VA has a contract or agreement or where there is a subcontract to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

68. Disclosure to other Federal agencies may be made to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

69. VA may on its own initiative, disclose any information or records to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) VA has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to the economic or property interests, identity theft or fraud, or harm to the programs (whether maintained by VA or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the VA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by VA to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724, as the terms are defined in 38 U.S.C. 5727.

* * * * *

[FR Doc. E8–11240 Filed 5–19–08; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Tuesday,
May 20, 2008

Part II

Environmental Protection Agency

40 CFR Parts 50, 51, 53 et al.
National Ambient Air Quality Standards for Lead; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50, 51, 53 and 58

[EPA–HQ–OAR–2006–0735; FRL–8563–9]

RIN 2060–AN83

National Ambient Air Quality Standards for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria and national ambient air quality standards (NAAQS) for lead (Pb), EPA proposes to make revisions to the primary and secondary NAAQS for Pb to provide requisite protection of public health and welfare, respectively. EPA proposes to revise various elements of the primary standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurocognitive and neurobehavioral effects, in children. With regard to the level and indicator of the standard, EPA proposes to revise the level to within the range of 0.10 to 0.30 $\mu g/m^3$ in conjunction with retaining the current indicator of Pb in total suspended particles (Pb-TSP) but with allowance for the use of Pb-PM_{10} data, and solicits comment on alternative levels up to 0.50 $\mu g/m^3$ and down below 0.10 $\mu g/m^3$. With regard to the averaging time and form of the standard, EPA proposes two options: To retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, revised to apply across a 3-year span; and to revise the averaging time to a calendar month and the form to the second-highest monthly average across a 3-year span. EPA also solicits comment on revising the indicator to Pb-PM_{10} and on the same broad range of levels on which EPA is soliciting comment for the Pb-TSP indicator (up to 0.50 $\mu g/m^3$). EPA also invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. EPA proposes to make the secondary standard identical in all respects to the proposed primary standard.

EPA is also proposing corresponding changes to data handling procedures, including the treatment of exceptional events, and to ambient air monitoring and reporting requirements for Pb including those related to sampling and analysis methods, network design, sampling schedule, and data reporting. Finally, EPA is providing guidance on its proposed approach for implementing the proposed revised primary and secondary standards for Pb.

Consistent with the terms of a court order, by September 15, 2008 the Administrator will sign a notice of final rulemaking for publication in the **Federal Register**.

DATES: Comments must be received by July 21, 2008. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before June 19, 2008.

Public Hearings: EPA intends to hold public hearings on this proposed rule in June 2008 in St. Louis, Missouri and Baltimore, Maryland. These will be announced in a separate **Federal Register** notice that provides details, including specific times and addresses, for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–0735 by one of the following methods:

- *http://www.regulations.gov:* Follow the online instructions for submitting comments.
- *E-mail: a-and-r-Docket@epa.gov*.
- *Fax:* 202–566–9744.
- *Mail:* Docket No. EPA–HQ–OAR–2006–0735, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* Docket No. EPA–HQ–OAR–2006–0735, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–0735. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For further information in general or specifically with regard to sections I through III or VII, contact Dr. Deirdre Murphy, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C504–06, Research Triangle Park, NC 27711; telephone: 919–541–0729; fax: 919–541–0237; e-mail: *Murphy.deirdre@epa.gov*. With regard to Section IV, contact Mr. Mark Schmidt, Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–04, Research Triangle Park, NC 27711; telephone: 919–541–2416; fax: 919–541–1903; e-mail: *Schmidt.mark@epa.gov*. With regard to Section V, contact Mr. Kevin Cavender,

Air Quality Analysis Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C304–06, Research Triangle Park, NC 27711; *telephone:* 919–541–2364; fax: 919–541–1903; e-mail: *Cavender.kevin@epa.gov*. With regard to Section VI, contact Mr. Larry Wallace, Ph.D., Air Quality Policy Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail code C539–01, Research Triangle Park, NC 27711; *telephone:* 919–541–0906; fax: 919–541–0824; e-mail: *Wallace.larry@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of documents relevant to this rulemaking, including the advance notice of proposed rulemaking (72 FR 71488), the *Air Quality Criteria for Lead* (Criteria Document) (USEPA, 2006a), the Staff Paper, related risk assessment reports, and other related technical documents are available on EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_index.html*. These and other related documents are also available for inspection and copying in the EPA docket identified above.

Table of Contents

The following topics are discussed in this preamble:

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list each air pollutant that ''in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health and welfare'' and whose ''presence * * * in the ambient air results from numerous or diverse mobile or stationary sources'' and to issue air quality criteria for those that are listed. Air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *''. Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants listed under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on [air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] A secondary standard, as defined in Section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' [2]

The requirement that primary standards include an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied*, 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, see *Lead Industries Association* v. *EPA*, 647 F.2d at 1156 n. 51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA*, 647 F.2d at 1161–62. In addressing the requirement for an adequate margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the population(s) at risk, and the kind and degree of the uncertainties that must be addressed.

In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. *Whitman* v. *American Trucking Associations*, 531 U.S. 457, 473. Further the Supreme Court ruled that ''[t]he text of § 109(b), interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations from the NAAQS-setting process * * *'' *Id.* at 472.[3] Section 109(d)(1) of the Act requires that ''[n]ot later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 and subsection (b) of this section.'' Section 109(d)(2)(A) requires that ''The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.'' Section 109(d)(2)(B) requires that, ''[n]ot later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

[2] Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

[3] In considering whether the CAA allowed for economic considerations to play a role in the promulgation of the NAAQS, the Supreme Court rejected arguments that because many more factors than air pollution might affect public health, EPA should consider compliance costs that produce health losses in setting the NAAQS. 531 U.S. at 466. Thus, EPA may not take into account possible public health impacts from the economic cost of implementation. *Id.*

section.'' Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

B. History of Lead NAAQS Reviews

On October 5, 1978 EPA promulgated primary and secondary NAAQS for Pb under section 109 of the Act (43 FR 46246). Both primary and secondary standards were set at a level of 1.5 micrograms per cubic meter ($\mu g/m^3$), measured as Pb in total suspended particulate matter (Pb–TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 *Air Quality Criteria for Lead* (USEPA, 1977).

A review of the Pb standards was initiated in the mid-1980s. The scientific assessment for that review is described in the 1986 *Air Quality Criteria for Lead* (USEPA, 1986a), the associated Addendum (USEPA, 1986b) and the 1990 Supplement (USEPA, 1990a). As part of the review, the Agency designed and performed human exposure and health risk analyses (USEPA, 1989), the results of which were presented in a 1990 Staff Paper (USEPA, 1990b). Based on the scientific assessment and the human exposure and health risk analyses, the 1990 Staff Paper presented options for the Pb NAAQS level in the range of 0.5 to 1.5 $\mu g/m^3$, and suggested the second highest monthly average in three years for the form and averaging time of the standard (USEPA, 1990b). After consideration of the documents developed during the review and the significantly changed circumstances since Pb was listed in 1976, the Agency did not propose any revisions to the 1978 Pb NAAQS. In a parallel effort, the Agency developed the broad, multi-program, multimedia, integrated *U.S. Strategy for Reducing Lead Exposure* (USEPA, 1991). As part of implementing this strategy, the Agency focused efforts primarily on regulatory and remedial clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose more extensive public health risks to U.S. populations, as well as on actions to reduce Pb emissions to air, such as bringing more areas into compliance with the existing Pb NAAQS (USEPA, 1991).

C. Current Related Lead Control Programs

States are primarily responsible for ensuring attainment and maintenance of national ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 of the Act (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 of the Act (42 U.S.C. 7412).

As Pb is a multimedia pollutant, a broad range of Federal programs beyond those that focus on air pollution control provide for nationwide reductions in environmental releases and human exposures. In addition, the Centers for Disease Control and Prevention (CDC) programs provide for the tracking of children's blood Pb levels nationally and provide guidance on levels at which medical and environmental case management activities should be implemented (CDC, 2005a; ACCLPP, 2007).[4] In 1991, the Secretary of the Health and Human Services (HHS) characterized Pb poisoning as the ''number one environmental threat to the health of children in the United States'' (Alliance to End Childhood Lead Poisoning, 1991). In 1997, President Clinton created, by Executive Order 13045, the President's Task Force on Environmental Health Risks and Safety Risks to Children in response to increased awareness that children face disproportionate risks from environmental health and safety hazards (62 FR 19885).[5] By Executive Orders issued in October 2001 and April 2003, President Bush extended the work for the Task Force for an additional three and a half years beyond its original charter (66 FR 52013 and 68 FR 19931). The Task Force set a Federal goal of eliminating childhood Pb poisoning by the year 2010 and reducing Pb poisoning in children was the Task Force's top priority.

Federal abatement programs provide for the reduction in human exposures and environmental releases from in-place materials containing Pb (e.g., Pb-based paint, urban soil and dust, and contaminated waste sites). Federal regulations on disposal of Pb-based paint waste help facilitate the removal of Pb-based paint from residences.[6] Further, in 1991, EPA lowered the maximum levels of Pb permitted in public water systems from 50 parts per billion (ppb) to 15 ppb (56 FR 26460).

Federal programs to reduce exposure to Pb in paint, dust, and soil are specified under the comprehensive federal regulatory framework developed under the Residential Lead-Based Paint Hazard Reduction Act (Title X). Under Title X and Title IV of the Toxic Substances Control Act, EPA has established regulations and associated programs in the following five categories: (1) Training and certification requirements for persons engaged in lead-based paint activities; accreditation of training providers; authorization of State and Tribal lead-based paint programs; and work practice standards for the safe, reliable, and effective identification and elimination of lead-based paint hazards; (2) ensuring that, for most housing constructed before 1978, lead-based paint information flows from sellers to purchasers, from landlords to tenants, and from renovators to owners and occupants; (3) establishing standards for identifying dangerous levels of Pb in paint, dust and soil; (4) providing grant funding to establish and maintain State and Tribal lead-based paint programs, and to address childhood lead poisoning in the highest-risk communities; and (5) providing information on Pb hazards to the public, including steps that people can take to protect themselves and their families from lead-based paint hazards.

Under Title IV of TSCA, EPA established standards identifying hazardous levels of lead in residential paint, dust, and soil in 2001. This regulation supports the implementation of other regulations which deal with worker training and certification, Pb hazard disclosure in real estate transactions, Pb hazard evaluation and control in Federally-owned housing prior to sale and housing receiving Federal assistance, and U.S. Department of Housing and Urban Development grants to local jurisdictions to perform

[4] As described in Section III below the CDC stated in 2005 that no ''safe'' threshold for blood Pb levels in young children has been identified (CDC, 2005a).

[5] Co-chaired by the Secretary of the HHS and the Administrator of the EPA, the Task Force consisted of representatives from 16 Federal departments and agencies.

[6] See ''Criteria for Classification of Solid Waste Disposal Facilities and Practices and Criteria for Municipal Solid Waste Landfills: Disposal of Residential Lead-Based Paint Waste; Final Rule'' EPA–HQ–RCRA–2001–0017.

Pb hazard control. The TSCA Title IV term ''lead-based paint hazard'' implemented through this regulation identifies lead-based paint and all residential lead-containing dust and soil regardless of the source of Pb, which, due to their condition and location, would result in adverse human health effects. One of the underlying principles of Title X is to move the focus of public and private decision makers away from the mere presence of lead-based paint, to the presence of lead-based paint hazards, for which more substantive action should be undertaken to control exposures, especially to young children. In addition the success of the program will rely on the voluntary participation of states and tribes as well as counties and cities to implement the programs and on property owners to follow the standards and EPA's recommendations. If EPA were to set unreasonable standards (e.g., standards that would recommend removal of all Pb from paint, dust, and soil), States and Tribes may choose to opt out of the Title X Pb program and property owners may choose to ignore EPA's advice believing it lacks credibility and practical value. Consequently, EPA needed to develop standards that would not waste resources by chasing risks of negligible importance and that would be accepted by States, Tribes, local governments and property owners. In addition, a separate regulation establishes, among other things, under authority of TSCA section 402, residential Pb dust cleanup levels and amendments to dust and soil sampling requirements (66 FR 1206).

On March 31, 2008, the Agency issued a new rule (*Lead:* Renovation, Repair and Painting [RRP] Program) to protect children from lead-based paint hazards. This rule applies to renovators and maintenance professionals who perform renovation, repair, or painting in housing, child-care facilities, and schools built prior to 1978. It requires that contractors and maintenance professionals be certified; that their employees be trained; and that they follow protective work practice standards. These standards prohibit certain dangerous practices, such as open flame burning or torching of lead-based paint. The required work practices also include posting warning signs, restricting occupants from work areas, containing work areas to prevent dust and debris from spreading, conducting a thorough cleanup, and verifying that cleanup was effective. The rule will be fully effective by April 2010. States and tribes may become authorized to implement this rule, and the rule contains procedures for the authorization of states, territories, and tribes to administer and enforce these standards and regulations in lieu of a federal program. In announcing this rule, EPA noted that almost 38 million homes in the United States contain some lead-based paint, and that this rule's requirements were key components of a comprehensive effort to eliminate childhood Pb poisoning. To foster adoption of the rule's measures, EPA also intends to conduct an extensive education and outreach campaign to promote awareness of these new requirements.

Programs associated with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) and Resource Conservation Recovery Act (RCRA) also implement abatement programs, reducing exposures to Pb and other pollutants. For example, EPA determines and implements protective levels for Pb in soil at Superfund sites and RCRA corrective action facilities. Federal programs, including those implementing RCRA, provide for management of hazardous substances in hazardous and municipal solid waste.[7] For example, Federal regulations concerning batteries in municipal solid waste facilitate the collection and recycling or proper disposal of batteries containing Pb.[8] Similarly, Federal programs provide for the reduction in environmental releases of hazardous substances such as Pb in the management of wastewater (*http://www.epa.gov/owm/*).

A variety of federal nonregulatory programs also provide for reduced environmental release of Pb containing materials through more general encouragement of pollution prevention, promotion of reuse and recycling, reduction of priority and toxic chemicals in products and waste, and conservation of energy and materials. These include the Resource Conservation Challenge (*http://www.epa.gov/epaoswer/osw/conserve/index.htm*), the National Waste Minimization Program (*http://www.epa.gov/epaoswer/hazwaste/minimize/leadtire.htm*), ''Plug in to eCycling'' (a partnership between EPA and consumer electronics manufacturers and retailers; *http://www.epa.gov/epaoswer/hazwaste/recycle/electron/crt.htm#crts*), and activities to reduce the practice of backyard trash burning (*http://www.epa.gov/msw/backyard/pubs.htm*).

Efforts such as those programs described above have been successful in that blood Pb levels in all segments of the population have dropped significantly from levels observed around 1990. In particular, blood Pb levels for the general population of children 1 to 5 years of age have dropped to a median level of 1.6 µg/dL and a level of 3.9 µg/dL for the 90th percentile child in the 2003–2004 National Health and Nutrition Examination Survey (NHANES) as compared to median and 90th percentile levels in 1988–1991 of 3.5 µg/dL and 9.4 µg/dL, respectively (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*). These levels (median and 90th percentile) for the general population of young children [9] are at the low end of the historic range of blood Pb levels for general population of children aged 1–5 years. However, as discussed in Section II.B.1.b, levels have been found to vary among children of different socioeconomic status and other demographic characteristics (CD, p. 4–21) and racial/ethnic and income disparities in blood Pb levels in children persist. The decline in blood Pb levels in the United States has resulted from coordinated, intensive efforts at the national, state, and local levels. The Agency has continued to grapple with soil and dust Pb levels from the historical use of Pb in paint and gasoline and other sources.

EPA's research program, with other Federal agencies, defines, encourages and conducts research needed to locate and assess serious risks and to develop methods and tools to characterize and help reduce risks. For example, EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) for Pb in children and the Adult Lead Methodology are widely used and accepted as tools that provide guidance in evaluating site specific data. More recently, in recognition of the need for a single model that predicts Pb concentrations in tissues for children and adults, EPA is developing the All Ages Lead Model (AALM) to provide researchers and risk assessors with a

[7] See, e.g., ''Hazardous Waste Management System; Identification and Listing of Hazardous Waste: Inorganic Chemical Manufacturing Wastes; Land Disposal Restrictions for Newly Identified Wastes and CERCLA Hazardous Substance Designation and Reportable Quantities; Final Rule'', *http://www.epa.gov/epaoswer/hazwaste/state/revision/frs/fr195.pdf* and *http://www.epa.gov/epaoswer/hazwaste/ldr/basic.htm*.

[8] See, e.g., ''Implementation of the Mercury-Containing and Rechargeable Battery Management Act'' *http://www.epa.gov/epaoswer/hazwaste/recycle/battery.pdf* and ''Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2005'' *http://www.epa.gov/epaoswer/osw/conserve/resources/msw-2005.pdf*.

[9] The 95th percentile value for the 2003–2004 NHANES is 5.1 µg/dL (Axelrad, 2008).

pharmacokinetic model capable of estimating blood, tissue, and bone concentrations of Pb based on estimates of exposure over the lifetime of the individual. EPA research activities on substances including Pb focus on better characterizing aspects of health and environmental effects, exposure, and control or management of environmental releases (see *http://www.epa.gov/ord/researchaccomplishments/index.html*).

D. Current Lead NAAQS Review

EPA initiated the current review of the air quality criteria for Pb on November 9, 2004, with a general call for information (69 FR 64926). A project work plan (USEPA, 2005a) for the preparation of the Criteria Document was released in January 2005 for CASAC and public review. EPA held a series of workshops in August 2005, inviting recognized scientific experts to discuss initial draft materials that dealt with various lead-related issues being addressed in the Pb air quality criteria document. The first draft of the Criteria Document (USEPA, 2005b) was released for CASAC and public review in December 2005 and discussed at a CASAC meeting held on February 28–March 1, 2006.

A second draft Criteria Document (USEPA, 2006b) was released for CASAC and public review in May 2006, and discussed at the CASAC meeting on June 28, 2006. A subsequent draft of *Chapter 7—Integrative Synthesis* (Chapter 8 in the final Criteria Document), released on July 31, 2006, was discussed at an August 15, 2006, CASAC teleconference. The final Criteria Document was released on September 30, 2006 (USEPA, 2006a; cited throughout this preamble as CD). While the Criteria Document focuses on new scientific information available since the last review, it integrates that information with scientific criteria from previous reviews.

In February 2006, EPA released the *Plan for Review of the National Ambient Air Quality Standards for Lead* (USEPA, 2006c) that described Agency plans and a timeline for reviewing the air quality criteria, developing human exposure and risk assessments and an ecological risk assessment, preparing a policy assessment, and developing the proposed and final rulemakings.

In May 2006, EPA released for CASAC and public review a draft *Analysis Plan for Human Health and Ecological Risk Assessment for the Review of the Lead National Ambient Air Quality Standards* (USEPA, 2006d), which was discussed at a June 29, 2006, CASAC meeting (Henderson, 2006). The May 2006 assessment plan discussed two assessment phases: A pilot phase and a full-scale phase. The pilot phase of both the human health and ecological risk assessments was presented in the draft *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas* (ICF, 2006; henceforth referred to as the first draft Risk Assessment Report) which was released for CASAC and public review in December 2006. The first draft Staff Paper, also released in December 2006, discussed the pilot assessments and the most policy-relevant science from the Criteria Document. These documents were reviewed by CASAC and the public at a public meeting on February 6–7, 2007 (Henderson, 2007a).

Subsequent to that meeting, EPA conducted full-scale human exposure and health risk assessments, although no further work was done on the ecological assessment due to resource limitations. A second draft Risk Assessment Report (USEPA, 2007a), containing the full-scale human exposure and health risk assessments, was released in July 2007 for review by CASAC at a meeting held on August 28–29, 2007. Taking into consideration CASAC comments (Henderson, 2007b) and public comments on that document, we conducted additional human exposure and health risk assessments. A final Risk Assessment Report (USEPA, 2007b) and final Staff Paper (USEPA, 2007c) were released on November 1, 2007.

The final Staff Paper presents OAQPS staff's evaluation of the public health and welfare policy implications of the key studies and scientific information contained in the Criteria Document and presents and interprets results from the quantitative risk/exposure analyses conducted for this review. Further, the Staff Paper presents OAQPS staff recommendations on a range of policy options for the Administrator to consider concerning whether, and if so how, to revise the primary and secondary Pb NAAQS. Such an evaluation of policy implications is intended to help ''bridge the gap'' between the scientific assessment contained in the Criteria Document and the judgments required of the EPA Administrator in determining whether it is appropriate to retain or revise the NAAQS for Pb. In evaluating the adequacy of the current standard and a range of alternatives, the Staff Paper considered the available scientific evidence and quantitative risk-based analyses, together with related limitations and uncertainties, and focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: indicator,[10] averaging time, form,[11] and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the public health and welfare protection afforded by the Pb standards. The information, conclusions, and OAQPS staff recommendations presented in the Staff Paper were informed by comments and advice received from CASAC in its reviews of the earlier draft Staff Paper and drafts of related risk/exposure assessment reports, as well as comments on these earlier draft documents submitted by public commenters.

Subsequent to completion of the Staff Paper, EPA issued an advance notice of proposed rulemaking (ANPR) that was signed by the Administrator on December 5, 2007 (72 FR 71488–71544). The ANPR is one of the key features of the new NAAQS review process that EPA has instituted over the past two years to help to improve the efficiency of the process the Agency uses in reviewing the NAAQS while ensuring that the Agency's decisions are informed by the best available science and broad participation among experts in the scientific community and the public. The ANPR provided the public an opportunity to comment on a wide range of policy options that could be considered by the Administrator. The substantial number of comments we received on the Pb NAAQS ANPR helped inform the narrower range of options we are proposing and taking comment on today. The new process (described at *http://www.epa.gov/ttn/naaqs/*.) is being incorporated into the various ongoing NAAQS reviews being conducted by the Agency, including the current review of the Pb NAAQS.

A public meeting of the CASAC was held on December 12–13, 2007 to provide advice and recommendations to the Administrator based on its review of the ANPR and the previously released final Staff Paper and Risk Assessment Report. Information about this meeting was published in the **Federal Register** on November 20, 2007 (72 FR 65335–65336), transcripts of the meeting are in the Docket for this review and CASAC's letter to the Administrator (Henderson, 2008) is also available on the EPA Web site (*http://www.epa.gov/sab*).

[10] The ''indicator'' of a standard defines the chemical species or mixture that is to be measured in determining whether an area attains the standard.

[11] The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

A public comment period for the ANPR extended from December 17, 2007 through January 16, 2008 and comments received are in the Docket for this review. Comments were received from nearly 9000 private citizens (roughly 200 of them were not part of one of several mass comment campaign), 13 state and local agencies, one federal agency, three regional or national associations of government agencies or officials, 15 nongovernmental environmental or public health organizations (including one submission on behalf of a coalition of 23 organizations) and five industries or industry organizations. Although the Agency has not developed formal responses to comments received on the ANPR, these comments have been considered in the development of this notice and are generally described in subsequent sections on proposed conclusions with regard to the adequacy of the standards and with regard to the Administrator's proposed decisions on revisions to the standards.

The schedule for completion of this review is governed by a judicial order in *Missouri Coalition for the Environment*, v. *EPA* (No. 4:04CV00660 ERW, Sept. 14, 2005). The order governing this review, entered by the court on September 14, 2005 and amended on April 29, 2008, specifies that EPA sign, for publication, notices of proposed and final rulemaking concerning its review of the Pb NAAQS no later than May 1, 2008 and September 15, 2008, respectively. In light of the compressed schedule ordered by the court for issuing the final rule, EPA may be able to respond only to those comments submitted during the public comment period on this proposal. EPA has considered all of the comments submitted to date in preparing this proposal, but if commenters believe that comments submitted on the ANPR are fully applicable to the proposal and wish to ensure that those comments are addressed by EPA as part of the final rulemaking, the earlier comments should be resubmitted during the comment period on this proposal.

This action presents the Administrator's proposed decisions on the review of the current primary and secondary Pb standards. Throughout this preamble a number of judgments, conclusions, findings, and determinations proposed by the Administrator are noted. While they identify the reasoning that supports this proposal, they are not intended to be final or conclusive in nature. The EPA invites general, specific, and/or technical comments on all issues involved with this proposal, including all such proposed judgments, conclusions, findings, and determinations.

II. Rationale for Proposed Decision on the Primary Standard

This section presents the rationale for the Administrator's proposed decision that the current primary standard is not requisite to protect public health with an adequate margin of safety, and that the existing Pb primary standard should be revised. With regard to the primary standard for Pb, EPA is proposing options for the revision of the various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects in children, particularly neurocognitive and neurobehavioral effects. With regard to the level and indicator of the standard, EPA proposes to revise the level of the standard to a level within the range of 0.10 to 0.30 $\mu g/m^3$ in conjunction with retaining the current indicator of Pb in total suspended particles (Pb-TSP) but with allowance for the use of Pb-PM_{10} data. With regard to the form and averaging time of the standard, EPA proposes the following options: (1) To retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, revised so as to apply across a 3-year span, and (2) to revise the averaging time to a calendar month and the form to be the second-highest monthly average across a 3-year span. EPA also solicits comment on revising the indicator to Pb-PM_{10}.

As discussed more fully below, this proposal is based on a thorough review, in the Criteria Document, of the latest scientific information on human health effects associated with the presence of Pb in the ambient air. This proposal also takes into account: (1) Staff assessments of the most policy-relevant information in the Criteria Document and staff analyses of air quality, human exposure, and health risks presented in the Staff Paper, upon which staff recommendations for revisions to the primary Pb standard are based; (2) CASAC advice and recommendations, as reflected in discussions of the ANPR and drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately.

In developing this proposal, EPA has drawn upon an integrative synthesis of the entire body of evidence, published through late 2006, on human health effects associated with Pb exposure. Some 6000 newly available studies were considered in this review. As discussed below in section II.B, this body of evidence addresses a broad range of health endpoints associated with exposure to Pb (EPA, 2006a, chapter 8), and includes hundreds of epidemiologic studies conducted in the U.S., Canada, and many countries around the world since the time of the last review (EPA, 2006a, chapter 6). This proposal also draws upon the results of the quantitative exposure and risk assessments, discussed below in section II.C. Evidence- and exposure/risk-based considerations that form the basis for the Administrator's proposed decisions on the adequacy of the current standard and on the elements of the proposed alternative standards are discussed below in section II.D.2 and II.D.3, respectively.

A. Multimedia, Multipathway Considerations and Background

1. Atmospheric Emissions and Distribution of Lead

Lead is emitted into the air from many sources encompassing a wide variety of source types (Staff Paper, Section 2.2). Further, once deposited out of the air, Pb can subsequently be resuspended into the air (CD, pp. 2–62 to 2–66). There are over 100 categories of sources of Pb emissions included in the EPA's 2002 National Emissions Inventory (NEI),[12] the top five of which include: Mobile sources (leaded aviation gas)[13]; industrial, commercial, institutional and process boilers; utility boilers; iron and steel foundries; and primary Pb smelting (Staff Paper Section 2.2). Further, there are some 13,000 industrial, commercial or institutional point sources in the 2002 NEI, each with one or more processes that emit Pb to the atmosphere. In addition to these 13,000 sources, there are approximately 3,000 airports at which leaded gasoline is used (Staff Paper, p. 2–8). Among these sources, more than one thousand are estimated to emit at least a tenth of a ton of Pb per year (Staff Paper, Section 2.2.3). Because of its persistence, Pb emissions contribute to media

[12] As noted in the Staff Paper, quantitative estimates of emissions associated with resuspension of soil-bound Pb particles and contaminated road dust are not included in the 2002 NEI.

[13] The emissions estimates identified as mobile sources in the current NEI are currently limited to combustion of leaded aviation gas in piston-engine aircraft. Lead emissions estimates for other mobile source emissions of Pb (e.g., brake wear, tire wear, loss of Pb wheel weights and others) are not included in the current NEI.

concentrations for some time into the future.

Lead emitted to the air is predominantly in particulate form, with the particles occurring in many sizes. Once emitted, Pb particles can be transported long or short distances depending on their size, which influences the amount of time spent in aerosol phase. In general, larger particles tend to deposit more quickly, within shorter distances from emissions points, while smaller particles will remain in aerosol phase and travel longer distances before depositing. Additionally, once deposited, Pb particles can be resuspended back into the air and undergo a second dispersal. Thus, the atmospheric transport processes of Pb contribute to its broad dispersal, with larger particles generally occurring as a greater contribution to total airborne Pb at locations closer to the point of emission than at more distant locations where the relative contribution from smaller particles is greater (CD, Section 2.3.1 and p. 3–3).

Airborne concentrations of Pb in total suspended particulate matter (Pb-TSP) in the United States have fallen substantially since the current Pb NAAQS was set in 1978.[14] Despite this decline, there have still been a small number of areas, associated with large stationary sources of Pb, that have not met the NAAQS over the past few years. The average maximum quarterly mean concentration for the time period 2003–2005 among source-oriented monitoring sites in the U.S. is 0.48 $\mu g/m^3$, while the corresponding average for non-source-oriented sites is 0.03 $\mu g/m^3$.[15] The average and median among all monitoring-site-specific maximum quarterly mean concentrations for this time period are 0.17 $\mu g/m^3$ and 0.03 $\mu g/m^3$, respectively. Coincident with the historical trend in reduction in Pb levels, however, there has also been a substantial reduction in number of Pb-TSP monitoring sites. As described below in section II.B.3.b, many of the highest Pb emitting sources in the 2002 NEI do not have nearby Pb-TSP monitors, which may lead to underestimates of the extent of occurrences of relatively higher Pb concentrations (as recognized in the Staff Paper, Section 2.3.2 and, with regard to more recent analysis, in section II.B.3.b below).

2. Air-Related Human Exposure Pathways

As when the standard was set in 1978, we recognize that exposure to air Pb can occur directly by inhalation, or indirectly by ingestion of Pb-contaminated food, water or nonfood materials including dust and soil (43 FR 46247). This occurs as Pb emitted into the ambient air is distributed to other environmental media and can contribute to human exposures via indoor and outdoor dusts, outdoor soil, food and drinking water, as well as inhalation of air (CD, pp. 3–1 to 3–2). Accordingly, people are exposed to Pb emitted into ambient air by both inhalation and ingestion pathways. In general, air-related pathways include those pathways where Pb passes through ambient air on its path from a source to human exposure. EPA considers risks to public health from exposure to Pb that was emitted into the air as relevant to our consideration of the primary standard. Therefore , we consider these air-related pathways to be policy-relevant in this review. Air-related Pb exposure pathways include: Inhalation of airborne Pb (that may include Pb emitted into the air and deposited and then resuspended); and ingestion of Pb that, once airborne, has made its way into indoor dust, outdoor dust or soil, dietary items (e.g., crops and livestock), and drinking water (e.g., CD, Figure 3–1).

Ambient air Pb contributes to Pb in indoor dust through transport of Pb suspended in ambient air that is then deposited indoors and through transport of Pb that has deposited outdoors from ambient air and is transported indoors in ways other than through ambient air (CD, Section 3.2.3; Adgate *et al.*, 1998). For example, infiltration of ambient air into buildings brings airborne Pb indoors where deposition of particles contributes to Pb in dust on indoor surfaces (CD, p. 3–28; Caravanos *et al.*, 2006a). Indoor dust may be ingested (e.g., via hand-to-mouth activity by children; CD, p. 8–12) or may be resuspended through household activities and inhaled (CD, p. 8–12). Ambient air Pb can also deposit onto outdoor surfaces (including surface soil) with which humans may come into contact (CD, Section 2.3.2; Farfel *et al.*, 2003; Caravanos *et al.*, 2006a, b). Human contact with this deposited Pb may result in incidental ingestion from this exposure pathway and may also result in some of this Pb being carried indoors (e.g., on clothes and shoes) adding to indoor dust Pb (CD, p. 3–28; von Lindern *et al.*, 2003a, b). Additionally, Pb from ambient air that deposits on outdoor surfaces may also be resuspended and carried indoors in the air where it can be inhaled. Thus, indoor dust receives air-related Pb directly from ambient air coming indoors and also more indirectly, after deposition from ambient air onto outdoor surfaces.

As mentioned above, humans may contact Pb in dust on outdoor surfaces, including surface soil and other materials, that has deposited from ambient air (CD, Section 3.2; Caravanos *et al.*, 2006a; Mielke *et al.*, 1991; Roels *et al.,* 1980). Human exposure to this deposited Pb can occur through incidental ingestion, and, when the deposited Pb is resuspended, by inhalation. Atmospheric deposition of Pb also contributes to Pb in vegetation, both as a result of contact with above ground portions of the plant and through contributions to soil and transport of Pb into roots (CD, pp. 7–9 and AXZ7–39; USEPA, 1986a, Sections 6.5.3 and 7.2.2.2.1). Livestock may subsequently be exposed to Pb in vegetation (e.g., grasses and silage) and in surface soils via incidental ingestion of soil while grazing (USEPA 1986a, Section 7.2.2.2.2). Atmospheric deposition is estimated to comprise a significant proportion of Pb in food (CD, p. 3–48; Flegel *et al.*, 1990; Juberg *et al.*, 1997; Dudka and Miller, 1999). Atmospheric deposition outdoors also contributes to Pb in surface waters, although given the widespread use of settling or filtration in drinking water treatment, air-related Pb is generally a small component of Pb in treated drinking water (CD, Section 2.3.2 and p. 3–33).

Air-related exposure pathways are affected by changes to air quality, including changes in concentrations of Pb in air and/or changes in atmospheric deposition of Pb. Further, because of its persistence in the environment, Pb deposited from the air may contribute to human and ecological exposures for years into the future (CD, pp. 3–18 to 3–19, pp. 3–23 to 2–24). Thus, because of the roles in human exposure pathways of both air concentration and air deposition, and of the persistence of Pb, once deposited, some pathways respond more quickly to changes in air quality than others. Pathways most directly involving Pb in ambient air and exchanges of ambient air with indoor air respond more quickly while pathways involving exposure to Pb deposited from ambient air into the environment generally respond more slowly (CD, pp. 3–18 to 3–19).

[14] Air Pb concentrations nationally are estimated to have declined more than 90% since the early 1980s, in locations not known to be directly influenced by stationary sources (Staff Paper, pp. 2–22 to 2–23).

[15] The data set included data for 189 monitor sites meeting the data analysis screening criteria. Details with regard to the data set and analyses supporting the values provided here are presented in Section 2.3.2 of the Staff Paper.

Exposure pathways tied most directly to ambient air, and that consequently have the potential to respond relatively more quickly to changes in air Pb, include inhalation of ambient air, and ingestion of Pb in indoor dust directly contaminated with Pb from ambient air.[16] Lead from ambient air contaminates indoor dust directly when outdoor air comes inside (through open doors or windows, for example) and Pb in that air deposits to indoor surfaces (Caravanos *et al.*, 2006a; CD, p. 8–22). This includes Pb that was previously deposited outdoors and is then resuspended and transported indoors. Lead in dust on outdoor surfaces also responds to air deposition (Caravanos *et al.*, 2006). Pathways in which the air quality impact is reflected over a somewhat longer time frame generally are associated with outdoor atmospheric deposition, and include ingestion pathways such as the following: (1) Ingestion of Pb in outdoor soil; (2) ingestion of Pb in indoor dust indirectly contaminated with Pb from the outdoor air (e.g, ''tracking in'' of Pb deposited to outdoor surface soil, as compared to ambient air transport of resuspended outdoor soil); (3) ingestion of Pb in diet that is attributable to deposited air Pb, and; (4) ingestion of Pb in drinking water that is attributable to deposited air Pb (e.g., Pb entering water bodies used for drinking supply).

3. Nonair-Related and Air-Related Background Human Exposure Pathways

As when the standard was set in 1978, there continue to be multiple sources of exposure, both air-related and others (nonair-related). Human exposure pathways that are not air-related are those in which Pb does not pass through ambient air. These pathways as well as air-related human exposure pathways that involve natural sources of Pb to air are considered policy-relevant background in this review. In the context of NAAQS for other criteria pollutants which are not multimedia in nature, such as ozone, the term policy-relevant background is used to distinguish anthropogenic air emissions from naturally occurring non-anthropogenic emissions to separate pollution levels that can be controlled by U.S. regulations from levels that are generally uncontrollable by the United States (USEPA, 2007d). In the case of Pb, however, due to the multimedia, multipathway nature of human exposures to Pb, policy-relevant background is defined more broadly to include not only the ''quite low'' levels of naturally occurring Pb emissions into the air from non-anthropogenic sources such as volcanoes, sea salt, and windborne soil particles from areas free of anthropogenic activity (see below), but also Pb from nonair sources. These are collectively referred to as ''policy-relevant background.''

The pathways of human exposure to Pb that are not air-related include ingestion of Pb from indoor Pb paint[17], Pb in diet as a result of inadvertent additions during food processing, and Pb in drinking water attributable to Pb in distribution systems (CD, Chapter 3). Other less prevalent, potential pathways of Pb exposure that are not air-related include ingestion of some calcium supplements or of food contaminated during storage in some Pb glazed glassware, and hand-to-mouth contact with some imported vinyl miniblinds or with some hair dyes containing Pb acetate, as well as some cosmetics and folk remedies (CD, pp. 3–50 to 3–51).

Some amount of Pb in the air derives from background sources, such as volcanoes, sea salt, and windborne soil particles from areas free of anthropogenic activity (CD, Section 2.2.1). The impact of these sources on current air concentrations is expected to be quite low (relative to current concentrations) and has been estimated to fall within the range from 0.00002 μg/m^3 and 0.00007 μg/m^3 based on mass balance calculations for global emissions (CD, Section 3.1 and USEPA 1986, Section 7.2.1.1.3). The midpoint in this range, 0.00005 μg/m^3, has been used in the past to represent the contribution of naturally occurring air Pb to total human exposure (USEPA 1986, Section 7.2.1.1.3). The data available to derive such an estimate are limited and such a value might be expected to vary geographically with the natural distribution of Pb. Comparing this to reported air Pb measurements is complicated by limitations of the common analytical methods and by inconsistent reporting practices. This value is one half the lowest reported nonzero value in AQS. Little information is available regarding anthropogenic sources of airborne Pb located outside of North America, which would also be considered policy-relevant background. In considering contributions from policy-relevant background to human exposures and associated health effects, however, any credible estimate of policy-relevant background in air is likely insignificant in comparison to the contributions from exposures to nonair media.

4. Contributions to Children's Lead Exposures

As when the standard was set in 1978, EPA recognizes that there remain today contributions to blood Pb levels from nonair sources. The relative contribution of Pb in different exposure media to human exposure varies, particularly for different age groups. For example, some studies have found that dietary intake of Pb may be a predominant source of Pb exposure among adults, greater than consumption of water and beverages or inhalation (CD, p. 3–43).[18] For young children, however, ingestion of indoor dust can be a significant Pb exposure pathway, such that dust ingested via hand-to-mouth activity can be a more important source of Pb exposure than inhalation, although indoor dust can also be resuspended through household activities and pose an inhalation risk as well (CD, p. 3–27 to 3–28; Melnyk *et al.* 2000).[19]

Estimating contributions from nonair sources is complicated by the existence of multiple and varied air-related pathways (as described in section II.A.2 above), as well as the persistent nature of Pb. For example, Pb that is a soil or dust contaminant today may have been airborne yesterday or many years ago. The studies currently available and reviewed in the Criteria Document that evaluate the multiple pathways of Pb exposure, when considering exposure contributions from outdoor dust/soil, do

[16] We note that in the risk assessment, we only assessed alternate standard impacts on the subset of air-related pathways that respond relatively quickly to changes in air Pb.

[17] Weathering of outdoor Pb paint may also contribute to soil Pb levels adjacent to the house.

[18] ''Some recent exposure studies have evaluated the relative importance of diet to other routes of Pb exposure. In reports from the NHEXAS, Pb concentrations measured in households throughout the Midwest were significantly higher in solid food compared to beverages and tap water (Clayton *et al.*, 1999; Thomas *et al.*, 1999). However, beverages appeared to be the dominant dietary pathway for Pb according to the statistical analysis (Clayton *et al.*, 1999), possibly indicating greater bodily absorption of Pb from liquid sources (Thomas *et al.*, 1999). Dietary intakes of Pb were greater than those calculated for intake from home tap water or inhalation on a μg/day basis (Thomas *et al.*, 1999). The NHEXAS study in Arizona showed that, for adults, ingestion was a more important Pb exposure route than inhalation (O'Rourke *et al.*, 1999).'' (CD, p. 3–43)

[19] For example, the Criteria Document states the following: ''Given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant. For children, dust ingested via hand-to-mouth activity is often a more important source of Pb exposure than inhalation. Dust can be resuspended through household activities, thereby posing an inhalation risk as well. House dust Pb can derive both from Pb-based paint and from other sources outside the home. The latter include Pb-contaminated airborne particles from currently operating industrial facilities or resuspended soil particles contaminated by deposition of airborne Pb from past emissions.'' (CD, p. E–6)

not usually distinguish between outdoor soil/dust Pb resulting from historical emissions and outdoor soil/dust Pb resulting from recent emissions. Further, while indoor dust Pb has been identified as being a predominant contributor to children's blood Pb, available studies do not generally distinguish the different pathways (air-related and other) contributing to indoor dust Pb. The exposure assessment for children performed for this review has employed available data and methods to develop estimates intended to inform a characterization of these pathways (as described in section II.C below).

Relative contributions to a child's total Pb exposure from air-related exposure pathways (such as those identified in the sections above) compared to other (nonair-related) Pb exposures depends on many factors including ambient air concentrations and air deposition in the area where the child resides (as well as in the area from which the child's food derives), access to other sources of Pb exposure such as Pb paint, tap water affected by plumbing containing Pb and access to Pb-tainted products. Studies indicate that in the absence of paint-related exposures, Pb from other sources such as stationary sources of Pb emissions may dominate a child's Pb exposures (CD, section 3.2). In other cases, such as children living in older housing with peeling paint or where renovations have occurred, the dominant source may be lead paint used in the house in the past (CD, pp. 3–50 and 3–51). Depending on Pb levels in a home's tap water, drinking water can sometimes be a significant source (CD, section 3.3). And in still other cases, there may be more of a mixture of contributions from multiple sources, with no one source dominating (CD, Chapter 3).

As recognized in sections B.1.1 and II.B.3.a, blood Pb levels are the commonly used index of exposure for Pb and they reflect external sources of exposure, behavioral characteristics and physiological factors. Lead derived from differing sources or taken into the body as a result of differing exposure pathways (e.g., air- as compared to nonair-related), is not easily distinguished. As mentioned above, complications to consideration of estimates of air-related or conversely, nonair, blood Pb levels are the roles of air Pb in human exposure pathways and the persistence of Pb in the environment. As described in section II.A.2, air-related pathways (those in which Pb passes through the air on its path from source to human exposure) are varied, including inhalation and ingestion, indoor dust, outdoor dust/soil and diet, Pb suspended in and deposited from air, and encompassing a range of time frames from more immediate to less so. Estimates of blood Pb levels associated with air-related exposure pathways or only with nonair exposure pathways will vary depending on how completely the air-related pathways are characterized.

Consistent with reductions in air Pb concentrations (as described in section II.A.1 above) which contribute to blood Pb, nonair contributions have also been reduced. For example, the use of Pb paint in new houses has declined substantially over the 20th century, such that according to the *National Survey of Lead and Allergens in Housing* (USHUD, 2002) an estimated 24% of U.S. housing constructed between 1960 and 1978; 69% of the housing constructed between 1940 and 1959; and 87% of the pre-1940 housing contains lead-based paint. Additionally, Pb contributions to diet have been reported to have declined significantly since 1978, perhaps as much as 70% or more between then and 1990 (WHO, 1995) and the 2006 Criteria Document identifies a drop in dietary Pb intake by 2 to 5 year olds of 96% between the early 1980s and mid 1990s (CD, Section 3.4 and p. 8–14).[20] These reductions are generally attributed to reductions in gasoline-related airborne Pb as well as the reduction in use of Pb solder in canning food products (CD, Section 3.4).[21] There have also been reductions in tap water Pb levels (CD, section 3.3 and pp. 8–13 to 8–14). Contamination from the distribution/plumbing system appears to remain the predominant source of Pb in the drinking water (CD, section 3.3 and pp. 8–013 to 8–14).

The availability of estimates of blood Pb levels resulting only from air-related sources and exposures or only from those unrelated to air is limited and, given the discussion above, would be expected to vary for different populations. In addition to potential differences in air-related and nonair-related blood Pb levels among populations with different exposure circumstances (e.g., relatively more or lesser exposure to air-related Pb), the absolute levels may also vary among different age groups. As described in section II.B.1.b, average total blood Pb levels in the U.S. differ among age groups, with levels being highest in children aged one to five years old. We also note that behavioral characteristics that influence Pb exposures vary among age groups. For example as noted above, the predominant Pb exposure pathways may differ between adults and children. The extent of any quantitative impact of these differences on estimates of nonair blood Pb levels is unknown.[22]

In their advice to the Agency on levels for the standard, the CASAC Pb Panel explored several approaches to deriving a level, one of which required an estimate of the nonair component of blood Pb for the average child. They recommended consideration of 1.0 to 1.4 µg/dL or lower for such an estimate for the average nonair blood Pb level for young children (Henderson, 2007a, p. D–1). This range was developed with consideration of simulations of the integrated exposure and uptake biokinetic (IEUBK) model for lead for which the exposure concentration inputs included zero air concentration and concentrations for soil and dust of 50 ppm and 35 ppm, respectively (Henderson, 2007a, p. F–60).[23] [24] [25]

As is evident from the prior discussion, the many different exposure pathways contributing to children's blood Pb levels, and other factors, complicate our consideration of the available data with regard to characterization of levels particular to specific pathways, air-related or otherwise.

B. Health Effects Information

The following summary focuses on health endpoints associated with the range of exposures considered to be most relevant to current exposure levels and makes note of several key aspects of the health evidence for Pb. First (as

[20] Additionally, the 1977 Criteria Document included a dietary Pb intake estimate for the general population of 100 to 350 µg Pb/day, with estimates near and just below 100 µg/day for young children (USEPA 1977, pp. 1–2 and 12–32) and the 2006 Criteria Document cites recent studies (for the mid-1990s) indicating a dietary intake ranging from 2 to 10 µg Pb/day for children (CD, Section 3.4 and p. 8–14).

[21] Sources of Pb in food were identified in the 1986 Criteria Document as including air-related sources, metals used in processing raw foodstuffs, solder used in packaging and water used in cooking (1986a, section 3.1.2).

[22] As noted earlier in this section, for children, dust ingestion by hand-to-mouth activity can be an important source of Pb exposure, while for adults, dietary Pb can be predominant.

[23] The soil and dust levels are described as ''typical geochemical non-air input levels for dust and soil'' (Henderson, 2007a, p. F–60). The values used for these levels in this simulation fall within the range of 1 to 200 ppm described in the Criteria Document for soil not influenced by sources (CD, p. 3–18).

[24] The other IEUBK inputs (e.g., exposure and biokinetic factors) were those used in the IEUBK modeling for the risk assessment in this review (Henderson, 2007a, p. F–60).

[25] Individual CASAC member comments describing the IEUBK simulations stated that the modeling produced a nonair blood Pb level of ''1.4 µg/dL as a geometric mean'' (Henderson, 2007a, p. F–61).

described in Section II.A, above), because exposure to atmospheric Pb particles occurs not only via direct inhalation of airborne particles, but also via ingestion of deposited ambient Pb, the exposure considered is multimedia and multipathway in nature, occurring via both the inhalation and ingestion routes. Second, the exposure index or dose metric most commonly used and associated with health effects information is an internal biomarker (*i.e.*, blood Pb). Additionally, the exposure duration of interest (*i.e.*, that influencing internal dose pertinent to health effects of interest) may span months to potentially years, as does the time scale of the environmental processes influencing Pb deposition and fate. Lastly, the nature of the evidence for the health effects of greatest interest for this review, neurological effects, particularly neurocognitive and neurobehavioral effects, in young children, are epidemiological data substantiated by toxicological data that provide biological plausibility and insights on mechanisms of action (CD, sections 5.3, 6.2 and 8.4.2).

In recognition of the multi-pathway aspects of Pb, and the use of an internal exposure metric in health risk assessment, the next section describes the internal disposition or distribution of Pb, and the use of blood Pb as an internal exposure or dose metric. This is followed by a discussion of the nature of Pb-induced health effects that emphasizes those with the strongest evidence. Potential impacts of Pb exposures on public health, including recognition of potentially susceptible or vulnerable subpopulations, are then discussed. Finally, key observations about Pb-related health effects are summarized.

1. Blood Lead

The health effects of Pb are remote from the portals of entry to the body (i.e., the respiratory system and gastrointestinal tract). Consequently, the internal disposition and distribution of Pb in the blood is an integral aspect of the relationship between exposure and effect. Additionally, the focus on blood Pb as the dose metric in consideration of the Pb health effects evidence, while reducing our uncertainty with regard to causality, leads to an additional consideration with regard to contribution of air-related sources and exposure pathways to blood Pb.

a. Internal Disposition of Lead

This section briefly summarizes the current state of knowledge of Pb disposition pertaining to both inhalation and ingestion routes of exposure as described in the Criteria Document.

Inhaled Pb particles deposit in the different regions of the respiratory tract as a function of particle size (CD, pp. 4–3 to 4–4). Lead associated with smaller particles, which are predominantly deposited in the pulmonary region, may, depending on solubility, be absorbed into the general circulation or transported to the gastrointestinal tract (CD, pp. 4–3). Lead associated with larger particles, which are predominantly deposited in the head and conducting airways (e.g., nasal pharyngeal and tracheobronchial regions of respiratory tract), may be transported into the esophagus and swallowed, thus making its way to the gastrointestinal tract (CD, pp. 4–3 to 4–4), where it may be absorbed into the blood stream. Thus, Pb can reach the gastrointestinal tract either directly through the ingestion route or indirectly following inhalation.

Once in the blood stream, where approximately 99% of the Pb associates with red blood cells, the Pb is quickly distributed throughout the body (e.g., within days) with the bone serving as a large, long-term storage compartment, and soft tissues (e.g., kidney, liver, brain, etc.) serving as smaller compartments, in which Pb may be more mobile (CD, sections 4.3.1.4 and 8.3.1.). Additionally, the epidemiologic evidence indicates that Pb freely crosses the placenta resulting in continued fetal exposure throughout pregnancy, and that exposure increases during the later half of pregnancy (CD, section 6.6.2).

During childhood development, bone represents approximately 70% of a child's body burden of Pb, and this accumulation continues through adulthood, when more than 90% of the total Pb body burden is stored in the bone (CD, section 4.2.2). Accordingly, levels of Pb in bone are indicative of a person's long-term, cumulative exposure to Pb. In contrast, blood Pb levels are usually indicative of recent exposures. Depending on exposure dynamics, however, blood Pb may—through its interaction with bone—be indicative of past exposure or of cumulative body burden (CD, section 4.3.1.5).

Throughout life, Pb in the body is exchanged between blood and bone, and between blood and soft tissues (CD, section 4.3.2), with variation in these exchanges reflecting ''duration and intensity of the exposure, age and various physiological variables'' (CD, p. 4–1). Past exposures that contribute Pb to the bone, consequently, may influence current levels of Pb in blood. Where past exposures were elevated in comparison to recent exposures, this influence may complicate interpretations with regard to recent exposure (CD, sections 4.3.1.4 to 4.3.1.6). That is, higher blood Pb concentrations may be indicative of higher cumulative exposures or of a recent elevation in exposure (CD, pp. 4–34 and 4–133).

In several studies investigating the relationship between Pb exposure and blood Pb in children (e.g., Lanphear and Roghmann 1997; Lanphear *et al.*, 1998), blood Pb levels have been shown to reflect Pb exposures, with particular influence associated with exposures to Pb in surface dust. Further, as stated in the Criteria Document ''these and other studies of populations near active sources of air emissions (e.g., smelters, etc.) substantiate the effect of airborne Pb and resuspended soil Pb on interior dust and blood Pb'' (CD, p. 8–22).

b. Use of Blood Lead as Dose Metric

Blood Pb levels are extensively used as an index or biomarker of exposure by national and international health agencies, as well as in epidemiological (CD, sections 4.3.1.3 and 8.3.2) and toxicological studies of Pb health effects and dose-response relationships (CD, Chapter 5). The prevalence of the use of blood Pb as an exposure index or biomarker is related to both the ease of blood sample collection (CD, p. 4–19; Section 4.3.1) and by findings of association with a variety of health effects (CD, Section 8.3.2). For example, the U.S. Centers for Disease Control and Prevention (CDC), and its predecessor agencies, have for many years used blood Pb level as a metric for identifying children at risk of adverse health effects and for specifying particular public health recommendations (CDC, 1991; CDC, 2005a). In 1978, when the current Pb NAAQS was established, the CDC recognized a blood Pb level of 30 µg/dL as a level warranting individual intervention (CDC, 1991). In 1985, the CDC recognized a level of 25 µg/dL for individual child intervention, and in 1991, they recognized a level of 15 µg/dL for individual intervention and a level of 10 µg/dL for implementing community-wide prevention activities (CDC, 1991; CDCa, 2005). In 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 µg/dL [26] and the data demonstrating that

[26] As described by the Advisory Committee on Childhood Lead Poisoning Prevention, ''In 1991,

no ''safe'' threshold for blood Pb had been identified, and emphasizing the importance of preventative measures (CDC, 2005a, ACCLPP, 2007).[27]

Since 1976, the CDC has been monitoring blood Pb levels nationally through the National Health and Nutrition Examination Survey (NHANES). This survey monitors blood Pb levels in multiple age groups in the U.S. This information indicates variation in mean blood Pb levels across the various age groups monitored. For example, mean values in 2001–2002 for ages 1–5, 6–11, 12–19 and greater than or equal to 20 years of age, are 1.70, 1.25, 0.94, and 1.56, respectively (CD, p. 4–22).

The NHANES information has documented the dramatic decline in mean blood Pb levels in the U.S. population that has occurred since the 1970s and that coincides with regulations regarding leaded fuels, leaded paint, and Pb-containing plumbing materials that have reduced Pb exposure among the general population (CD, Sections 4.3.1.3 and 8.3.3; Schwemberger *et al.*, 2005). The Criteria Document summarizes related information as follows (CD, p. E–6).

In the United States, decreases in mobile sources of Pb, resulting from the phasedown of Pb additives created a 98% decline in emissions from 1970 to 2003. NHANES data show a consequent parallel decline in blood-Pb levels in children aged 1 to 5 years from a geometric mean of ~15 μg/dL in 1976–1980 to ~1–2 μg/dL in the 2000–2004 period.

While levels in the U.S. general population, including geometric mean levels in children aged 1–5, have declined significantly, levels have been found to vary among children of different socioeconomic status (SES) and other demographic characteristics (CD, p. 4–21). For example, while the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 μg/dL, the median for the subset living below the poverty level is 2.3 μg/dL and 90th percentile values for these two groups are 4.0 μg/dL and 5.4 μg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-Hispanic children aged 1–5 is 2.5 μg/dL, while the median level for the subset of that group living below the poverty level is 2.9 μg/dL and the median level for the subset living in more well-off households (i.e., with income more than 200% of the poverty level) is 1.9 μg/dL. Associated 90th percentile values for 2001–2004 are 6.4 μg/dL (for black, non-Hispanic children aged 1–5), 7.7 μg/dL (for the subset of that group living below the poverty level) and 4.1 μg/dL (for the subset living in a household with income more than 200% of the poverty level).[28] The recently released RRP rule (discussed above in section I.C) is expected to contribute to further reductions in BLL for children living in houses with Pb paint.

Bone measurements, as a result of the generally slower Pb turnover in bone, are recognized as providing a better measure of cumulative Pb exposure (CD, Section 8.3.2). The bone pool of Pb in children, however, is thought to be much more labile than that in adults due to the more rapid turnover of bone mineral as a result of growth (CD, p. 4–27). As a result, changes in blood Pb concentration in children more closely parallel changes in total body burden (CD, pp. 4–20 and 4–27). This is in contrast to adults, whose bone has accumulated decades of Pb exposures (with past exposures often greater than current ones), and for whom the bone may be a significant source long after exposure has ended (CD, Section 4.3.2.5).

c. Air-to-Blood Relationships

As described in Section II.A, Pb in ambient air contributes to Pb in blood by multiple pathways, with the pertinent exposure routes including both inhalation and ingestion (CD, Sections 3.1.3.2, 4.2 and 4.4; Hilts, 2003). The quantitative relationship between ambient air Pb and blood Pb, which is often termed a slope or ratio, describes the increase in blood Pb (in μg/dL) per unit of air Pb (in μg/m^3).[29]

The evidence on this quantitative relationship is now, as in the past, limited by the circumstances in which the data are collected. These estimates are generally developed from studies of populations in various Pb exposure circumstances. The 1986 Criteria Document discussed the studies available at that time that addressed the relationship between air Pb and blood Pb,[30] recognizing that there is significant variability in air-to-blood ratios for different populations exposed to Pb through different air-related exposure pathways and at different exposure levels.

In discussing the available evidence, the 1986 Criteria Document observed that estimates of air-to-blood ratios that included air-related ingestion pathways in addition to the inhalation pathway are ''necessarily higher'' (in terms of blood Pb response) than those estimates based on inhalation alone (USEPA 1986a, p. 11–106). Thus, the extent to which studies account for the full set of air-related exposure pathways affects the magnitude of the resultant air-to-blood estimates, such that fewer pathways included as ''air-related'' yield lower ratios. The 1986 Criteria Document also observed that ratios derived from studies focused only on inhalation pathways (e.g., chamber studies, occupational studies) have generally been on the order of 1:2 or lower, while ratios derived from studies including more air-related pathways were generally higher (USEPA, 1986a, p. 11–106). Further, the current evidence appears to indicate higher ratios for children as compared to those for adults (USEPA, 1986a), perhaps due to behavioral differences between the age groups.

Reflecting these considerations, the 1986 Criteria Document identified a range of air-to-blood ratios for children that reflected both inhalation and ingestion-related air Pb contributions as generally ranging from 1:3 to 1:5 based on the information available at that time (USEPA 1986a, p. 11–106). Table 11–36 (p. 11–100) in the 1986 Criteria Document (drawn from Table 1 in Brunekreef, 1984) presents air-to-blood ratios from a number of studies in children (i.e., those with identified air monitoring methods and reliable blood Pb data). For example, air-to-blood ratios from the subset of those studies that used quality control protocols and presented adjusted slopes[31] include

CDC defined the blood lead level (BLL) that should prompt public health actions as 10 μg/dL. Concurrently, CDC also recognized that a BLL of 10 μg/dL did not define a threshold for the harmful effects of lead. Research conducted since 1991 has strengthened the evidence that children's physical and mental development can be affected at BLLS <10 μg/dL'' (ACCLPP, 2007).

[27] With the 2005 statement, CDC did not lower the 1991 level of concern and identified a variety of reasons, reflecting both scientific and practical considerations, for not doing so, including a lack of effective clinical or public health interventions to reliably and consistently reduce blood Pb levels that are already below 10 μg/dL, the lack of a demonstrated threshold for adverse effects, and concerns for deflecting resources from children with higher blood Pb levels (CDC, 2005a). CDC's Advisory Committee on Childhood Lead Poisoning Prevention recently provided recommendations regarding interpreting and managing blood Pb levels below 10 μg/dL in children and reducing childhood exposures to Pb (ACCLPP, 2007).

[28] This information is available at: *http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm* (click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[29] Ratios are presented in the form of 1:x, with the 1 representing air Pb (in μg/m^3) and x representing blood Pb (in μg/dL). Description of ratios as higher or lower refers to the values for x (i.e., the change in blood Pb per unit of air Pb). Slopes are presented as simply the value of x.

[30] We note that the 2006 Criteria Document did not include a discussion of more recent studies on air-to-blood ratios.

[31] Brunekreef *et al.* (1984) discusses potential confounders to the relationship between air Pb and

Continued

adjusted ratios of 3.6 (Zielhuis *et al.*, 1979), 5.2 (Billick *et al.*, 1979, 1980), 2.9 (Billick *et al.*, 1983), and 8.5 (Brunekreef *et al*, 1983).

Additionally, the 1986 Criteria Document noted that ratios derived from studies involving higher blood and air Pb levels are generally smaller than ratios from studies involving lower blood and air Pb levels (USEPA, 1986a. p. 11–99). In consideration of this factor, we note that the range of 1:3 to 1:5 in air-to-blood ratios for children noted in the 1986 Criteria Document generally reflected study populations with blood Pb levels in the range of approximately 10–30 μg/dL (USEPA 1986a, pp. 11–100; Brunekreef, 1984), much higher than those common in today's population. This observation suggests that air-to-blood ratios relevant for today's population of children would likely extend higher than the 1:3 to 1:5 range identified in the 1986 Criteria Document.

More recently, a study of changes in children's blood Pb levels associated with reduced Pb emissions and associated air concentrations near a Pb smelter in Canada (for children through six years of age) reports a ratio of 1:6 and additional analysis of the data by EPA for the initial time period of the study resulted in a ratio of 1:7 (CD, pp. 3–23 to 3–24; Hilts, 2003).[32] Ambient air and blood Pb levels associated with the Hilts (2003) study range from 1.1 to 0.03 μg/m^3, and associated population mean blood Pb levels range from 11.5 to 4.7 μg/dL, which are lower than levels associated with the older studies cited in the 1986 Criteria Document (USEPA, 1986).

Sources of uncertainty related to air-to-blood ratios obtained from Hilts (2003) study have been identified. One such area of uncertainty relates to the pattern of changes in indoor Pb dustfall (presented in Table 3 in the article) which suggests a potentially significant decrease in Pb impacts to indoor dust prior to closure of an older Pb smelter and start-up of a newer facility in 1997. Some have suggested that this earlier reduction in indoor dustfall suggests that a significant portion of the reduction in Pb exposure (and therefore, the blood Pb reduction reflected in air-to-blood ratios) may have resulted from efforts to increase public awareness of the Pb contamination issue (e.g., through increased cleaning to reduce indoor dust levels) rather than reductions in ambient air Pb and associated indoor dust Pb contamination. In addition, notable fluctuations in blood Pb levels observed prior to 1997 (as seen in Figure 2 of the article) have raised questions as to whether factors other than ambient air Pb reduction could be influencing decreases in blood Pb.[33]

In addition to the study by Hilts (2003), we are aware of two other studies published since the 1986 Criteria Document that report air-to-blood ratios for children (Tripathi *et al.*, 2001 and Hayes *et al.*, 1994). These studies were not cited in the 2006 Criteria Document, but were referenced in public comments received by EPA during this review.[34] The study by Tripathi *et al.* (2001) reports an air-to-blood ratio of approximately 1:3.6 for an analysis of children aged six through ten in India. The ambient air and blood Pb levels in this study (geometric mean blood Pb levels generally ranged from 10 to 15 μg/dL) are similar to levels reported in older studies reviewed in the 1986 Criteria Document and are much higher than current conditions in the U.S. The study by Hayes (1994) compared patterns of ambient air Pb reductions and blood Pb reductions for large numbers of children in Chicago between 1971 and 1988, a period when significant reductions occurred in both measures. The study reports an air-to-blood ratio of 1:5.6 associated with ambient air Pb levels near 1 μg/m^3 and a ratio of 1:16 for ambient air Pb levels in the range of 0.25 μg/m^3, indicating a pattern of higher ratios with lower ambient air Pb and blood Pb levels consistent with conclusions in the 1986 Criteria Document.[35]

In their advice to the Agency, CASAC identified air-to-blood ratios of 1:5, as used by the World Health Organization (2000), and 1:10, as supported by an empirical analysis of changes in air Pb and changes in blood Pb between 1976 and the time when the phase-out of Pb from gasoline was completed (Henderson, 2007a).[36]

Beyond considering the evidence presented in the published literature and that reviewed in Pb Criteria Documents, we have also considered air-to-blood ratios derived from the exposure assessment for this review (discussed below in section II.C). In that assessment, current modeling tools and information on children's activity patterns, behavior and physiology (e.g., CD, Section 4.4) were used to estimate blood Pb levels associated with

blood Pb, recognizing that ideally all possible confounders should be taken into account in deriving an adjusted air-to-blood relationship from a community study. The studies cited here adjusted for parental education (Zielhuis *et al.*, 1979), age and race (Billick *et al.*, 1979, 1980) and additionally measuring height of air Pb (Billick *et al.*, 1983); Brunekreef *et al.* (1984) used multiple regression to control for several confounders. The authors conclude that ''presentation of both unadjusted and (stepwise) adjusted relationships is advisable, to allow insight in the range of possible values for the relationship'' (p. 83). Unadjusted ratios were presented for two of these studies, including ratios of 4.0 (Zielhuis *et al.*, 1979) and 18.5 (Brunekreef *et al.*, 1983). Note, that the Brunekreef *et al.*, 1983 study is subject to a number of sources of uncertainty that could result in air-to-blood Pb ratios that are biased high, including the potential for underestimating ambient air Pb levels due to the use of low volume British Smoke air monitors and the potential for ongoing (higher historical) ambient air Pb levels to have influenced blood Pb levels (see Section V.B.2 of the 1989 Pb Staff Report for the Pb NAAQS review, EPA, 1989). In addition, the 1989 Staff Report notes that the higher air-to-blood ratios obtained from this study could reflect the relatively lower blood Pb levels seen across the study population (compared with blood Pb levels reported in other studies from that period).

[32] This study considered changes in ambient air Pb levels and associated blood Pb levels over a five-year period which included closure of an older Pb smelter and subsequent opening of a newer facility in 1997 and a temporary (3 month) shutdown of all smelting activity in the summer of 2001. The author observed that the air-to-blood ratio for children in the area over the full period was approximately 1:6. The author noted limitations in the dataset associated with exposures in the second time period, after the temporary shutdown of the facility in 2001, including sampling of a different age group at that time and a shorter time period (3 months) at these lower ambient air Pb levels prior to collection of blood Pb levels. Consequently, EPA calculated an alternate air-to-blood Pb ratio based on consideration for ambient air Pb and blood Pb reductions in the first time period (after opening of the new facility in 1997).

[33] In the publication, the author acknowledges that remedial programs (e.g., community and home-based dust control and education) may have been responsible for some of the blood Pb reduction seen during the study period (1997 to 2001). However, the author points out that these programs were in place in 1992 and he suggests that it is unlikely that they contributed to the sudden drop in blood Pb levels occurring after 1997. In addition, the author describes a number of aspects of the analysis, which could have implications for air-to-blood ratios including a tendency over time for children with lower blood Pb levels to not return for testing, and inclusion of children aged 6 to 36 months in Pb screening in 2001 (in contrast to the wider age range up to 60 months as was done in previous years).

[34] EPA is not basing its proposed decisions on these two studies, but notes that these estimates are consistent with other studies that were included in the 1986 and 2006 Criteria Documents and accordingly considered by CASAC and the public.

[35] As with all studies, we note that there are strengths and limitations for these two studies which may affect the specific magnitudes of the reported ratios, but that the studies' findings and trends are generally consistent with the conclusions from the 1986 Criteria Document.

[36] The CASAC Panel stated ''The Schwartz and Pitcher analysis showed that in 1978, the midpoint of the National Health and Nutrition Examination Survey (NHANES) II, gasoline Pb was responsible for 9.1 μg/dL of blood Pb in children. Their estimate is based on their coefficient of 2.14 μg/dL per 100 metric tons (MT) per day of gasoline use, and usage of 426 MT/day in 1976. Between 1976 and when the phase-out of Pb from gasoline was completed, air Pb concentrations in U.S. cities fell a little less than 1 μg/m^3 (24). These two facts imply a ratio of 9–10 μg/dL per μg/m^3 reduction in air Pb, taking all pathways into account.'' (Henderson, 2007a, pp. D–2 to D–3).

multimedia and multipathway Pb exposure. The results from the various case studies included in this assessment, with consideration of the context in which they were derived (e.g., the extent to which the range of air-related pathways were simulated), are also informative to our understanding of air-to-blood ratios.

For the general urban case study, air-to-blood ratios ranged from 1:2 to 1:9 across the alternative standard levels assessed, which ranged from the current standard of 1.5 μg/m^3 down to a level of 0.02 μg/m^3. This pattern of model-derived ratios generally supports the range of ratios obtained from the literature and also supports the observation that lower ambient air Pb levels are associated with higher air-to-blood ratios. There are a number of sources of uncertainty associated with these model-derived ratios. The hybrid indoor dust Pb model, which is used in estimating indoor dust Pb levels for the urban case studies, uses a HUD dataset reflecting housing constructed before 1980 in establishing the relationship between dust loading and concentration, which is a key component in the hybrid dust model (see Section Attachment G–1 of the Risk Assessment, Volume II). Given this application of the HUD dataset, there is the potential that the non-linear relationship between indoor dust Pb loading and concentration (which is reflected in the structure of the hybrid dust model) could be driven more by the presence of indoor Pb paint than contributions from outdoor ambient air Pb. We also note that only recent air pathways were adjusted in modeling the impact of ambient air Pb reductions on blood Pb levels in the urban case studies, which could have implications for the air-to-blood ratios.

For the primary Pb smelter (subarea) case study, air-to-blood ratios ranged from 1:10 to 1:19 across the same range of alternative standard levels, from 1.5 down to 0.02 μg/m^3.[37] Because these ratios are based on regression modeling developed using empirical data, there is the potential for these ratios to capture more fully the impact of ambient air on indoor dust Pb (and ultimately blood Pb), including longer timeframe impacts resulting from changes in outdoor deposition. Therefore, given that these ratios are higher than ratios developed for the general urban case study using the hybrid indoor dust Pb model (which only considers reductions in recent air), the ratios estimated for the primary Pb smelter (subarea) support the evidence-based observation discussed above that consideration of more of the exposure pathways relating ambient air Pb to blood Pb, may result in higher air-to-blood Pb ratios. In considering this case study, some have suggested, however, that the regression modeling fails to accurately reflect the temporal relationship between reductions in ambient air Pb and indoor dust Pb, which could result in an over-estimate of the degree of dust Pb reduction associated with a specified degree of ambient air Pb reduction, which in turn could produce air-to-blood Pb ratios that are biased high.

In summary, in EPA's view, the current evidence in conjunction with the results and observations drawn from the exposure assessment, including related uncertainties, supports consideration of a range of air-to-blood ratios for children ranging from 1:3 to 1:7, reflecting multiple air-related pathways beyond simply inhalation and the lower air and blood Pb levels pertinent to this review. In light of the uncertainties that remain in the available information on air-to-blood ratios, EPA requests comment on this range and on the appropriate weight to place on specific ratios within this range.

2. Nature of Effects

a. Broad Array of Effects

Lead has been demonstrated to exert ''a broad array of deleterious effects on multiple organ systems via widely diverse mechanisms of action'' (CD, p. 8–24 and Section 8.4.1). This array of health effects includes effects on heme biosynthesis and related functions; neurological development and function; reproduction and physical development; kidney function; cardiovascular function; and immune function. The weight of evidence varies across this array of effects and is comprehensively described in the Criteria Document. There is also some evidence of Pb carcinogenicity, primarily from animal studies, together with limited human evidence of suggestive associations (CD, Sections 5.6.2, 6.7, and 8.4.10).[38]

This review is focused on those effects most pertinent to ambient exposures, which given the reductions in ambient Pb levels over the past 30 years, are generally those associated with individual blood Pb levels in children and adults in the range of 10 μg/dL and lower. Tables 8–5 and 8–6 in the Criteria Document highlight the key such effects observed in children and adults, respectively (CD, pp. 8–60 to 8–62). The effects include neurological, hematological and immune effects for children, and hematological, cardiovascular and renal effects for adults. As evident from the discussions in Chapters 5, 6 and 8 of the Criteria Document, ''neurotoxic effects in children and cardiovascular effects in adults are among those best substantiated as occurring at blood Pb concentrations as low as 5 to 10 μg/dL (or possibly lower); and these categories are currently clearly of greatest public health concern'' (CD, p. 8–60).[39] The toxicological and epidemiological information available since the time of the last review ''includes assessment of new evidence substantiating risks of deleterious effects on certain health endpoints being induced by distinctly lower than previously demonstrated Pb exposures indexed by blood Pb levels extending well below 10 μg/dL in children and/or adults'' (CD, p. 8–25). Some health effects associated with individual blood Pb levels extend below 5 μg/dL, and some studies have observed these effects at the lowest blood levels considered.

With regard to population mean levels, the Criteria Document points to studies reporting ''Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 μg/dL'' (CD, p. E–9).

We note that many studies over the past decade have, in investigating effects at lower blood Pb levels, utilized the CDC advisory level for individual children (10 μg/dL) as a benchmark for assessment, and this is reflected in the numerous references in the Criteria Document to 10 μg/dL. Individual study conclusions stated with regard to effects observed below 10 μg/dL are usually referring to individual blood Pb levels. In fact, many such study groups have been restricted to individual blood Pb levels below 10 μg/dL or below levels lower than 10 μg/dL. We note that the

[37] As noted below in section II.C.3.a, air-to-blood ratios for the primary Pb smelter (full study area) range from 1:3 to 1:7 across the same range of alternative standard levels (from 1.5 down to 0.02 μg/m^3).

[38] Lead has been classified as a probable human carcinogen by the International Agency for Research on Cancer, based mainly on sufficient animal evidence, and as reasonably anticipated to be a human carcinogen by the U.S. National Toxicology Program (CD, Section 6.7.2). U.S. EPA considers Pb a probable carcinogen (*http://www.epa.gov/iris/subst/0277.htm*; CD, p. 6–195).

[39] With regard to blood Pb levels in individual children associated with particular neurological effects, the Criteria Document states ''Collectively, the prospective cohort and cross-sectional studies offer evidence that exposure to Pb affects the intellectual attainment of preschool and school age children at blood Pb levels <10 μg/dL (most clearly in the 5 to 10 μg/dL range, but, less definitively, possibly lower).'' (p. 6–269)

mean blood Pb level for these groups will necessarily be lower than the blood Pb level they are restricted below.

Threshold levels, in terms of blood Pb levels in individual children, for neurological effects cannot be discerned from the currently available studies (CD, pp. 8–60 to 8–63). The Criteria Document states ''There is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects'' (CD, p. 8–63). As discussed in the Criteria Document, ''a threshold for Pb neurotoxic effects may exist at levels distinctly lower than the lowest exposures examined in these epidemiologic studies'' (CD, p. 8–67).[40]

In summary, the Agency has identified neurological, hematological and immune effects in children and neurological, hematological, cardiovascular and renal effects in adults as the effects observed at blood Pb levels near or below 10 μg/dL and further considers neurological effects in children and cardiovascular effects in adults to be categories of effects that ''are currently clearly of greatest public health concern'' (CD, pp. 8–60 to 8–62). Neurological effects in children are discussed further below.

b. Neurological Effects in Children

Among the wide variety of health endpoints associated with Pb exposures, there is general consensus that the developing nervous system in young children is among, if not, the most sensitive. As described in the Criteria Document, neurotoxic effects in children and cardiovascular effects in adults are categories of effects that are ''currently clearly of greatest public health concern'' (CD, p. 8–60).[41] While also recognizing the occurrence of adult cardiovascular effects at somewhat similarly low blood Pb levels[42], neurological effects in children are considered to be the sentinel effects in this review and are the focus of the quantitative risk assessment conducted for this review (discussed below in section III.C).

The nervous system has long been recognized as a target of Pb toxicity, with the developing nervous system affected at lower exposures than the mature system (CD, Sections 5.3, 6.2.1, 6.2.2, and 8.4). While blood Pb levels in U.S. children ages one to five years have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels (CD, Chapter 6). Functional manifestations of Pb neurotoxicity during childhood include sensory, motor, cognitive and behavioral impacts. Numerous epidemiological studies have reported neurocognitive, neurobehavioral, sensory, and motor function effects in children with blood Pb levels below 10 μg/dL (CD, Sections 6.2 and 8.4).[43] As discussed in the Criteria Document, ''extensive experimental laboratory animal evidence has been generated that (a) substantiates well the plausibility of the epidemiologic findings observed in human children and adults and (b) expands our understanding of likely mechanisms underlying the neurotoxic effects'' (CD, p. 8–25; Section 5.3).

The evidence for neurotoxic effects in children is a robust combination of epidemiological and toxicological evidence (CD, Sections 5.3, 6.2 and 8.5). The epidemiological evidence is supported by animal studies that substantiate the biological plausibility of the associations, and contributes to our understanding of mechanisms of action for the effects (CD, Section 8.4.2).

Cognitive effects associated with Pb exposures that have been observed in epidemiological studies have included decrements in intelligence test results, such as the widely used IQ score, and in academic achievement as assessed by various standardized tests as well as by class ranking and graduation rates (CD, Section 6.2.16 and pp 8–29 to 8–30). As noted in the Criteria Document with regard to the latter, ''Associations between Pb exposure and academic achievement observed in the above-noted studies were significant even after adjusting for IQ, suggesting that Pb-sensitive neuropsychological processing and learning factors not reflected by global intelligence indices might contribute to reduced performance on academic tasks'' (CD, pp 8–29 to 8–30).

Other cognitive effects observed in studies of children have included effects on attention, executive functions, language, memory, learning and visuospatial processing (CD, Sections 5.3.5, 6.2.5 and 8.4.2.1), with attention and executive function effects associated with Pb exposures indexed by blood Pb levels below 10 μg/dL (CD, Section 6.2.5 and pp. 8–30 to 8–31). The evidence for the role of Pb in this suite of effects includes experimental animal findings (discussed in CD, Section 8.4.2.1; p. 8–31), which provide strong biological plausibility of Pb effects on learning ability, memory and attention (CD, Section 5.3.5), as well as associated mechanistic findings. With regard to persistence of effects the Criteria Document states the following (CD, p. 8–67):

> Persistence or apparent ''irreversibility'' of effects can result from two different scenarios: (1) Organic damage has occurred without adequate repair or compensatory offsets, or (2) exposure somehow persists. As Pb exposure can also derive from endogenous sources (e.g., bone), a performance deficit that remains detectable after external exposure has ended, rather than indicating irreversibility, could reflect ongoing toxicity due to Pb remaining at the critical target organ or Pb deposited at the organ post-exposure as the result of redistribution of Pb among body pools. The persistence of effect appears to depend on the duration of exposure as well as other factors that may affect an individual's ability to recover from an insult. The likelihood of reversibility also seems to be related, at least for the adverse effects observed in certain organ systems, to both the age-at-exposure and the age-at-assessment.

The evidence with regard to persistence of Pb-induced deficits observed in animal and epidemiological studies is described in discussion of those studies in the Criteria Document (CD, Sections 5.3.5, 6.2.11, and 8.5.2). It is additionally important to note that there may be long-term consequences of such deficits over a lifetime. Poor academic skills and achievement can have ''enduring and important effects on objective parameters of success in real life,'' as well as increased risk of antisocial and delinquent behavior (CD, Section 6.2.16).

As discussed in the Criteria Document, while there is no direct animal test parallel to human IQ tests, ''in animals a wide variety of tests that assess attention, learning, and memory suggest that Pb exposure {of animals} results in a global deficit in functioning,

[40] In consideration of the evidence from experimental animal studies with regard to the issue of threshold for neurotoxic effects, the CD notes that there is little evidence that allows for clear delineation of a threshold, and that ''blood-Pb levels associated with neurobehavioral effects appear to be reasonably parallel between humans and animals at reasonably comparable blood-Pb concentrations; and such effects appear likely to occur in humans ranging down at least to 5–10 μg/dL, or possibly lower (although the possibility of a threshold for such neurotoxic effects cannot be ruled out at lower blood-Pb concentrations)'' (CD, p. 8–38).

[41] The Criteria Document states ''neurotoxic effects in children and cardiovascular effects in adults are among those best substantiated as occurring at blood-Pb concentrations as low as 5 to 10 μg/dL (or possibly lower); and these categories of effects are currently clearly of greatest public health concern (CD, p. 8–60).''

[42] For example, the Criteria Document describes associations of blood Pb in adults with blood pressure in studies with population mean blood Pb levels ranging from approximately 2 to 6 μg/dL (CD, section 6.5.2 and Table 6–2).

[43] Further, neurological effects in general include behavioral effects, such as delinquent behavior (CD, sections 6.2.6 and 8.4.2.2), sensory effects, such as those related to hearing and vision (CD, sections 6.2.7 and 8.4.2.3), and deficits in neuromotor function (CD, p. 8–36).

just as it is indicated by decrements in IQ scores in children'' (CD, p. 8–27). The animal and epidemiological evidence for this endpoint are consistent and complementary (CD, p. 8–44). As stated in the Criteria Document (p. 8–44):

Findings from numerous experimental studies of rats and of nonhuman primates, as discussed in Chapter 5, parallel the observed human neurocognitive deficits and the processes responsible for them. Learning and other higher order cognitive processes show the greatest similarities in Pb-induced deficits between humans and experimental animals. Deficits in cognition are due to the combined and overlapping effects of Pb-induced perseveration, inability to inhibit responding, inability to adapt to changing behavioral requirements, aversion to delays, and distractibility. Higher level neurocognitive functions are affected in both animals and humans at very low exposure levels (<10 μg/dL), more so than simple cognitive functions.

Epidemiologic studies of Pb and child development have demonstrated inverse associations between blood Pb concentrations and children's IQ and other cognitive-related outcomes at successively lower Pb exposure levels over the past 30 years (CD, p. 6–64). This is supported by multiple studies performed over the past 15 years (as discussed in the CD, Section 6.2.13). For example, the overall weight of the available evidence, described in the Criteria Document, provides clear substantiation of neurocognitive decrements being associated in children with mean blood Pb levels in the range of 5 to 10 μg/dL, and some analyses indicate Pb effects on intellectual attainment of children for which population mean blood Pb levels in the analysis ranged from 2 to 8 μg/dL (CD, Sections 6.2, 8.4.2 and 8.4.2.6).[44] That is, while blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with blood Pb levels similar to the more recent blood Pb levels (CD, Chapter 6).

The evidence described in the Criteria Document with regard to the effect on children's cognitive function of blood Pb levels at the lower concentration range includes the international pooled analysis by Lanphear and others (2005), studies of individual cohorts such as the Rochester, Boston, and Mexico City cohorts (Canfield *et al.*, 2003a; Canfield *et al.*, 2003b; Bellinger and Needleman, 2003; Tellez-Rojo *et al.*, 2006), the study of African-American inner-city children from Detroit (Chiodo *et al.*, 2004), the cross-sectional study of young children in three German cities (Walkowiak *et al.*, 1998) and the cross-sectional analysis of a nationally representative sample from the NHANES III[45] (Lanphear *et al.*, 2000). These studies included differing adjustments for different important potential confounders (e.g., parental IQ or HOME score) or surrogates of these measures (e.g., parental education and SES factors) through multivariate analyses.[46] [47] Each of these studies has individual strengths and limitations, however, a pattern of positive findings is demonstrated across the studies. In these studies, statistically significant associations of neurocognitive decrement[48] with blood Pb were found in the full study cohorts, as well as in some subgroups restricted to children with lower blood Pb levels for which mean blood Pb levels extended below 5 μg/dL. More specifically, a statistically significant association was reported for full-scale IQ with blood Pb at age five in a subset analysis (n=71) of the Rochester cohort for which the population mean blood Pb level was 3.32 μg/dL, as well as in the full study group (mean=5.8 μg/dL, n=171) (Canfield *et al.*, 2003a; Canfield, 2008). Full-scale IQ was also significantly associated with blood Pb at age seven and a half in a subset analysis (n=200) in the Detroit inner-city study for which the population mean blood Pb level was 4.1 μg/dL, as well as the other subgroup with higher blood Pb levels (mean=4.6 μg/dL, n=224) and in the full study group (mean=5.4 μg/dL, n=246); additionally, performance IQ was significantly associated with blood Pb in those analyses as well as in the subset analysis (n=120) for which the population mean blood Pb level was 3 μg/dL (although full-scale IQ was not significantly associated with blood Pb in this lowest blood Pb subgroup) (Chiodo *et al.*, 2004, Chiodo, 2008). Vocabulary, one of ten subtests of the full-scale IQ, was significantly associated with blood

[44] ''The overall weight of the available evidence provides clear substantiation of neurocognitive decrements being associated in young children with blood-Pb concentrations in the range of 5–10 μg/dL, and possibly somewhat lower. Some newly available analyses appear to show Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 μg/dL.'' (CD, p. E–9)

[45] The NHANES III survey was conducted in 1988–1994.

[46] Some studies also employed exclusion criteria which limited variation in socioeconomic status across the study population. Further, with regard to adjustment for potential confounders in the large pooled international analysis (Lanphear *et al.* 2005), discussed below, the authors adjusted for HOME score, birth weight, maternal IQ and maternal education. Canfield *et al.* (2003) adjusted for maternal IQ, maternal education, HOME score, birth weight, race, tobacco use during pregnancy, household income, gender, and iron status. Bellinger and Needleman (2003) adjusted for maternal IQ, HOME score, SES, child stress, maternal age, race, gender, birth order, marital status. Chiodo *et al.* (2004) adjusted for primary care-giver education and vocabulary, HOME score, family environment scale, SES, gender, number of children under 18, birth order. Tellez-Rojo *et al.* (2006) adjusted for maternal IQ, birth weight and gender; the authors also state that other potentially confounding variables that were not found to be significant at p<.10 were not adjusted for. Walkoviak *et al.* (1998) adjusted for parental education, breastfeeding, nationality and gender. In Lanphear *et al.* (2000), the authors adjusted for race/ethnicity and poverty index ratio, as surrogates for HOME score/SES status, and adjusted for the parental education level as a surrogate for maternal IQ; they also adjusted for gender, serum ferritin level and serum cotinine level.

[47] The Criteria Document notes that a ''major challenge to observational studies examining the impact of Pb on parameters of child development has been the assessment and control for confounding factors'' (CD, p. 6–73). However, the Criteria Document further recognizes that ''[m]ost of the important confounding factors in Pb studies have been identified, and efforts have been made to control them in studies conducted since the 1990 Supplement'' (CD, p. 6–75). On this subject, the Criteria Document further concludes the following: ''Invocation of the poorly measured confounder as an explanation for positive findings is not substantiated in the database as a whole when evaluating the impact of Pb on the health of U.S. children (Needleman, 1995). Of course, it is often the case that following adjustment for factors such as social class, parental neurocognitive function, and child rearing environment using covariates such as parental education, income, and occupation, parental IQ, and HOME scores, the Pb coefficients are substantially reduced in size and statistical significance (Dietrich *et al.*, 1991). This has sometimes led investigators to be quite cautious in interpreting their study results as being positive (Wasserman *et al.*, 1997). This is a reasonable way of appraising any single study, and such extreme caution would certainly be warranted if forced to rely on a single study to confirm the Pb effects hypothesis. Fortunately, there exists a large database of high quality studies on which to base inferences regarding the relationship between Pb exposure and neurodevelopment. In addition, Pb has been extensively studied in animal models at doses that closely approximate the human situation. Experimental animal studies are not compromised by the possibility of confounding by such factors as social class and correlated environmental factors. The enormous experimental animal literature that proves that Pb at low levels causes neurobehavioral deficits and provides insights into mechanisms must be considered when drawing causal inferences (Bellinger, 2004; Davis *et al.*, 1990; U.S. Environmental Protection Agency, 1986a, 1990).'' (CD, p. 6–75)

[48] The tests for cognitive function in these studies include age-appropriate Wechsler intelligence tests (Lanphear *et al.*, 2005), the Stanford-Binet intelligence test (Canfield *et al.*, 2003a), and the Bayley Scales of Infant Development (Tellez-Rojo *et al.*, 2006). In some cases, individual subtests of the Wechsler intelligence tests (Lanphear *et al.*, 2000; Walkowiak *et al.*, 1998), and individual subtests of the Wide Range Achievement Test (Lanphear *et al.*, 2000) were used. The Wechsler and Stanford-Binet tests are widely used to assess neurocognitive function in children and adults, however, these tests are not appropriate for children under age three. For such children, studies generally use the age-appropriate Bayley Scales of Infant Development as a measure of cognitive development. See footnote 63 for further information.

Pb at age six in the German three-city study (n=384) in which the mean blood Pb level was 4.2 µg/dL (Walkowiak *et al.*, 1998). In a Mexico City cohort of infants age two, the mental development index (MDI) and psychomotor development index (PDI) were significantly associated with blood Pb in the full study group (mean=4.28 µg/dL, n=294); further, the MDI (but not the PDI) was significantly associated with blood Pb in the subset analysis (n=193) for which the population mean blood Pb level was 2.9 µg/dL, and PDI (but not the MDI) was significantly associated with blood Pb in the subset analysis (n=101) for which the population mean blood Pb was 6.9 µg/dL (Tellez-Rojo *et al.*, 2006; Tellez-Rojo, 2008). Scores on academic achievement tests for reading and math were significantly associated with blood Pb at age six through sixteen in a subgroup analysis (n=4043) of the NHANES III data for which the population mean blood Pb level was 1.7 µg/dL, as discussed below (Lanphear *et al.* 2000; Auinger, 2008).

The study by Lanphear *et al.* (2000) is a large cross-sectional study using NHANES III dataset, with 4853 subjects in the full study and more than 4000 in the subgroup analyses, that reports statistically significant [49] associations of concurrent blood Pb levels [50] with neurocognitive decrements in the full study population and in subgroup analyses down to and including the subgroup with individual blood Pb levels below 5 µg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000). Specifically the study by Lanphear *et al.* (2000) reported a statistically significant association between math (p<0.001), reading (p<0.001), block design (p=0.009), and digit span (p=0.04) scores and blood Pb levels in the analysis that included all study subjects. Additionally, the study reports statistically significant associations for block design and digit span scores down to and including the subgroup with individual blood Pb levels below 7.5 µg/dL and 10 µg/dL, respectively.[51] Further, statistically significant associations were observed for reading and math scores down to and including the subgroup with individual blood Pb levels below 5 µg/dL, which included 4043 of the 4853 children.[52] A similar pattern in the magnitude of the effect estimates was observed across all the subgroup analyses and for all four tests, including the subgroup with individual blood Pb levels less than 2.5 µg/dL, although not all the effect estimates were statistically significant (Lanphear *et al.*, 2000).[53] In particular, the lack of statistical significance in the subset of individuals with blood Pb levels less than 2.5 µg/dL may be attributable to the smaller sample size (2467 children) and reduced variability of blood Pb levels.[54] Blood Pb levels in the full study population ranged from below detection to above 10 µg/dL, with a population geometric mean of 1.9 µg/dL, and the subgroups were composed of children with blood Pb levels less than 10 µg/dL (geometric mean of 1.8 µg/dL), less than 7.5 µg/dL (geometric mean of 1.8 µg/dL), less than 5 µg/dL (geometric mean of 1.7 µg/dL), and less than 2.5 µg/dL (geometric mean of 1.2 µg/dL), respectively (Lanphear *et al.*, 2000; Auinger, 2008).[55]

The epidemiological studies that have investigated blood Pb effects on IQ (as discussed in the CD, Section 6.2.3) have considered a variety of specific blood Pb metrics, including: (1) Blood concentration ''concurrent'' with the response assessment (e.g., at the time of IQ testing), (2) average blood concentration over the ''lifetime'' of the child at the time of response assessment (e.g., average of measurements taken over child's first 6 or 7 years), (3) peak blood concentration during a particular age range, and (4) early childhood blood concentration (e.g., the mean of measurements between 6 and 24 months age). With regard to the latter two, the Criteria Document (e.g., CD, chapters 3 and 6) has noted that age has been observed to strongly predict the period of peak exposure (around 18–27 months when there is maximum hand-to-mouth activity). The CD further notes, this maximum exposure period coincides with a period of time in which major events are occurring in central nervous system (CNS) development (CD, p. 6–60). Accordingly, the belief that the first few years of life are a critical window of vulnerability is evident particularly in the earlier literature (CD, p. 6–60). However, more recent analyses have found even stronger associations between blood Pb at school age and IQ at school age (i.e., concurrent blood Pb), indicating the important role that is continued to be played by Pb exposures later in life. In fact, concurrent and lifetime averaged measurements were stronger predictors of adverse neurobehavioral effects (better than the peak or 24 month metrics) in all but one of the prospective cohort studies (CD, pp. 6–61 to 6–62). While all four specific blood Pb metrics were correlated with IQ in the international pooled analysis by Lanphear and others (2005), the concurrent blood Pb level exhibited the strongest relationship with intellectual deficits (CD, p. 6–29).

The Criteria Document presentation on toxicological evidence also recognizes neurological effects elicited by exposures subsequent to earliest childhood (CD, sections 5.3.5 and 5.3.7). For example, research with monkeys has indicated that while exposure only during infancy may elicit a response, exposures (with similar blood Pb levels) that only occurred post-infancy also elicit responses. Further, in the monkey research, exposures limited to post-infancy resulted in a greater response than exposures limited to infancy (Rice and Gilbert, 1990; Rice, 1992).

A study by Chen and others (2005) involving 622 children has attempted to directly address the question regarding periods of enhanced susceptibility to Pb effects (CD, pp. 6–62 to 6–64).[56] The authors found that the concurrent blood

[49] The statistical significance refers to the effect estimate of the linear relationship across the range of data, as presented in Table 4 of Lanphear *et al.* (2000).

[50] A limitation noted for this study is with regard to the use of concurrent blood Pb levels in children of this age. The authors state that ''it is not clear whether the cognitive and academic deficits observed in the present analysis are due to lead exposure that occurred during early childhood or due to concurrent exposure'', however, they further note that ''concurrent blood lead concentration was the best predictor of adverse neurobehavioral effects of lead exposure in all but one of the published prospective studies''. The average blood Pb level for 1–5 year olds was approximately 15 µg/dL in the 1976–1980 NHANES. When in that age range, some of the children included in the NHANES III dataset may have had blood Pb levels comparable to those of the earlier NHANES. The general issue regarding blood Pb metrics is further discussed in subsequent text.

[51] The associations with block design score were not statistically significant for subgroups limited to blood Pb of <5 and <2.5 µg/dL. The associations with digit span score were not statistically significant for the blood Pb subgroups of <7.5 and lower.

[52] The associations with math and reading scores were not statistically significant for the subgroup limited to blood Pb <2.5 µ/dL.

[53] For example, for reading scores, effect estimates were –0.99, –1.44, –1.53, –1.66, and –1.71 points per µg/dL for all children, the subgroup with blood Pb <10 µg/dL, the subgroup with blood Pb <7.5, the subgroup with blood Pb <5 and the subgroup with blood Pb<2.5, respectively (Lanphear *et al.*, 2000, Table 4).

[54] The authors state ''Indeed, while the average effects of lead exposure on reading scores were not significant for blood lead concentrations less that 2.5 µg/dL, the size of the effect and the borderline significance level ($\beta = -1.71$, p=0.07) suggests that the smaller sample size and the imprecision of the relationship of blood Pb concentration with performance on the reading subtest—as indicated by the large standard error—may be the reason we did not find a statistically significant association for children in that range.''

[55] We note that the datasets for each subgroup include children for the lower blood Pb subgroups (in Table 4 of Lanphear *et al.*, 2000). For example, the dataset of children with blood Pb levels <2.5 is a component of the dataset of children with blood Pb levels <5 (Lanphear *et al.*, 2000).

[56] In the children in this study, the mean blood Pb concentration was 26.2 µg/dL at age 2, 12.0 µg/dL at age 5 and 8.0 µg/dL at age 7 (Chen *et al.* 2005).

Pb association with IQ was always stronger than that for 24-month blood Pb. As children aged, the relationship with concurrent blood Pb grew stronger while that with 24-month blood Pb grew weaker. Further, in models including both prior blood Pb (at 24-months age) and concurrent blood Pb (at 7-years age), concurrent blood Pb was always more predictive of IQ. In fact, concurrent blood Pb explained most of Pb-related variation in IQ such that prior blood Pb (at 24-months age) was rendered nonsignificant and nearly null.[57] The effect estimate for concurrent blood Pb was robust and remained significant, little changed from its value without adjustment for 24-month blood Pb level. The Criteria Document concluded the following regarding the results of this study (CD, pp. 6–63 to 6–64).

These results support the idea that Pb exposure continues to be toxic to children as they reach school age, and do not lend support to the interpretation that all the damage is done by the time the child reaches 2 to 3 years of age. These findings also imply that cross-sectional associations seen in children, such as the study recently conducted by Lanphear *et al.* (2000) using data from NHANES III, should not be dismissed. Chen *et al.* (2005) concluded that if concurrent blood Pb remains important until school age for optimum cognitive development, and if 6- and 7-year-olds are as or more sensitive to Pb effects than 2-year-olds, then the difficulties in preventing Pb exposure are magnified but the potential benefits of prevention are greater.

In addition to findings of association with neurocognitive decrement (including IQ) at study group mean blood Pb levels well below 10 µg/dL, the evidence indicates that the slope for Pb effects on IQ is steeper at lower blood Pb levels (CD, section 6.2.13). As stated in the CD, ''the most compelling evidence for effects at blood Pb levels <10 µg/dL, as well as a nonlinear relationship between blood Pb levels and IQ, comes from the international pooled analysis of seven prospective cohort studies (n=1,333) by Lanphear *et al.* (2005)'' (CD, pp. 6–67 and 8–37 and section 6.2.3.1.11).[58] Using the full pooled dataset with concurrent blood Pb level as the exposure metric and IQ as the response from the pooled dataset of seven international studies, Lanphear and others (2005) employed mathematical models of various forms, including linear, cubic spline, log-linear, and piece-wise linear, in their investigation of the blood Pb concentration-response relationship (CD, p. 6–29; Lanphear *et al.*, 2005). They observed that the shape of the concentration-response relationship is nonlinear and the log-linear model provides a better fit over the full range of blood Pb measurements[59] than a linear one (CD, p. 6–29 and pp. 6–67 to 6–70; Lanphear *et al.*, 2005). In addition, they found that no individual study among the seven was responsible for the estimated nonlinear relationship between Pb and deficits in IQ (CD p. 6–30). Others have also analyzed the same dataset and similarly concluded that, across the range of the dataset's blood Pb levels, a log-linear relationship was a significantly better fit than the linear relationship (p=0.009) with little evidence of residual confounding from included model variables (CD, Section 6.2.13; Rothenberg and Rothenberg, 2005).

The impact of the nonlinear slope is illustrated by the log-linear model-based estimates of IQ decrements for similar changes in blood Pb level at different absolute values of blood Pb level (Lanphear *et al.*, 2005). These estimates of IQ decrement are 3.9 (with 95% confidence interval, CI, of 2.4–5.3), 1.9 (95% CI, 1.2–2.6) and 1.1 IQ points per µg/dL blood Pb (95% CI, 0.7–1.5), for increases in concurrent blood Pb from 2.4 to 10 µg/dL, 10 to 20 µg/dL, and 20 to 30 µg/dL, respectively (Lanphear *et al.*, 2005). For an increase in concurrent blood Pb levels from <1 to 10 µg/dL, the log-linear model estimates a decline of 6.2 points in full scale IQ which is comparable to the 7.4 point decrement in IQ for an increase in lifetime mean blood Pb levels up to 10 µg/dL observed in the Rochester study (CD, pp. 6–30 to 6–31).

A nonlinear blood Pb concentration-response relationship is also suggested by several other analyses that have observed that each µg/dL increase in blood Pb may have a greater effect on IQ at lower blood Pb levels (e.g., below 10 µg/dL) than at higher levels (CD, pp. 8–63 to 8–64; Figure 8–7). As noted in the Criteria Document, while this may at first seem at odds with certain fundamental toxicological concepts, a number of examples of non- or supralinear dose-response relationships exist in toxicology (CD, pp. 6–76 and 8–38 to 8–39). With regard to the effects of Pb on neurodevelopmental outcome such as IQ, the CD suggests that initial neurodevelopmental effects at lower Pb levels may be disrupting very different biological mechanisms (e.g., early developmental processes in the central nervous system) than more severe effects of high exposures that result in symptomatic Pb poisoning and frank mental retardation (CD, p. 6–76).

The Criteria Document describes this issue with regard to Pb as follows (CD, p. 8–39).

In the case of Pb, this nonlinear dose-effect relationship occurs in the pattern of glutamate release (Section 5.3.2), in the capacity for long term potentiation (LTP; Section 5.3.3), and in conditioned operant responses (Section 5.3.5). The 1986 Lead AQCD also reported U-shaped dose-effect relationships for maze performance, discrimination learning, auditory evoked potential, and locomotor activity. Davis and Svendsgaard (1990) reviewed U-shaped dose-response curves and their implications for Pb risk assessment. An important implication is the uncertainty created in identification of thresholds and ''no-observed-effect-levels'' (NOELS). As a nonlinear relationship is observed between IQ and low blood Pb levels in humans, as well as in new toxicologic studies wherein neurotransmitter release and LTP show this same relationship, it is plausible that these nonlinear cognitive outcomes may be due, in part, to nonlinear mechanisms underlying these observed Pb neurotoxic effects.

More specifically, various findings within the toxicological evidence presented in the Criteria Document provides biologic plausibility for a steeper IQ loss at low blood levels, with a potential explanation being that the predominant mechanism at very low blood-Pb levels is rapidly saturated and that a different, less-rapidly-saturated process, becomes predominant at blood-Pb levels greater than 10 µg/dL.[60]

[57] We note that blood Pb levels at any point in time are influenced by current as well as past exposures, e.g., through exchanges between blood and bone (as summarized in section II.B.1 above and discussed in more detail in the Criteria Document).

[58] We note that a public comment submitted on March 19, 2008 on behalf of the Association of Battery Recyclers described concerns the commenter had with the conclusion by Lanphear *et al.* (2005) of a nonlinear relationship of blood Pb with IQ, citing a publication by Surkan *et al.* (2007), a study published since the completion of the Criteria Document, and the Tellez-Rojo *et al.* (2006) finding, discussed in the Criteria Document, of two different slopes for their study subgroups of young children with blood Pb levels below 5 µg/d (n=193, for which the slope of –1.7 was statistically significant, p=0.01) and those with blood Pb levels between 5 and 10 µg/dL (n=101, for which the slope of –0.94 was not statistically significant, p=0.12). The commenter also cites another publication published since the completion of the Criteria Document, Jusko *et al.* (2007) related to this issue. EPA notes that it is not basing its proposed decisions on studies that are not included in the Criteria Document.

[59] The geometric mean of the concurrent blood Pb levels modeled was 9.7 µg/dL; the 5th and 95th percentile values were 2.5 and 33.2 µg/dL, respectively (Lanphear *et al.*, 2005).

[60] The toxicological evidence presented in the Criteria Document of biphasic dose-effect relationships includes: Suppression of stimulated hippocampal glutamate release at low exposure levels and induction of glutamate exocytosis at higher exposure levels (CD, Section 5.3.2); downregulation of NMDA receptors at low blood Pb levels and upregulation at higher levels (CD, section 5.3.2); Pb causes elevated induction threshold and

Continued

In addition to the observed associations between neurocognitive decrement (including IQ) and blood Pb at study group mean levels well below 10 µg/dL (described above), the current evidence includes multiple studies that have examined the quantitative relationship between IQ and blood Pb level in analyses of children with individual blood Pb concentrations below 10 µg/dL. In comparing across the individual epidemiological studies and the international pooled analysis, the Criteria Document observed that at higher blood Pb levels (e.g., above 10 µg/dL), the slopes (for change in IQ with blood Pb) derived for log-linear and linear models are almost identical, and for studies with lower blood Pb levels, the slopes appear to be steeper than those observed in studies involving higher blood Pb levels (CD, p. 8–78, Figure 8–7). In making these observations, the Criteria Document focused on the curves from the models from the 10th percentile to the 90th percentile saying that the ''curves are restricted to that range because log-linear curves become very steep at the lower end of the blood Pb levels, and this may be an artifact of the model chosen.''

The quantitative relationship between IQ and blood Pb level has been examined in the Criteria Document using studies where all or the majority of study subjects had blood Pb levels below 10 µg/dL and also where an analysis was performed on a subset of children whose blood Pb levels have never exceeded 10 µg/dL (CD, Table 6–1). The datasets for three of these studies included concurrent blood Pb levels above 10 µg/dL; the C–R relationship reported for one of the three was linear while it was log-linear for the other two. For the one of these three studies with the linear C–R relationship, the highest blood Pb level was just below 12 µg/dL (Kordas *et al.*, 2006). Of the two studies with log-linear functions, one reported 69% of the children with blood Pb levels below 10 µg/dL and a population mean blood Pb level of 7.44 µg/dL (Al-Saleh *et al.*, 2001), and the second reported a population median blood Pb level of 9.7 µg/dL and a 95th percentile of 33.2 µg/dL (Lanphear *et al.*, 2005). In order to compare slopes across all of these studies (linear and log-linear), EPA estimated, for each, the average slope of change in IQ with change in blood Pb between the 10th percentile[61] blood Pb level and 10 µg/dL (CD, Table 6–1). The resultant group of reported and estimated average linear slopes for IQ change with blood Pb levels up to 10 µg/dL range from −0.4 to −1.8 IQ points per µg/dL blood Pb (CD, Tables 6–1 and 8–7), with a median of −0.9 IQ points per µg/dL blood Pb (CD, pp. 8–80).[62]

Among this group of quantitative IQ-blood Pb relationships examined in the Criteria Document (CD, Tables 6–1 and 8–7), the steepest slopes for change in IQ with change in blood Pb level are those derived for the subsets of children in the Rochester and Boston cohorts for which peak blood Pb levels were <10 µg/dL; these slopes, in terms of IQ points per µg/dL blood Pb, are −1.8 (for concurrent blood Pb influence on IQ) and −1.6 (for 24-month blood Pb influence on IQ), respectively. The mean blood Pb levels for children in these subsets of the Rochester and Boston cohorts are 3.32 and 3.8 µg/dL, respectively, which are the lowest population mean levels among the datasets included in the table (Canfield, 2008; Bellinger, 2008). Other studies with analyses involving similarly low blood Pb levels (e.g., mean levels below 4 µg/dL) also had slopes steeper than −1.5 points per µg/dL blood Pb. These include the slope of −1.71 points per µg/dL blood Pb[63] for the subset of 24-month-old children in the Mexico City cohort with blood Pb levels less than 5 µg/dL (n=193), for which the mean concurrent blood Pb level was 2.9 µg/dL (Tellez-Rojo *et al.* 2006, 2008)[64] and also the slope of −2.94 points per µg/dL blood Pb for the subset of 6–10-year-old children whose peak blood Pb levels never exceeded 7.5 µg/dL (n=112), and for which the mean concurrent blood Pb level was 3.24 µg/dL (Lanphear *et al.* 2005; Hornung 2008). Thus, from these subset analyses, the slopes range from −1.71 to −2.94 IQ points per µg/dL of concurrent blood Pb. We also note that the nonlinear C–R function in which greatest confidence is placed in estimating IQ loss in the quantitative risk assessment (described below in section II.C) has a slope that falls

diminished magnitude of long-term potentiation at low exposures, but not at higher exposures (CD, section 5.3.3); and low-level Pb exposures increase fixed-interval response rates and high-level Pb exposures decrease fixed interval response rates in learning deficit testing in rats (CD, section 5.3.5). Additional in vitro evidence includes Pb stimulation of PKC activity at picomolar concentrations and inhibition of PKC activity at nano- and micro-molar concentrations (CD, section 5.3.2).

[61] In the Criteria Document analysis, the 10th percentile was chosen as a common point of comparison for the loglinear (and linear) models at a point prior to the lowest end of the blood Pb levels.

[62] Among this group of slopes (CD, Table 6–1) is that from the analysis of the IQ-blood Pb (concurrent) relationship for children whose peak blood Pb levels are below 10 µg/dL in the international pooled dataset studied by Lanphear and others (2005); these authors reported this slope along with the companion slope for blood Pb levels for the remaining children with peak blood Pb level equal to or above 10 µg/dL (Lanphear *et al.*, 2005). In the economic analysis for EPA's recent Lead Renovation, Repair and Painting (RRP) Program rule (described above in section I.C), changes in IQ loss as a function of changes in lifetime average blood Pb level were estimated using the corresponding piecewise model for lifetime average blood Pb derived from the pooled dataset (USEPA, 2008; USEPA, 2007e). Selection of this model for the RRP economic analysis reflects consideration of the distribution of blood Pb levels in that analysis, those for children living in houses with Pb-based paint. With consideration of these blood Pb levels, the economic analysis document states that ''[s]electing a model with a node, or changing one segment to the other, at a lifetime average blood Pb concentration of 10 µg/dL rather than at 7.5 µg/dL, is a small protection against applying an incorrectly rapid change (steep slope with increasingly smaller effect as concentrations lower) to the calculation''. We note that the slope for the less-than-10-µg/dL portion of the model used in the RRP analysis (−0.88) is similar to the median for the slopes included in the Criteria Document analysis of quantitative relationships for distributions of blood Pb levels extending from just below 10 µg/dL and lower.

[63] This slope reflects effects on cognitive development in this cohort of 24-month-old children based on the age-appropriate test described earlier, and is similar in magnitude to slopes for the cohorts of older children described here. The strengths and limitations of this age-appropriate text, the Mental Development Index (MDI) of the Bayley Scales of Infant Development (BSID), were discussed in a letter to the editor by Black and Baqui (2005). The authors state that ''the MDI is a well-standardized, psychometrically strong measure of infant mental development.'' The MDI represents a complex integration of empirically-derived cognitive skills, for example, sensory/perceptual acuities, discriminations, and response; acquisition of object constancy; memory learning and problem solving; vocalization and beginning of verbal communication; and basis of abstract thinking. Black and Baqui state that although the MDI is one of the most well-standardized, widely used assessment of infant mental development, evidence indicates low predictive validity of the MDI for infants younger than 24 months to subsequent measures of intelligence. They explain that the lack of continuity may be partially explained by ''the multidimensional and rapidly changing aspects of infant mental development and by variations in performance during infancy, variations in tasks used to measure intellectual functioning throughout childhood, and variations in environmental challenges and opportunities that may influence development.'' Martin and Volkmar (2007) also noted that correlations between BSID performance and subsequent IQ assessments were variable, but they also reported high test-retest reliability and validity, as indicated by the correlation coefficients of 0.83 to 0.91, as well as high interrater reliability, correlation coefficient of 0.96, for the MDI. Therefore, the BSID has been found to be a reliable indicator of current development and cognitive functioning of the infant. Martin and Volkmar (2007) further note that ''for the most part, performance on the BSID does not consistently predict later cognitive measures, particularly when socioeconomic status and level of functioning are controlled''.

[64] In this study, the slope for blood Pb levels between 5 and 10 µg/dL (population mean blood Pb of 6.9 µg/dL; n=101) was −0.94 points per µg/dL blood Pb but was not statistically significant, with a P value of 0.12. The difference in the slope between the <5 µg/dL and the 5–10 µg/dL groups was not statistically significant (Tellez-Rojo *et al.*, 2006; Tellez-Rojo, 2008).

intermediate between these two for blood Pb levels up to approximately 3.7 μg/dL (USEPA, 2007b).

The C–R functions discussed above are presented in two sets in Table 1 below.

TABLE 1. SUMMARY OF QUANTITATIVE RELATIONSHIPS OF IQ AND BLOOD PB FOR TWO SETS OF STUDIES DISCUSSED ABOVE

Study/Analysis	Study cohort	Analysis dataset	N	Range BLL (μg/dL) 5th–95th percentile]	Geometric mean BLL (μg/dL)	Form of model from which average slope derived	Average linear slope [A] (points per μg/dL)
Set of studies from which steeper slopes are drawn							
Tellez-Rojo <5 subgroup based on Lanphear *et al.* 2005,[B] Log-linear with low-exposure linearization (LLL) [B].	Mexico City, age 24 mo.	Children—BLL<5 μg/dL.	193	0.8–4.9	2.9	Linear	−1.71
	Dataset from which the log-linear function is derived is the pooled International dataset of 1333 children, age 6–10 yr, having median blood Pb of 9.7 μg/dL and 5th–95th percentile of 2.5–33.2 μg/dL.Slope presented here is the slope at a blood Pb level of 2 μg/dL.[C]					LLL[C]	−2.29 at 2 μg/dL[C]
Lanphear *et al.* 2005,[B] <7.5 peak subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <7.5 μg/dL.	103	[1.3–6.0]	3.24	Linear	−2.94
Set of studies with shallower slopes (Criteria Document, Table 6–1) [D]							
Canfield *et al.* 2003 [B], <10 peak subgroup.	Rochester, age 5 yr ..	Children—peak BLL <10 μg/dL.	71	Unspecified	3.32	Linear	−1.79
Bellinger and Needleman 2003[B].	Boston[A E]	Children—peak BLL <10 μg/dL.	48	1–9.3[E]	3.8[E]	Linear	−1.56
Tellez-Rojo *et al.* 2006.	Mexico City, age 24 mo.	Full dataset	294	0.8–<10	4.28	Linear	−1.04
Tellez-Rojo *et al.* 2006 full—loglinear.	Mexico City, age 24 mo.	Full dataset	294	0.8–<10	4.28	Log-linear	−0.94
Lanphear *et al.* 2005,[B] <10 peak[F] subgroup.	Pooled International, age 6–10 yr.	Children—peak BLL <10 μg/dL.	244	[1.4–8.0]	4.30	Linear	−0.80
Al-Saleh *et al.* 2001 full—loglinear.	Saudi Arabia, age 6–12 yr.	Full dataset	533	2.3–27.36[G] ..	7.44	Log-linear	−0.76
Kordas *et al.* 2006, <12 subgroup.	Torreon, Mexico, age 7 yr.	Children—BLL<12 μg/dL.	377	2.3–<12	7.9	Linear	−0.40
Lanphear *et al.* 2005[B] full—loglinear.	Pooled International, age 6–10 yr.	Full dataset	1333	[2.5–33.2]	9.7 (median)	Log-linear	−0.41
						Median value	−0.9 [D]

[A] Average slope for change in IQ from 10th percentile to 10 μg/dL Slope estimates here are for relationship between IQ and concurrent blood Pb levels (BLL), except for Bellinger & Needleman which used 24 month BLLs with 10 year old IQ.

[B] The Lanphear *et al.* 2005 pooled International study includes blood Pb data from the Rochester and Boston cohorts, although for different ages (6 and 5 years, respectively) than the ages analyzed in Canfield *et al.* 2003 and Bellinger and Needleman 2003.

[C] The LLL function (described in section II.C.2.b) was developed from Lanphear *et al.* 2005 loglinear model with a linearization of the slope at BLL below 1 μg/dL. The slope shown is that at 2 μg/dL. In estimating IQ loss with this function in the risk assessment (section II.C) and in the evidence-based considerations in section II.E.3, the nonlinear form of the model was used, with varying slope for all BLL above 1 μg/dL.

[D] These studies and quantitative relationships are discussed in the Criteria Document (CD, sections 6.2, 6.2.1.3 and 8.6.2).

[E] The BLL for Bellinger and Needleman (2003) are for age 24 months.

[F] As referenced above and in section II.C.2.b, the form of this function derived for lifetime average blood Pb was used in the economic analysis for the RRP rule. The slope for that function was -0.88 IQ points per μg/dL lifetime averaged blood Pb.

[G] 69% of children in Al-Saleh *et al.* (2001) study had BLL<10 μg/dL.

3. Lead-Related Impacts on Public Health

In addition to the advances in our knowledge and understanding of Pb health effects at lower exposures (e.g., using blood Pb as the index), there has been some change with regard to the U.S. population Pb burden since the time of the last Pb NAAQS review. For example, the geometric mean blood Pb level for U.S. children aged 1–5, as estimated by the U.S. Centers for Disease Control, declined from 2.7 μg/dL (95% CI: 2.5–3.0) in the 1991–1994 survey period to 1.7 μg/dL (95% CI: 1.55–1.87) in the 2001–2002 survey period (CD, Section 4.3.1.3) and 1.8 μg/dL in the 2003–2004 survey period (Axelrad, 2008).[65] Blood Pb levels have also declined in the U.S. adult population over this time period (CD, Section 4.3.1.3).[66] As noted in the Criteria Document, ''blood-Pb levels have been declining at differential rates for various general subpopulations, as a function of income, race, and certain other demographic indicators such as age of housing'' (CD, pp. 8–21). For example, the geometric mean blood Pb level for children (aged one to five) living in poverty in the 2003–2004 survey period is 2.4 μg/dL. For black, non-Hispanic children, the geometric mean is 2.7 μg/dL, and for the subset of this group that is living in poverty, the geometric mean is 3.1 μg/dL. Further, the 95th percentile blood Pb level in the 2003–2004 NHANES for children aged 1–5 of all races and ethnic groups is 5.1 μg/dL, while the corresponding level for the subset of children living below the poverty level is 6.6 μg/dL. The 95th percentile level for black, non-Hispanic children is 8.9 μg/dL, and for the subset of that group living below the poverty level, it is 10.5 μg/dL (Axelrad, 2008).[67]

a. At-Risk Subpopulations

Potentially at-risk subpopulations include those with increased susceptibility (i.e., physiological factors contributing to a greater response for the same exposure) and those with increased exposure (including that resulting from behavior leading to increased contact with contaminated media) (USEPA 1986a, pp. 1–154). A behavioral factor of great impact on Pb exposure is the incidence of hand-to-mouth activity that is prevalent in very young children (CD, Section 4.4.3). Physiological factors include both conditions contributing to a subgroup's increased risk of effects at a given blood Pb level, and those that contribute to blood Pb levels higher than those otherwise associated with a given Pb exposure (CD, Section 8.5.3). These factors include nutritional status (e.g., iron deficiency, calcium intake), as well as genetic and other factors (CD, chapter 4 and sections 3.4, 5.3.7 and 8.5.3).

We also considered evidence pertaining to vulnerability to pollution-related effects which additionally encompasses situations of elevated exposure, such as residing in older housing with Pb-containing paint or near sources of ambient Pb, as well as socioeconomic factors, such as reduced access to health care or low socioeconomic status (SES) (USEPA, 2003, 2005c) that can contribute to increased risk of adverse health effects from Pb. With regard to elevated exposures in particular socioeconomic and minority subpopulations, we observe notably higher blood Pb levels in children in poverty and in black, non-Hispanic children compared to those for more economically well-off children and white children, in general (as recognized in section II.B.1.b above).

Three particular physiological factors contributing to increased risk of Pb effects at a given blood Pb level are recognized in the Criteria Document (e.g., CD, Section 8.5.3): age, health status, and genetic composition. With regard to age, the susceptibility of young children to the neurodevelopmental effects of Pb is well recognized (e.g., CD, Sections 5.3, 6.2, 8.4, 8.5, 8.6.2), although the specific ages of vulnerability have not been established (CD, pp. 6–60 to 6–64). Early childhood may also be a time of increased susceptibility for Pb immunotoxicity (CD, Sections 5.9.10, 6.8.3 and 8.4.6). Further early life exposures have been associated with increased risk of cardiovascular effects in humans later in life (CD, pp. 8–74). Early life exposures have also been associated with increased risk, in animals, of neurodegenerative effects later in life (CD, pp. 8–74).[68] Health status is another physiological factor in that subpopulations with pre-existing health conditions may be more susceptible (as compared to the general population) for particular Pb-associated effects, with this being most clear for renal and cardiovascular outcomes. For example, African Americans as a group have a higher frequency of hypertension than the general population or other ethnic groups (NCHS, 2005), and as a result may face a greater risk of adverse health impact from Pb-associated cardiovascular effects. A third physiological factor relates to genetic polymorphisms. That is, subpopulations defined by particular genetic polymorphisms (e.g., presence of the δ-aminolevulinic acid dehydratase-2 [ALAD–2] allele) have also been recognized as sensitive to Pb toxicity, which may be due to increased susceptibility to the same internal dose and/or to increased internal dose associated with the same exposure (CD, pp. 8–71, Sections 6.3.5, 6.4.7.3 and 6.3.6).

Childhood is well recognized as a time of increased susceptibility, and as summarized in section II.B.2.b above and described in more detail in the Criteria Document, a large body of epidemiological evidence describes neurological effects on children at low blood Pb levels. The toxicological evidence further helps inform an understanding of specific periods of development with increased vulnerability to specific types of neurological effect (CD, Section 5.3). Additionally, the toxicological evidence of a differing sensitivity of the immune system to Pb across and within different periods of life stages indicates the potential importance of exposures of duration as short as weeks to months. For example, the animal studies suggest that, for immune effects, the gestation period is the most sensitive life stage followed by early neonatal stage, and that within these life stages, critical windows of vulnerability are likely to exist (CD, Section 5.9 and p. 5–245).

In summary, there are a variety of ways in which Pb exposed populations might be characterized and stratified for consideration of public health impacts. Age or lifestage was used to distinguish

[65] These levels are in contrast to the geometric mean blood Pb level of 14.9 μg/dL reported for U.S. children (aged 6 months to 5 years) in 1976–1980 (CD, Section 4.3.1.3).

[66] For example, NHANES data for older adults (60 years of age and older) indicate a decline in overall population geometric mean blood Pb level from 3.4 μg/dL in 1991–1994 to 2.2 μg/dL in 1999–2002; the trend for adults between 20 and 60 years of age is similar to that for children 1 to 5 years of age (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5420a5.htm*).

[67] Although the 90th percentile statistic for these subgroups is not currently available for the 2003–04 survey period, the 2001–2004 90th percentile blood Pb level for children aged 1–5 of all races and ethnic groups is 4.0 μg/dL, while the corresponding level for the subset of children living below the poverty level is 5.4 μg/dL, and that level for black, non-Hispanic children living below the poverty level is 7.7 μg/dL (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*—then click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[68] Specifically, among young adults who lived as children in an area heavily polluted by a smelter and whose current Pb exposure was low, higher bone Pb levels were associated with higher systolic and diastolic blood pressure (CD, pp. 8–74). In adult rats, greater early exposures to Pb are associated with increased levels of amyloid protein precursor, a marker of risk for neurodegenerative disease (CD, pp. 8–74).

potential groups on which to focus the quantitative risk assessment because of its influence on exposure and susceptibility. Young children were selected as the priority population for the risk assessment in consideration of the health effects evidence regarding endpoints of greatest public health concern. The Criteria Document recognizes, however, other population subgroups as described above may also be at risk of Pb-related health effects of public health concern.

b. Potential Public Health Impacts

As discussed in the Criteria Document, there are potential public health implications of low-level Pb exposure, indexed by blood Pb levels, associated with several health endpoints identified in the Criteria Document (CD, Section 8.6).[69] These include potential impacts on population IQ, which is the focus of the quantitative risk assessment conducted for this review, as well as heart disease and chronic kidney disease, which are not included in the quantitative risk assessment (CD, Sections 8.6, 8.6.2, 8.6.3 and 8.6.4). It is noted that there is greater uncertainty associated with effects at the lower levels of blood Pb, and that there are differing weights of evidence across the effects observed.[70] With regard to potential implications of Pb effects on IQ, the Criteria Document recognizes the ''critical'' distinction between population and individual risk, noting that a ''point estimate indicating a modest mean change on a health index at the individual level can have substantial implications at the population level'' (CD, p. 8–77).[71] A downward shift in the mean IQ value is associated with both substantial decreases in percentages achieving very high scores and substantial increases in the percentage of individuals achieving very low scores (CD, p. 8–81).[72] For an individual functioning in the low IQ range due to the influence of developmental risk factors other than Pb, a Pb-associated IQ decline of several points might be sufficient to drop that individual into the range associated with increased risk of educational, vocational, and social handicap (CD, p. 8–77).

The magnitude of a public health impact is dependent upon the size of population affected and type or severity of the effect. As summarized above, there are several population groups that may be susceptible or vulnerable to effects associated with exposure to Pb, including young children, particularly those in families of low SES (CD, p. E–15), as well as individuals with hypertension, diabetes, and chronic renal insufficiency (CD, p. 8–72). Although comprehensive estimates of the size of these groups residing in proximity to sources of ambient Pb have not been developed, total estimates of these population subpopulations within the U.S. are substantial (as noted in Table 3–3 of the Staff Paper).[73]

With regard to estimates of the size of potentially vulnerable subpopulations living in areas of increased exposure related to ambient Pb, the information is still more limited. The limited information available on air and surface soil concentrations of Pb indicates elevated concentrations near stationary sources as compared with areas remote from such sources (CD, Sections 3.2.2 and 3.8). Air quality analyses (presented in Chapter 2 of the Staff Paper) indicate dramatically higher Pb concentrations at monitors near sources as compared with those more remote. As described in Section 2.3.2.1 of the Staff Paper, however, since the 1980s the number of Pb monitors has been significantly reduced by states (with EPA guidance that monitors well below the current NAAQS could be shut down) and a lack of monitors near some large sources may lead to underestimates of the extent of occurrences of relatively higher Pb concentrations. The significant limitations of our monitoring and emissions information constrain our efforts to characterize the size of at-risk populations in areas influenced by sources of ambient Pb. For example, the limited size and spatial coverage of the current Pb monitoring network constrains our ability to characterize current levels of airborne Pb in the U.S. Further, as noted above in section II.A.1, the Staff Paper review of the available information on emissions and locations of sources (as described in section 2.3.2.1 of the Staff Paper) indicates that the network is inconsistent in its coverage of the largest sources identified in the 2002 National Emissions Inventory (NEI). The most recent analysis of monitors near sources greater than 1 ton per year (tpy) indicates that less than 15% of stationary sources with emissions greater than or equal to 1 tpy have a monitor within one mile. Additionally, there are various uncertainties and limitations associated with source information in the NEI (as described in section 2.2.5 of the Staff Paper; USEPA, 2007c).

In recognition of the significant limitations associated with the currently available information on Pb emissions and airborne concentrations in the U.S. and the associated exposure of potentially at-risk populations, Chapter 2 of the Staff Paper summarizes the information in several different ways. For example, analyses of the current monitoring network indicated the numbers of monitoring sites that would exceed alternate standard levels, taking into consideration different statistical forms. These analyses are also summarized with regard to population size in counties home to those monitoring sites (as presented in Appendix 5.A of the Staff Paper). Information for the monitors and from the NEI indicates a range of source sizes in proximity to monitors at which various levels of Pb are reported. Together this information suggests that there is variety in the magnitude of Pb emissions from sources that could influence air Pb concentrations. Identifying specific emissions levels of sources expected to result in air Pb concentrations of interest, however, would be informed by a comprehensive analysis using detailed source characterization information, which was not feasible within the time and data constraints of this review. Instead, we have developed a summary of the emissions and demographic information for Pb sources that includes estimates of the numbers of people residing in counties in which the aggregate Pb emissions from NEI sources is greater than or equal to 0.1 tpy or in counties in which the aggregate Pb emissions is greater than or equal to 0.1 tpy per 1000 square miles (as presented in Tables 3–4 and 3–5, respectively, in the Staff Paper).

Additionally, the potential for resuspension of recently and historically deposited Pb near roadways to contribute to increased risks of Pb exposure to populations residing nearby is suggested in the Criteria Document (e.g., CD, pp. 2–62 and 3–32).

[69] The differing evidence and associated strength of the evidence for these different effects is described in detail in the Criteria Document.

[70] As is described in Section II.C.2.a, CASAC, in their comments on the analysis plan for the risk assessment described in this notice, placed higher priority on modeling the child IQ metric than the adult endpoints (e.g., cardiovascular effects).

[71] Similarly, ''although an increase of a few mmHg in blood pressure might not be of concern for an individual's well-being, the same increase in the population mean might be associated with substantial increases in the percentages of individuals with values that are sufficiently extreme that they exceed the criteria used to diagnose hypertension'' (CD, p. 8–77).

[72] For example, for a population mean IQ of 100 (and standard deviation of 15), 2.3% of the population would score above 130, but a shift of the population to a mean of 95 results in only 0.99% of the population scoring above 130 (CD, pp. 8–81 to 8–82).

[73] For example, approximately 4.8 million children live in poverty, while the estimates of numbers of adults with hypertension, diabetes or chronic kidney disease are on the order of 20 to 50 million (see Table 3–3 of Staff Paper).

4. Key Observations

The following key observations are based on the available health effects evidence and the evaluation and interpretation of that evidence in the Criteria Document.

• Lead exposures occur both by inhalation and by ingestion (CD, Chapter 3). As stated in the Criteria Document, ''given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant'' (CD, p. 3–27).

• Children, in general and especially those of low SES, are at increased risk for Pb exposure and Pb-induced adverse health effects. This is due to several factors, including enhanced exposure to Pb via ingestion of soil Pb and/or dust Pb due to normal childhood hand-to-mouth activity (CD, p. E–15, Chapter 3 and Section 6.2.1).

• Once inhaled or ingested, Pb is distributed by the blood, with long-term storage accumulation in the bone. Bone Pb levels provide a strong measure of cumulative exposure which has been associated with many of the effects summarized below, although difficulty of sample collection has precluded widespread use in epidemiological studies to date (CD, Chapter 4).

• Blood levels of Pb are well accepted as an index of exposure (or exposure metric) for which associations with the key effects (see below) have been observed. In general, associations with blood Pb are most robust for those effects for which past exposure history poses less of a complicating factor, i.e., for effects during childhood (CD, Section 4.3).

• Both epidemiological and toxicologic studies have shown that environmentally relevant levels of Pb affect many different organ systems (CD, p. E–8). With regard to the most important such effects observed in children and adults, the Criteria Document states (CD, p. 8–60) that ''neurotoxic effects in children and cardiovascular effects in adults are among those best substantiated as occurring at blood-Pb concentrations as low as 5 to 10 μg/dL (or possibly lower); and these categories of effects are currently clearly of greatest public health concern. Other newly demonstrated immune and renal system effects among general population groups are also emerging as low-level Pb-exposure effects of potential public health concern.''

• Many associations of health effects with Pb exposure have been found at levels of blood Pb that are currently relevant for the U.S. population, with individual children having blood Pb levels of 5–10 μg/dL and lower, being at risk for neurological effects (as described in the subsequent bullet). Supportive evidence from toxicological studies provides biological plausibility for the observed effects. (CD, Chapters 5, 6 and 8)

• Pb exposure is associated with a variety of neurological effects in children, notably intellectual attainment and school performance. Both qualitative and quantitative evidence, with further support from animal research, indicates a robust and consistent effect of Pb exposure on neurocognitive ability at mean concurrent blood Pb levels in the range of 5 to 10 μg/dL. Specific epidemiological analyses have further indicated association with neurocognitive effects in analyses restricted to children with individual blood Pb levels below 5–10 μg/dL, and for which group mean levels are lower. Further, ''[s]ome newly available analyses appear to show Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 μg/dL'' (CD, p. E–9; Sections 5.3, 6.2, 8.4.2 and 6.10).

• Deficits in cognitive skills may have long-term consequences over a lifetime. Poor academic skills and achievement can have enduring and important effects on objective parameters of success in life as well as increased risk of antisocial and delinquent behavior. (CD, Sections 6.1 and 8.4.2)

• The current epidemiological evidence indicates a steeper slope of the blood Pb concentration-response relationship at lower blood Pb levels, particularly those below 10 μg/dL (CD, Sections 6.2.13 and 8.6).

• At mean blood Pb levels, in children, on the order of 10 μg/dL, and somewhat lower, associations have been found with effects to the immune system, including altered macrophage activation, increased IgE levels and associated increased risk for autoimmunity and asthma (CD, Sections 5.9, 6.8, and 8.4.6).

• In adults, with regard to cardiovascular outcomes, the Criteria Document included the following summary (CD, p. E–10).

Epidemiological studies have consistently demonstrated associations between Pb exposure and enhanced risk of deleterious cardiovascular outcomes, including increased blood pressure and incidence of hypertension.[74] A meta-analysis of numerous studies estimates that a doubling of blood-Pb level (e.g., from 5 to 10 μg/dL) is associated with ~1.0 mm Hg increase in systolic blood pressure and ~0.6 mm Hg increase in diastolic pressure. Studies have also found that cumulative past Pb exposure (e.g., bone Pb) may be as important, if not more, than present Pb exposure in assessing cardiovascular effects. The evidence for an association of Pb with cardiovascular morbidity and mortality is limited but supportive.

Studies of nationally representative U.S. samples observed associations between blood Pb levels and increased systolic blood pressure at population mean blood Pb levels less than 5 μg/dL, particularly among African Americans (CD, Section 6.5.2). With regard to gender differences, the Criteria Document states the following (CD, p. 6–154).

Although females often show lower Pb coefficients than males, and Blacks higher Pb coefficients than Whites, where these differences have been formally tested, they are usually not statistically significant. The tendencies may well arise in the differential Pb exposure in these strata, lower in women than in men, higher in Blacks than in Whites. The same sex and race differential is found with blood pressure.

Animal evidence provides confirmation of Pb effects on cardiovascular functions (CD, Sections 5.5, 6.5, 8.4.3 and 8.6.3).

• Renal effects, evidenced by reduced renal filtration, have also been associated with Pb exposures indexed by bone Pb levels and also with mean blood Pb levels in the range of 5 to 10 μg/dL in the general adult population, with the potential adverse impact of such effects being enhanced for susceptible subpopulations including those with diabetes, hypertension, and chronic renal insufficiency (CD, Sections 6.4, 8.4.5, and 8.6.4). The full significance of this effect is unclear,

[74] The Criteria Document states that ''While several studies have demonstrated a positive correlation between blood pressure and blood Pb concentration, others have failed to show such association when controlling for confounding factors such as tobacco smoking, exercise, body weight, alcohol consumption, and socioeconomic status. Thus, the studies that have employed blood Pb level as an index of exposure have shown a relatively weak association with blood pressure. In contrast, the majority of the more recent studies employing bone Pb level have found a strong association between long-term Pb exposure and arterial pressure (Chapter 6). Since the residence time of Pb in the blood is relatively short but very long in the bone, the latter observations have provided rather compelling evidence for a positive relationship between Pb exposure and a subsequent rise in arterial pressure'' (CD, pp. 5–102 to 5–103). Further, in consideration of the meta-analysis also described here, the Criteria Document stated that ''The meta-analysis provides strong evidence for an association between increased blood Pb and increased blood pressure over a wide range of populations'' (CD, p. 6–130) and ''the meta-analyses results suggest that studies not detecting an effect may be due to small sample sizes or other factors affecting precision of estimation of the exposure effect relationship'' (CD, p. 6–133).

given that other evidence of more marked signs of renal dysfunction have not been detected at blood Pb levels below 30–40 μg/dL in large studies of occupationally exposed Pb workers (CD, pp. 6–270 and 8–50).[75]

• Other Pb associated effects in adults occurring at or just above 10 μg/dL include hematological (*e.g.*, impact on heme synthesis pathway) and neurological effects, with animal evidence providing support of Pb effects on these systems and evidence regarding mechanism of action (CD, Sections 5.2, 5.3, 6.3 and 6.9.2).

C. Human Exposure and Health Risk Assessments

This section presents a brief summary of the human exposure and health risk assessments conducted by EPA for this review. The complete full-scale assessment, which includes specific analyses conducted to address CASAC comments and advice on an earlier draft assessment, is presented in the final Risk Assessment Report (USEPA, 2007b).

The focus of this Pb NAAQS risk assessment is on characterizing risk resulting from exposure to policy-relevant Pb (i.e., exposure to Pb that has passed through ambient air on its path from source to human exposure—as described in section II.A.2). The design and implementation of this assessment needed to address significant limitations and complexity that go far beyond the situation for similar assessments typically performed for other criteria pollutants. Not only was the risk assessment constrained by the timeframe allowed for this review in the context of breadth of information to address, it was also constrained by significant limitations in data and modeling tools for the assessment, as discussed further in section II.C.2.h below. Furthermore, the multimedia and persistent nature of Pb, and the role of multiple exposure pathways (discussed in section II.A), add significant complexity to the assessment as compared to other assessments that focus only on the inhalation pathway. The impact of this on our estimates for air-related exposure pathways is discussed in section II.C.2.e.

The remainder of this overview of the human health risk assessment is organized as follows. An overview of the human health risk assessment completed in the last review of the Pb NAAQS in 1990 (USEPA, 1990a) is presented first. Next, design aspects of the current risk assessment are presented, including: (a) CASAC advice regarding the design of the risk assessment, (b) description of health endpoints and associated risk metrics modeled, including the concentration-response functions used, (c) overview of the case study approach employed, (d) description of air quality scenarios modeled, (e) explanation of air-related versus background classification of risk results in the context of this analysis, (f) overview of analytical (modeling) steps completed for the risk assessment and (g) description of the multiple sets of risk results generated for the analysis. Then, key sources of uncertainty associated with the analysis are presented. And finally, a summary of exposure and risk estimates and key observations is presented.

1. Overview of Risk Assessment From Last Review

The risk assessment conducted in support of the last review used a case study approach to compare air quality scenarios in terms of their impact on the percentage of modeled populations that exceeded specific blood Pb levels chosen with consideration of the health effects evidence at that time (USEPA, 1990b; USEPA, 1989). The case studies in that analysis, however, focused exclusively on Pb smelters including two secondary and one primary smelter and did not consider exposures in a more general urban context. The analysis focused on children (birth through 7 years of age) and middle-aged men. The assessment evaluated impacts of alternate NAAQS on numbers of children and men with blood Pb levels above levels of concern based on health effects evidence at that time. The primary difference between the risk assessment approach used in the current analysis and the assessment completed in 1990 involves the risk metric employed. Rather than estimating the percentage of study populations with exposures above blood Pb levels of interest as was done in the last review (i.e., 10, 12 and 15 μg/dL), the current analysis estimates changes in health risk, specifically IQ loss, associated with Pb exposure for child populations at each of the case study locations with that estimated IQ loss further differentiated between air-related and background Pb exposure categories.

2. Design Aspects of Exposure and Risk Assessments

This section provides an overview of key elements of the assessment design, inputs, and methods, and includes identification of key uncertainties and limitations.

a. CASAC Advice

The CASAC conducted a consultation on the draft analysis plan for the risk assessment (USEPA, 2006c) in June, 2006 (Henderson, 2006). Some key comments provided by CASAC members on the plan included: (1) Placing a higher priority on modeling the child IQ metric than the adult endpoints (e.g., cardiovascular effects), (2) recognizing the importance of indoor dust loading by Pb contained in outdoor air as a factor in Pb-related exposure and risk for sources considered in this analysis, and (3) concurring with use of the IEUBK biokinetic blood Pb model. Taking these comments into account, a pilot phase assessment was conducted to test the risk assessment methodology being developed for the subsequent full-scale assessment. The pilot phase assessment is described in the first draft Staff Paper and accompanying technical report (ICF 2006), which was discussed by the CASAC Pb panel on February 6–7 (Henderson, 2007a).

Results from the pilot assessment, together with comments received from CASAC and the public, informed the design of the full-scale analysis. The full-scale analysis included a substitution of a more generalized urban case study for the location-specific near-roadway case study evaluated in the pilot. In addition, a number of changes were made in the exposure and risk assessment approaches, including the development of a new indoor dust Pb model focused specifically on urban residential locations and specification of additional IQ loss concentration-response (C–R) functions to provide greater coverage for potential impacts at lower exposure levels.

The draft full-scale assessment was presented in the July 2007 draft risk assessment report (USEPA, 2007a) that was released for public comment and provided to CASAC for review. In their review of the July draft risk assessment report, the CASAC Pb Panel made several recommendations for additional exposure and health risk analyses (Henderson, 2007b). These included a recommendation that the general urban

[75] In the general population, both cumulative and circulating Pb has been found to be associated with longitudinal decline in renal functions. In the large NHANES III study, alterations in urinary creatinine excretion rate (one indicator of possible renal dysfunction) were observed in hypertensives at a mean blood Pb of only 4.2 μg/dL. These results provide suggestive evidence that the kidney may well be a target organ for effects from Pb in adults at current U.S. environmental exposure levels. The magnitude of the effect of Pb on renal function ranged from 0.2 to −1.8 mL/min change in creatinine clearance per 1.0 μg/dL increase in blood Pb in general population studies. However, the full significance of this effect is unclear, given that other evidence of more marked signs of renal dysfunction have not been detected at blood Pb levels below 30–40 μg/dL among thousands of occupationally exposed Pb workers that have been studied (CD, p. 6–270).

case study be augmented by the inclusion of risk analyses in specific urban areas of the U.S. In this regard, they specifically stated the following (Henderson, 2007b, p. 3)

> * * * the CASAC strongly believes that it is important that EPA staff make estimates of exposure that will have national implications for, and relevance to, urban areas; and that, significantly, the case studies of both primary lead (Pb) smelter sites as well as secondary smelter sites, while relevant to a few atypical locations, do not meet the needs of supporting a Lead NAAQS. The Agency should also undertake case studies of several urban areas with varying lead exposure concentrations, based on the prototypic urban risk assessment that OAQPS produced in the 2nd Draft Lead Human Exposure and Health Risk Assessments. In order to estimate the magnitude of risk, the Agency should estimate exposures and convert these exposures to estimates of blood levels and IQ loss for children living in specific urban areas.

Hence, EPA included additional case studies in the risk assessment focused on characterizing risk for residential populations in three specific urban locations. Further, CASAC recommended using a concentration-response function with a change in slope near 7.5 μg/dL. Accordingly, EPA included such an additional concentration-response function in the risk assessment. Results from the initial full-scale analyses, along with comments from CASAC, such as those described here, and the public resulted in a final version of the full-scale assessments which is briefly summarized here and presented in greater detail in the Risk Assessment Report and associated appendices (USEPA, 2007b).

In their review of the final risk assessment, CASAC expressed strong support, stating as follows (Henderson, 2008a, p. 4):

> The Final Risk Assessment report captures the breadth of issues related to assessing the potential public health risk associated with lead exposures; it competently documents the universe of knowledge and interpretations of the literature on lead toxicity, exposures, blood lead modeling and approaches for conducting risk assessments for lead.

b. Health Endpoint, Risk Metric and Concentration-Response Functions

The health endpoint on which the quantitative health risk assessment focuses is developmental neurotoxicity in children, with IQ decrement (or loss) as the risk metric. Among the wide variety of health endpoints associated with Pb exposures, there is general consensus that the developing nervous system in young children is the most sensitive and that neurobehavioral effects (specifically neurocognitive deficits), including IQ decrements, appear to occur at lower blood levels than previously believed (i.e., at levels <10 μg/dL). The selection of children's IQ for the quantitative risk assessment reflects consideration of the evidence presented in the Criteria Document as well as advice received from CASAC (Henderson, 2006, 2007a).

Given the evidence described in detail in the Criteria Document (Chapters 6 and 8), and in consideration of CASAC recommendations (Henderson, 2006, 2007a, 2007b), the risk assessment for this review relies on the functions presented by Lanphear and others (2005) that relate absolute IQ as a function of concurrent blood Pb or of the log of concurrent blood Pb, and lifetime average blood Pb, respectively. As discussed in the Criteria Document (CD, p. 8–63 to 8–64), the slope of the concentration-response relationship described by these functions is greater at the lower blood Pb levels (e.g., less than 10 μg/dL). As discussed in the Criteria Document and summarized in section II.B.2, threshold blood Pb levels for these effects cannot be discerned from the currently available epidemiological studies, and the evidence in the animal Pb neurotoxicity literature does not define a threshold for any of the toxic mechanisms of Pb (CD, Sections 5.3.7 and 6.2).

In applying relationships observed with the international pooled analysis by Lanphear and others (2005) to the risk assessment, which includes blood Pb levels below the range represented by the pooled analysis, several alternative blood Pb concentration-response models were considered in recognition of a reduced confidence in our ability to characterize the quantitative blood Pb concentration-response relationship at the lowest blood Pb levels represented in the recent epidemiological studies. The functions considered and employed in the initial risk analyses for this review include the following.

- Log-linear function with low-exposure linearization, for both concurrent and lifetime average blood metrics, applies the nonlinear relationship down to the blood Pb concentration representing the lower bound of blood Pb levels for that blood metric in the pooled analysis and applies the slope of the tangent at that point to blood Pb concentrations estimated in the risk assessment to fall below that level.
- Log-linear function with cutpoint, for both concurrent and lifetime average blood metrics, also applies the nonlinear relationship at blood Pb concentrations above the lower bound of blood Pb concentrations in the pooled analysis dataset for that blood metric, but then applies zero risk to all lower blood Pb concentrations estimated in the risk assessment (this cutpoint is 1 μg/dL for the concurrent blood Pb).

In the additional risk analyses performed subsequent to the August 2007 CASAC public meeting, the two functions listed above and the following two functions were employed (details on the forms of these functions as applied in this risk assessment are described in Section 5.3.1 of the Risk Assessment Report).

- Population stratified dual linear function for concurrent blood Pb, derived from the pooled dataset stratified at peak blood Pb of 10 μg/dL [76] and
- Population stratified dual linear function for concurrent blood Pb, derived from the pooled dataset stratified at 7.5 μg/dL peak blood Pb.

In interpreting risk estimates derived using the various functions, consideration should be given to the uncertainties with regard to the precision of the coefficients used for each analysis. The coefficients for the log-linear model from Lanphear *et al.* (2005) had undergone a careful development process, including sensitivity analyses, using all available data from 1,333 children. The shape of the exposure-response relationship was first assessed through tests of linearity, then by evaluating the restricted cubic spline model. After determining that the log-linear model provided a good fit to the data, covariates to adjust for potential confounding were included in the log-linear model with careful consideration of the stability of the parameter estimates. After the multiple regression models were developed, regression diagnostics were employed to ascertain whether the Pb coefficients were affected by collinearity or influential observations. To further investigate the stability of the model, a random-effects model (with sites

[76] As mentioned above (section II.B.2.b), this function (derived for lifetime average blood Pb), was used in the economic analysis for the RRP rule. This model was selected for the RRP economic analysis with consideration of advice from CASAC and of the distribution of blood Pb levels being considered in that analysis, which focused on children living in houses with lead-based paint (USEPA, 2008). With consideration of these blood Pb levels, the economic analysis document states that ''[s]electing a model with a node, or changing one segment to the other, at a lifetime average blood Pb concentration of 10 μg/dL rather than at 7.5 μg/dL, is a small protection against applying an incorrectly rapid change (steep slope with increasingly smaller effect as concentrations lower) to the calculation'' (USEPA, 2008).

random) was applied to evaluate the results and also the effect of omitting one of the seven cohorts on the Pb coefficient. In the various sensitivity analyses performed, the coefficient from the log-linear model was found to be robust and stable. The log-linear model, however, is not biologically plausible at the very lowest blood Pb concentrations as they approach zero; therefore, in the first two functions the log-linear model is applied down to a cutpoint (of 1 μg/dL for the concurrent blood Pb metric), selected based on the low end of the blood Pb levels in the pooled dataset, followed by a linearization or an assumption of zero risk at levels below that point.

In contrast, the coefficients from the two analyses using the population stratified dual linear function with stratification at 7.5 μg/dL and 10 μg/dL,[77] peak blood Pb, have not undergone as careful development. These analyses were primarily done to compare the lead-associated decrement at lower blood Pb concentrations and higher blood Pb concentrations. For these analyses, the study population was stratified at the specified peak blood Pb level and separate linear models were fitted to the concurrent blood Pb data for the children in the two study population subgroups.[78] While these analyses are quite suitable for the purpose of investigating whether the slope at lower concentration levels is greater compared to higher concentration levels, use of such coefficients as the primary C–R function in a risk analysis such as this may be inappropriate. Further, only 103 children had maximal blood Pb levels less than 7.5 μg/dL and 244 children had maximal blood Pb levels less than 10 μg/dL. While these children may better represent current blood Pb levels, not fitting a single model using all available data may lead to bias. Slob *et al.* (2005) noted that the usual argument for not considering data from the high dose range is that different biological mechanisms may play a role at higher doses compared to lower doses. However, this does not mean a single curve across the entire exposure range cannot describe the relationship. The fitted curve merely assumes that the underlying dose-response follows a smooth curve over the whole dose range. If biological mechanisms change when going from lower to higher doses, this change will result in a gradually changing slope of the dose-response. The major strength of the Lanphear *et al.* (2005) study was the large sample size and the pooled analysis of data from seven different cohorts. In the case of the study population subgroup with peak blood Pb below 7.5 μg/dL, less than 10% of the available data is used in the analysis (103 of the 1333 subjects in the pooled dataset), with more than half of the data coming from one cohort (Rochester) and the six other cohorts contributing zero to 13 children to the analysis. Such an analysis consequently does not make full use of the strength of the pooled study by Lanphear and others (2005).

In consideration of the preceding discussion and the range of blood Pb levels assessed in this analysis,[79] greater confidence is placed in the log-linear model form compared to the dual-linear stratified models for purposes of the risk assessment described in this notice. Further, in considering risk estimates derived from the four core functions (log-linear function with low-exposure linearization, log-linear function with cutpoint, dual linear function, stratified at 7.5 μg/dL peak blood Pb, and dual linear function, stratified at 10 μg/dL peak blood Pb), greatest confidence is assigned to risk estimates derived using the log-linear function with low-exposure linearization since this function (a) is a nonlinear function that describes greater response per unit blood Pb at lower blood Pb levels consistent with multiple studies identified in the discussion above, (b) is based on fitting a function to the entire pooled dataset (and hence uses all of the data in describing response across the range of exposures), (c) is supported by sensitivity analyses showing the model coefficients to be robust, and (d) provides an approach for predicting IQ loss at the lowest exposures simulated in the assessment (consistent with the lack of evidence for a threshold). Note, however, that risk estimates generated using the other three concentration-response functions are also presented to provide perspective on the impact of uncertainty in this key modeling step. We additionally note that the CASAC Pb Panel recommended that C–R function derived from the pooled dataset stratified at 7.5 μg/dL, peak blood Pb, be given weight in this analysis (Henderson, 2008).

c. Case Study Approach

For the risk assessment described in this notice, a case study approach was employed as described in Sections 2.2 (and subsections) and 5.1.3 of the Risk Assessment Report (USEPA, 2007b). In summarizing the assessment in this proposal, we have focused on five[80] case studies that generally represent two types of population exposures: (1) More highly air-pathway exposed children (as described below) residing in small neighborhoods or localized residential areas with air concentrations somewhat near the standard level being evaluated, and (2) urban populations with a broader range of air-related exposures. These five case studies are:

- *A general urban case study:* This case study is not based on a specific geographic location and reflects several simplifying assumptions used in representing exposure including uniform ambient air Pb levels associated with the standard of interest across the hypothetical study area and a uniform study population. This case study characterizes risk for a localized part of an urban area at different standard levels, but based on national average estimates of the relationships between the different standard form assessed and ambient air exposure concentrations. Thus, while this provides characterization of risk to children that are relatively more highly air pathway exposed (as compared to the location-specific case studies), this case study is not considered to represent a high-end scenario with regard to the characterization of ambient air Pb levels and associated risk.[81]
- *A primary Pb smelter case study:*[82] This case study estimates risk for children living in an area currently not in attainment with the current NAAQS that is impacted by Pb emissions from a primary Pb smelter. Results described

[77] See previous footnote.

[78] Neither fit of the model nor other sensitivity analyses were conducted (or reported) for these coefficients.

[79] The median concurrent values in all case studies and air quality scenarios are below 5 μg/dL and those for air quality scenarios within the range of standard levels proposed in this notice are below 3 μg/dL (as shown in Table 1).

[80] A sixth case study (the secondary Pb smelter case study) is also described in the Risk Assessment Report. However, as discussed in Section 4.3.1 of that document (USEPA, 2007b), significant limitations in the approaches employed for this case study have contributed to large uncertainties in the corresponding estimates.

[81] In representing the different forms of each standard level assessed (maximum monthly or maximum quarterly) as annual air concentrations for input to the blood Pb model for this case study, however, we relied on averages of these relationships for large urban areas nationally. As the averages are higher than the medians, localized areas near more than half the urban monitoring locations would have higher exposures and associated risks than those reported for this case study. Further, we note that exposure concentrations would be twice those used here if the 25th percentile values for these relationships had been used in place of the averages. For this reason, this case study should not be interpreted as representing a high-end scenario with regard to the characterization of ambient air Pb levels and associated risk.

[82] See Section II.C.2.a for a summary of CASAC's comment with regard to the primary and secondary Pb smelter case studies.

here are those for the area within 1.5 km of the facility (the ''subarea'') where airborne Pb concentrations are closest to the current standard. As such, this case study characterizes risk for a specific more highly exposed population and also provides insights on risk to child populations living in areas near large sources of Pb emissions.[83]

• *Three location-specific urban case studies:* These urban case studies focus on specific urban areas (Cleveland, Chicago and Los Angeles) to provide representations of the distribution of ambient air-related risk in specific densely populated urban locations. These case studies represent areas with specific population distributions and that experience a broader range of air-related exposures due both to potential spatial gradients in ambient air Pb levels and population density. A large majority of the population in these case studies resides in areas with much lower air concentrations than those in the very small subareas of these case studies with the highest concentrations. Ambient air Pb concentrations are characterized using source-oriented and other Pb-TSP monitors in these cities, while location-specific U.S. Census demographic data are used to characterize the spatial distribution of residential child populations in these study areas.

These different case studies generally represent two types of population exposures. The general urban and primary Pb smelter subarea provide estimates of risk for more highly air-pathway exposed children residing in small neighborhoods or localized residential areas with air concentrations somewhat near the standard level being evaluated. By contrast, the three location-specific urban case studies included in the analysis provide risk estimates for an urban population with a broader range of air-related exposures. In fact, for the location-specific urban case studies, the majority of the modeled populations experience ambient air Pb levels significantly lower than the standard level being evaluated, with only a small population experiencing ambient air Pb levels at or near the standard.[84]

In considering risk results generated for the location-specific urban case studies, we note that, given the wide range of monitored Pb levels in urban areas, combined with the relatively limited monitoring network characterizing ambient levels in the urban setting, it is not possible to determine where these case studies fall within the distribution of ambient air-related risk in U.S. cities.

d. Air Quality Scenarios

Air quality scenarios assessed include (a) a current conditions scenario for the location-specific urban case studies and the general urban case study, (b) a current NAAQS scenario for the location-specific urban case studies, the general urban case study and the primary Pb smelter case study, and (c) a range of alternative NAAQS scenarios for all case studies. The alternative NAAQS scenarios include levels of 0.5, 0.2, 0.05, and 0.02 $\mu g/m^3$, with a monthly averaging time, as well as a level of 0.2 $\mu g/m^3$ scenario using a quarterly averaging time.[85]

The current NAAQS scenario for the urban case studies assumes ambient air Pb concentrations higher than those currently occurring in nearly all urban areas nationally.[86] While it is extremely unlikely that Pb concentrations in urban areas would rise to meet the current NAAQS and there are limitations and uncertainties associated with the roll-up procedure used for the location-specific urban case studies (as described in Section III.B.2.h below), this scenario was included for those case studies to provide perspective on potential risks associated with raising levels to the point that the highest level across the study area just meets the current NAAQS. When evaluating these results it is important to keep these limitations and uncertainties in mind.

Current conditions for the three location-specific urban case studies in terms of maximum quarterly average air Pb concentrations are 0.09, 0.14 and 0.36 $\mu g/m^3$ for the study areas in Los Angeles, Chicago and Cleveland, respectively. In terms of maximum monthly average the values are 0.17 $\mu g/m^3$, 0.31 $\mu g/m^3$ and 0.56 $\mu g/m^3$ for the study areas in Los Angeles, Chicago and Cleveland, respectively.

Details of the assessment scenarios, including a description of the derivation of Pb concentrations for air and other media are presented in Sections 2.3 (and subsections) and Section 5.1.1 of the Risk Assessment Report (USEPA, 2007b).

e. Categorization of Policy-Relevant Exposure Pathways

As discussed in Section IIA, this review focuses on air-related exposure pathways (i.e., those pathways where Pb passes through ambient air on its path from source to human exposure). These include both inhalation of ambient air Pb (including both Pb emitted directly into ambient air as well as resuspended Pb); and ingestion of Pb that, once airborne, has made its way into indoor dust, outdoor dust or soil, dietary items (e.g., crops and livestock), and drinking water. Because of the nonlinear response of blood Pb to exposure (simulated in the IEUBK blood Pb model) and also the nonlinearity reflected in the C-R functions for estimation of IQ loss, this assessment first estimates total blood Pb and risk (air- and nonair-related), and then separates out those estimates of blood Pb and associated risk associated with the pathways of interest in this review.

To separate out risk for the pathways of interest in this review, we split the estimates of total (all-pathway) blood Pb and IQ loss into background and two air-related categories (referred to as ''recent air'' and ''past air''). However, significant limitations in our modeling tools and data resulted in an inability to parse specific risk estimates into specific pathways, such that we have approximated estimates for the air-related and background categories.

Those Pb exposure pathways identified in section II.A.2 as being tied most directly to ambient air, which consequently have the potential to respond relatively more quickly to changes in air Pb (inhalation and ingestion of indoor dust loaded directly from ambient air Pb) were placed into the ''recent air'' category. The other air-related Pb exposure pathways, associated with atmospheric deposition, were placed into the ''past air'' category. These include ingestion of Pb in

[83] Result for the full study area, which extends 10 km out from the facility, are presented in the Risk Assessment Report (USEPA, 2007a), but are not presented here. Exposures in the full study area were dominated by modeled children farther from the facility where, as discussed in the ANPR (section III.B.2.h), there is likely underestimation of ambient air-related Pb exposure due to increasing influence of other sources relative to that of the facility, which were not included in the dispersion modeling performed to estimate air concentrations for this case study.

[84] Based on the nature of the population exposures represented by the two categories of case study, the first category (the general urban and primary Pb smelter case studies) relates more closely to the second evidence-based framework (see Sections II.D.2.a and II.E.3.a) with regard to estimates of air-related IQ loss. As mentioned above these case studies, as compared to the other category of case studies, include populations that are relatively more highly air pathway exposed to air Pb concentrations somewhat near the standard level evaluated.

[85] For further discussion of the air quality scenarios and averaging times included in the risk assessment, see section 2.3.1 of the Risk Assessment Report (USEPA, 2007b).

[86] This scenario was simulated for the location-specific urban case studies using a proportional roll-up procedure. For the general urban case study, the maximum quarterly average ambient air concentration was set equal to the current NAAQS.

outdoor dust/soil and ingestion of the portion of Pb in indoor dust that after deposition from ambient air outdoors is carried indoors with humans (as described in section II.A.2 above).[87]

Thus, total blood Pb and IQ loss estimates were apportioned into the following pathways or pathway combinations:

• Inhalation of ambient air Pb (i.e., ''recent air'' Pb): This is derived using the blood Pb estimate resulting from Pb exposure limited to the inhalation pathway (and includes inhalation of Pb in ambient air from all sources contributing to the ambient air concentration estimate, including potentially resuspension).

• Ingestion of ''recent air'' indoor dust Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of the Pb in indoor dust that is predicted in this assessment from infiltration of ambient air indoors and subsequent deposition.[88]

• Ingestion of ''other'' indoor dust Pb (considered part of ''past air'' exposure): This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of the Pb in indoor dust that is not predicted from infiltration of ambient air indoors and subsequent deposition.[89] This is interpreted to represent indoor paint, outdoor soil/dust, and additional sources of Pb to indoor dust including historical air (as discussed in the Risk Assessment Report, Section 2.4.3). As the intercept in regression dust models will be inclusive of error associated with the model coefficients, this category also includes some representation of dust Pb associated with current ambient air concentrations (described in previous bullet). For the primary Pb smelter case study, estimates for this pathway are not separated from estimates for the pathway described above due to uncertainty regarding this categorization with the model used for this case study (Risk Assessment Report, Section 3.1.4.2). This pathway is included in the ''past air'' category.

• Ingestion of outdoor soil/dust Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of outdoor soil/dust Pb. This pathway is included in the ''past air'' category (and could include contamination from historic Pb emissions from automobiles and Pb paint).

• Ingestion of drinking water Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of drinking water Pb. This pathway is included in the policy-relevant background category.

• Ingestion of dietary Pb: This is derived using the blood Pb estimate resulting from Pb exposure limited to ingestion of dietary Pb. This pathway is included in the policy-relevant background category.

As noted above, significant limitations in our modeling tools and data resulted in an inability to parse risk estimates for specific pathways, such that we approximated estimates for the air-related and background categories. Of note in this regard is the apportionment of background (nonair) pathways. For example, while conceptually indoor Pb paint contributions to indoor dust Pb would be considered background and included in the ''background'' category for this assessment, due to technical limitations related to indoor dust Pb modeling, ultimately, dust from Pb paint was included as part of ''other'' indoor dust Pb (i.e., as part of past air exposure). The inclusion of indoor lead Pb as a component of ''other'' indoor air (and consequently as a component of the ''past air'' category) represents a source of potential high bias in our prediction of exposure and risk associated with the ''past air'' category because conceptually, exposure to indoor paint Pb is considered part of background exposure. Further, Pb in ambient air does contribute to the exposure pathways included in the ''background'' category (drinking water and diet), and is likely a substantial contribution to diet (CD, p. 3–48). But we could not separate the air contribution from the nonair contributions, and the total contribution from both the drinking water and diet pathways are categorized as ''background'' in this assessment. As a result, our ''background'' risk estimate includes some air-related risk.

Further, we note that in simulating reductions in exposure associated with reducing ambient air Pb levels through alternative NAAQS (and increases in exposure if the current NAAQS was reached in certain case studies) only the exposure pathways categorized as ''recent air'' (inhalation and ingestion of that portion of indoor dust associated with outdoor ambient air) were varied with changes in air concentration. The assessment did not simulate decreases in ''past air'' exposure pathways (e.g., reductions in outdoor soil Pb levels following reduction in ambient air Pb levels and a subsequent decrease in exposure through incidental soil ingestion and the contribution of outdoor soil to indoor dust). These exposures were held constant across all air quality scenarios. In comparing total risk estimates between alternate NAAQS scenarios, this aspect of the analysis will tend to underestimate the reductions in risk associated with alternative NAAQS. However, this does not mean that overall risk has been underestimated. The net effect of all sources of uncertainty or bias in the analysis, which may also tend to under- or overestimate risk, could not be quantified. Interpretation of risk estimates is discussed more fully in section II.C.3.b.

In summary, because of limitations in the assessment design, data and modeling tools, our risk estimates for the ''past air'' category include both risks that are truly air-related and potentially, some background risk. Because we could not sharply separate Pb linked to ambient air from Pb that is background, some of the three categories of risk are underestimated and others overestimated. On balance, we believe this limitation leads to a slight overestimate of the risks in the ''past air'' category. At the same time, as discussed above, the ''recent air'' category does not fully represent the risk associated with all air-related pathways. Thus, we consider the risk attributable to air-related exposure pathways to be bounded on the low end by the risk estimated for the ''recent air'' category and on the upper end by the risk estimated for the ''recent air'' plus ''past air'' categories.

f. Analytical Steps

The risk assessment includes four analytical steps, briefly described below and presented in detail in Sections 2.4.4, 3.1, 3.2, 4.1, and 5.1 of the Risk Assessment Report (USEPA, 2007b).

• *Characterization of Pb in ambient air:* The characterization of outdoor ambient air Pb levels uses different approaches depending on the case study (as explained in more detail below): (a) source-oriented and non-source oriented monitors are assumed to represent different exposure zones in the city-specific case studies, (b) a single exposure level is assumed for the entire

[87] As discussed below, due to technical limitations related to indoor dust Pb modeling, dust from Pb paint may be included to some extent in the ''past air'' category of exposure pathways.

[88] Recent air indoor dust Pb was estimated using the mechanistic component of the hybrid blood Pb model (see Section 3.1.4 of the Risk Assessment Report). For the primary Pb smelter case study, estimates for this pathway are not separated from estimates for the pathway described in the subsequent bullet due to uncertainty regarding this categorization with the model used for this case study (Section 3.1.4.2 of the Risk Assessment Report).

[89] ''Other'' indoor dust Pb is estimated using the intercept in the dust models plus that predicted by the outdoor soil concentration coefficient (for models that include soil Pb as a predictor of indoor dust Pb) (Section 3.1.4 of the Risk Assessment Report).

population in the general urban case study, and (c) ambient levels are estimated using air dispersion modeling based on Pb emissions from a particular facility in the primary Pb smelter case study.

• *Characterization of outdoor soil/dust and indoor dust Pb concentrations:* Outdoor soil Pb levels are estimated using empirical data and fate and transport modeling. Indoor dust Pb levels are predicted using a combination of (a) regression-based models that relate indoor dust to ambient air Pb and outdoor soil Pb, and (b) mechanistic models.[90]

• *Characterization of blood Pb levels:* Blood Pb levels for each exposure zone are derived from central-tendency blood Pb concentrations estimated using the Integrated Exposure and Uptake Biokinetic (IEUBK) model, and concurrent or lifetime average blood Pb is estimated from these outputs as described in Section 3.2.1.1 of the Risk Assessment Report (USEPA, 2007b). For the point source and location-specific urban case studies, a probabilistic exposure model is used to generate population distributions of blood Pb concentrations based on: (a) The central tendency blood Pb levels for each exposure zone, (b) demographic data for the distribution of children (less than 7 years of age) across exposure zones in a study area, and (c) a geometric standard deviation (GSD) intended to characterize interindividual variability in blood Pb (e.g., reflecting differences in behavior and biokinetics related to Pb). For the general urban case study, as demographic data for a specific location are not considered, the GSD is applied directly to the central tendency blood Pb level to estimate a population distribution of blood Pb levels. Additional detail on the methods used to model population blood Pb levels is presented in Sections 3.2.2 and 5.2.2.3 of the Risk Assessment Report (USEPA, 2007b).

• *Risk characterization (estimating IQ loss):* Concurrent or lifetime average blood Pb estimates for each simulated child in each case study population are converted into total Pb-related IQ loss estimates using the concentration-response functions described above in section II.C.2.b.[91]

We have also used the results of exposure modeling to estimate air-to-blood ratios for two of the case studies (the general urban and primary Pb smelter case studies). Specifically, we compared the change in ambient air Pb between adjacent NAAQS levels with the associated reduction in concurrent blood Pb levels (for the median population percentile) to derive air-to-blood ratios. As they relate air concentrations[92] input to the first analytical step to blood Pb estimates output from the third analytical step, they may be viewed as a collapsed alternate to the three steps for the exposure pathways directly linked to air concentrations in this assessment. The values for these ratios are affected by design aspects of the risk assessment, most notably those identified here:

• Because they are derived from differences in blood Pb estimates between air quality scenarios and the only pathways varied with air quality scenarios are ambient air and indoor dust (as described in section II.C.2.e above), the exposure pathways reflected in the ratios are generally the ''recent air'' pathways (described in section II.C.2.e above), which include inhalation of ambient air and ingestion of indoor dust loaded by infiltration of ambient air. Ratios for the primary Pb smelter case study subarea may additionally reflect some contributions to indoor dust from other ambient air-related pathways (e.g., ''tracking in'' of soil containing ambient air Pb), yet still not all air-related pathways. Thus, the air-to-blood ratios derived for both case studies (described in section II.C.3.a) are lower than they would be if they reflected all air-related pathways.

• The blood Pb estimates used in this calculation are for the ''concurrent'' metric (i.e., concentrations during the 7th year of life). Accordingly, the resultant air-to-blood ratios are lower than they would be if based on blood Pb estimates for the 2nd year of life (e.g., peak) or estimates averaged over the exposure period.

Key limitations and uncertainties associated with the application of these specific analytical steps are summarized in Section III.B.2.k below.

g. Generating Multiple Sets of Risk Results

In the initial analyses for the full-scale assessment (USEPA, 2007a), EPA implemented multiple modeling approaches for each case study scenario in an effort to characterize the potential impact on exposure and risk estimates of uncertainty associated with the limitations in the tools, data and methods available for this risk assessment and with key analytical steps in the modeling approach. These multiple modeling approaches are described in Section 2.4.6.2 of the final Risk Assessment Report (USEPA, 2007b). In consideration of comments provided by CASAC (Henderson, 2007b) on these analyses regarding which modeling approach they felt had greater scientific support, a pared down set of modeling combinations was identified as the core approach for the subsequent analyses. The core modeling approach includes the following key elements:

• Ambient air Pb estimates (based on monitors or modeling and proportional rollbacks, as described below),

• Background exposure from food and water (as described above),

• The hybrid indoor dust model specifically developed for urban residential applications (which predicts Pb in indoor dust as a function of ambient air Pb and nonair contribution),

• The IEUBK blood Pb model (which predicts blood Pb in young children exposed to Pb from multiple exposure pathways),

• The concurrent blood Pb metric,

• A GSD for concurrent blood Pb of 2.1 to characterize interindividual variability in blood Pb levels for a given ambient level for the urban case studies,[93] and

[90] Indoor dust Pb modeling for the urban case studies is based on a hybrid mechanistic-empirical model which considers the direct impact of Pb in ambient air on indoor dust Pb (i.e., which models the infiltration of ambient air indoors and subsequent deposition of Pb to indoor surfaces). This modeling does not consider other ambient air-related contributions to indoor dust, such as ''tracking in'' of outdoor soil Pb. By contrast, indoor dust Pb modeling for the primary Pb smelter case study subarea uses a site-specific regression model which relates average dust Pb values (based on a recent multi-year dataset) to annual average air Pb concentrations (based on air dispersion modeling). In this way, modeling for the primary Pb smelter subarea may reflect some contributions to indoor dust Pb that relate to longer term impacts of ambient air (e.g., ''tracking in'' of outdoor soil), as well as contributions from infiltration of ambient air. Additional detail on the methods used in characterizing Pb concentrations in outdoor soil and indoor dust are presented in Sections 3.1.3 and 3.1.4 of the Risk Assessment, respectively. Data, methods and assumptions here used in characterizing Pb concentrations in these exposure media may differ from those in other analyses that serve different purposes.

[91] The four C–R functions applied in the risk assessment, which are based on analyses presented in Lanphear *et al.* (2005) include a log-linear function with low-exposure linearization, a log-linear function with a cutpoint, and two dual linear functions (based on population stratification at peak blood Pb levels of 7.5 and 10 μg/dL) (see section II.C.2.b).

[92] Because the IEUBK blood Pb model runs with an annual time step, the air concentrations input to the ''recent air'' pathways modeling steps were in terms of annual average air concentration.

[93] In the economic analysis for the RRP rule, a GSD of 1.6 was used in its probabilistic simulations, reflecting the fact that the simulated exposures focus on a subset of Pb exposure pathways (exposure to dust and airborne Pb resulting from renovation activity) and a CASAC recommendation to use the IEUBK-recommended GSD with the Leggett model, where no GSD is provided. In addition, the accompanying sensitivity analysis used a GSD of 2.1 to consider the impact on IQ change estiamtes of using a larger GSD, which

• Four different functions relating concurrent blood Pb to IQ loss (described in section II.C.2.b), including two log-linear models (one with a cutpoint and one with low-exposure linearization) and two dual-linear models with stratification, one stratified at 7.5 μg/dL peak blood Pb and the other at 10 μg/dL peak blood Pb.

For each case study, the core modeling approach employs a single set of modeling elements to estimate exposure and the four different concentration-response functions referenced above to derive four sets of risk results from the single set of exposure estimates. The spread of estimates resulting from application of all four functions captures much of the uncertainty associated model choice in this analytical step. Among these four functions, EPA has greater confidence in estimates derived using the log-linear with low-exposure linearization concentration-response function as discussed above.

In addition to employing multiple concentration-response functions, the assessment includes various sensitivity analyses to characterize the potential impact of uncertainty in other key analysis steps on exposure and risk estimates. The sensitivity analyses and uncertainty characterization completed for the risk analysis are described in Sections 3.5, 4.3, 5.2.5 and 5.3.3 of the Risk Assessment Report (USEPA, 2007b).

h. Key Limitations and Uncertainties

As recognized above, EPA has made simplifying assumptions in several areas of this assessment due to the limited data, models, and time available. These assumptions and related limitations and uncertainties are described in the Risk Assessment Report (USEPA, 2007b). Key assumptions, limitations and uncertainties are briefly identified below, with emphasis on those sources of uncertainty considered most critical in interpreting risk results. In the presentation below, limitations (and associated uncertainty) are listed, beginning with those regarding design of the assessment or case studies, followed by those regarding estimation of Pb concentrations in ambient air indoor dust, outdoor soil/dust, and blood, and lastly regarding estimation of Pb-related IQ loss.

• *Temporal aspects:* Exposure modeling uses a 7 year exposure period for each simulated child, during which time, media concentrations remain fixed (at levels associated with the ambient air Pb level being modeled) and the child remains at the same residence, while exposure factors and physiological parameters are adjusted to match the age of the child. These aspects are a simplification of population exposures that contributes some uncertainty to our exposure and risk estimates.

• *General urban case study:* As described in section II.C.2.c, this case study is not based on a specific location and is instead intended to represent a smaller neighborhood experiencing ambient air Pb levels at or near the standard of interest. Consequently, it assumes (a) a single exposure zone within which all media concentrations of Pb are assumed to be spatially uniform and (b) a uniformly distributed population of unspecified size. While these assumptions are reasonable in the context of evaluating risk for a smaller subpopulation located close to a monitor reporting values at or near the standard of interest, there is significant uncertainty associated with extrapolating these risks to a specific urban location, particularly if that urban location is relatively large, given that larger urban areas are expected to have increasingly varied patterns of ambient air Pb levels and population density. The risk estimates for this general urban case study, while generally representative of an urban residential population exposed to the specified ambient air Pb levels, cannot be readily related to a specific large urban population.

• *Location-specific urban case studies:* The Pb-TSP monitoring network is currently quite limited and consequently, the number of monitors available to represent air concentrations in these case studies is limited, ranged from six for Cleveland to 11 for Chicago. Accordingly, our estimates of the magnitude of and spatial variation of air Pb concentrations are subject to uncertainty associated with the limited monitoring data and method used in extrapolating from those data to characterize an ambient air Pb level surface for these modeled urban areas. Details on the approach used to derive ambient air Pb surfaces for the urban case studies based on monitoring data are presented in Section 5.1.3 of the Risk Assessment Report (USEPA, 2007b). As recognized in Section, III.B.2.a, the analyses for these case studies were developed in response to CASAC recommendations on the July 2007 draft Risk Assessment (Henderson, 2007b). Subsequently, the CASAC has reviewed the approach used in conducting the final draft of the full-scale risk assessment, including the inclusion of the location-specific urban case studies and expressed broad support for the technical approach used (Henderson, 2008).

• *Current NAAQS air quality scenarios:* For the location-specific urban case studies, proportional roll-up procedures were used to adjust ambient air Pb concentrations up to just meet the current NAAQS (a detailed discussion is provided in Sections 2.3.1 and 5.2.2.1 of the Risk Assessment Report, USEPA, 2007b). This procedure was used to provide insights into the degree of risk which could be associated with ambient air Pb levels at or near the current standard in urban areas. EPA recognizes that it is extremely unlikely that Pb concentrations would rise to just meet the current NAAQS in urban areas nationwide and that there is substantial uncertainty with our simulation of such conditions. For the primary Pb smelter case study, where current conditions exceed the current NAAQS, attainment of the current NAAQS was simulated using air quality modeling, emissions and source parameters used in developing the 2007 proposed revision to the State Implementation Plan for the area (described in Section 3.1.1.2 of the Risk Assessment Report (USEPA, 2007b)).

• *Alternative NAAQS air quality scenarios:* In all case studies, proportional roll-down procedures were used to adjust ambient air Pb concentrations downward to attain alternative NAAQS (described in Sections 2.3.1 and 5.2.2.1 of the Risk Assessment Report, USEPA, 2007b). There is significant uncertainty in simulating conditions associated with the implementation of emissions reduction actions to meet a lower standard.

• *Estimates of outdoor soil/dust Pb concentrations:* Outdoor soil Pb concentration for both the urban case studies and the primary Pb smelter case study are based on empirical data (as described in Section 3.1.3 of the Risk Assessment). To the extent that these data are from areas containing older structures, the impact of Pb paint weathered from older structures on soil Pb levels will be reflected in these empirical estimates. In the case of the urban case studies, a mean value from a sample of houses built between 1940 and 1998 was used to represent soil Pb levels (as described in Section 3.1.3.1 of the Risk Assessment). In the case of the primary Pb smelter case study subarea, site-specific data are used. As there has been remediation of soil in this subarea, the measurements do not reflect historical air quality. Additionally,

would reflect greater heterogeneity in the study population with regard to Pb exposure and blood Pb response.

studies since remediation have reported increasing soil Pb levels indicating that soil concentrations are still responding to current air quality, and consequently underestimate eventual steady state conditions for the current air quality. In all case studies, the same outdoor soil/dust Pb concentrations (based on these datasets) are used for all air quality scenarios (i.e., the potential longer-term impact of reductions in ambient air Pb on outdoor soil/dust Pb levels and associated impacts on indoor dust Pb have not be simulated). In areas where air concentrations have been greater in the past, however, implementation of a reduced NAAQS might be expected to yield reduced soil Pb levels over the long term. As described in Section 2.3.3 of the Risk Assessment Report (USEPA, 2007b), however, there is potentially significant uncertainty associated with this conclusion, particularly with regard to implications for areas in which a Pb source may locate where one of comparable size had not been previously. Additionally, it is possible that control measures implemented to meet alternative NAAQS may result in changes to soil Pb concentrations; these are not reflected in the assessment.

• *Estimates of indoor dust Pb concentrations for the urban case studies (application of the hybrid model)*: The hybrid mechanistic-empirical model for estimating indoor dust Pb for the urban case studies (as described in Section 3.1.4.1 of the Risk Assessment Report, USEPA, 2007b) utilizes a mechanistic model to simulate the exchange of outdoor ambient air Pb indoors and subsequent deposition (and buildup) of Pb on indoor surfaces, which relies on a number of empirical measurements for parameterization (e.g., infiltration rates, deposition velocities, cleaning frequencies and efficiencies). There is considerable uncertainty associated with these parameter estimates. In addition, there is uncertainty associated with the partitioning of total indoor dust Pb estimates between the infiltration-related (''recent air'') component and other contributions (''other'' as described in section II.C.2.e).

• *Estimates of indoor dust Pb concentrations for the primary Pb smelter case study (application of the site-specific regression model)*: There is uncertainty associated with the site-specific regression model applied in the remediation zone (as described in Section 3.1.4.2 of the Risk Assessment Report), and relatively greater uncertainty associated with its application to air quality scenarios that simulate notably lower air Pb levels (as is typically the case when applying regression-based models beyond the bounds of the datasets used in their derivation). The log-log form of the regression model prevents the ready identification of an intercept term handicapping us in partitioning estimates of air-related indoor dust (and consequently exposure and risk estimates) between ''recent air'' and ''other'' components. In addition, limitations in the model-derived air estimates used in deriving the regression model prevented effective consideration for the role of ambient air Pb related to resuspension in influencing indoor dust Pb levels. A public commenter suggested that indoor dust Pb levels using this model may be overestimated due to factors associated with the model's derivation. Factors identified by the commenter, however, may contribute to a potential for either over- or underestimation, and as noted by the commenter, additional research might reduce this uncertainty.

• *Characterizing interindividual variability using a GSD:* There is uncertainty associated with the GSD specified for each case study (as described in Sections 3.2.3 and 5.2.2.3 of the Risk Assessment Report). Two factors are described here as contributors to that uncertainty. Interindividual variability in blood Pb levels for any study population (as described by the GSD) will reflect, to a certain extent, spatial variation in media concentrations, including outdoor ambient air Pb levels and indoor dust Pb levels, as well as differences in physiological response to Pb exposure. For each case study, there is significant uncertainty in the specification of spatial variability in ambient air Pb levels and associated indoor dust Pb levels, as noted above. In addition, there are a limited number of datasets for different types of residential child populations from which a GSD can be derived (e.g., NHANES datasets [94] for more heterogeneous populations and individual study datasets for likely more homogeneous populations near specific industrial Pb sources). This uncertainty associated with the GSDs introduces significant uncertainty in exposure and risk estimates for the 95th population percentile.

• *Exposure pathway apportionment for higher percentile blood Pb level and IQ loss estimates:* Apportionment of blood Pb levels for higher population percentiles is assumed to be the same as that estimated using the central tendency estimate of blood Pb in an exposure zone. This introduces significant uncertainty into projections of pathway apportionment for higher population percentiles of blood Pb and IQ loss. In reality, pathway apportionment may differ in higher exposure percentiles. For example, paint and/or drinking water exposures may increase in importance, with air-related contributions decreasing as an overall percentage of blood Pb levels and associated risk. Because of this uncertainty related to pathway apportionment, as mentioned earlier, greater confidence is placed in estimates of total Pb exposure and risk in evaluating the impact of the current NAAQS and alternative NAAQS relative to current conditions.

• *Relating blood Pb levels to IQ loss:* Specification of the quantitative relationship between blood Pb level and IQ loss is subject to significant uncertainty at lower blood Pb levels (e.g., below 5 µg/dL concurrent blood Pb). As discussed earlier, there are limitations in the datasets and concentration-response analyses available for characterizing the concentration-response relationship at these lower blood Pb levels. For example, the pooled international dataset analyzed by Lanphear and others (2005) includes relatively few children with blood Pb levels below 5 µg/dL and no children with levels below 1 µg/dL. In recognition of the uncertainty in specifying a quantitative concentration-response relationship at such levels, our core modeling approach involves the application of four different functions to generate a range of risk estimates (as described in Section 4.2.6 and Section 5.3.1 of the Risk Assessment Report, USEPA, 2007b). The difference in absolute IQ loss estimates for the four concentration-response functions for a given case study/air quality scenario combination is typically close to a factor of 3. Estimates of differences in IQ loss between air quality scenarios (in terms of percent), however, are more similar across the four functions, although the function producing higher overall risk estimates (the dual linear function, stratified at 7.5 µg/dL, peak blood Pb) also produces larger absolute reductions in IQ loss compared with the other three functions.

3. Summary of Estimates and Key Observations

This section presents blood Pb and IQ loss estimates generated in the exposure and risk assessments. Blood Pb estimates (and air-to-blood Pb ratios) are presented first, followed by IQ loss estimates.

[94] The GSD for the urban case studies, in the risk assessment described in this notice, was derived using NHANES data for the years 1999–2000.

a. Blood Pb Estimates

This section presents a summary of blood Pb modeling results for concurrent blood Pb drawn from the more detailed presentation in the Staff Paper and the Risk Assessment Report (USEPA, 2007a, 2007b, 2007c).

Blood Pb level estimates for the current conditions air quality scenarios for these case studies differ somewhat from the national values associated with recent NHANES information. For example, median blood Pb levels for the current conditions scenario for the urban case studies are somewhat larger than the national median from the NHANES data for 2003–2004. Specifically, values for the three location-specific urban case studies range from 1.7 to 1.8 μg/dL with the general urban case study having a value of 1.9 μg/dL (current-conditions mean) (presented in Risk Assessment Report, Volume I, Table 5–5), while the median value from NHANES (2003–2004) is 1.6 μg/dL (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*). Additionally, NHANES values for the 90th percentile (for 2003–2004) were identified and these values can be compared against 90th percentile estimates generated for the urban case studies (see Risk Assessment Report, Appendix O, Section O.3.2 for the location-specific urban case study and Appendix N, Section N.2.1.2 for the general urban case study). The 90th percentile blood Pb levels for the current conditions scenario, for the three location-specific urban case studies range from 4.5 to 4.6 μg/dL, while the estimate for the general urban case study is 5.0 μg/dL. These 90th percentile values for the case study populations are larger than the 90th percentile value of 3.9 μg/dL reported by NHANES for all children in 2003–2004. It is noted that ambient air levels reflected in the urban case studies are likely to differ from those underlying the NHANES data.[95]

Table 2 presents total blood Pb estimates for alternative standards, focusing on the median in the assessed population, and associated estimates for the air-related percentage of total blood Pb (i.e., bounded on the low end by the ''recent air'' contributions and on the high end by the ''recent'' plus ''past air'' contribution to total Pb exposure).

Generally, 95th percentile blood Pb estimates across air quality scenarios for all case studies (not shown here) are 2–3 times higher than the median estimates in Table 2. For example, 95th percentile estimates of total blood Pb for the current NAAQS scenario are 10.6 μg/dL for the general urban case study, 12.3 μg/dL for the primary Pb smelter subarea, and 7.4 to 10.2 μg/dL for the three location-specific urban case studies (Staff Paper, Table 4–2). While the estimates indicate similar fractions of total blood Pb that is air-related between the 95th percentile and median, there is greater uncertainty in pathway apportionment among air-related and other sources for higher percentiles, including the 95th percentile.

TABLE 2.—SUMMARY OF MEDIAN BLOOD PB ESTIMATES FOR CONCURRENT BLOOD PB

[Total]

NAAQS Level simulated (μg/m³ max monthly, except as noted below)	Total blood Pb (μg/dL) (air-related percentage) [A]				
	General urban case study	Primary Pb smelter (subarea) case study [B C]	Location-specific urban case studies		
			Cleveland (0.56 μg/m³)	Chicago (0.31 μg/m³)	Los Angeles (0.17 μg/m³)
1.5 max quarterly [D]	3.1 (61 to 84%)	4.6 (up to 87%)	2.1 [D] (57 to 86%)	3.0 [E] (63 to 83%)	2.6 [E] (50 to 81%).
0.50	2.2 (41 to 73%)	3.2 (up to 81%)	1.8 (39 to 72%)	([F])	([F])
0.20	1.9 (26 to 74%)	2.3 (up to 78%)	1.7 (6 to 65%)	1.8 (17 to 67%)	1.7 ([G]) (18 to 71%).
0.05	1.7 (12 to 65%)	1.7 (up to 65%)	1.6 (1 to 63%)	1.6 (6 to 69%)	1.6 (13 to 69%).
0.02	1.6 (6 to 69%)	1.6 (up to 69%)	1.6 (1 to 63%)	1.6 (1 to 63%)	1.6 (6 to 63%).

[A]—Blood Pb estimates are rounded to one decimal place. Air-related percentage is bracketed by ''recent air'' (lower bound of presented range) and ''recent'' plus ''past air'' (upper bound of presented range). The term ''past air'' includes contributions from the outdoor soil/dust contribution to indoor dust, historical air contribution to indoor dust, and outdoor soil/dust pathways; ''recent air'' refers to contributions from inhalation of ambient air Pb or ingestion of indoor dust Pb predicted to be associated with outdoor ambient air Pb levels, with outdoor ambient air also potentially including resuspended, previously deposited Pb (see Section II.C.2.e).

[B]—In the case of the primary Pb smelter subarea, only recent plus past air estimates are available.

[C]—Median blood Pb levels for the primary smelter (full study area) are estimated at 1.5 μg/dL (for the 1.5 μg/m³ max quarterly level) and 1.4 μg/dL for the remaining NAAQS levels simulated. The air-related percentages for these standard levels range from 36% to 79%.

[D]—This corresponds to roughly 0.7–1.0 μg/m³ maximum monthly mean, across the urban case studies.

[E]—A ''roll-up'' was performed so that the highest monitor in the study area is increased to just meet this level.

[F]—A ''roll-up'' to this level was not performed.

[G]—A ''roll-up'' to this level was not performed; these estimates are based on current conditions in this area.

As described in section II.C.2.f, the risk assessment also developed estimates for air-to-blood ratios, which are described in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b). These ratios reflect a subset of air-related pathways related to inhalation and ingestion of indoor dust; inclusion of the remaining pathways would be expected to yield higher ratios. Additionally, these ratios are based on blood Pb estimates for the 7th year of exposure (concurrent blood Pb) which are lower than blood Pb estimates at younger ages (and than the lifetime-averaged blood Pb metric). Ratios based on other blood Pb estimates (e.g., lifetime-averaged or peak blood Pb) would be higher.

- For the general urban case study, estimates of air-to-blood ratios, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b) ranged from 1:2 to 1:9, with the majority of the estimates ranging from 1:4 to 1:6.[96] As noted in Section II.C.2.f,

[95] The maximum quarterly mean Pb concentrations in the location-specific case studies ranged from 0.09–0.36 μg/m³, which are higher levels than the maximum quarterly mean values in most monitoring sites in the U.S. The median of the maximum quarterly mean values across all sites in the 2003–05 national dataset is 0.03 μg/m³ (USEPA, 2007a, appendix A).

[96] The ratios increase as the level of the alternate standard decreases. This reflects nonlinearity in the Pb response, which is greater on a per-unit basis for lower ambient air Pb levels.

because the risk assessment only reflects the impact of reductions on recent air-related pathways in predicting changes in indoor dust Pb for urban case studies, these ratios are lower than they would be if they had also reflected potential reductions in other air-related pathways (e.g., changes in outdoor surface soil/dust Pb levels and diet with changes in ambient air Pb levels). We also note that the median blood Pb levels associated with exposure pathways that were not varied in this assessment (and consequently are not reflected in these ratios) generally range from 1.3 to 1.5 µg/dL for this case study.

• For the primary Pb smelter subarea, estimates of air-to-blood ratios, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b) ranged from 1:10 and higher.[97] [98] One reason for these estimates being higher than those for the urban case study is that the dust Pb model used may reflect somewhat ambient air-related pathways other than that of ambient air infiltrating a home (as described in Section II.C.2.f above).[99]

b. IQ Loss Estimates

The risk assessment estimated IQ loss associated with both total Pb exposure and air-related Pb exposure. This section focuses on findings in relation to air-related Pb exposure, since this is the category of risk results considered most relevant to the review in considering whether the current NAAQS and potential alternative NAAQS provide protection of public health with an adequate margin of safety (additional categories of risk results, including IQ loss estimates based on total Pb exposure and population incidence results, are presented at the end of the section).[100]

In considering air-related risk results, we note that IQ loss associated with air-related exposure for each NAAQS scenario is bounded by *recent-air* on the low-end and *recent plus past air* on the high-end (as described in section II.C.2.e above). In considering differences in these risk estimates (or in the total risk estimates presented in the final Risk Assessment Report) for alternative NAAQS, we note that these comparisons underestimate the true impacts of the alternate NAAQS and accordingly, the benefit to public health that would result from lower NAAQS levels. This is due to our inability to simulate in this assessment reductions in several outdoor air deposition-related pathways (e.g., diet, ingestion of outdoor surface soil). The magnitude of this underestimation is unknown.

As with the discussion of blood Pb results, the IQ loss estimates are summarized here according to air quality scenario and case study category (Table 3). In presenting these results, we have focused this presentation on estimates for the median in each case study population of children because of the greater confidence associated with estimates for the median as compared to those for 95th percentile.[101] Generally, 95th percentile IQ loss estimates for all case studies are 80 to 100% higher than the median results in Table 3. The fraction of total IQ loss that is air-related for the 95th percentile is generally similar to that for the median (for a particular combination of case study and air quality scenario).

The risk estimates presented in boldface in Table 3 are those derived using the log-linear with low-exposure linearization concentration-response function, while the range of estimates associated with all four concentration-response functions is presented in parentheses. These functions are discussed above in section II.C.2.b.

[97] As with such estimates for the urban case study, ratios are higher at lower ambient air Pb levels, reflecting the nonlinearity of the dust Pb response with air concentration.

[98] For the primary Pb smelter (full study area), for which limitations are noted above in section II.C.2.c, the air-to-blood ratio estimates, presented in section 5.2.5.2 of the Risk Assessment Report (USEPA, 2007b), ranged from 1:3 to 1:7. As in the other case studies, ratios are higher at lower ambient air Pb levels. It is noted that the underlying changes in both ambient air Pb and blood Pb across standard levels are extremely small, introducing uncertainty into ratios derived using these data.

[99] Also, as noted above (Section II.C.2.h), there is increased uncertainty with application of this regression-based model in air quality scenarios of notably lower air Pb levels than the data set used in its derivation.

[100] The detailed results are provided in the Risk Assessment Report (USEPA, 2007b).

[101] A complete presentation of risk estimates is available in the final Risk Assessment Report, including a presentation of estimates for the 95th percentile in Table 5–10 of that report.

TABLE 3.—SUMMARY OF RISK ATTRIBUTABLE TO AIR-RELATED PB EXPOSURE

NAAQS level simulated (μg/m³ max monthly, except as noted below)	Median air-related IQ loss [A]				
	General urban case study	Primary Pb smelter (sub-area) case study [B, C]	Location-specific urban case studies		
			Cleveland (0.56 μg/m³)	Chicago (0.31 μg/m³)	Los Angeles (0.17 μg/m³)
1.5 max quarterly [D]	3.5–4.8	< 6	2.8–3.9 [E]	3.4–4.7 [E]	2.7–4.2 [E]
	(1.5–7.7)	<(3.2–9.4)	(0.6–4.6)	(1.4–7.4)	(1.1–6.2)
0.5	1.9–3.6	< 4.5	0.6–2.9	[F]	[F]
	(0.7–4.8)	<(2.1–7.7)	(0.2–3.9)		
0.2	1.2–3.2	< 3.7	0.6–2.8	0.6–2.9	0.7–2.9 [G]
	(0.4–4.0)	<(1.2–5.1)	(0.1–3.2)	(0.3–3.6)	(0.2–3.5)
0.05	0.5–2.8	< 2.8	0.1–2.6	0.2–2.6	0.3–2.7
	(0.2–3.3)	<(0.9–3.4)	(<0.1–3.1)	(0.1–3.2)	(0.1–3.2)
0.02	0.3–2.6	< 2.9	<0.1–2.6	0.1–2.6	0.1–2.6
	(0.1–3.1)	<(0.9–3.3)	(<0.1–3.0)	(<0.1–3.1)	(<0.1–3.1)

[A]—Air-related risk is bracketed by ''recent air'' (lower bound of presented range) and ''recent'' plus ''past air'' (upper bound of presented range). While differences between standard levels are better distinguished by differences in the ''recent'' plus ''past air'' estimates (upper bounds shown here), these differences are inherently underestimates. The term ''past air'' includes contributions from the outdoor soil/dust contribution to indoor dust, historical air contribution to indoor dust, and outdoor soil/dust pathways; ''recent air'' refers to contributions from inhalation of ambient air Pb or ingestion of indoor dust Pb predicted to be associated with outdoor ambient air Pb levels, with outdoor ambient air also potentially including resuspended, previously deposited Pb (see Section II.C.2.e). Boldface values are estimates generated using the log-linear with low-exposure linearization function. Values in parentheses reflect the range of estimates associated with all four concentration-response functions.

[B]—In the case of the primary Pb smelter case study, only recent plus past air estimates are available.

[C]—Median air-related IQ loss estimates for the primary Pb smelter (full study area) range from <1.7 to <2.9 points, with no consistent pattern across simulated NAAQS levels. This lack of a pattern reflects inclusion of a large fraction of the study population with relatively low ambient air impacts such that there is lower variation (at the population median) across standard levels (see Section 4.2 of the Risk Assessment, Volume 1).

[D]—This corresponds to roughly 0.7—1.0 μg/m³ maximum monthly mean, across the urban case studies

[E]—A ''roll-up'' was performed so that the highest monitor in the study area is increased to just meet this level.

[F]—A ''roll-up'' to this level was not performed.

[G]—A ''roll-up'' to this level was not performed; these estimates are based on current conditions in this area.

Key observations regarding the median estimates of air-related risk for the current NAAQS and alternative standards presented in Table 3 include:

• For the scenario for the current NAAQS (1.5 μg/m³, maximum quarterly average), air-related risk exceeds 2 points IQ loss at the median and the upper bound of air-related risk is near or above 4 points IQ loss in all five case studies.[102]

• Alternate standards provide substantial reduction in estimates of air-related risk across the full set of alternative NAAQS considered in this analysis (i.e., 0.5 to 0.02 μg/m³ max monthly). This is particularly the case for the lower bounds of the air-related estimates presented in Table 3, which reflect the estimates for ''recent air''-related pathways, which are the pathways that were varied with changes in air concentrations (as described above in section II.C.2.e). There is less risk reduction associated with the upper bounds of these estimates as the upper bound values are inclusive of the exposure pathways categorized as ''past air'' which were not varied with changes in air concentrations (as described in section II.C.2.3). The upper bound estimates for the lowest level assessed (0.02 μg/m³) are 2.6–2.9 points IQ loss.

• In the general urban case study, the lower bound of air-related risk falls below 2 points IQ loss for an alternative NAAQS of 0.5 μg/m³ max monthly, and below 1 point IQ loss somewhere between an alternative NAAQS of 0.2 and 0.05 μg/m³ max monthly.

• The upper-bound of air-related risk for the primary Pb smelter subarea is generally higher than that for the general urban case study, likely due to the difference in indoor dust models used for the two case studies. The indoor dust Pb model used for the primary Pb smelter considered more completely, the impact of outdoor ambient air Pb on indoor dust (compared to the hybrid indoor dust Pb model used in the urban case studies). Specifically, the regression model used for the primary Pb smelter included consideration for longer-term relationships between outdoor ambient air and indoor dust (e.g., changes in outdoor soil and subsequent tracking in of soil Pb).

• As noted above (section II.C.2.c), the three location-specific urban case studies provide risk estimates for populations with a broader range of air-related exposures. Accordingly, because of the population distribution in these three case studies, the air-related risk is smaller for them than for the other case studies, particularly at the population median. Further, the majority of the population in each case study resides in areas with ambient air Pb levels well below each standard level assessed, particularly for levels above 0.05 μg/m³ max monthly. Consequently, risk estimates indicate little response to alternative standard levels above 0.05 μg/m³ max monthly.

In addition to the air-related risk results described above, we present two additional categories of risk results, including (a) estimates of median IQ loss based on total Pb exposure for each case study (Table 4) and (b) IQ loss incidence estimates for each of the location-specific case studies (Tables 4 and 5).[103] Each of these categories of risk results are described in creater detail below:

• *Estimates of IQ loss for all air quality scenarios (based on total Pb exposure):* Table 4 presents median IQ loss estimates for total Pb exposure for each of the air quality scenarios simulated for each case study (as noted earlier in this section, there is greater uncertainty associated with higher-end risk percentiles and therefore, they are

[102] As noted in Table 3 and section II.C.2.d above, and discussed further, with regard to associated limitations and uncertainties, in section II.C.2.h above, a proportional roll-up procedure was used to estimate air Pb concentrations in this scenario for the location-specific case studies.

[103] As recognized in section II.C.2.d above, to simulate air concentrations associated with the current NAAQS, a proportional roll-up of concentrations from those for current conditions was performed for the location-specific urban case studies. This was not necessary for the primary Pb smelter case study in which air concentrations currently exceed the current standard.

not presented in tabular format here—see Table 5–10 of Risk Assessment Volume 1 for 95th percentile total IQ loss estimates). As with the incremental risk results presented in Table 3 above, in order to reflect the variation in estimates derived from the four different concentration-response functions included in the analysis, three categories of estimates are presented in Table 4 including (a) IQ loss estimates generated using the low concentration-response function (the model that generated the lowest IQ loss estimates), (b) estimates generated using the log-linear with low-exposure linearization (LLL) model, and (c) IQ loss estimates generated using the high concentration-response function (the model that generated the highest IQ loss estimates). It is important to emphasize, that, as noted in Section II.C.2.e, because of limitations in modeling methods, we were only able to simulate reduction in recent air-related exposures in considering alternate standard levels and could not simulate reduction in past air-related exposures. This likely results in an underestimate of the total degree of reduction in exposure and risk associated with each standard level. Therefore, in comparing total risk estimates between alternate NAAQS scenarios (i.e., considering incremental risk reductions), this aspect of the analysis will tend to underestimate the reductions in risk associated with alternative NAAQS.

• *IQ loss incidence estimates for the three location-specific urban case studies:* Estimates of the number of children for each location-specific urban case study projected to have total Pb-related IQ loss greater than one point are summarized in Table 5, and similar estimates for IQ loss greater than 7 points are summarized in Table 6. Also presented are the changes in incidence of the current NAAQS and alternative NAAQS scenarios compared to current conditions, with emphasis placed on estimates generated using the LLL concentration-response function. Estimates are presented for each of the four concentration-response functions used in the risk analysis. This metric illustrates the overall number of children within a given urban case study location projected to experience various levels of IQ loss due to Pb exposure and how that distribution of incidence changes with alternate standard levels. These incidence estimates were only generated for the location-specific urban case studies, since these have larger enumerated study populations (additional detail on the derivation of these incidence estimates is presented in Section 5.3.1.2 of the Risk Assessment Report). The complete set of incidence results is presented in Risk Assessment Report Appendix O, Section O.3.4.

Total IQ loss results presented in Table 4 for the primary Pb smelter case study (full study area) illustrate the reason why these results were not presented earlier in summarizing air-related IQ loss estimates for the primary Pb smelter case study in Table 3 (and instead, results for the subarea were presented). As mentioned earlier in Section II.C.2.c, the full study area for the primary Pb smelter case study incorporates a large number of simulated children with relatively low air-related impacts, which results in little differentiation between alternate standard levels in terms of total IQ loss (as well as air-related IQ loss). This can be seen by considering the results in Table 4 for the primary Pb smelter (full study area). Those results suggest that total IQ loss varies little across alternate standard levels for the full study area simulation, with the only noticeable difference in total IQ loss resulting from analysis of the current standard (when compared to alternate levels). By contrast, there are notable differences in total IQ loss between alternative standard levels for the sub-area of the primary Pb smelter case study.

TABLE 4.—SUMMARY OF RISK ESTIMATES FOR MEDIANS OF TOTAL-EXPOSURE RISK DISTRIBUTIONS

Case study and air quality scenario	Points IQ loss (total Pb exposure) [a]		
	Low C–R function estimate	LLL [b]	High C–R function estimate
Location-specific (Chicago)			
Current NAAQS (1.5 μg/m³, max quarterly)	2.4	5.6	8.8
Current conditions (0.14 μg/m³ max quarterly; 0.31 μg/m³ max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.2 μg/m³, max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.05 μg/m³, max monthly)	1.3	4.0	4.8
Alternative NAAQS (0.02 μg/m³, max monthly)	1.3	4.0	4.7
Location-specific (Cleveland)			
Current NAAQS (1.5 μg/m³, max quarterly)	1.7	4.7	6.3
Current conditions (0.36 μg/m³ max quarterly; 0.56 μg/m³ max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.5 μg/m³, max monthly)	1.4	4.2	5.2
Alternative NAAQS (0.2 μg/m³, max quarterly)	1.4	4.1	5.0
Alternative NAAQS (0.2 μg/m³, max monthly)	1.3	4.1	4.9
Alternative NAAQS (0.05 μg/m³, max monthly)	1.3	4.0	4.7
Alternative NAAQS (0.02 μg/m³, max monthly)	1.2	3.9	4.6
Location-specific (Los Angeles)			
Current NAAQS (1.5 μg/m³, max quarterly)	2.1	5.3	7.7
Current conditions (0.09 μg/m³ max quarterly; 0.17 μg/m³ max monthly)	1.4	4.2	5.1
Alternative NAAQS (0.05 μg/m³, max monthly)	1.3	4.0	4.8
Alternative NAAQS (0.02 μg/m³, max monthly)	1.3	4.0	4.7
General Urban			
Current NAAQS (1.5 μg/m³, max quarterly)	2.5	5.8	9.2

TABLE 4.—SUMMARY OF RISK ESTIMATES FOR MEDIANS OF TOTAL-EXPOSURE RISK DISTRIBUTIONS—Continued

Case study and air quality scenario	Points IQ loss (total Pb exposure) [a]		
	Low C–R function estimate	LLL [b]	High C–R function estimate
Alternative NAAQS (0.5 μg/m³, max monthly)	1.7	4.8	6.4
Current conditions—high-end (0.87 μg/m³ max quarterly)	1.7	4.7	6.3
Alternative NAAQS (0.2 μg/m³, max quarterly)	1.6	4.6	5.9
Current conditions—mean (0.14 μg/m³ max quarterly)	1.5	4.5	5.6
Alternative NAAQS (0.2 μg/m³, max monthly)	1.5	4.4	5.6
Alternative NAAQS (0.05 μg/m³, max monthly)	1.3	4.1	5.0
Alternative NAAQS (0.02 μg/m³, max monthly)	1.3	4.0	4.8
Primary Pb smelter—full study area			
Current NAAQS (1.5 μg/m³, max quarterly)	1.2	3.8	4.4
Alternative NAAQS (0.5 μg/m³, max monthly)	1.0	3.7	4.2
Alternative NAAQS (0.2 μg/m³, max quarterly)	0.9	3.6	4.2
Alternative NAAQS (0.2 μg/m³, max monthly)	0.9	3.6	4.1
Alternative NAAQS (0.05 μg/m³, max monthly)	0.9	3.6	4.0
Alternative NAAQS (0.02 μg/m³, max monthly)	0.9	3.6	4.1
Primary Pb smelter—1.5km subarea			
Current NAAQS (1.5 μg/m³, max quarterly)	3.7	6.8	11.2
Alternative NAAQS (0.5 μg/m³, max monthly)	2.6	5.8	9.4
Alternative NAAQS (0.2 μg/m³, max quarterly)	2.0	5.2	7.4
Alternative NAAQS (0.2 μg/m³, max monthly)	1.9	5.0	6.9
Alternative NAAQS (0.05 μg/m³, max monthly)	1.4	4.2	5.1
Alternative NAAQS (0.02 μg/m³, max monthly)	1.3	4.0	4.8

[a]—These columns present the estimates of total IQ loss resulting from total Pb exposure (policy-relevant plus background). Estimates below 1.0 are rounded to one decimal place, all values below 0.05 are presented as <0.1 and values between 0.05 and 0.1 as 0.1. All values above 1.0 are rounded to the nearest whole number.
[b]—Log-linear with low-exposure linearization concentration-response function.

TABLE 5.—INCIDENCE OF CHILDREN WITH >1 POINT PB-RELATED IQ LOSS

Air quality scenario (for location-specific urban case studies)	Dual linear—stratified at 7.5 μg/dl peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 μ/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of >1 point IQ loss	Delta (change inincidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)
Chicago (total modeled child population: 396,511):								
Chicago Current Conditions	391,602	.....	389,754	.....	271,031	.....	236,257	
Current NAAQS (1.5 μg/m³ Maximum Quarterly)	395,797	4,195	395,528	5,773	347,415	76,384	314,053	77,795
Alternative NAAQS (0.2 μg/m³ Maximum Monthly)	391,158	−444	389,461	−293	271,444	412	235,559	−698
Alternative NAAQS (0.05 μg/m³ Maximum Monthly)	389,572	−2,030	387,407	−2,347	253,775	−17,256	224,394	−11,864
Alternative NAAQS (0.02 μg/m³ Maximum Monthly)	389,176	−2,427	386,630	−3,125	249,865	−21,166	219,294	−16,963
Cleveland (total modeled child population: 13,990):								
Cleveland Current Conditions	13,809	.....	13,745	.....	9,526	.....	8,515	
Current NAAQS (1.5 μg/m³ Maximum Quarterly)	13,893	84	13,857	112	10,664	1,137	9,769	1,254
Alternative NAAQS (0.2 μg/m³ Maximum Quarterly)	13,770	−38	13,703	−42	9,221	−305	8,160	−354
Alternative NAAQS (0.5 μg/m³ Maximum Monthly)	13,789	−20	13,720	−25	9,497	−29	8,464	−51
Alternative NAAQS (0.2 μg/m³ Maximum Monthly)	13,759	−50	13,694	−51	9,083	−443	8,010	−505
Alternative NAAQS (0.05 μg/m³ Maximum Monthly)	13,729	−80	13,642	−103	8,785	−741	7,720	−795
Alternative NAAQS (0.02 μg/m³ Maximum Monthly)	13,720	−88	13,628	−117	8,736	−790	7,668	−846
Los Angeles (total modeled child population: 372,252):								
Los Angeles Current Conditions	282,216	.....	280,711	.....	191,675	.....	170,474	.....
Current NAAQS (1.5 μg/m³ Maximum, Quarterly)	285,272	3,056	284,945	4,234	240,988	49,313	226,608	56,134

TABLE 5.—INCIDENCE OF CHILDREN WITH >1 POINT PB-RELATED IQ LOSS—Continued

Air quality scenario (for location-specific urban case studies)	Dual linear—stratified at 7.5 μg/dl peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 μ/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of >1 point IQ loss	Delta (change inincidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)	Incidence of >1 point IQ loss	Delta (change in incidence compared to current conditions)
Alternative NAAQS (0.05 μg/m³ Maximum Monthly)	281,112	−1,104	279,658	−1,053	183,395	−8,280	161,914	−8,560
Alternative NAAQS (0.02 μg/m³ Maximum Monthly)	280,740	−1,476	279,057	−1,654	180,745	−10,929	158,234	−12,240

TABLE 6.—INCIDENCE OF CHILDREN WITH >7 POINTS PB-RELATED IQ LOSS

Air quality scenario (location-specific urban case studies)	Dual linear—stratified at 7.5 ug/dL peak blood Pb		Log-linear with linearization		Dual linear—stratified at 10 ug/dL peak blood Pb		Log-linear with cutpoint	
	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)	Incidence of > 7 points IQ loss	Delta (change in incidence compared to current conditions)
Chicago (total modeled child population: 396,511):								
Chicago Current Conditions	136,709	.....	33,664	.....	63	.....	1,015	.....
Current NAAQS (1.5 μg/m³ Maximum Quarterly)	244,401	107,692	100,159	66,495	555	492	5,226	4,211
Alternative NAAQS (0.2 μg/³ Maximum Monthly)	136,067	−642	32,546	−1,118	48	−16	1,007	−8
Alternative NAAQS (0.05 μg/³ Maximum Monthly)	120,706	−16,003	27,367	−6,297	16	−48	864	−151
Alternative NAAQS (0.02 μg/³ Maximum Monthly)	117,819	−18,890	26,027	−7,637	8	−56	690	−325
Cleveland (total modeled child population: 13,990):								
Cleveland Current Conditions	4,834	.....	1,212	.....	3	.....	46	.....
Current NAAQS (1.5 μg/m³ Maximum Quarterly)	6,139	1,305	1,858	647	4	2	105	59
Alternative NAAQS (0.2 μg/m³ Maximum Quarterly)	4,525	−309	1,073	−139	1	−2	40	−6
Alternative NAAQS (0.5 μg/m³ Maximum Monthly)	4,806	−28	1,180	−31	1	−2	43	−3
Alternative NAAQS (0.2 μg/m³ Maximum Monthly)	4,424	−410	1,026	−186	1	−2	43	−3
Alternative NAAQS (0.05 μg/m³ Maximum Monthly)	4,106	−728	886	−326	0	−3	24	−22
Alternative NAAQS (0.02 μg/m³ Maximum Monthly)	4,051	−783	866	−345	0	−3	27	−18
Los Angeles (total modeled child population: 372,252):								
Los Angeles Current Conditions	94,684	.....	22,665	.....	23	.....	732	.....
Current NAAQS (1.5 μg/m³ Maximum, Quarterly)	158,171	63,487	57,834	35,168	183	160	3,771	3,038
Alternative NAAQS (0.05 μg/m³ Maximum, Monthly)	87,303	−7,382	19,781	−2,884	11	−11	624	−109
Alternative NAAQS (0.02 μg/m³ Maximum, Monthly)	83,909	−10,775	17,939	−4,726	17	−6	498	−235

D. Conclusions on Adequacy of the Current Primary Standard

The initial issue to be addressed in the current review of the primary Pb standard is whether, in view of the advances in scientific knowledge and additional information, the existing standard should be retained or revised. In evaluating whether it is appropriate to retain or revise the current standard, the Administrator builds on the general approach used in the initial setting of the standard, as well as that used in the last review, and reflects the broader body of evidence and information now available.

The approach used is based on an integration of information on health effects associated with exposure to ambient Pb; expert judgment on the adversity of such effects on individuals; and policy judgments as to when the standard is requisite to protect public health with an adequate margin of safety, which are informed by air quality and related analyses, quantitative exposure and risk assessments when possible, and qualitative assessment of impacts that could not be quantified.

The Administrator has taken into account both evidence-based [104] and quantitative exposure- and risk-based considerations in developing conclusions on the adequacy of the current primary Pb standard. Evidence-based considerations include the assessment of evidence for a variety of

[104] The term ''evidence-based'' as used here refers to the drawing of information directly from published studies, with specific attention to those reviewed and described in the Criteria Document, and is distinct from considerations that draw from the results of the quantitative exposure and risk assessement.

Pb-related health endpoints from epidemiological, and animal toxicological studies. Consideration of quantitative exposure- and risk-based information draws from the results of the exposure and risk assessments described above. More specifically, estimates of the magnitude of Pb-related exposures and risks associated with air quality levels associated with just meeting the current primary Pb NAAQS have been considered.[105]

In this review, a series of general questions frames the approach to reaching a decision on the adequacy of the current standard, such as the following: (1) To what extent does newly available information reinforce or call into question evidence of associations of Pb exposures with effects identified when the standard was set?; (2) to what extent has evidence of new effects or at-risk populations become available since the time the standard was set?; (3) to what extent have important uncertainties identified when the standard was set been reduced and have new uncertainties emerged?; and (4) to what extent does newly available information reinforce or call into question any of the basic elements of the current standard?

The question of whether the available evidence supports consideration of a standard that is more protective than the current standard includes consideration of: (1) Whether there is evidence that associations with blood Pb in epidemiological studies extend to ambient Pb concentration levels that are as low as or lower than had previously been observed, and the important uncertainties associated with that evidence; (2) the extent to which exposures of potential concern and health risks are estimated to occur in areas upon meeting the current standard and the important uncertainties associated with the estimated exposures and risks; and (3) the extent to which the Pb-related health effects indicated by the evidence and the exposure and risk assessments are considered important from a public health perspective, taking into account the nature and severity of the health effects, the size of the at-risk populations, and the kind and degree of the uncertainties associated with these considerations.

This approach is consistent with the requirements of the NAAQS provisions of the Act and with how EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that, in the Administrator's judgment, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.

The following discussion starts with background information on the current standard (section II.D.1), including both the basis for derivation of the current standard and considerations and conclusions from the 1990 Staff Paper (USEPA, 1990b). This is followed by a discussion of the Agency's approach in this review for evaluating the adequacy of the current standard, in section II.D.2, including both evidence-based and exposure/risk-based considerations (sections II.D.2.a and b, respectively). CASAC advice and recommendations concerning adequacy of the current standard are summarized in section II.D.3. Lastly, the Administrator's proposed conclusions with regard to the adequacy of the current standard are presented in section II.D.4.

1. Background

a. The Current Standard

The current primary standard is set at a level of 1.5 $\mu g/m^3$, measured as Pb-TSP, not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. The standard was set in 1978 to provide protection to the public, especially children as the particularly sensitive population subgroup, against Pb-induced adverse health effects (43 FR 46246). In setting the standard, EPA relied on conclusions regarding sources of exposure, air-related exposure pathways, variability and susceptibility of young children, the most sensitive health endpoints, blood Pb level thresholds for various health effects and the stability and distributional characteristics of Pb (both in the human body and in the environment) (43 FR 46247). The specific basis for selecting each of the elements of the standard is described below.

i. Level

EPA's objective in selecting the level of the current standard was ''to estimate the concentration of Pb in the air to which all groups within the general population can be exposed for protracted periods without an unacceptable risk to health'' (43 FR 46252). As stated in the notice of final rulemaking, ''This estimate was based on EPA's judgment in four key areas:

(1) Determining the 'sensitive population' as that group within the general population which has the lowest threshold for adverse effects or greatest potential for exposure. EPA concludes that young children, aged 1 to 5, are the sensitive population.

(2) Determining the safe level of total lead exposure for the sensitive population, indicated by the concentration of lead in the blood. EPA concludes that the maximum safe level of blood lead for an individual child is 30 µg Pb/dl and that population blood lead, measured as the geometric mean, must be 15 µg Pb/dl in order to place 99.5 percent of children in the United States below 30 µg Pb/dl.

(3) Attributing the contribution to blood lead from nonair pollution sources. EPA concludes that 12 µg Pb/dl of population blood lead for children should be attributed to nonair exposure.

(4) Determining the air lead level which is consistent with maintaining the mean population blood lead level at 15 µg Pb/dl [the maximum safe mean level]. Taking into account exposure from other sources (12 µg Pb/dl), EPA has designed the standard to limit air contribution after achieving the standard to 3 µg Pb/dl. On the basis of an estimated relationship of air lead to blood lead of 1 to 2, EPA concludes that the ambient air standard should be 1.5 µg Pb/m^3.'' (43 FR 46252)

EPA's judgments in these key areas, as well as margin of safety considerations, are discussed below.

The assessment of the science that was presented in the 1977 Criteria Document (USEPA, 1977), indicated young children, aged 1 to 5, as the population group at particular risk from Pb exposure. Children were recognized to have a greater physiological sensitivity than adults to the effects of Pb and a greater exposure. In identifying young children as the sensitive population, EPA also recognized the occurrence of subgroups with enhanced risk due to genetic factors, dietary deficiencies or residence in urban areas. Yet information was not available to estimate a threshold for adverse effects for these subgroups separate from that of all young children. Additionally, EPA recognized both a concern regarding potential risk to pregnant women and fetuses, and a lack of information to establish that these subgroups are more at risk than young children. Accordingly, young children, aged 1 to 5, were identified as the group which has the lowest threshold for adverse

[105] As described in seciton II.C.2.d above, levels in the location-specific urban case studies were increased from current conditions such that the portion of each case study with highest concentrations would just meet the current NAAQS.

effects of greatest potential for exposure (*i.e.*, the sensitive population) (43 FR 46252).

In identifying the maximum safe exposure, EPA relied upon the measurement of Pb in blood (43 FR 46252–46253). The physiological effect of Pb that had been identified as occurring at the lowest blood Pb level was inhibition of an enzyme integral to the pathway by which heme (the oxygen carrying protein of human blood) is synthesized, *i.e.*, delta-aminolevulinic acid dehydratase (δ-ALAD). The 1977 Criteria Document reported a threshold for inhibition of this enzyme in children at 10 μg Pb/dL. The 1977 Criteria Document also reported a threshold of 15–20 μg/dL for elevation of erythrocyte protoporphyrin (EP), which is an indication of some disruption of the heme synthesis pathway. EPA concluded that this effect on the heme synthesis pathway (indicated by EP) was potentially adverse. EPA further described a range of blood levels associated with a progression in detrimental impact on the heme synthesis pathway. At the low end of the range (15–20 μg/dL), the initial detection of EP associated with blood Pb was not concluded to be associated with a significant risk to health. The upper end of the range (40 μg/dL), the threshold associated with clear evidence of heme synthesis impairment and other effects contributing to clinical symptoms of anemia, was regarded by EPA as clearly adverse to health. EPA also noted that for some children with blood Pb levels just above those for these effects (*e.g.*, 50 μg/dL), there was risk for additional adverse effects (*e.g.*, nervous system deficits). Additionally, in the Agency's statement of factors on which the conclusion as to the maximum safe blood Pb level for an individual child was based, EPA stated that the maximum safe blood level should be ''no higher than the blood Pb range characterized as undue exposure by the Center for Disease Control of the Public Health Service, as endorsed by the American Academy of Pediatrics, because of elevation of erythrocyte protoporphyrin (above 30 μg Pb/dL)''.[106]

Having identified the maximum safe blood level in individual children, EPA next made a public health policy judgment regarding the target mean blood level for the U.S. population of young children (43 FR 46252–46253). With this judgment, EPA identified a target of 99.5 percent of this population to be brought below the maximum safe blood Pb level. This judgment was based on consideration of the size of the sensitive subpopulation, and the recognition that there are special high-risk groups of children within the general population. The population statistics available at the time (the 1970 U.S. Census) indicated a total of 20 million children younger than 5 years of age, with 15 million residing in urban areas and 5 million in center cities where Pb exposure was thought likely to be ''high''. Concern about these high-risk groups influenced EPA's determination of 99.5 percent, deterring EPA from selecting a population percentage lower than 99.5 (43 FR 46253). EPA then used standard statistical techniques to calculate the population mean blood Pb level that would place 99.5 percent of the population below the maximum safe level. Based on the then available data, EPA concluded that blood Pb levels in the population of U.S. children were normally distributed with a GSD of 1.3. Based on standard statistical techniques, EPA determined that a thus described population in which 99.5 percent of the population has blood Pb levels below 30 μg/dL would have a geometric mean blood level of 15 μg/dL. EPA described 15 μg/dL as ''the maximum safe blood lead level (geometric mean) for a population of young children'' (43 FR 46247).

When setting the current NAAQS, EPA recognized that the air standard needed to take into account the contribution to blood Pb levels from Pb sources unrelated to air pollution. Consequently, the calculation of the current NAAQS included the subtraction of Pb contributed to blood Pb from nonair sources, from the estimate of a safe mean population blood Pb level. Without this subtraction, EPA recognized that the combined exposure to Pb from air and nonair sources would result in a blood Pb concentration exceeding the safe level (43 FR 46253). In developing an estimate of this nonair contribution, EPA recognized the lack of detailed or widespread information about the relative contribution of various sources to children's blood Pb levels, such that an estimate could only be made by inference from other empirical or theoretical studies, often involving adults. Additionally, EPA recognized the expectation that the contribution to blood Pb levels from nonair sources would vary widely, was probably not in constant proportion to air Pb contribution, and in some cases may alone exceed the target mean population blood Pb level (43 FR 46253–46254). The amount of blood Pb attributed to nonair sources was selected based primarily on findings in studies of blood Pb levels in areas where air Pb levels were low relative to other locations in U.S. The air Pb levels in these areas ranged from 0.1 to 0.7 μg/m^3. The average of the reported blood Pb levels for children of various ages in these areas was on the order of 12 μg/dL. Thus, 12 μg/dL was identified as the nonair contribution, and subtracted from the population mean target level of 15 μg/dL to yield a value of 3 μg/dL as the limit on the air contribution to blood Pb.

In determining the air Pb level consistent with an air contribution of 3 μg Pb/dL, EPA reviewed studies assessed in the 1977 Criteria Document that reported changes in blood Pb with different air Pb levels. These studies included a study of children exposed to Pb from a primary Pb smelter, controlled exposures of adult men to Pb in fine particulate matter, and a personal exposure study involving several male cohorts exposed to Pb in a large urban area in the early 1970s (43 FR 46254).[107] Using all three studies, EPA calculated an average slope or ratio over the entire range of data. That value was 1.95 (rounded to 2 μg/dL blood Pb concentration to 1 μg/m^3 air Pb concentration), and is recognized to fall within the range of values reported in the 1977 Criteria Document. On the basis of this 2-to-1 relationship, EPA concluded that the ambient air standard should be 1.5 μg Pb/m^3 (43 FR 46254).

In consideration of the appropriate margin of safety during the development of the current NAAQS, EPA identified the following factors: (1) The 1977 Criteria Document reported multiple biological effects of Pb in practically all cell types, tissues and organ systems, of which the significance for health had not yet been fully studied; (2) no beneficial effects of Pb at then current environmental levels were recognized;

[106] The CDC subsequently revised their advisory level for children's blood Pb to 25 μg/dL in 1985, and to 10 μg/dL in 1991. In 2005, with consideration of a review of the evidence by their advisory committee, CDC revised their statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children with blood Pb levels below 10 μg/dL and the data demonstrating that no ''safe'' threshold for blood Pb in children had been identified, and emphasizing the importance of preventative measures (CDC, 2005a). Recently, CDC's Advisory Committee on Childhood Lead Poisoning Prevention noted the 2005 CDC statements and reported on a review of the clinical interpretation and management of blood Pb levels below 10 μg/dL (ACCLPP, 2007). More details on this level are provided in Section II.B.1.

[107] Mean blood Pb levels in the adult study groups ranged from 10 μg/dL to approximately 30 μg/dL and in the child groups they ranged from approximately 20 μg/dL up to 65 μg/dL (USEPA, 1986a, section 11.4.1).

(3) data were incomplete as to the extent to which children are indirectly exposed to air Pb that has moved to other environmental media, such as water, soil and dirt, and food; (4) Pb is chemically persistent and with continued uncontrolled emissions would continue to accumulate in human tissue and the environment; and (5) the possibility that exposure associated with blood Pb levels previously considered safe might influence neurological development and learning abilities of the young child (43 FR 46255). Recognizing that estimating an appropriate margin of safety for the air Pb standard was complicated by the multiple sources and media involved in Pb exposure, EPA chose to use margin of safety considerations principally in establishing a maximum safe blood Pb level for individual children (30 µg Pb/dL) and in determining the percentage of children to be placed below this maximum level (about 99.5 percent). Additionally, in establishing other factors used in calculating the standard, EPA used margin of safety considerations in the sense of making careful judgment based on available data, but these judgments were not considered to be at the precautionary extreme of the range of data available at the time (43 FR 46251).

EPA further recognized that, because of the variability between individuals in a population experiencing a given level of Pb exposure, it was considered impossible to provide the same margin of safety for all members in the sensitive population or to define the margin of safety in the standard as a simple percentage. EPA believed that the factors it used in designing the standards provided an adequate margin of safety for a large proportion of the sensitive population. The Agency did not believe that the margin was excessively large or on the other hand that the air standard could protect everyone from elevated blood Pb levels (43 FR 46251).

ii. Averaging Time, Form, and Indicator

The averaging time for the current standard is a calendar quarter. In the decision for this aspect of the standard, the Agency also considered a monthly averaging period, but concluded that ''a requirement for the averaging of air quality data over calendar quarter will improve the validity of air quality data gathered without a significant reduction in the protectiveness of the standards.'' As described in the notice for this decision (43 FR 46250), this conclusion was based on several points, including the following:

- An analysis of ambient measurements available at the time indicated that the distribution of air Pb levels was such that there was little possibility that there could be sustained periods greatly above the average value in situations where the quarterly standard was achieved.
- A recognition that the monitoring network may not actually represent the exposure situation for young children, such that it seemed likely that elevated air Pb levels when occurring would be close to Pb air pollution sources where young children would typically not encounter them for the full 24-hour period reported by the monitor.
- Medical evidence available at the time indicated that blood Pb levels re-equilibrate slowly to changes in air exposure, a finding that would serve to dampen the impact of short-term period of exposure to elevated air Pb.
- Direct exposure to air is only one of several routes of total exposure, thus lessening the impact of a change in air Pb on blood Pb levels.

The statistical form of the current standard is a not-to-be-exceeded or maximum value. EPA set the standard as a ceiling value with the conclusion that this air level would be safe for indefinite exposure for young children (43 FR 46250).

The indicator is total airborne Pb collected by a high volume sampler (43 FR 46258). EPA's selection of Pb-TSP as the indicator for the standard was based on explicit recognition both of the significance of ingestion as an exposure pathway for Pb that had deposited from the air and of the potential for Pb deposited from the air to become re-suspended in respirable size particles in the air and available for human inhalation exposure. As stated in the final rule, ''a significant component of exposure can be ingestion of materials contaminated by deposition of lead from the air,'' and that, ''in addition to the indirect route of ingestion and absorption from the gastrointestinal tract, non-respirable Pb in the environment may, at some point become respirable through weathering or mechanical action'' (43 FR 46251).

b. Policy Options Considered in the Last Review

During the 1980s, EPA initiated a review of the air quality criteria and NAAQS for Pb. CASAC and the public were fully involved in this review, which led to the publication of a criteria document with associated addendum and a supplement (USEPA, 1986a, 1986b, 1990a), an exposure analysis methods document (USEPA, 1989), and a staff paper (USEPA, 1990b).

Total emissions to air were estimated to have dropped by 94 percent between 1978 and 1987, with the vast majority of it attributed to the reduction of Pb in gasoline. Accordingly, the focus of the last review was on areas near stationary sources of Pb emissions. Although such sources were not considered to have made a significant contribution (as compared to Pb in gasoline) to the overall Pb pollution across large-urban or regional areas, Pb emissions from such sources were considered to have the potential for a significant impact on a local scale. Air Pb concentrations, and especially soil and dust Pb concentrations, had been associated with elevated levels of Pb absorption in children and adults in numerous Pb point source community studies. Exceedances of the current NAAQS were found at that time only in the vicinity of nonferrous smelters or other point sources of Pb.

In summarizing and interpreting the health evidence presented in the 1986 Criteria Document and associated documents, the 1990 Staff Paper described the collective impact on children of the effects at blood Pb levels above 15 µg/dL as representing a clear pattern of adverse effects worthy of avoiding. This is in contrast to EPA's identification of 30 µg/dL as a safe blood Pb level for individual children when the NAAQS was set in 1978. The Staff Paper further stated that at blood Pb levels of 10–15 µg/dL, there was a convergence of evidence of Pb-induced interference with a diverse set of physiological functions and processes, particularly evident in several independent studies showing impaired neurobehavioral function and development. Further, the available data did not indicate a clear threshold in this blood Pb range. Rather, it suggested a continuum of health risks down to the lowest levels measured.[108]

For the purposes of comparing the relative protectiveness of alternative Pb NAAQS, the staff conducted analyses to estimate the percentages of children with blood Pb levels above 10 µg/dL and above 15 µg/dL for several air quality scenarios developed for a small set of stationary source exposure case studies. The results of the analyses of child populations living near two Pb smelters indicated that substantial reductions in Pb exposure could be achieved through just meeting the current Pb NAAQS. According to the best estimate analyses, over 99.5% of children living in areas significantly affected by the smelters would have blood Pb levels below 15

[108] In 1991, the CDC reduced their advisory level for children's blood Pb from 25 µg/dL to 10 µg/dL.

μg/dL if the current standard was achieved. Progressive changes in this number were estimated for the alternative monthly Pb NAAQS levels evaluated in those analyses, which ranged from 1.5 μg/m^3 to 0.5 μg/m^3.

In light of the health effects evidence available at the time, the 1990 Staff Paper presented air quality, exposure, and risk analyses, and other policy considerations, as well as the following staff conclusions with regard to the primary Pb NAAQS (USEPA, 1990b, pp. xii to xiv):

(1) ''The range of standards * * * should be from 0.5 to 1.5 μg/m^3.''

(2) ''A monthly averaging period would better capture short-term increases in lead exposure and would more fully protect children's health than the current quarterly average.''

(3) ''The most appropriate form of the standard appears to be the second highest monthly averages {sic} in a 3-year span. This form would be nearly as stringent as a form that does not permit any exceedances and allows for discounting of one 'bad' month in 3 years which may be caused, for example, by unusual meteorology.''

(4) ''With a revision to a monthly averaging time more frequent sampling is needed, except in areas, like roadways remote from lead point sources, where the standard is not expected to be violated. In those situations, the current 1-in-6 day sampling schedule would sufficiently reflect air quality and trends.''

(5) ''Because exposure to atmospheric lead particles occurs not only via direct inhalation, but via ingestion of deposited particles as well, especially among young children, the hi-volume sampler provides a reasonable indicator for determining compliance with a monthly standard and should be retained as the instrument to monitor compliance with the lead NAAQS until more refined instruments can be developed.''

Based on its review of a draft Staff Paper, which contained the above recommendations, the CASAC strongly recommended to the Administrator that EPA should actively pursue a public health goal of minimizing the Pb content of blood to the extent possible, and that the Pb NAAQS is an important component of a multimedia strategy for achieving that goal (CASAC, 1990, p. 4). In noting the range of levels recommended by staff, CASAC recommended consideration of a revised standard that incorporates a ''wide margin of safety, because of the risk posed by Pb exposures, particularly to the very young whose developing nervous system may be compromised by even low level exposures'' (id., p. 3). More specifically, CASAC judged that a standard within the range of 1.0 to 1.5 μg/m^3 would have ''relatively little, if any, margin of safety;'' that greater consideration should be given to a standard set below 1.0 μg/m^3; and, to provide perspective in setting the standard, it would be appropriate to consider the distribution of blood Pb levels associated with meeting a monthly standard of 0.25 μg/m^3, a level below the range considered by staff (id.).

After consideration of the documents developed during the review, EPA chose not to propose revision of the NAAQS for Pb. During the same time period, the Agency published and embarked on the implementation of a broad, multi-program, multi-media, integrated national strategy to reduce Pb exposures (USEPA, 1991). As discussed above in section I.C., as part of implementing this integrated Pb strategy, the Agency focused efforts primarily on regulatory and remedial clean-up actions aimed at reducing Pb exposures from a variety of nonair sources judged to pose more extensive public health risks to U.S. populations, as well as on actions to reduce Pb emissions to air, particularly near stationary sources.[109]

2. Considerations in the Current Review

a. Evidence-Based Considerations

In considering the broad array of health effects evidence assessed in the Criteria Document with respect to the adequacy of the current standard, the discussion here, like that in the Staff Paper and ANPR, focuses on those health endpoints associated with the Pb exposure and blood levels most pertinent to ambient exposures. In so doing, EPA gives particular weight to evidence available today that differs from that available at the time the standard was set with regard to its support of the current standard.

First, with regard to the sensitive population, the susceptibility of young children to the effects of Pb is well recognized, in addition to more recent recognition of effects of chronic or cumulative Pb exposure with advancing age (CD, Sections 5.3.7 and pp. 8–73 to 8–75). The prenatal period and early childhood are periods of increased susceptibility to Pb exposures, with evidence of adverse effects on the developing nervous system that generally appear to persist into later childhood and adolescence (CD, Section 6.2).[110] Thus, while the sensitivity of the elderly and other particular subgroups is recognized, as at the time the standard was set, young children continue to be recognized as a key sensitive population for Pb exposures.

With regard to the exposure levels at which adverse health effects occur, the current evidence demonstrates the occurrence of adverse health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set, at which time the Agency identified 30 μg/dL as the maximum safe blood Pb level for individual children and 15 μg/dL as the maximum safe geometric mean blood Pb level for a population of children (as described in section II.D.1.a above). This change in the evidence since the time the standard was set is reflected in changes made by the CDC in their advisory level for Pb in children's blood, and changes they have made in their characterization of that level (as described in section II.B.1.b). Although CDC recognized a level of 30 μg/dL blood Pb as warranting individual intervention in 1978 when the Pb NAAQS was set, in 2005 they recognized the evidence of adverse health effects in children with blood Pb levels below 10 μg/dL and the data demonstrating that no ''safe'' threshold for blood Pb had been identified (CDC, 1991; CDC, 2005).

As summarized in section II.B above, the Criteria Document describes current evidence regarding the occurrence of a variety of health effects, including neurological effects in children associated with blood Pb levels extending well below 10 μg/dL (CD, Sections 6.2, 8.4 and 8.5).[111] As stated

[109] A description of the various programs implemented since 1990 to reduce Pb exposures, including the recent RRP rule, is provided in section I.C.

[110] For example, the following statement is made in the Criteria Document ''Negative Pb impacts on neurocognitive ability and other neurobehavioral outcomes are robust in most recent studies even after adjustment for numerous potentially confounding factors (including quality of care giving, parental intelligence, and socioeconomic status). These effects generally appear to persist into adolescence and young adulthood.'' (CD, p.E–9)

[111] For context, it is noted that the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 μg/dL, the median for the subset living below the poverty level is 2.3 μg/dL and 90th percentile values for these two groups are 4.0 μg/dL and 5.4 μg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-hispanic children aged 1–5 is 2.5 μg/dL, while the median level for the subset of that group living below the poverty level is 2.9 μg/dL and the median level for the subset living in a household with income more than 200% of the poverty level is 1.9 μg/dL. Associated 90th percentile values for 2001–2004 are 6.4 μg/dL (for black, non-hispanic children aged 1–5), 7.7 μg/dL (for the subset of that group living below the poverty level) and 4.1 μg/dL (for the subset living in a household with income more than 200% of the poverty level). (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*—then click on

in the Criteria Document, ''The overall weight of the available evidence provides clear substantiation of neurocognitive decrements being associated in young children with blood-Pb concentrations in the range of 5–10 μg/dL, and possibly somewhat lower. Some newly available analyses appear to show Pb effects on the intellectual attainment of preschool and school age children at population mean concurrent blood-Pb levels ranging down to as low as 2 to 8 μg/dL'' (CD, p. E–9). With regard to the evidence of neurological effects at these low levels, EPA notes, in particular (and discusses more completely in section II.B.2.b above), the international pooled analysis by Lanphear and others (2005), studies of individual cohorts such as the Rochester, Boston, and Mexico City cohorts (Canfield *et al.*, 2003a; Canfield *et al.*, 2003b; Bellinger and Needleman, 2003; Tellez-Rojo *et al.*, 2006), the study of African-American inner-city children from Detroit (Chiodo *et al.*, 2004), the cross-sectional study of young children in three German cities (Walkowiak *et al.*, 1998) and the cross-sectional analysis of a nationally representative sample from the NHANES III (collected from 1988–1994) (Lanphear *et al.*, 2000). In the study by Lanphear *et al* (2000), the mean blood Pb for the full study group was 1.9 μg/dL and the mean blood Pb level in the lowest blood Pb subgroup with which a statistically significant association with neurocognitive effects was found (individual blood Pb values <5 μg/dL) was 1.7 μg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000; Auinger, 2008).[112] These studies and associated limitations are discussed above in section II.B.2.b.

As stated in the Criteria Document with regard to the neurocognitive effects in children, the ''weight of overall evidence strongly substantiates likely occurrence of type of effect in association with blood-Pb concentrations in range of 5–10 μg/dL, or possibly lower, as implied by (???) [in associated Table 8–5 of Criteria Document]. Although no evident threshold has yet been clearly established for those effects, the existence of such effects at still lower blood-Pb levels cannot be ruled out based on available data.'' (CD, p. 8–61). The Criteria Document further notes that any such threshold may exist ''at levels distinctly lower than the lowest exposures examined in these epidemiological studies'' (CD, p. 8–67).

i. Evidence-Based Framework Considered in the Staff Paper

In considering the adequacy of the current standard, the Staff Paper considered the evidence in the context of the framework used to determine the standard in 1978, as adapted to reflect the current evidence. In so doing, the Staff Paper recognized that the health effects evidence with regard to characterization of a threshold for adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level. As described in section II.D.1.a, parameters for this framework include estimates for average nonair blood Pb level, and air-to-blood ratio, as well as a maximum safe individual and/or geometric mean blood Pb level. For this last parameter, the Staff Paper for the purposes of this evaluation considered the lowest population mean blood Pb levels with which some neurocognitive effects have been associated in the evidence.

As when the standard was set in 1978, there remain today contributions to blood Pb levels from nonair sources. In 1978, the Agency estimated the average blood Pb level for young children associated with nonair sources to be 12 μg/dL (as described in section II.D.1.a). However, consistent with reductions since that time in air Pb concentrations[113] which contribute to blood Pb, nonair contributions have also been reduced (as described in section II.A.4 above). The Staff Paper noted that the current evidence is limited with regard to estimates of the aggregate reduction since 1978 of all nonair sources to blood Pb and with regard to an estimate of current nonair blood Pb levels (discussed in sections II.A.4). In recognition of temporal reductions in nonair sources discussed in section II.A.4 and in the context of estimates pertinent to an application of the 1978 framework, the CASAC Pb Panel recommended consideration of 1.0–1.4 μg/dL or lower as an estimate of the nonair component of blood Pb pertinent to average blood Pb levels (as more fully described in section II.A.4 above; Henderson, 2007b).

As in 1978, the evidence demonstrates that Pb in ambient air contributes to Pb in blood, with the pertinent exposure routes including both inhalation and ingestion (CD, Sections 3.1, 3.2, 4.2 and 4.4). In 1978, the evidence indicated a quantitative relationship between ambient air Pb and blood Pb in terms of an air-to-blood ratio that ranged from 1:1 to 1:2 (USEPA, 1977). In setting the standard, the Agency relied on a ratio of 1:2, i.e., 2 μg/dL blood Pb per 1 $\mu g/m^3$ air Pb (as described in section II.D.1.a above). The Staff Paper observed that ''[W]hile there is uncertainty and variability in the absolute value of an air-to-blood relationship, the current evidence indicates a notably greater ratio * * * e.g., on the order of 1:3 to 1:10'' (USEPA, 2007c).

Based on the information described above, the Staff Paper concluded that young children remain the sensitive population of primary focus in this review, ''there is now no recognized safe level of Pb in children's blood and studies appear to show adverse effects at population mean concurrent blood Pb levels as low as approximately 2 μg/dL (CD, pp. 6–31 to 6–32; Lanphear *et al.*, 2000)'' (USEPA, 2007c). The Staff Paper further stated that ''while the nonair contribution to blood Pb has declined, perhaps to a range of 1.0–1.4 μg/dL, the air-to-blood ratio appears to be higher at today's lower blood Pb levels than the estimates at the time the standard was set, with current estimates on the order of 1:3 to 1:5 and perhaps up to 1:10'' (USEPA, 2007c). Adapting the framework employed in setting the standard in 1978, the Staff Paper concluded that ''the more recently available evidence suggests a level for the standard that is lower by an order of magnitude or more'' (USEPA, 2007c).

ii. Air-Related IQ Loss Evidence-Based Framework

Since completion of the Staff Paper and ANPR, the Agency has further considered the evidence with regard to adequacy of the current standard using an approach other than the adapted 1978 framework considered in the Staff Paper. This alternative evidence-based framework, referred to as the air-related IQ loss framework, shifts focus from identifying an appropriate target population mean blood lead level and instead focuses on the magnitude of effects of air-related Pb on neurocognitive functions. This framework builds on a recommendation by the CASAC Pb Panel to consider the evidence in a more quantitative manner,

''Download a universal spreadsheet file of the Body Burdens data tables'').

[112] These findings include significant associations in some of the study sample subsets of children, namely those with blood Pb levels less than 10 μg/dL, less than 7.5 μg/dL, and less than 5 μg/dL. The mean blood Pb level in the third subset was 1.7 μg/dL (Auinger, 2008). A positive, but not statistically significant association, was observed in the less than 2.5 μg/dL subset (mean blood Pb of 1.2 μg/dL [Auinger, 2008]), although the effect estimate for this subset was largest among all the subsets (Lanphear *et al.*, 2000). The lack of statistical significance for this subset may be due to the smaller sample size of this subset which would lead to lower statistical power.

[113] Air Pb concentrations nationally are estimated to have declined more than 90% since the early 1980s, in locations not known to be directly influenced by stationary sources (Staff Paper, pp. 2–22 to 2–23).

and is discussed in more detail below in section II.E.3.a, concerning the level of the standard.

In this air-related IQ loss framework, we have drawn from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and population IQ loss.[114] We have also drawn more quantitatively from the evidence by using evidence-based C-R functions to quantify the association between air Pb concentrations and air-related population mean IQ loss. Thus, this framework more fully considers the evidence with regard to the concentration-response relationship for the effect of Pb on IQ, and it also draws from estimates for air-to-blood ratios.

While we note the evidence of steeper slope for the C-R relationship for blood Pb concentration and IQ loss at lower blood Pb levels (described in sections II.B.2.b and II.E.3.a), for purposes of consideration of the adequacy of the current standard we are concerned with the C-R relationship for blood Pb levels that would be associated with exposure to air-related Pb at the level of the current standard. For this purpose, we have focused on a median linear estimate of the slope of the C-R function for blood Pb levels up to, but no higher than, 10 μg/dL (described in section II.B.2.b above). The median slope estimate is −0.9 IQ points per μg/dL blood Pb[115] (CD, p. 8–80).

Applying estimates of air-to-blood ratios ranging from 1:3 to 1:5, drawing from the discussion of air-to-blood ratios in section II.B.1.c above, a population of children exposed at the current level of the standard might be expected to result in an average air-related blood Pb level above 4 μg/dL.[116] Multiplying these blood Pb levels by the slope estimate, identified above, for blood Pb levels extending up to 10 μg/dL (−0.9 IQ points per μg/dL), would imply an average air-related IQ loss for such a group of children on the order of 4 or more IQ points.

b. Exposure- and Risk-Based Considerations

As discussed above in section II.C, we have estimated exposures and health risks associated with air quality that just meets the current standard to help inform judgments about whether or not the current standard provides adequate protection of public health, taking into account key uncertainties associated with the estimated exposures and risks (summarized above in section II.C and more fully in the Risk Assessment Report).

As discussed above, children are the sensitive population of primary focus in this review. The exposure and risk assessment estimates Pb exposure for children (less than 7 years of age), and associated risk of neurocognitive effects in terms of IQ loss. In addition to the risks (IQ loss) that were quantitatively estimated, EPA recognizes that there may be long-term adverse consequences of such deficits over a lifetime, and there are other, unquantified adverse neurocognitive effects that may occur at similarly low exposures which might additionally contribute to reduced academic performance, which may have adverse consequences over a lifetime (CD, pp. 8–29 to 8–30).[117] Other impacts at low levels of childhood exposure that were not quantified in the risk assessment include: other neurological effects (sensory, motor, cognitive and behavioral), immune system effects (including some related to allergic responses and asthma), and early effects related to anemia. Additionally, as noted in section II.B.2, other health effects evidence demonstrates associations between Pb exposure and adverse health effects in adults (e.g., cardiovascular and renal effects).[118]

As noted in the Criteria Document, a modest change in the population mean of a health index, that is quantified for each individual, can have substantial implications at the population level (CD, p. 8–77, Sections 8.6.1 and 8.6.2; Bellinger, 2004; Needleman *et al.*, 1982; Weiss, 1988; Weiss, 1990)). For example, for an individual functioning in the low range of IQ due to the influence of risk factors other than Pb, a Pb-associated IQ loss of a few points might be sufficient to drop that individual into the range associated with increased risk of educational, vocational, and social handicap (CD, p. 8–77), while such a decline might create less significant impacts for the individual near the mean of the population. Further, given a uniform manifestation of Pb-related decrements across the range of IQ scores in a population, a downward shift in the mean IQ value is associated not only with a substantial increase in the percentage of individuals achieving very low scores, but also with substantial decreases in percentages achieving very high scores (CD, p. 8–81). The CASAC Pb Panel has advised on this point that ''a population loss of 1–2 IQ points is highly significant from a public health perspective'' (Henderson, 2007a, p. 6).

In considering exposure and risk estimates with regard to adequacy of the current standard, EPA has focused on IQ loss for air-related exposure pathways. As described in section II.C.2.e above, limitations in our data and modeling tools have resulted in an inability to develop specific estimates such that we have approximated estimates for the air-related pathways, bounded on the low end by exposure/risk estimated for the ''recent air'' category and on the upper end by the exposure/risk estimated for the ''recent air'' plus ''past air'' categories. Thus, the following discussion presents air-related IQ loss estimates in terms of upper and lower bounds. In addition, as noted above (section II.C.3.b), this discussion focuses predominantly on risk estimates derived using the log-linear with low-exposure linearization (LLL) C–R function, with the range associated with the other three functions used in the assessment also being noted. Further, air-related risk estimates are presented for the median and for an upper percentile (i.e., the 95th percentile of the population assessed).

EPA and CASAC recognize uncertainties in the risk estimates in the tails of the distribution and consequently the 95th percentile is reported as the estimate of the high end of the risk distribution (Henderson, 2007b, p. 3). In so doing, however, EPA notes that it is important to consider that there are individuals in the population expected to have higher risk, particularly in light of the risk management objectives for the current standard which was set in 1978 to

[114] For example, as stated in the Criteria Document, ''Fortunately, there exists a large database of high quality studies on which to base inferences regarding the relationship between Pb exposure and neurodevelopment. In addition, Pb has been extensively studied in animal models at doses that closely approximate the human situation. Experimental animal studies are not compromised by the possibility of confounding by such factors as social class and correlated environmental factors. The enormous experimental animal literature that proves that Pb at low levels causes neurobehavioral deficits and provides insights into mechanisms must be considered when drawing causal inferences (Bellinger, 2004; Davis *et al.*, 1990; U.S. Environmental Protection Agency, 1986a, 1990).'' (CD, p. 6–75)

[115] As noted above (in section II.B.2.b), this slope is similar to the slope for the below 10 μg/dL piece of the piecewise model used in the RRP rule economic analysis.

[116] This is based on the calculation in which 1.5 $\mu g/m^3$ is multiplied by a ratio of 3 μg blood Pb per 1 $\mu g/m^3$ air Pb to yield an air-related blood Pb estimate of 4.5 μg/dL; using a 1:5 ratio yields an estimate of 7.5 μg/dL. As with the 1978 framework considered in the Staff Paper, the context for use of the air-to-blood ratio here is a population being exposed at the level of the standard.

[117] For example, the Criteria Document notes particular findings with regard to academic achievement as ''suggesting that Pb-sensitive neuropsychological processing and learning factors not reflected by global intelligence indices might contribute to reduced performance on academic tasks'' (CD, pp. 8–29 to 8–30).

[118] The weight of the evidence differs for the different endpoints.

protect the 99.5th percentile. Further, we note an increased uncertainty in our estimates of air-related risk for the upper percentiles, such as the 95th percentile, due to limitations in the data and tools available to us to estimate pathway contributions to blood Pb and associated risk for individuals at the upper ends of the distribution.

In order to consider exposure and risk associated with the current standard, EPA developed estimates for a case study based on air quality projected to just meet the standard in a location of the country where air concentrations currently do not meet the current standard (the primary Pb smelter case study). Estimates of median air-related IQ loss associated with just meeting the current NAAQS in the primary Pb smelter case study subarea had a lower bound estimate of <3.2 points IQ loss (''recent air'' category of Pb exposures) and an upper bound estimate of <9.4 points IQ loss (''recent air'' plus ''past air'' category) for the range of C–R functions (Table 3). This estimate (recent air plus past air) for the subarea based on the LLL C–R function is 6.0 points IQ loss for the median and 8.0 points IQ loss for the 95th percentile, with which we note a greater uncertainty than for the median estimate (as discussed above).[119] Modeling limitations have affected our ability to derive lower bound estimates for this case study (as described above in section II.C.2.c).

Additionally, we developed estimates of blood Pb and associated IQ loss associated with the current standard for the urban case studies. We note that we consider it extremely unlikely that air concentrations in urban areas across the U.S. that are currently well below the current standard would increase to just meet the standard. However, we recognize the potential, although not the likelihood, for air Pb concentrations in some limited areas currently well below the standard to increase to just meet the standard by way of, for example, expansion of existing sources (e.g., facilities operating as secondary smelters may exercise previously used capabilities as primary smelters) or by the congregation of multiple Pb sources in adjacent locations. We have simulated this scenario (increased Pb concentrations to just meet the current standard) in a general urban case study and three location-specific urban case studies. For the location-specific urban case studies, we note substantial uncertainty in simulating how the profile of Pb concentrations might change in the hypothetical case where concentrations increase to just meet the current standard.

Turning first to the exposure/risk estimates for the current NAAQS scenario simulated for the general urban case study, which is a simplified representation of a location within an urban area (described in section II.C.2.h above), median estimates of air-related IQ loss range from 1.5 to 7.7 points (across all four C–R functions), with an estimate based on the LLL function bounded at the low end by 3.4 points and at the high end by 4.8 points (Table 3). At the 95th percentile for total IQ loss (LLL estimate), IQ loss associated with air-related Pb is estimated to fall somewhere between 5.5 and 7.6 points (Staff Paper, Table 4–6).

In considering the estimates for the three location-specific urban case studies, we first note the extent to which exposures associated with increased air Pb concentrations that simulate just meeting the current standard are estimated to increase blood Pb levels in young children. The magnitude of this for the median total blood Pb ranges from 0.3 μg/dL (an increase of 20 percent) in the case of the Cleveland study area (where the highest monitor is estimated to be approximately one fourth of the current NAAQS), up to approximately 1 μg/dL (an increase of 50 to 70%) for the Chicago and Los Angeles study areas, where the highest monitor is estimated to be at or below one tenth of the current NAAQS (Table 1). Median estimates of air-related risk for these case studies range from 0.6 points IQ loss (recent air estimate using low-end C–R function) to 7.4 points IQ loss (recent plus past air estimate using the high-end C–R function). The corresponding estimates based on the LLL C–R function range from 2.7 points (lowest location-specific recent air estimate) to 4.7 points IQ loss (highest location-specific recent plus past air estimate). The comparable estimates of air-related risk for children at the 95th percentile in these three case studies range from 2.6 to 7.6 points IQ loss for the LLL C–R function (Staff paper, Table 4–6), although we note increased uncertainty in the magnitude of these 95th percentile air-related estimates.

Another way in which the risk assessment results might be considered is by comparing current NAAQS scenario estimates to current conditions, although in so doing, it is important to recognize that, as stated below and described in section II.C., this will underestimate air-related impacts associated with the current NAAQS. In making such a comparison of estimates for the three location-specific urban case studies, the estimated difference in total Pb-related IQ loss for the median child is about 0.5 to 1.4 points using the LLL C–R function and a similar magnitude of difference is estimated for the 95th percentile. The corresponding comparison for the general urban case study indicates the current NAAQS scenario median total Pb-related IQ loss is 1.1 to 1.3 points higher than the two current conditions scenarios. As described in section II.C, such comparisons are underestimates of air-related impacts brought about as a result of increased air Pb concentrations, and consequently they are inherently underestimates of the true impact of an increased NAAQS level on public health.

In considering the exposure/risk information with regard to adequacy of the current standard, the Staff Paper first considered the estimates described above, particularly those associated with air-related risk.[120] The Staff Paper described these estimates for the current NAAQS as being indicative of levels of IQ loss associated with air-related risk that may ''reasonably be judged to be highly significant from a public health perspective'' (USEPA, 2007c).

The Staff Paper also describes a different risk metric that estimated differences in the numbers of children with different amounts of Pb-related IQ loss between air quality scenarios for current conditions and for the current NAAQS in the three location-specific urban case studies. For example, estimates of the additional number of children with IQ loss greater than one point (based on the LLL C–R function) in these three study areas, for the current NAAQS scenario as compared to current conditions, range from 100 to 6,000 across the three locations (as shown above in Table 5). The corresponding estimates for the additional number of children with IQ

[119] We note that while we have termed risk estimates derived for the sum of ''recent air'' plus ''past air'' exposure pathways as ''upper bound'' estimates of air-related risk, the primary Pb smelter subarea is an area where soil has been remediated and thus does not reflect any historical deposition. Further, soil Pb concentrations in this area are not stable and may be increasing, seeming to indicate ongoing response to current atmospheric depositon in the area. Thus, for this case study, the ''recent air'' plus ''past air'' estimates are less of an ''upper bound'' for air-related risk than in other case studies where historical Pb deposition may have some representation in the ''past air'' soil ingestion pathway.

[120] As recognized in section III.B.2.d above, to simulate air concentrations associated with the current NAAQS, a proportional roll-up of concentrations from those for current conditions was performed for the location-specific urban case studies. This was not necessary for the primary Pb smelter case study in which air concentrations currently exceed the current standard, nor for the general urban case study.

loss greater than seven points, for the current NAAQS as compared to current conditions, range from 600 to 66,000 (as shown above in Table 6). These latter values for the change in incidence of children with greater than seven points Pb-related IQ loss represent 5 to 17 percent of the children (aged less than 7 years of age) in these study areas. This increase corresponds to approximately a doubling in the number of children with this magnitude of Pb-related IQ loss in the study area most affected. The Staff Paper concluded that these estimates indicate the potential for significant numbers of children to be negatively affected if air Pb concentrations increased to levels just meeting the current standard.

Beyond the findings related to quantified IQ loss, the Staff Paper recognized the potential for other, unquantified adverse effects that may occur at similarly low exposures. In summary, the Staff Paper concluded that taken together, ''the quantified IQ effects associated with the current NAAQS and other, nonquantified effects are important from a public health perspective, indicating a need for consideration of revision of the standard to provide an appreciable increase in public health protection'' (USEPA, 2007c).

3. CASAC Advice and Recommendations and Public Comment

CASAC's recommendations in this review builds upon the CASAC recommendations during the 1990 review, which also advised on consideration of more health protective NAAQS. In CASAC's review of the 1990 Staff Paper, as discussed in Section II.D.1.b, they generally recommended consideration of levels below 1.0 $\mu g/m^3$, specifically recommended analyses of a standard set at 0.25 $\mu g/m^3$, and also recommended a revision to a monthly averaging time (CASAC, 1990).

In its letter to the Administrator subsequent to consideration of the ANPR, the final Staff Paper and the final Risk Assessment Report, the CASAC Pb Panel unanimously and fully supported ''Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 $\mu g/m^3$ with a monthly averaging time'' (Henderson, 2008, p. 1). This recommendation is consistent with their recommendations conveyed in two earlier letters in the course of this review (Henderson, 2007a, 2007b). Further, in their advice to the Agency over the course of this review, CASAC has provided rationale for their conclusions that has included their statement that the current Pb NAAQS ''are totally inadequate for assuring the necessary decreases of lead exposures in sensitive U.S. populations below those current health hazard markers identified by a wealth of new epidemiological, experimental and mechanistic studies'', and stated that ''Consequently, it is the CASAC Lead Review Panel's considered judgment that the NAAQS for Lead must be decreased to fully-protect both the health of children and adult populations'' (Henderson, 2007a, p. 5). CASAC drew support for their recommendation from the current evidence, described in the Criteria Document, of health effects occurring at dramatically lower blood Pb levels than those indicated by the evidence available when the standard was set and of a recognition of effects that extend beyond children to adults.

The Agency has also received comments from the public on drafts of the Staff Paper and related technical support document, as well as on the ANPR.[121] Public comments received to date that have addressed adequacy of the current standard overwhelmingly concluded that the current standard is inadequate and should be substantially revised, in many cases suggesting specific reductions to a level at or below 0.2 $\mu g/m^3$. Two comments were received from specific industries expressing the view that the current standard might need little or no adjustment. One comment received early in the review stated that current conditions justified revocation of the standard.

4. Administrator's Proposed Conclusions Concerning Adequacy

Based on the large body of evidence concerning the public health impacts of Pb, including significant new evidence concerning effects at blood Pb concentrations substantially below those identified when the current standard was set, the Administrator proposes that the current standard does not protect public health with an adequate margin of safety and should be revised to provide additional public health protection.

In considering the adequacy of the current standard, the Administrator has carefully considered the conclusions contained in the Criteria Document, the information, exposure/risk assessments, conclusions, and recommendations presented in the Staff Paper, the advice and recommendations from CASAC, and public comments received on the ANPR and other documents to date.

The Administrator notes that the body of available evidence, summarized above in section III.B and discussed in the Criteria Document, is substantially expanded from that available when the current standard was set three decades ago. The Criteria Document presents evidence of the occurrence of health effects at appreciably lower blood Pb levels than those demonstrated by the evidence at the time the standard was set. Subsequent to the setting of the standard, the Pb NAAQS criteria review during the 1980s and the current review have provided (a) expanded and strengthened evidence of still lower Pb exposure levels associated with slowed physical and neurobehavioral development, lower IQ, impaired learning, and other indicators of adverse neurological impacts; and (b) other effects of Pb on cardiovascular function, immune system components, calcium and vitamin D metabolism and other health endpoints (discussed fully in the Criteria Document).

The Administrator notes particularly the robust evidence of neurotoxic effects of Pb exposure in children, both with regard to epidemiological and toxicological studies. While blood Pb levels in U.S. children have decreased notably since the late 1970s, newer studies have investigated and reported associations of effects on the neurodevelopment of children with these more recent blood Pb levels. The toxicological evidence includes extensive experimental laboratory animal evidence that substantiates well the plausibility of the epidemiologic findings observed in human children and expands our understanding of likely mechanisms underlying the neurotoxic effects. Further, the Administrator notes the current evidence that suggests a steeper dose-response relationship at these lower blood Pb levels than at higher blood Pb levels, indicating the potential for greater incremental impact associated with exposure at these lower levels.

In addition to the evidence of health effects occurring at significantly lower blood Pb levels, the Administrator recognizes that the current health effects evidence together with findings from the exposure and risk assessments (summarized above in section III.B), like the information available at the time the standard was set, supports our finding that air-related Pb exposure pathways contribute to blood Pb levels in young children, by inhalation and ingestion. Furthermore, the Administrator takes

[121] All written comments submitted to the Agency are available in the docket for this rulemaking, are transcripts of the public meetings held in conjunction with CASAC's review of the Staff Paper, the Risk Assessment Report, the Criteria Document and the ANPR.

note of the information that suggests that the air-to-blood ratio (i.e., the quantitative relationship between air concentrations and blood concentrations) is now likely larger, when air inhalation and ingestion are considered, than that estimated when the standard was set.

Based on evidence discussed above, the Administrator first considered the evidence in the context of an adaptation of the 1978 framework, as presented in the Staff Paper, recognizing that the health effects evidence with regard to characterization of a threshold for adverse effects has changed dramatically since the standard was set in 1978. As discussed above, however, the 1978 framework was premised on an evidentiary basis that clearly identified an adverse health effect and a health-based policy judgment that identified a level that would be safe for an individual child with respect to this adverse health effect. The adaptation to the 1978 framework applies this framework to a situation where there is no longer an evidentiary basis to determine a safe level for individual children. In addition, this approach does not address explicitly what magnitude of effect should be considered adverse. Given these two limitations, the Administrator has focused primarily instead on the air-related IQ loss evidence-based framework described above in considering the adequacy of the current standard.

In considering the application the air-related IQ loss framework to the current evidence as discussed above in section II.D.2.a, the Administrator notes that this framework suggests an average air-related IQ loss for a population of children exposed at the level of the current standard on the order of 4 or more IQ points. The Administrator judges that an air-related IQ loss of this magnitude is large from a public health perspective and that this evidence-based framework supports a conclusion that the current standard does not protect public health with an adequate margin of safety. Further, the Administrator believes that the current evidence indicates the need for a standard level that is substantially lower than the current level to provide increased public health protection, especially for at-risk groups, including most notably children, against an array of effects, most importantly including effects on the developing nervous system.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review, which provides some further perspective on the potential magnitude of air-related IQ loss. However, taking into consideration the uncertainties and limitations in the assessments, notably including questions as to whether the assessment scenarios that roll up current air quality to simulate just meeting the current standard are realistic in wide areas across the U.S., the Administrator has not placed primary reliance on the exposure and risk assessments. Nonetheless, the Administrator observes that in areas projected to just meet the current standard, the quantitative estimates of IQ loss associated with air-related Pb, as summarized above in section II.D.2.b, indicate risk of a magnitude that in his judgment is significant from a public health perspective. Further, although the current monitoring data indicate few areas with airborne Pb near or just exceeding the current standard, the Administrator recognizes significant limitations with the current monitoring network and thus the potential that the prevalence of such levels of Pb concentrations may be underestimated by currently available data.

The Administrator believes that the air-related blood Pb and IQ loss estimates discussed in the Staff Paper and Risk Assessment Report, summarized above, as well as the estimates of air-related IQ loss suggested by this evidence-based framework, are important from a public health perspective and are indicative of potential risks to susceptible and vulnerable groups. In reaching this proposed judgment, the Administrator considered the following factors: (1) The estimates of blood Pb and IQ loss for children from air-related Pb exposures associated with the current standard, (2) the estimates of numbers of children with different amounts of increased Pb-related IQ loss associated with the current standard, (3) the variability within and among areas in both the exposure and risk estimates, (4) the uncertainties in these estimates, and (5) the recognition that there is a broader array of Pb-related adverse health outcomes for which risk estimates could not be quantified and that the scope of the assessment was limited to a sample of case studies and to some but not all at-risk populations, leading to an incomplete estimation of public health impacts associated with Pb exposures across the country.[122] In addition to the evidence-based and risk-based conclusions described above, the Administrator also notes that it was the unanimous conclusion of the CASAC Panel that EPA needed to ''substantially lower'' the level of the primary Pb NAAQS to fully protect the health of children and adult populations (Henderson, 2007a, 2007b, 2008).

Based on all of these considerations, the Administrator proposes that the current Pb standard is not requisite to protect public health with an adequate margin of safety because it does not provide sufficient protection, and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups.

E. Conclusions on the Elements of the Standard

The four elements of the standard—indicator, averaging time, form, and level—serve to define the standard and must be considered collectively in evaluating the health and welfare protection afforded by the standard. In considering revisions to the current primary Pb standard, as discussed in the following sections, EPA considers each of the four elements of the standard as to how they might be revised to provide a primary standard for Pb that is requisite to protect public health with an adequate margin of safety. Considerations and proposed conclusions on indicator are discussed in section II.E.1, and on averaging time and form in section II.E.2. Considerations and proposed conclusions on a level for a Pb NAAQS with a Pb-TSP indicator are discussed in section II.E.3, and considerations on a level for a Pb NAAQS with a Pb-PM_{10} indicator are discussed in section II.E.4.

1. Indicator

The indicator for the current standard is Pb-TSP (as described in section II.D.1.a above).[123] When the standard was set in 1978, the Agency proposed Pb-TSP as the indicator, but considered identifying Pb in particulate matter less than or equal to 10 μm in diameter (Pb-PM_{10}) as the indicator. EPA had received comments expressing concern

[122] While recognizing that there are significant uncertainties associated with the risk estimates from the case studies, EPA places an appropriate weight on the risk assessment results for purposes of evaluating the adequacy of the current standard, given the strength of the evidence of the existence of effects at blood Pb levels associated with exposures at the level of the current standard, the magnitude of the IQ losses that are estimated, and the consistency of these IQ losses with the estimates of IQ loss derived from the alternative evidence-based framework. The weight to place on the risk assessment results for purposes of evaluating alterative levels of the standard is discussed later in the discussion on the level of the standard.

[123] The current standard specifies the measurement of airborne Pb with a high-volume TSP federal reference method (FRM) sampler with atomic absorption spectrometry of a nitric acid extract from the filter for Pb, or with an approved equivalent method.

that because only a fraction of airborne particulate matter is respirable, an air standard based on total air Pb would be unnecessarily stringent. The Agency responded that while it agreed that some Pb particles are too small or too large to be deposited in the respiratory system, a significant component of exposures can be ingestion of materials contaminated by deposition of Pb from the air. In addition to the route of ingestion and absorption from the gastrointestinal tract, nonrespirable Pb in the environment may, at some point, become respirable through weathering or mechanical action. EPA concluded that total airborne Pb, both respirable and nonrespirable fractions, should be addressed by the air standard (43 FR 46251). The federal reference method (FRM) for Pb-TSP specifies the use of the high-volume FRM sampler for TSP.

In the 1990 Staff Paper, this issue was reconsidered in light of information regarding limitations of the high-volume sampler used for the Pb-TSP measurements, and the continued use of Pb-TSP as the indicator was recommended in the Staff Paper (USEPA, 1990):

> Given that exposure to lead occurs not only via direct inhalation, but via ingestion of deposited particles as well, especially among young children, the hi-vol provides a more complete measure of the total impact of ambient air lead. * * * Despite its shortcomings, the staff believes the high-volume sampler will provide a reasonable indicator for determination of compliance * * *

In the current review, the Staff Paper evaluated the evidence with regard to the indicator for a revised primary standard. This evaluation included consideration of the basis for using Pb-TSP as the current indicator, information regarding the sampling methodology for the current indicator, and CASAC advice with regard to indicator (described below). Based on this evaluation, the Staff Paper recommended retaining Pb-TSP as the indicator for the primary standard. The Staff Paper also recommended activities intended to encourage collection and development of datasets that will improve our understanding of national and site-specific relationships between Pb-PM_{10} (collected by low-volume sampler) and Pb-TSP to support a more informed consideration of indicator during the next review. The Staff Paper suggested that such activities might include describing a federal equivalence method (FEM) in terms of PM_{10} and allowing its use for a TSP-based standard in certain situations, such as where sufficient data are available to adequately demonstrate a relationship between Pb-TSP and Pb-PM_{10} or, in combination with more limited Pb-TSP monitoring, in areas where Pb-TSP data indicate Pb levels well below the NAAQS level.

The ANPR further identified issues and options associated with consideration of the potential use of Pb-PM_{10} data for judging attainment or nonattainment with a Pb-TSP NAAQS. These issues included the impact of controlling Pb-PM_{10} for sources predominantly emitting Pb in particles larger than those captured by PM_{10} monitors [124] (i.e., ultra-coarse), [125] and the options included potential application of Pb-PM_{10} FRM/FEMs at sites with established relationships between Pb-TSP and Pb-PM_{10}, and use of Pb-PM_{10} data, with adjustment, as a surrogate for Pb-TSP data. The ANPR broadly solicited comment in these areas.

In the current review, both the CASAC Pb Panel and members of the CASAC Ambient Air Monitoring and Methods (AAMM) Subcommittee have recommended that EPA consider a change in the indicator to PM_{10}, utilizing low-volume PM_{10} sampling (Henderson, 2007a, 2007b, 2008; Russell, 2008). [126] In their January 2008 letter, the CASAC Lead Panel unanimously recommended that EPA revise the Pb NAAQS indicator to rely on low-volume PM_{10} sampling (Henderson, 2008). They indicated support for their recommendation in a range of areas. First, they noted poor precision in high-volume TSP sampling, wide variation in the upper particle size-cut as a function of wind speed and direction, and greater difficulties in capturing the spatial non-homogeneity of ultra-coarse particles with a national monitoring network. They stated that the low-volume PM_{10} collection method is a much more accurate and precise collection method, and would provide a more representative characterization on a large spatial scale of monitored particles which remain airborne longer, thus providing a characterization that is more broadly representative of ambient exposures over large spatial scales. They also noted the automated sequential sampling capability of low-volume PM_{10} monitors which would be particularly useful if the averaging time is revised (i.e., to a monthly averaging time, as recommended by CASAC), which, in CASAC's view would necessitate an increased monitoring frequency. Further, they noted the potential for utilization of the more widespread PM_{10} sampling network (Henderson, 2007a, 2007b, 2008).[127] In their advice, CASAC also stated that they ''recognize the importance of coarse dust contributions to total Pb ingestion and acknowledge that TSP sampling is likely to capture additional very coarse particles which are excluded by PM_{10} samplers'' (Henderson 2007b). They suggested that an adjustment of the NAAQS level would accommodate the loss of these ultra-coarse Pb particles, and that development of such a quantitative adjustment might appropriately be based on concurrent Pb-PM_{10} and Pb-TSP sampling data [128] (Henderson, 2007a, 2007b, 2008).

The Agency received comments on the discussion of the indicator in the ANPR from several state and local agencies and national/regional air pollution control organizations, as well as a national environmental organization. These public comments

[124] For simplicity, the discussion here and below speaks as if PM_{10} samplers have a sharp size cut-off. In reality, they have a size selection behavior in which 50% of particles 10 microns in size are captured, with a progressively higher capture rate for smaller particles and a progressively lower capture rate for larger particles. The ideal capture efficiency curve for PM_{10} samplers specifies that particles above 15 microns not be captured at all, although real samplers may capture a very small percentage of particles above 15 microns. TSP samplers have 50% capture points in the range of 25 to 50 microns, which is broad enough to include virtually all particles capable of being transported any significant distance from their source except under extreme wind events. As explained below, the capture efficiency of a high-volume TSP sampler for any given size particle is affected by wind speed and wind direction.

[125] In this notice, we use ''ultra-coarse'' to refer to particles collected by a TSP sampler but not by a PM_{10} sampler (we note that CASAC has variously also referred to these particles as ''very coarse'' or ''larger coarse-mode'' particles), ''fine'' to refer to particles collected by a $PM_{2.5}$ sampler, and ''coarse'' to refer to particles collected by a PM_{10} sampler but not by a $PM_{2.5}$ sampler, recognizing that there will be some overlap in the particle sizes in the three types of collected material.

[126] ''Low-volume PM_{10} sampling'' refers to sampling using any of a number of monitor models that draw 16.67 liters/minute (1 m^3/hour) of air through the filter, in contrast to ''high-volume'' sampling of either TSP or PM_{10} in which the monitor draws 1500 liters/minute (90 m^3/hour). All commercial TSP FRM samplers at this time are high-volume samplers; both high-volume and low-volume PM_{10} FRM samplers are available. Low-volume sampling is the more recently introduced method. Low-volume and high-volume samplers differ in many other ways also, including filter size, accuracy of the flow control, and degree of computerization.

[127] EPA notes that costs, including those of operating a monitoring network, may not be considered in establishing or revising the NAAQS.

[128] In their advice, CASAC recognized the potential for site-to-site variability in the relationship between Pb-TSP and Pb-PM_{10} (Henderson, 2007a, 2007b). They also stated in their September 2007 letter, ''The Panel urges that PM_{10} monitors, with appropriate adjustments, be used to supplement the data. * * * A single quantitative adjustment factor could be developed from a short period of collocated sampling at multiple sites; or a PM_{10} Pb/TSP Pb 'equivalency ratio' could be determined on a regional or site-specific basis.''

were somewhat mixed. Most of these commenters recommended maintaining Pb-TSP as the indicator to ensure that Pb emitted in larger particles is not overlooked by the Pb NAAQS. Some of those comments and others suggested keeping TSP as the indicator but revising the FRM to a low-volume TSP method [129] and considering tighter sampling height criteria to reduce variability.[130] Others, in considering a potential PM_{10}-based indicator or the use of PM_{10} data as a surrogate for Pb-TSP, noted the need for characterization of the relationship between Pb-PM_{10} and Pb-TSP, which varies with proximity to some sources. One state agency and a national organization of regulatory air agencies expressed clear support for revising the indicator to Pb-PM_{10}, predominantly citing advantages associated with improved technology and efficiency in data collection.

In considering these issues concerning the appropriate indicator, EPA takes note of previous Agency conclusions that the health evidence indicates that Pb in all particle size fractions, not just respirable Pb, contributes to Pb in blood and to associated health effects. Further, the evidence and exposure/risk estimates in the current review indicate that ingestion pathways dominate air-related exposure. Lead is unlike other criteria pollutants, where inhalation of the airborne pollutant is the key contributor to exposure. For Pb it is the quantity of Pb in ambient particles with the potential to deposit indoors or outdoors, thereby leading to a role in ingestion pathways, that is the key contributor to air-related exposure. As recognized by the Agency in setting the standard, and as noted by CASAC in their advice during this review, these particles include ultra-coarse particles. Thus, choosing the appropriate indicator requires consideration of the impact of the indicator on protection from both the inhalation and ingestion pathways of exposure and Pb in all particle sizes, including ultra-coarse particles.

As discussed in section V.A., the Agency recognizes the body of evidence indicating that the high-volume Pb-TSP sampling methodology contributes to imprecision in resultant Pb measurements due to variability in the efficiency of capture of particles of different sizes and thus, in the mass of Pb measured. For example, the measured values from a high-volume TSP sampler may differ substantially, depending on wind speed and direction, for the same actual ambient concentration of Pb-TSP.[131] Variability is most substantial in samples with a large portion of Pb particles greater than 10 microns, such as those samples collected near sources with emissions of ultra-coarse particles. The result is a clear risk of error from underestimating the ambient level of total Pb in the air, especially in areas near sources of ultra-coarse particles, by underestimating the amount of the ultra-coarse particles. There is also the potential for overestimation of individual sampling period measurements associated with high wind events.[132]

The low-volume PM_{10} sampling methodology does not exhibit such variability [133] due both to increased precision of the monitor and decreased spatial variation of Pb-PM_{10} concentrations. As a result, greater precision is associated with sample measurements for Pb collected using the PM_{10} sampling methodology. The result is a lower risk of error in measuring the ambient Pb in the PM_{10} size class than there is risk of error in measuring the ambient Pb in the TSP size class using Pb TSP samplers. On the other hand, PM_{10} samplers do not include the Pb in particles greater than PM_{10} that also contributes to the health risks posed by air-related Pb, especially in areas influenced by sources of ultra-coarse particles. There are also concerns over whether control strategies put in place to meet a NAAQS with a Pb-PM_{10} indicator will be effective in controlling ultra-coarse Pb-containing particles. In evaluating these two indicators, the differences in the nature and degree of these sources of error between Pb-TSP and Pb-PM_{10} need to be considered and weighed, to determine the appropriate way to protect the public from exposure to air-related Pb.

As noted above, EPA is concerned about the total mass of all Pb particles emitted into the air and subsequently inhaled or ingested. Measurements of Pb-TSP address a greater fraction of the particles of concern from a public health perspective than measurements of Pb-PM_{10}, but limitations with regard to the sampler mean that these data are less precise. EPA recognizes substantial variability in the high-volume Pb-TSP method, meaning there is a risk of not consistently identifying sites that fail to achieve the standard, both across sites and across time periods for the same site.

Alternatively, using low-volume Pb-PM_{10} as the indicator would allow the use of a technology that has better precision in measuring PM_{10}. In addition, since Pb-PM_{10} concentrations have less spatial variability, such monitoring data may be representative of Pb-PM_{10} air quality conditions over a larger geographic area (and larger populations) than would Pb-TSP measurements. The larger scale of representation for Pb-PM_{10} would mean that reported measurements of this indicator, and hence designation outcomes, would be less sensitive to exact monitor siting than with Pb-TSP as the indicator.[134] However, there would be a different source of error, in that larger Pb particles not captured by PM_{10} samplers would not be measured.

[129] The Pb-TSP FRM specification, 40 CFR 50 appendix G, currently explicitly requires the use of the high-volume TSP FRM sampler which is required by appendix B for the mass of TSP. Therefore it would require amendments to 40 CFR 50 appendix B and/or G (or a new dedicated appendix) to establish a low-volume TSP sampler as the only FRM, or as an alternative FRM, for TSP and/or Pb-TSP measurement. A number of researchers have utilized both self-built and commercially available low-volume TSP samplers in ambient air studies. Typically, these samplers are identical to low-volume PM_{10} FRM samplers with the exception that their inlets and other size separation devices (or lack thereof) are aimed at collecting TSP. EPA is not aware of any rigorous evaluation of the performance of these available, non-designated low-volume TSP samplers or their equivalence to the TSP FRM. No one has applied to date for designation of a low-volume TSP sampler as a FEM, either for TSP measurement per se or for purposes of Pb-TSP measurement.

[130] Currently, probe heights for Pb-TSP and PM_{10} sampling are allowed to be between 2 and 15 meters above ground level for neighborhood-scale monitoring sites (those intended to represent concentrations over a relatively large area around the site) and between 2 and 7 meters for microscale sites. Near very low-height sources of TSP, including fugitive dust sources at ground level, concentrations of TSP, especially the concentrations of particles larger than 10 microns, can vary substantially across this height range with higher concentrations closer to the ground; near-ground concentrations can also vary more in time than concentrations higher up.

[131] As noted in section V, the collection efficiency (over the 24-hour collection period) of particles larger than approximately 10 microns in a high-volume TSP FRM sampler varies with wind speed due to aerodynamic effects, with a lower collection efficiency under high winds. The collection efficiency also varies with wind direction due to the non-cylindrical shape of the TSP sampler inlet. These characteristics tend in the direction of reporting less than the true TSP concentration over the 24-hour collection period.

[132] We note that it is possible for high winds to blow Pb particles onto a high-volume TSP sampler's filter after the end of its 24-hour collection period before the filter is retrieved, causing the reported concentration for the 24-hour period to be higher than the actual 24-hour concentration.

[133] Low-volume PM_{10} samplers are equipped with an omni-directional (cylindrical) inlet, which reduces the effect of wind direction, and a sharp particle separator which excludes most of the particles greater than 10–15 microns in diameter whose collection efficiency is most sensitive to wind speed. Also, in low-volume samplers, the filter is protected from post-sampling contamination.

[134] The larger scale would also make comparisons between two or more monitoring sites more indicative of the true comparison between the areas surrounding the monitoring sites, with regard to the Pb captured by Pb-PM_{10} monitors, which could be informative in studies of Pb uptake and health effects in populations.

The fraction of Pb collected with a TSP sampler that would not be collected by a PM_{10} sampler varies depending on proximity to sources of ultra-coarse Pb particles and the size mix of the particles they emit (as well as the sampling variability inherent in the method discussed above). This means that this error is of most concern in locations in closer proximity to such sources, which may also be locations with some of the higher ambient air levels. As discussed below, such variability would be a consideration in determining the appropriate level for a standard based on a Pb-PM_{10} indicator.

Accordingly, we believe it is reasonable to consider continued use of a Pb-TSP indicator, focusing on the fact that it specifically includes the ultra-coarse Pb particles in the air that are of concern and need to be addressed in protecting public health from air-related exposures. In considering the option of retaining Pb-TSP as the indicator, EPA recognizes that high-volume FRM TSP samplers would continue to be used at many monitoring sites operated by State and local agencies. In addition, it is possible that one or more low-volume TSP monitors would be approved as FEM, under the provisions of 40 CFR 53, Ambient Air Monitoring Reference and Equivalent Methods. EPA believes, along with some commenters as noted above, that low-volume Pb-TSP sampling would have important advantages over high-volume Pb-TSP sampling.[135] To facilitate the ability of monitor vendors and monitoring agencies to gain FEM status for low-volume Pb-TSP monitors, EPA is proposing certain revisions to the side-by-side equivalence testing requirements in 40 CFR 53 regarding the ambient Pb concentrations required during testing so that testing is more practical for a monitor vendor to conduct, as described in more detail in section V below. We note that 40 CFR 53.7, Testing of Methods at the Initiative of the Administrator, allows EPA itself to conduct the required equivalence testing for a method and then determine whether the requirements for equivalence are met. It would also be possible for EPA to promulgate amendments to 40 CFR 50 establishing one or more particular designs of a low-volume sampler as a Pb-TSP FRM, or to establish performance specifications that would facilitate the approval of low-volume samplers as FRM on a performance basis rather than a design basis; this could be done as a replacement for the high-volume TSP and Pb-TSP FRM or as an alternative TSP and/or Pb-TSP FRM. Either path to FRM status would avoid the need for the side-by-side testing, prescribed by 40 CFR 53, of low-volume samplers to demonstrate equivalence to the high-volume FRM sampler, although some amount and type of new testing in the field or in a wind tunnel may be appropriate before such changes should be made. EPA invites comments on the low-volume TSP sampler concept.

Within the option of continued use of a Pb-TSP indicator, EPA recognizes that some State, local, or tribal monitoring agencies, or other organizations, for the sake of the advantages noted above, may wish to deploy low-volume Pb-PM_{10} samplers rather than Pb-TSP samplers. In anticipation of this, we have also considered an approach within the option of retaining Pb-TSP as the indicator that would allow the use of Pb-PM_{10} data (when and if low-volume Pb-PM_{10} samplers have been approved by EPA as either FRM or FEM), with adjustment(s), for monitoring for compliance with the Pb-TSP NAAQS. This approach would have five components: (1) The establishment of a FRM specification for low-volume Pb-PM_{10} monitoring including both a PM_{10} sampler specification and a reference chemical analysis method for determination of Pb in the collected particulate matter; (2) the establishment of a path to FEM designation for Pb-PM_{10} monitoring methods that differ from the FRM in either the sampler or the analytical method; (3) flexibility for monitoring agencies to deploy low-volume Pb-PM_{10} monitors anywhere that Pb monitoring is required by the revised Pb monitoring requirements to help implement the revised NAAQS; (4) specific steps for applying an adjustment to low-volume Pb-PM_{10} data for purposes of making comparisons to the level of the NAAQS specified in terms of Pb-TSP, and (5) a provision in the data interpretation guidelines that, whenever and wherever Pb-TSP data from a monitoring site is available and sufficient for determining whether or not the Pb-TSP standard has been exceeded, any collocated Pb-PM_{10} data from that site for the associated time period will not be considered. The first three and the last components are discussed in depth in sections IV and V below. Because the issue of adjustment to low-volume Pb-PM_{10} data is linked closely to considerations of the advantages of one indicator option versus another, it is discussed here.

In considering how to identify the appropriate adjustment(s) to be made to Pb-PM_{10} data for purposes of making comparisons to the level of the NAAQS specified in terms of Pb-TSP, we recognize the importance to protecting public health of taking into account the ultra-coarse particles that are not included in Pb-PM_{10} measurement. As discussed below, one approach to doing so would be to adjust or scale Pb-PM_{10} data upwards before comparison to a Pb-TSP NAAQS level where the data are collected in an area that can be expected to have ultra-coarse particles present.

Pb-PM_{10}/Pb-TSP relationships vary from site to site and time to time. These Pb-PM_{10}/Pb-TSP relationships have a systematic variation with distance from emissions sources emitting particles larger than would be captured by Pb-PM_{10} samplers, such that generally there are larger differences between Pb-PM_{10} and Pb-TSP near sources. This is due to the faster deposition of the ultra-coarse particles (as described in section II.A.1). The exact size mix of particles at the point(s) of emissions release and the height of the release point(s) also affect the relationship. Accordingly, EPA is proposing to require the one-time development and the continued use of site-specific adjustments for Pb-PM_{10} data, for those sites for which a State prefers to conduct Pb-PM_{10} monitoring rather than Pb-TSP monitoring. Site-specific studies to establish the relationships between Pb-TSP and Pb-PM_{10}, conducted using side-by-side paired samplers, would allow Pb-PM_{10} monitoring using locally determined factors based on local study data to determine compliance with a NAAQS based on Pb-TSP.

In addition, EPA invites comment on also providing in the final rule default scaling factor(s) for use of Pb-PM_{10} data in conjunction with a Pb-TSP indicator, as an alternative for States which wish to conduct Pb-PM_{10} monitoring rather than Pb-TSP monitoring near Pb sources but prefer not to conduct a site-specific scaling factor study. EPA has identified and analyzed available collocated Pb-PM_{10} and Pb-TSP data from 23 monitoring sites in seven States. (Schmidt and Cavender, 2008). This analysis considered both source-

[135] Low-volume Pb-TSP samplers could be assembled by making low-cost parts substitution to either low-volume PM_{10} or low-volume $PM_{2.5}$ samplers; some models would have the same sequential sampling ability as CASAC has noted for low-volume Pb-PM_{10} samplers; sensitivity to wind direction would be eliminated; and their flow control and data processing and reporting abilities would be substantially better than high-volume Pb-TSP samplers. Low-volume Pb-TSP sampling data would have the same geographic variability as high-volume Pb-TSP sampling data, however. The size-specific capture efficiency curves of currently available commercial low-volume sampling systems are not well characterized, nor their sensitivity to wind speed. EPA therefore recognizes some uncertainty about their equivalence to high-volume samplers in terms of the capture of ultra-coarse particles.

oriented and nonsource-oriented sites. In this analysis, EPA identified only three of the 23 monitoring sites with collocated data as being source-oriented. One of these sites was near an operating Pb smelter at the time of the collocated monitoring; Pb emissions from smelters typically contain both ultra-coarse particles from materials handling and resuspension of contaminated dust, and fine and coarse particles from the high temperature smelting operation itself. However, since this study was conducted, EPA has promulgated a Maximum Achievable Control Technology (MACT) standard for primary lead smelting that controls process and fugitive dust emissions. (64 FR 30194, June 4, 1999). The other two source-oriented sites include one located near a battery manufacturer, and one located near an automobile plant. The data for the smelter site was collected in 1988 and indicate an average Pb-TSP concentration of about 2.5 $\mu g/m^3$. The data for the battery manufacturer site were collected in the mid-1990s and indicate an average Pb-TSP concentration of about 0.09 $\mu g/m^3$; data for the third site, located near an automotive plant, collected within the past 5 years, indicate an average Pb-TSP concentration at that site of about 0.03 $\mu g/m^3$. As discussed in Schmidt and Cavender (2008), ratios between Pb-TSP and Pb-PM_{10} concentrations varied somewhat within the data for each site, but the ratios between the Pb-TSP and Pb-PM_{10} concentration averages were 2.0 for the smelter site (based on 20 data pairs), 1.6 at the site near the battery manufacturer (based on 107 data pairs), and 1.1 at the site located near an automotive plant (based on 167 data pairs).

Collectively, these three monitoring sites suggest that site-specific scaling factors for source-oriented monitoring sites may vary between 1.1 and 2.0; the range may also be greater. EPA notes that in selecting a default factor for source-oriented monitoring sites, if that approach is taken in the final rule, it may be appropriate to consider default adjustment factors from within the mid to upper part of this range rather than the lower end to avoid the possibility of underestimating the appropriate scaling factor for a large proportion of the source-oriented sites for which States might choose the default factor rather than conduct a local study. On this basis, EPA invites comment on the possibility of providing a default factor(s) for source-oriented sites and on the selection of a value(s) from within this range for all source-oriented monitoring sites, as an option to the proposed requirement for development a site-specific factor through analysis of paired monitoring data. EPA invites comment on the selection of a single or multiple default factors for source-oriented sites from within this range. While the selection of the scaling factor in concept could depend on a characterization of the particle size mix emitted by the Pb source, we note that reliable information on the mix of coarse and ultra-coarse particles may often be unavailable. For example, EPA could select a default factor that is at or near the upper end of the range, 2.0, to avoid the risk of underprotection in situations in which there is as high or nearly as high a proportion of ultra-coarse Pb as at the smelter site. Alternatively, EPA could discount the smelter data set on the basis that the 1988 data set does not reasonably represent any likely current or future smelter situation. Similarly, EPA could rely on the data taken near the automotive plant since it is the most recent and largest dataset. EPA also invites comment on other sets of paired data from near Pb sources of which we may be unaware, and comment on other approaches of selecting a default factor for the final rule based on paired data, including approaches that might use more than one default factor for source-oriented monitoring sites with the selection of the factor for a given monitoring site depending on the characteristics of the nearby sources, the ambient concentration of Pb-PM_{10}, or other factors.

EPA also invites comment on whether and what default scaling factor(s) should be established for monitoring sites which, as far as is known, are not influenced by nearby emission sources. We have reviewed paired data from the 20 monitoring sites that appear to fit this description (Schmidt and Cavender, 2008). Average Pb-TSP concentrations at nearly all these sites were near to or below the lowest concentration on which comments are invited as to the NAAQS level. Judging from ratios at these 20 sites, it appears that site-specific factors generally range from 1.0 to 1.4 (with the factors for three sites ranging from 1.8 to 1.9), and the ratios may be influenced by measurement variability in both samplers as well as by actual air concentrations. Given the relatively low ambient concentrations that we believe currently prevail at nonsource-oriented sites, the value of a default scaling factor selected within the range of 1.0 to 1.4 would have little effect on the NAAQS compliance determination at such sites. EPA invites comment on the approach of requiring use of a default factor(s) for adjusting Pb-PM_{10} data at nonsource-oriented sites and on the selection of a value(s) from within the range of 1.0 to 1.4 and also solicits comment on selection of a default scaling factor from within the broader range of 1.0 to 1.9. We note that allowing the use of a default scaling factor of 1.0 for nonsource-oriented sites would in effect allow a State the option of comparing Pb-PM_{10} data directly to the level of the Pb-TSP standard at nonsource-oriented monitoring sites, without conducting a site-specific study. Below, and in section II.E.4, EPA discusses the possibility of revising the indicator to Pb-PM_{10}, which would result in such unadjusted comparisons of Pb-PM_{10} data to the standard at all monitoring sites.

EPA recognizes that the available data from collocated monitoring of Pb-TSP and Pb-PM_{10}, described above, have limitations which make their interpretation and use in selecting default scaling factors subject to considerable uncertainty. All of the Pb-PM_{10} measurements at these sites were made with high-volume PM_{10} samplers, which are more variable than the low-volume samplers for which scaling factors would actually be applied after the final rule; this greater variability no doubt has added to the variation in ratios discussed above. Only three source-oriented sites have collocated data; with such a small sample of sites both the range of ratios and the distribution of ratios among all current and future source-oriented sites remains uncertain. There were many more nonsource-oriented sites which tended to show notably lower ratios, implying lower scaling factors, but all had relatively low concentrations; these ratios may or may not be representative of monitoring sites near well controlled Pb sources. In many cases, the period of collocated testing was only a few months; ratios observed in such a short period may not be representative of ratios that occur at other times of the year that may be more critical to attainment status. Also, EPA has not yet had the benefit of CASAC review of the detailed compilation of these data, as (Schmidt and Cavender, 2008) was prepared subsequent to the most recent consultation with CASAC's AAMM Subcommittee. Because of these uncertainties, EPA is proposing to require States that wish to use Pb-PM_{10} data for a Pb-TSP standard to develop site-specific scaling factors based on their own collocated monitoring using paired Pb-TSP and low-volume Pb-PM_{10} samplers over at least a one-year period, as described in section IV. EPA intends

to encourage States to consider conducting local studies, even if the final rule allows the use of default factors. Also, EPA invites comment on whether to provide for the use of default scaling factors, and the values of those factors.

As a possible second option, taking into consideration the advice of the CASAC Pb Panel and members of the CASAC AAMM Subcommittee, EPA has also considered potential revision of the indicator to Pb-PM_{10}. In so doing, we recognize several potential important benefits of such a revision, as well as the need to reflect such a revision in the selection of level of the standard.[136] We recognize that the low volume PM_{10} sampler provides better precision and size selection characteristics which would make the associated data more comparable across sites.

In considering a potential revision of the indicator to Pb-PM_{10}, we recognize that an important issue is whether regulating concentrations of Pb-PM_{10} will lead to appropriate controls on all particle size Pb emissions from sources. For example, it would be of concern if a NAAQS based on a Pb-PM_{10} indicator resulted in different emissions control decisions at sources with a large percentage of Pb in the size range not substantially captured by PM_{10} sampling (e.g., fugitive dust emissions from Pb smelters) than the emission control decisions that would be made if the NAAQS was based on Pb-TSP. In that case, a PM_{10}-based NAAQS might not yield emissions changes by some Pb sources which under a Pb-TSP indicator would have contributed to NAAQS exceedances and subsequent emissions changes. Alternatively, while collocated Pb-TSP and Pb-PM_{10} data are lacking for a broad range of source types, there are likely many sources (e.g., high temperature combustion processes) for which virtually all of the emitted particles represented in a Pb-TSP measurement would be captured by a Pb-PM_{10} measurement. Further, there are likely other source types with a range of particle sizes extending beyond Pb-PM_{10}, for which controls adopted to meet a Pb-PM_{10} requirement would also achieve a proportional reduction in ultra-coarse particles. In these situations, one might not expect any difference in emissions control decisions whether the NAAQS is Pb-PM_{10}-based or Pb-TSP-based.

If the indicator were to be revised to Pb-PM_{10}, low-volume Pb-PM_{10} samplers would become the required approach to Pb monitoring at required monitoring sites and would be a logical choice wherever else NAAQS-oriented Pb monitoring is undertaken. Nonetheless EPA notes that retaining Pb-TSP monitors at some relatively small subset of the Pb-PM_{10} monitoring sites would be beneficial for purposes of scientific understanding of both ambient conditions and the performance of the two types of measurement systems.

For reasons discussed here, and taking into account information and assessments presented in the Criteria Document, Staff Paper, and ANPR, the advice and recommendations of CASAC and of members of the CASAC AAMM Subcommittee, and public comments to date, the Administrator proposes to retain the current indicator of Pb-TSP, measured by the current FRM, a current FEM, or an FEM approved under the proposed revisions to 40 CFR part 53, but with expansion of the measurements accepted for determining attainment or nonattainment of the Pb NAAQS to provide an allowance for use of Pb-PM_{10} data, measured by the new low-volume Pb-PM_{10} FRM specified in the proposed appendix Q to 40 CFR part 50 or by a FEM approved under the proposed revisions to 40 CFR part 53, with site-specific scaling factors as described above and more specifically below in section IV. The Administrator invites comment on also providing States the option of using default scaling factors instead of conducting the testing that would be needed to develop the site-specific scaling factors. In consideration of all of the issues discussed above, the Administrator also invites comment on a second option, a revision of the current indicator to Pb-PM_{10}. (Considerations related to the level of a standard based on a PM_{10} indicator are discussed below in section II.E.4.) The Administrator solicits comment on all of the issues discussed above, and specifically with regard to the potential for a Pb-PM_{10} indicator to influence implementation of controls in ways that would lead to less control associated with larger particles than might be achieved with a Pb-TSP-based NAAQS, taking into account the variability noted above for TSP sampling.

2. Averaging Time and Form

The statistical form of the current standard is a not-to-be-exceeded or maximum value, averaged over a calendar quarter. This might also be described as requiring that no average air Pb concentration representing a time period of duration as long as calendar quarter (or longer) may exceed the level of the standard. As noted in section II.D.1.a, EPA set the standard in 1978 as a ceiling value with the conclusion that this air level would be safe for indefinite exposure for young children (43 FR 46250).

The basis for selection of the current standard's averaging time of calendar quarter reflects consideration of the evidence available when the Pb NAAQS were promulgated in 1978. At that time, the Agency had concluded that the level of the standard, 1.5 $\mu g/m^3$, would be a ''safe ceiling for indefinite exposure of young children'' (43 FR 46250), and that the slightly greater possibility of elevated air Pb levels for shorter periods within the quarterly averaging period as contrasted to the monthly averaging period proposed in 1977 (43 FR 63076), was not significant for health. These conclusions were based in part on the Agency's interpretation of the health effects evidence as indicating that 30 $\mu g/dL$ was the maximum safe level of blood Pb for an individual child.

With regard to averaging time, after consideration of the evidence available at that time, the 1990 Staff Paper concluded that ''[a] monthly averaging period would better capture short-term increases in lead exposure and would more fully protect children's health than the current quarterly average'' (USEPA, 1990b). The 1990 Staff Paper further concluded that ''[t]he most appropriate form of the standard appears to be the second highest monthly average in a 3-year span. This form would be nearly as stringent as a form that does not permit any exceedances and allows for discounting of one 'bad' month in 3 years which may be caused, for example, by unusual meteorology.'' In their review of the 1990 Staff Paper, the CASAC Pb Panel concurred with the staff recommendation to express the lead NAAQS as a monthly standard not to be exceeded more than once in three years.

As summarized in section II.B above and discussed in detail in the Criteria Document, the currently available health effects evidence[137] indicates a wider variety of neurological effects, as well as immune system and hematological effects, associated with substantially lower blood Pb levels in children than were recognized when the standard was set in 1978. Further, the health effects evidence with regard to characterization of a threshold for

[136] EPA recognizes and has specifically considered that such a decision would affect the selection of the level of the standard, recognizing that it is the combination of indicator and level (with averaging and time and form) that determine the degree of protection afforded by the standard. Section II.E.4 further considers the impact of adoption of a Pb-PM_{10} indicator on the selection of a level for the standard.

[137] The differing evidence and associated strength of the evidence for these different effects is described in detail in the Criteria Document.

adverse effects has changed since the standard was set in 1978, as have the Agency's views on the characterization of a safe blood Pb level.[138] In consideration of averaging time for the Pb NAAQS, we note the following aspects of the current health effects evidence.

- Children are exposed to ambient Pb via inhalation and ingestion, with Pb that is taken into the body absorbed through the lungs and through the gastrointestinal tract. Studies on Pb uptake, elimination, and distribution show that Pb is absorbed into peripheral tissues in adults within a few days (USEPA 1986a; USEPA 1990b, p. IV–2). Absorption of Pb from the gastrointestinal tract appears to be greater and faster in children as compared to adults (CD, Section 4.2.1). Once absorbed, it is quickly distributed from plasma to red blood cells and throughout the body.
- Lead accumulates in the body and is only slowly removed, with bone Pb serving as a blood Pb source for years after exposure and as a source of fetal Pb exposure during pregnancy (CD, Sections 4.3.1.4 and 4.3.1.5).
- Blood Pb levels, including levels of the toxicologically active fraction, respond quickly to increased Pb exposure, such that an abrupt increase in Pb uptake rapidly changes blood Pb levels. The associated time to reach a new quasi-steady state with the total body burden after such an occurrence is projected to be approximately 75 to 100 days (CD, p. 4–27).
- The elimination half-life, which describes the time for blood Pb levels to stabilize after a reduction in exposure, for the dominant phase for blood Pb responses to changes in exposure is on the order of 20 to 30 days for adults (CD, p. 4–25). Blood elimination half-lives are influenced by contributions from bone. Given the tighter coupling in children of bone stores with blood levels, children's blood Pb is expected to respond more quickly than adults (CD, pp. 4–20 and 4–27).
- Data from NHANES II and an analysis of the temporal relationship between gasoline consumption data and blood lead data generally support the inference of a prompt response of children's blood Pb levels to changes in exposure. Children's blood Pb levels and the number of children with elevated blood Pb levels appear to respond to monthly variations in Pb emissions from Pb in gasoline (EPA, 1986a, p. 11–39; Rabinowitz and Needleman, 1983; Schwartz and Pitcher, 1989; USEPA, 1990b).
- The evidence with regard to sensitive neurological effects is limited in what it indicates regarding the specific duration of exposure associated with effect, although it indicates both the sensitivity of the first 3 years of life and a sustained sensitivity throughout the lifespan as the human central nervous system continues to mature and be vulnerable to neurotoxicants (CD, Section 8.4.2.7). The animal evidence supports our understanding of periods of development with increased vulnerability to specific types of effect (CD, Section 5.3), and indicates a potential importance of exposures on the order of months.
- Evidence of a differing sensitivity of the immune system to Pb across and within different periods of life stages indicates a potential importance of exposures as short as weeks to months duration. For example, the animal evidence suggests that the gestation period is the most sensitive life stage followed by early neonatal stage, and within these life stages, critical windows of vulnerability are likely to exist (CD, Section 5.9 and p. 5–245).

Evidence described in the Criteria Document and the risk assessment indicate that ingestion of dust can be a predominant exposure pathway for young children to air-related Pb, and that there is a strong association between indoor dust Pb levels and children's blood Pb levels. As stated in the Criteria Document, ''given the large amount of time people spend indoors, exposure to Pb in dusts and indoor air can be significant'' (CD, p. 3–27). The Criteria Document further describes studies that evaluated the influence of dust Pb exposure on children's blood Pb: ''Using a structural equation model, Lanphear and Roghmann (1997) also found the exposure pathway most influential on blood Pb was interior dust Pb loading, directly or through its influence on hand Pb. Both soil and paint Pb influenced interior dust Pb; with the influence of paint Pb greater than that of soil Pb. Interior dust Pb loading also showed the strongest influence on blood Pb in a pooled multivariate regression analysis (Lanphear *et al.*, 1998).'' (CD, p. 4–134). Further, a recent study of dustfall near an open window in New York City indicates the potential for a relatively rapid response of indoor dust Pb loading to ambient airborne Pb, on the order of weeks (CD, p. 3–28; Caravanos *et al.*, 2006a).

We note that the health effects evidence identifies varying length durations in exposure that may be relevant and important. In light of uncertainties in aspects such as response times of children's exposure to airborne Pb, we recognize, as in the past, that this evidence provides a basis for consideration of both calendar quarter and calendar month as averaging times.

In considering averaging time and form, EPA has combined the current quarterly averaging time with the current not-to-be exceeded (maximum) form and has also combined a monthly averaging time with a second maximum form, so as to provide an appropriate degree of year-to-year stability that a maximum monthly form would not afford. We also note that, as discussed below, the second maximum monthly form provides a roughly comparable degree of protection on a broad national scale.

In this consideration of averaging time and form, EPA has taken into account analyses using air quality data for 2003–2005 that are presented in the Staff Paper (chapter 2). These analyses consider both a period of three calendar years and a period of one calendar year (with the form of the current standard being the maximum quarterly mean). These analyses indicate that, with regard to either single-year or 3-year statistics for the 2003–2005 dataset, a second maximum monthly mean yields very similar, although just slightly greater, numbers of sites exceeding various alternative levels as a maximum quarterly mean, with both yielding fewer exceedances than a maximum monthly mean.[139] That is, these two averaging time and form combinations resulted in roughly the same number of areas that would not attain a standard at any given level on a broad national scale, suggesting roughly comparable public health protection. However, the relative protection provided by these two forms may differ from area to area. For example, some of the areas meeting a maximum quarterly mean standard over the 2003–2005 period at a given level did not meet a second maximum monthly mean standard at the same level because there were at least two months with high monthly concentrations which were averaged with a lower concentration month in the same quarter. On the other hand,

[138] For example, EPA recognizes today that ''there is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects'' (CD, p. 8–63).

[139] For example, 49 sites (of 189) exceed a standard level of 0.10 $\mu g/m^3$ based on a form of maximum quarterly mean while 54 sites exceed based on a form of second maximum monthly mean. Further, 25 sites exceed a standard level of 0.30 $\mu g/m^3$ based on a form of maximum quarterly mean while 29 sites exceed based on a form of second maximum monthly mean (Staff Paper, Table 2–6).

theoretically it is possible for an area to meet a given standard level with a second maximum monthly mean averaging time and form and not meet it for a maximum quarterly mean (e.g., the second highest monthly average may be below the standard level while the quarterly average may exceed it). Moreover, control programs to reduce quarterly mean concentrations may not have the same protective effect as control programs aimed at reducing concentrations in every individual month. Given the limited scope of the current monitoring network which lacks monitors near many significant Pb sources and uncertainty about Pb source emissions and possible controls, it is difficult to more quantitatively compare the protectiveness of the quarterly mean versus the second maximum monthly mean approaches.

In their advice to the Agency in this review, CASAC has recommended that consideration be given to changing from a calendar quarter to a monthly averaging time (Henderson, 2007a, 2007b, 2008). In making that recommendation, CASAC emphasizes support from studies that suggest that blood Pb concentrations respond at shorter time scales than would be captured completely by quarterly values, as indicated by their description of their recommendation for adoption of a monthly averaging time as ''more protective of human health in light of the response of blood lead concentrations that occur at sub-quarterly time scales'' (Henderson, 2007a). With regard to form of the standard, CASAC has stated that one could ''consider having the lead standards based on the second highest monthly average, a form that appears to correlate well with using the maximum quarterly value'', while also indicating that ''the most protective form would be the highest monthly average in a year'' (Henderson, 2007a).

Among the public comments the Agency received on the discussion of averaging time and form in the ANPR, the majority concurred with the CASAC recommendation for a revision of the averaging time to a calendar month.

The 1990 Staff Paper and the Staff Paper for this review both recommended that the Administrator consider specifying, in the form of the NAAQS, that compliance with the NAAQS will be evaluated over a 3-year period. The Administrator has considered this recommendation and is proposing to adopt it. In the 3-year approach, a monitor would be considered to be in violation of the NAAQS as of a certain date if in any of the three previous calendar years with sufficiently complete data (as explained in detail in section IV below), the value of the selected form of the indicator (e.g., second maximum monthly average or maximum quarterly average) exceeded the level of the NAAQS. A monitor, initially or after once having violated the NAAQS, would not be considered to have attained the NAAQS until three years have passed without the form and level of the standard being violated. Many types of Pb sources have variable emissions from day-to-day and year-to-year due to market conditions for their products and/or weather variations that can affect the generation of fugitive dust from contaminated roadways and grounds. In addition, variations in wind patterns from year to year can cause a near-source Pb monitor to be exposed to high concentrations on more days in one year than in another, even if source emissions are constant, especially if it operates on only some days. Thus, it is possible for a monitor to indicate a violation of a hypothetical form and level in one period but not in another, even if no permanent controls have been applied at nearby source(s). Analysis of historical Pb air concentration data has confirmed that this pattern of fluctuating monitoring results can happen at the levels and forms being proposed. It would potentially reduce the public health protection afforded by the standard if areas fluctuated in and out of formal nonattainment status so frequently that states do not have opportunity and incentive to identify sources in need of more emission control and to require those controls to be put in place. The 3-year approach would help ensure that areas initially found to be violating the NAAQS have effectively controlled the contributing lead emissions before being redesignated to attainment/maintenance.

In considering averaging time and form for the standard, the Administrator has considered the information summarized above (described in more detail in Criteria Document and Staff Paper), as well as the advice from CASAC and public comments. The Administrator recognizes that there is support in the evidence for a monthly averaging time consistent with the following observations: (1) The health evidence indicates that very short exposures can lead to increases in blood Pb levels, (2) the time period of response of indoor dust Pb to airborne Pb can be on the order of weeks, and (3) the health evidence indicates that adverse effects may occur with exposures during relatively short windows of susceptibility, such as prenatally and in developing infants.[140] The Administrator also recognizes limitations and uncertainties in the evidence including the limited available evidence specific to the consideration of the particular duration of sustained airborne Pb levels having the potential to contribute to the adverse health effects identified as most relevant to this review, as well as variability in the response time of indoor dust Pb loading to ambient airborne Pb.

Based on these considerations and the air quality analyses summarized above, the Administrator concludes that this information provides support for an averaging time no longer than a calendar quarter. Further, the Administrator recognizes that if substantial weight is given to the evidence of even shorter times for response of dust Pb, blood Pb, and associated effects to airborne Pb, a monthly averaging time may be appropriate. Accordingly, the Administrator is proposing two options with regard to the form and averaging time for the standard, and with both he proposes making the time period evaluated in considering attainment be 3 years. One option is to retain the current not-to-be-exceeded form with an averaging time of a calendar quarter, such that the form would be maximum quarterly average across a 3-year span. The second option is to revise the averaging time to a calendar month and the form to be the second highest monthly average across a 3-year span. Based on the considerations discussed above, EPA requests comment on whether a level for a NAAQS with a monthly averaging time and a second-highest monthly average form should be based on an adjustment to a higher level than the level for a NAAQS with a quarterly averaging time and a not-to-be-exceeded form, and, if so, on the magnitude of the adjustment that would be appropriate.

3. Level for a Pb NAAQS With a Pb-TSP Indicator

With regard to level of the standard, for a standard using a Pb-TSP indicator, we first discuss evidence-based and exposure/risk-based considerations, including considerations and

[140] The health evidence with regard to the susceptibility of the developing fetus and infants is well documented in the evidence as described in the 1986 Criteria Document, the 1990 Supplement (e.g., chapter III) and the 2006 Criteria Document. For example, ''[n]eurobehavioral Neurobehavioral effects of Pb-exposure early in development (during fetal, neonatal, and later postnatal periods) in young infants and children (#7 years old) have been observed with remarkable consistency across numerous studies involving varying study designs, different developmental assessment protocols, and diverse populations.'' (CD, p. E–9)

conclusions of the Staff Paper, in sections II.E.3.a and II.E.3.b below. This is followed by a summary of CASAC advice and recommendations and public comments (section II.E.3.c) and the Administrator's proposed conclusions (section II.E.3.d). In addition, we discuss considerations and solicit comment with regard to a level of a standard using a Pb-PM_{10} indicator in section II.E.4 below.

a. Evidence-Based Considerations

As a general matter, EPA recognizes that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard. As summarized above and discussed in greater depth in the Criteria Document (CD, Sections 4.3 and 6.1.3), the epidemiological evidence that associates Pb exposures with health effects generally focuses on blood Pb for the dose metric.[141] In addition, exposure to Pb comes from various media, only some of which are air-related. This presents a more complex situation than does evidence of associations between occurrences of health effects and ambient air concentrations of an air pollutant, such as is the case for particulate matter and ozone. Further, for the health effects receiving greatest emphasis in this review (neurological effects, particularly neurocognitive and neurobehavioral effects, in children), no threshold levels can be discerned from the evidence. As was recognized at the time of the last review, estimating a threshold for toxic effects of Pb on the central nervous system entails a number of difficulties (CD, pp. 6–10 to 6–11). The task is made still more complex by support in the evidence for a nonlinear rather than linear relationship of blood Pb with neurocognitive decrement, with greater risk of decrement-associated changes in blood Pb at the lower levels of blood Pb in the exposed population (Section 3.3.7; CD, Section 6.2.13). In this context EPA notes that the health effects evidence most useful in determining the appropriate level of the NAAQS is this large body of epidemiological studies. Unlike the recent review of the NAAQS for ozone, there are no clinical studies useful for informing a determination of the appropriate level for a standard.[142] The discussion below therefore focuses on the epidemiological studies, recognizing and taking into consideration the complexity and resulting uncertainty in using this body of evidence to determine the appropriate level for the NAAQS.

In considering the evidence with regard to selection of the level of the standard, the Agency has considered the same evidence-based frameworks discussed above in section II.D.2.a on the adequacy of the current standard. That is, the Staff Paper considered how to apply an adapted 1978 framework to the much expanded body of evidence that is now available, and the Agency has further considered this evidence in the context of the air-related IQ loss evidence-based framework that builds on a recommendation by the CASAC Pb Panel. These evidence-based approaches are discussed below in considering the appropriate standard levels to propose.

As noted in section II.D.2.a above, this review focuses on young children as a key sensitive population for Pb exposures. In this sensitive population, the current evidence demonstrates the occurrence of health effects, including neurological effects, associated with blood Pb levels extending well below 10 µg/dL (CD, sections 6.2, 8.4 and 8.5). As further described in section II.D.2.a above, some studies indicate Pb effects on intellectual attainment of children for which population mean blood Pb levels in the analysis ranged from approximately 2 to 8 µg/dL (CD, Sections 6.2, 8.4.2 and 8.4.2.6). Further, as noted above, the current evidence does not indicate a threshold for the more sensitive health endpoints such as neurological effects in children (CD, pp. 5–71 to 5–74 and Section 6.2.13).[143]

As when the standard was set in 1978, there remain today contributions to blood Pb levels from nonair sources. As discussed above (section II.D.2), current evidence is limited with regard to estimates of the aggregate reduction since 1978 of all nonair sources to blood Pb and with regard to an estimate of current nonair blood Pb levels (discussed more fully in sections II.A.4) In recognition of temporal reductions in nonair sources discussed in section II.A.4 and in the context of estimates pertinent to an application of the 1978 framework, the CASAC Pb Panel recommended consideration of 1.0 to 1.4 µg/dL or lower as an estimate of the nonair component of blood Pb pertinent to average blood Pb levels in children (as described in section II.A.4 above; Henderson, 2007a). The Staff Paper considered this range of 1.0 to 1.4 µg/dL for the nonair component of blood Pb in its application of the adapted 1978 evidence-based framework.

As discussed in section II.B.1.c, the current evidence in conjunction with the results and observations drawn from the exposure assessment support a focus on air-to-blood ratios for children in the range of 1:3 to 1:7, based on consideration of both inhalation and ingestion exposure pathways and on the lower air and blood Pb levels pertinent to this review. In considerations here, we have described the value of 1:5 as falling somewhat central within the range supported by the evidence.

i. Evidence-Based Framework Considered in the Staff Paper

Recommendations in the Staff Paper on standard levels were based upon an approach that built upon and adapted the general approach used by EPA in setting the standard in 1978. In adapting this approach to the currently available information, the Staff Paper recognized the more extensive and stronger body of evidence now available on a broader range of health effects associated with exposure to Pb. For example, EPA recognizes that today ''there is no level of Pb exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects'' (CD, p. 8–63). This is in contrast to the situation in 1978 when the Agency judged that the maximum safe individual and geometric mean blood Pb levels for a population of young children were 30 µg/dL and 15 µg/dL, respectively.[144]

In the Staff Paper application of an adapted 1978 framework, the focus shifted away from identifying a safe blood Pb level for an individual child (and then determining an ambient air level that would keep a very high percentage of children at or below that safe level), because information was no longer available to identify such a level. Rather, the Staff Paper approach focused on identifying an appropriate population mean blood Pb level, and then identifying an ambient air level that would keep the mean blood Pb levels of children exposed at that air level below the target population mean blood Pb level. Based on the review of

[141] Among the studies of Pb health effects, in which blood Pb level is generally used as an index of exposure, the sources of exposure vary and are inclusive of air-related sources of Pb such as smelters (e.g., CD, chapter 6).

[142] See, e.g., 72 FR 37878–9 (July 11, 2007) (Ozone NAAQS Notice of Proposed Rulemaking).

[143] This differs from the Agency's recognition in the 1978 rulemaking of a threshold of 40 µg/dL blood Pb for an individual child for effects of Pb considered clearly adverse to health at that time, i.e., impairment of heme synthesis and other effects which result in anemia.

[144] More specifically, when the standard was set in 1978, the Agency stated that the population mean, measured as the geometric mean, must be 15 µg/dL in order to ensure that 99.5 percent of children in the United States would have a blood Pb level below 30 µg/dL, which was identified as the maximum safe blood Pb level for individual children based on the information available at that time (43 FR 46247–46252).

the evidence, the Staff Paper approach substituted a level of 2 μg/dL for the target population geometric mean blood Pb of 15 μg/dL used in 1978. In the absence of a demonstrated safe level, at either an individual or a population level, the Staff Paper used 2 μg/dL as representative of the lowest population mean level for which there is evidence of a statistically significant association between blood lead levels and health effects (e.g., CD, p. E–9; Lanphear *et al.*, 2000).

This approach does not evaluate the magnitude or degree of health effects occurring across the population at that mean blood lead level. In this adaptation of the 1978 approach the focus is solely on the existence of a relationship between blood lead levels and neurocognitive effects. The approach takes as the public health goal the identification of an ambient air lead level that can be expected to keep the mean blood lead level of an exposed population of children at or below the lowest level at which a statistically significant association has been demonstrated between blood lead level and neurocognitive effects.[145]

Starting with a target population geometric mean blood lead level of 2 μg/dL for the population of exposed children, then subtracting 1 to 1.4 μg/dL for the nonair component of blood Pb, yields 0.6 to 1 μg/dL as a target for the geometric mean air contribution to blood Pb. The adapted 1978 approach divides the air-related target by 5, an air-to-blood ratio somewhat central within the range of air Pb to blood Pb ratios generally supported by the currently available evidence. This resulted in a potential standard level of 0.1 to 0.2 μg/m^3.

The Staff Paper conclusions on level for the primary Pb standard built on the staff's conclusion that the overall body of evidence clearly calls into question the adequacy of the current standard with regard to health protection afforded to at-risk populations. Based on consideration of the health effects evidence, as described above, the Staff Paper concluded that it is reasonable to consider a range for the level of the standard, for which the upper part is represented by 0.1 to 0.2 μg/m^3.

ii. Air-related IQ Loss Evidence-Based Framework

As mentioned above, in analyses subsequent to the Staff Paper and ANPR, the Agency has primarily considered the evidence in the context of an alternative evidence-based framework, referred to as the air-related IQ loss framework. This framework focuses on the contribution of air-related Pb to neurocognitive effects, with a public health goal of identifying the appropriate ambient air level of Pb to protect exposed children from health effects that are considered adverse, and are associated with their exposure to air-related Pb. This framework does not focus on overall blood lead levels or on nonair contribution to blood lead levels. While this avoids some of the limitations noted above with the adapted 1978 approach, EPA recognizes that looking at air-related Pb in isolation from other sources of Pb could be considered a limitation for this framework. The different limitations of each of these frameworks derive from the limitations in the underlying body of evidence available for this review.

In this air-related IQ loss evidence-based framework, we have drawn from the entire body of evidence as a basis for concluding that there are causal associations between air-related Pb exposures and population IQ loss. We have drawn more quantitatively from the evidence by combining air-to-blood ratios with evidence-based C–R functions from the epidemiological studies to quantify the association between air Pb concentrations and air-related population mean IQ loss in exposed children. This air-related IQ loss framework focuses on selecting a standard that would prevent air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in populations of children exposed to the level of the standard, taking into consideration such factors as the uncertainties inherent in such estimates. In addition to this judgment by the Administrator, this framework is also based on specifying an air-to-blood ratio (also used in the adapted 1978 framework) and a C–R function(s) for population mean IQ response associated with blood Pb level.

In considering the evidence with regard to C–R functions, and in recognition of the finding in the evidence of a steeper slope at lower blood Pb levels (i.e., the nonlinear relationship), we have identified two sets of C–R functions (discussed more fully above in section II.B.2.b). The first set focuses on C–R functions reflecting population mean concurrent blood Pb levels of approximately 3 μg/dL.[146] The second set (CD, pp. 8–78 to 8–80) considers functions descriptive of the C–R relationship from a larger set of studies that include population mean blood Pb levels ranging from a mean of 3.3 up to a median of 9.7 μg/dL (see Table 1).[147]

As discussed above in section II.B.2.b, the C–R functions from analyses involving the lower mean blood Pb levels, that are closer to current mean blood Pb levels in U.S. children, provide slopes of IQ loss with increasing blood Pb that range from −1.71 to −2.94 IQ points per μg/dL blood Pb. These include C–R function from Lanphear *et al.* (2005) recommended for consideration by CASAC, in light of the current blood Pb levels of U.S. children (Henderson, 2008),[148] and also the C–R function

[145] There are some similarities between this approach and the approach employed in determining the levels for the daily and annual PM standards in the latest PM review, where EPA determined an ambient PM level based on the ambient levels in the epidemiology studies that found statistically significant associations between changes in ambient PM levels and changes in occurrences of health effects. See 71 FR 61144 (October 17, 2006). However, there are several important differences in this adaptation to the 1978 approach for lead. For example, the health effects evaluated in the PM epidemiological studies were clearly adverse health effects, ranging from hospital admissions to premature mortality. In addition, the studies looked directly at the association between ambient level and occurrences of health effects. Here the epidemiology studies look at the association between blood lead level and neurocognitive effect, and there is an additional step to link the blood lead level to air-related lead. In addition, at a population level there is a less clear delineation of when the neurocognitive effect is adverse to public health. This is discussed below in this section with respect to the impact on public health of a shift in the mean IQ of a population of children.

[146] As noted above in section II.B.2.b, the log-linear C–R function with low-exposure linearization (LLL) used in the quantitative risk assessment, based on log-linear model in Lanphear *et al* 2005), has a slope that falls intermediate within this first set of functions at low blood Pb levels. The log-linear model by Lanphear *et al* (2005) is derived from the pooled International dataset for which the median blood Pb is 9.7 μg/dL.

[147] For context, it is noted that the 2001–2004 median blood level for children aged 1–5 of all races and ethnic groups is 1.6 μg/dL, the median for the subset living below the poverty level is 2.3 μg/dL and 90th percentile values for these two groups are 4.0 μg/dL and 5.4 μg/dL, respectively. Similarly, the 2001–2004 median blood level for black, non-hispanic children aged 1–5 is 2.5 μg/dL, while the median level for the subset of that group living below the poverty level is 2.9 μg/dL and the median level for the subset living in a household with income more than 200% of the poverty level is 1.9 μg/dL. Associated 90th percentile values for 2001–2004 are 6.4 μg/dL (for black, non-hispanic children aged 1–5), 7.7 μg/dL (for the subset of that group living below the poverty level) and 4.1 μg/dL (for the subset living in a household with income more than 200% of the poverty level). (*http://www.epa.gov/envirohealth/children/body_burdens/b1-table.htm*—then click on ''Download a universal spreadsheet file of the Body Burdens data tables'').

[148] In their September 2007 letter, the CASAC Pb Panel ''recommends using the two-piece linear function for relating IQ alterations to current blood lead levels with a slope change or ''hinge'' point closer to 7.5 μg/dL than 10.82 μg/dL as used by EPA staff in the second draft exposure/risk assessments document. The higher value used by staff underestimates risk at lower blood Pb levels, where most of the population will be located.

given greatest weight in the risk assessment (discussed above in section II.C.2.b), the loglinear function with low-exposure linearization (the LLL function). The function yielding the lowest slope in this range is from the analysis by Tellez-Rojo and others (2006) of very young children with blood Pb levels below 5 μg/dL, with a group mean blood Pb level of 2.9 μg/dL. The function yielding the highest slope in this range is from the analysis by Lanphear and others (2005) of children whose blood Pb levels never exceeded 7.5 μg/dL, with a group mean blood Pb level of 3.24 μg/dL. The LLL function falls within the range of the other two functions at lower blood Pb levels, with an average slope of −2.29 IQ points per μg/dL across blood Pb levels extending below 2 μg/dL.

The second set of C–R functions discussed in section II.B.2.b is drawn from a larger group of studies, although these studies include groups of children with higher blood Pb levels (CD, pp. 8–78 to 8–80) such that the population mean levels for these studies include population mean blood Pb levels ranging from a mean of 3.3 up to a median of 9.7 μg/dL (see Table 1). This second set of C–R functions is represented by a median of −0.9 IQ points per μg/dL blood Pb (CD, p. 8–80).[149]

In applying the air-related IQ loss evidence-based framework, as with the adapted 1978 framework, we recognize uncertainty in our estimates for the two input parameters (air-to-blood ratio and C–R function slope). Accordingly, in associating various standard levels with the estimated magnitudes of air-related mean IQ loss that would likely be prevented by keeping exposed populations below such standard levels, we have considered combinations of parameter estimates that are potentially supportable within this framework. With regard to the C–R functions we have drawn estimates from both sets of functions. For the first set of C–R functions, we have relied on the upper and lower-end values to provide a range at lower blood Pb levels, and have focused on the LLL function for blood Pb levels above approximately 2.5 to 3.0 μg/dL, as shown in Table 7.[150] From the second set of C–R functions, we have relied on the median estimate across the range of blood Pb levels considered. For air-to-blood ratios, we have focused on the estimate of 1:5 as above, and also provided IQ loss estimates using higher and lower estimates of air-to-blood ratio (i.e., 1:3 and 1:7) within the range supported by the evidence. These estimates are presented in Table 7 below.

TABLE 7.—ESTIMATES OF AIR-RELATED POPULATION MEAN IQ LOSS FOR CHILDREN EXPOSED AT THE LEVEL OF THE STANDARD

Potential level for standard ($\mu g/m^3$)	Air-related population mean IQ loss (points) for children exposed at level of the standard									
	Air-to-blood ratio of 1:3		Air-to-blood ratio of 1:4		Air-to-blood ratio of 1:5		Air-to-blood ratio of 1:6		Air-to-blood ratio of 1:7	
	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions	1st group of C–R functions	2nd group of C–R functions
0.50	*2.9–3.1	1.4	*3.5–3.8	1.8	*4.1–4.3	2.3	*4.6–4.8	2.7	*5.0–5.3	3.2
0.40	*2.4–2.6	1.1	*3.0–3.2	1.4	*3.5–3.8	1.8	*4.0–4.2	2.2	*4.4–4.6	2.5
0.30	1.5–2.6	0.8	*2.4–2.6	1.1	*2.9–3.1	1.4	*3.3–3.5	1.6	*3.6–3.9	1.9
0.20	1.0–1.8	0.5	1.4–2.4	0.7	1.7–2.9	0.9	*2.4–2.6	1.1	*2.7–3.0	1.3
0.10	0.5–0.9	0.3	0.7–1.2	0.4	0.9–1.5	0.5	1.0–1.8	0.5	1.2–2.1	0.6
0.05	0.3–0.4	0.14	0.3–0.6	0.18	0.4–0.7	0.2	0.5–0.9	0.27	0.6–1.0	0.3
0.02	0.1–0.2	0.05	0.1–0.2	0.07	0.2–0.3	0.09	0.2–0.4	0.1	0.2–0.4	0.1

*These estimates were derived using only the nonlinear C–R function from the risk assessment which, given its nonlinearity, EPA considers to better assess risk across the range that includes extending into these higher standard levels (and the associated higher blood Pb levels). That is, the upper and lower values presented in the asterisked cells are both derived using the LLL function, as described in the text and associated footnote above, rather than using the two linear functions of −1.71 from Tellez-Rojo, 2005 (<5 μg/dL subgroup) and −2.94 from Lanphear, 2005 (<7.5 μg/dL peak blood Pb subgroup) as is the case in the cells without asterisks.

Using the air-to-blood ratio of 1:5 with the range of slopes from the first set of C–R functions indicates an air-related mean IQ loss estimate of 0.9 to 1.5 points for a population of children exposed at the standard level of 0.10 μg/m³. Similarly, the air-related mean IQ loss estimate for a standard level of 0.20 μg/m³ is 1.7 to 2.9 points. Using the air-to-blood ratio of 1:5 and the slope from the second set of C–R functions (from blood Pb levels extending up to 10 μg/dL) in the calculation indicates an air-related mean IQ loss of 0.5 points for a population of children exposed at the standard level of 0.10 μg/m³; the corresponding air-related mean IQ loss estimate for a standard level of 0.20 μg/m³ is 0.9 points. Using the 1:5 air-to-blood ratio with first set of C–R functions indicates an air-related mean IQ loss estimate of approximately 3 points for a population of children exposed at the standard level of 0.30 μg/m³. Using the slope from the second set of C–R functions indicates an air-related mean IQ loss estimate of 1.4 points for a population of children exposed at the standard level of 0.30 μg/m³.

Epidemiologic data indicate that the slope of the line below 7.5 μg/dL is approximately minus three (−3) IQ decrements per 1 μg/dL blood lead and the vast majority of children in the U.S. have maximal baseline Pb blood levels below 7.5 μg/dL (Lanphear *et al.*, EHP 2005; MMWR 2005). On a population level, the mean increase in blood lead concentration from airborne lead would generally be up to, but not exceeding, a blood lead concentration of 7.5 μg/dL. This approach should also account for sensitive subpopulations of children.'' In in their January 2008 letter, the Panel also points to several other studies ''confirming that the relationship of lead exposure is non-linear and per-sists at blood lead levels considerably lower than 5 μg/dL (Lanphear, 2000; Wasserman, 2003; Kordas, 2006; Tellez-Rojo, 2006). In particular, Tellez-Rojo and co-workers reported that the slope of the association between 24-month blood lead and the 24-month Mental Development Index (MDI) for 294 children who had peak blood lead levels below 5 μg/dL was negative (−1.7 points for each 1 μg/dL increase in blood lead concentration, p=0.01). Collectively, these studies indicate that there is sufficient evidence to support the use of the dose-response relationship from the pooled analysis at blood lead levels < 5 μg/dL (Lanphear, 2005), as described in the Final Lead Staff Paper and previously recommended by CASAC.''

[149] As noted above (in section II.B.2.b), this slope is similar to the slope for the below 10 μg/dL piece of the piecewise model used in the RRP rule economics analysis.

[150] We derived estimates of air-related IQ loss using the LLL (nonlinear) function giving equal weight to all contributions of Pb to total blood Pb as illustrated by the following example. For a level of 0.30 μg/m³, and an air-to-blood ratio of 1:5, the resultant estimate of air-related blood Pb is 1.5 μg/dL. Using estimates for nonair blood Pb levels of 1 and 1.4 μg/dL, the estimates of total blood Pb are 2.5 and 2.9 μg/dL. The corresponding total Pb-related IQ loss estimates based on the LLL function are 5.2 and 5.6 points IQ loss. These estimates are then multiplied by the fraction of total Pb that is air-related (*i.e.*, 1.5/2.5 and 1.5/2.9) to derive the estimated range of air-related IQ loss (2.9–3.1 points).

As mentioned above, we recognize uncertainty in the air-to-blood values, and have accordingly also considered estimates of air-to-blood ratio that are lower and higher than the 1:5 value used above. Accordingly, we note that using a lower air-to-blood ratio, such as 1:3 (low end of range from evidence) generally results in lower air-related IQ loss estimates with either set of C–R functions (approximately 40% lower than those using a ratio of 1:5). Similarly, use of a higher air-to-blood ratio, such as 1:7, yields higher air-related mean IQ loss estimates with either set of C–R functions (approximately 40% higher than those using a ratio of 1:5).

In applying this framework, we have also considered higher standard levels, above 0.30 μg/m^3 up to the highest alternative level included in the risk assessment (e.g., up to 0.50 μg/m^3). Using the 1:5 air-to-blood ratio with the first set of C–R functions, the air-related mean IQ loss estimate for a standard level of 0.50 μg/m^3 is approximately 4 points. Using the slope from the second set of C–R functions indicates an air-related mean IQ loss estimate of 2.3 points for a population of children exposed at the standard level of 0.50 μg/m^3. Using the 1:3 air-to-blood ratio with the first set of C–R functions indicates an air-related mean IQ loss estimate of approximately 3 points for a population of children exposed at the standard level of 0.50 μg/m^3. Using the 1:3 air-to-blood ratio and the slope for the second set of C–R functions indicates an air-related mean IQ loss estimate of 1.4 points for a population of children exposed at the standard level of 0.50 μg/m^3.

Further, we have also considered lower standard levels, down to the lowest alternative levels included in the risk assessment (e.g., 0.05 to 0.02 μg/m^3). For example, across both sets of C–R functions and the range of air-to-blood ratios considered above (1:3 to 1:7), a standard level of 0.05 μg/m^3 indicates an air-related mean IQ loss of approximately 0.1 to 1 point. The estimates for either set of C–R functions are approximately 50% lower at the standard level of 0.02 μg/m^3.

b. Exposure- and Risk-Based Considerations

To inform judgments about a range of levels for the standard that could provide an appropriate degree of public health protection, in addition to considering the health effects evidence, EPA also considered the quantitative estimates of exposure and health risks attributable to air-related Pb upon meeting specific alternative levels of alternative Pb standards and the uncertainties in the estimated exposures and risks, as discussed above in Section III.B. As discussed above, the risk assessment conducted by EPA is based on exposures that have been estimated for children of less than 7 years of age in several case studies. The assessment estimated the risk of adverse neurocognitive effects in terms of IQ loss associated with total and air-related Pb exposures, including incidence of different magnitudes of IQ loss in the three location-specific case studies. In so doing, EPA is mindful of the important uncertainties and limitations that are associated with the exposure and risk assessments. For example, with regard to the risk assessment important uncertainties include those related to estimation of blood Pb C–R functions, particularly for blood Pb concentrations at and below the lower end of those represented in the epidemiological studies characterized in the Criteria Document.

EPA also recognizes important limitations in the design of, and data and methods employed in, the exposure and risk analyses. For example, the available monitoring data for Pb relied upon for estimating current conditions for the urban case studies are quite limited, in that monitors are not located near many of the larger known Pb sources, which results in potential underestimation of current conditions, and there is uncertainty about the proximity of existing monitors to other Pb sources potentially influencing exposures, such as old urban roadways and areas where housing with Pb paint has been demolished or has undergone extensive exterior renovation. All of these limitations raise uncertainty as to whether these data adequately capture the magnitude of ambient Pb concentrations to which the target population is currently exposed. Additionally, EPA recognizes that there is not sufficient information available to evaluate all relevant sensitive groups (e.g., adults with chronic kidney disease) or all Pb-related health effects (e.g., neurological effects other than IQ loss, immune system effects, adult cardiovascular or renal effects), and the scope of our analyses was generally limited to estimating exposures and risks in case studies intended to illustrate a variety of Pb exposure situations across the U.S., with three of them focused on specific areas in three cities. As noted above, however, coordinated intensive efforts over the last 20 years have yielded a substantial decline in blood Pb levels in the United States. Recent NHANES data (2003–2004) yield blood lead level estimates for children age 1 to 5 years of 1.6 μg/dL (median) and 3.9 μg/dL (90th percentile). These median and 90th percentile national-level data are lower than modeled values generated for the three location-specific urban case studies current conditions scenarios (described in section II.C.3.a above). As noted in section II.C.3.a, however, the urban case studies and the NHANES study are likely to differ with regard to factors related to Pb exposure, including ambient air levels (e.g., the national median ambient air Pb concentrations are generally lower than those in the location-specific case studies).

As described in section II.C.2.e, we also recognize limitations in our ability to characterize the contribution of air-related Pb to total Pb exposure and Pb-related health risk. As a result, we have approximated estimates for the air-related pathways, bounded on the low end by exposure/risk estimated for the ''recent air'' category and on the upper end by the exposure/risk estimated for the ''recent air'' plus ''past air'' categories.[151]

We generally focus in this discussion on risk estimates derived using the LLL (log-linear with low exposure linearization) C–R function. Further, in considering the risk estimates in light of IQ loss estimates (described in section II.E.3.a) of the air-related IQ loss evidence-based framework, we focus here on risk estimates for the general urban and primary Pb smelter subarea case studies as these cases studies generally represent population exposures for more highly air-pathway exposed children residing in small neighborhoods or lozalized residential areas with air concentrations nearer the standard level being evaluated than do the location-specific case studies in which populations have a broader range of air-related exposures including many well below the standard level being evaluated.

In considering the results of the risk assessment for the alternative standard levels assessed, we note that the risk estimates are roughly consistent with and generally supportive of the evidence-based mean air-related IQ loss estimates described above (section II.E.3.a). For example, at a standard level of 0.20 μg/m^3, the evidence-based approach indicates estimates of mean air-related IQ loss ranging from less than

[151] As noted in section II.C.2.e above, the recent air category does not include a variety of air-related categories (including some associated with air deposition to outdoor surfaces and diet) and both the recent air and past categories may include some Pb in soil or dust from the historical use of Pb in paint.

1 to approximately 3 points IQ loss, while the median air-related risk estimates for this level in the general urban case study are represented by a lower bound near 1 point IQ loss and an upper bound near 3 points IQ loss. The corresponding upper bound air-related IQ loss estimate for the primary Pb smelter case study subarea is 3.7 points. Alternatively, at a standard level of 0.50 μg/m^3, the evidence-based approach indicates estimates of mean air-related IQ loss ranging from approximately 1.5 points to greater than 4 points, while the median air-related risk estimates for this level for the general urban case study are represented by a lower bound near 2 points IQ loss and an upper bound just below 4 points IQ loss (section II.C.3.b). The corresponding upper bound air-related IQ loss estimate for the primary Pb smelter case study subarea is 4.5 points. Also, while the risk assessment did not specifically assess the standard levels of 0.10 and 0.30 μg/m^3, we note that estimates for these levels based on interpolation from the estimates described above are also roughly consistent with and generally supportive of the evidence-based mean air-related IQ loss estimates described in section II.E.3.a above (Murphy and Pekar, 2008).

As mentioned above (section II.E.3.a), the Staff Paper conclusions on level for the primary Pb standard built on staff 's conclusion that the overall body of evidence clearly calls into question the adequacy of the current standard with regard to health protection afforded to at-risk populations. Drawing from both consideration of the evidence and consideration of the quantitative risk and exposure information (described in section II.E.3.b), staff concluded that the available information provides strong support for consideration of a range of standard levels that are appreciably below the level of the current standard in order to provide increased public health protection for these populations, with support for this conclusion. With regard to the risk estimates, the Staff Paper recognized that, to the extent one places weight on risk estimates for the lower standard levels, those estimates may suggest consideration of a range of levels that extend down to the lowest levels assessed in the risk assessment, 0.02 to 0.05 μg/m^3. In summary, the Staff Paper concluded that ''a level for the standard set in the upper part of [the staff] recommended range (0.1–0.2 μg/m^3, particularly with a monthly averaging time) is well supported by the evidence and also supported by estimates of risk associated with policy-relevant Pb that overlap with the range of IQ loss that may reasonably be judged to be highly significant from a public health perspective, and is judged to be so by CASAC'' (USEPA, 2007c). Further, the Staff Paper concluded that ''a standard set in the lower part of the range would be more precautionary and would place weight on the more highly uncertain range of estimates from the risk assessment'' (USEPA, 2007c).

c. CASAC Advice and Recommendations and Public Comments

Beyond the evidence- and risk/exposure-based information discussed above, EPA's consideration of the level for the TSP-based standard also takes into account the advice and recommendations of CASAC, based on their review of the Criteria Document, the Staff Paper and the related technical support document, and the ANPR, as well as comments from the public on drafts of the Staff Paper and related technical support document and the ANPR.

In their advice to the Agency during this review CASAC has recognized the importance of both the health effects evidence and the exposure and risk information in selecting the level for the TSP-based standard (Henderson, 2007a, 2007b, 2008). In two separate letters sent prior to publication of the ANPR, CASAC stated that it is the unanimous judgment of the CASAC Lead Panel that the primary NAAQS should be ''substantially lowered'' to ''a level of about 0.2 μg/m^3 or less,'' reflecting their view of the health effects evidence (Henderson, 2007a,b). In their most recent letter, reflecting their review of the ANPR and Staff Paper, the Panel reiterated their earlier judgment, stating that *''[t]he Committee unanimously and fully supports Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 μg/m^3 with a monthly averaging time.''*

The CASAC Pb Panel also provided advice regarding how the Agency should consider IQ loss estimates derived from the risk assessment in selecting a level for the standard (Henderson, 2007a). The Panel stated that they consider a population loss of 1–2 IQ points to be ''highly significant from a public health perspective''.

Among the many public comments the Agency has received in this review regarding the level of the standard, the overwhelming majority recommended appreciable reductions in the level, e.g., setting it at 0.2 μg/m^3 or less, while only a few recommended that the Agency make no or only a modest adjustment. Among the comments recommending appreciable reduction, many noted the importance of considering exposures and risks to vulnerable and susceptible populations. Some recognized that blood Pb levels are disproportionately elevated among minority and low-income children, and recommended more explicit consideration of issues of environmental justice. And some comments also noted the need for the standard to provide an adequate margin of safety, indicating that such a need might provide support for consideration of much lower levels. The American Academy of Pediatrics recommended that EPA set the level at 0.2 or lower, and also recommended that EPA consider the approach developed by the State of California Environmental Protection Agency (Cal-EPA) for the purposes of school site assessment, which has at its goal prevention of a rise in blood Pb level that Cal-EPA has predicted to be associated with an incremental increase estimated to decrease IQ by 1 point.

d. Administrator's Proposed Conclusion Concerning Level

For the reasons discussed below, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and the public comments to date, the Administrator proposes to revise the existing primary Pb standard. Specifically, the Administrator proposes to revise the level of the primary Pb standard, defined in terms of the current Pb-TSP indicator, to within the range of 0.10 to 0.30 μg/m^3, conditional on judgments as to the appropriate values of key parameters to use in the context of the air-related IQ loss evidence-based framework discussed below.

Further, in recognition of alternative views of the science, the exposure and risk assessments, the uncertainties inherent in the science and these assessments, and the appropriate public health policy responses based on the currently available information, the Administrator also solicits comments on whether to proceed instead with alternative levels of a primary Pb-TSP standard within ranges from above 0.30 μg/m^3 up to 0.50 μg/m^3 and below 0.10 μg/m^3. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternative levels identified above in lieu of the standards he is proposing today. In addition, as discussed below, the Administrator also solicits comments on when, if ever, it would be

appropriate to set a NAAQS for Pb at a level of zero.

The Administrator's consideration of alternative levels of the primary Pb-TSP standard builds on his proposed conclusion, discussed above in section II.D.4, that the overall body of evidence indicates that the current Pb standard is not requisite to protect public health with an adequate margin of safety and that the standard should be revised to provide increased public health protection, especially for members of at-risk groups, notably including children, against an array of adverse health effects. These effects range from IQ loss, a health outcome that could be quantified in the risk assessment, to health outcomes that could not be directly estimated, including decrements in other neurocognitive functions, other neurological effects and immune system effects, as well as cardiovascular and renal effects in adults. In reaching a proposed decision about the level of the Pb primary standard, the Administrator has considered: the evidence-based considerations from the Criteria Document and the Staff Paper and those based on the air-related IQ loss evidence-based framework discussed above; the results of the exposure and risk assessments discussed above and in the Staff Paper, giving weight to the exposure and risk assessments as judged appropriate; CASAC advice and recommendations, as reflected in discussions of the Criteria Document, Staff Paper, and ANPR at public meetings, in separate written comments, and in CASAC's letters to the Administrator; EPA staff recommendations; and public comments received during the development of these documents, either in connection with CASAC meetings or separately. In considering what standard is requisite to protect public health with an adequate margin of safety, the Administrator is mindful that this choice requires judgment based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn.

In reaching a proposed decision on a range of levels for a revised standard, as in reaching a proposed decision on the adequacy of the current standard, the Administrator primarily considered the evidence in the context of the air-related IQ loss evidence-based framework described above in section II.E.3.a.ii. As a general matter, in considering this evidence-based framework, the Administrator recognizes that in the case of Pb there are several aspects to the body of epidemiological evidence that add complexity to the selection of an appropriate level for the primary standard. As discussed above, these complexities include evidence based on blood Pb as the dose metric, exposure pathways that are both air-related and nonair-related, and the absence of any discernible threshold levels in the health effects evidence. Further, the Administrator recognizes that there are a number of important uncertainties and limitations inherent in the available health effects evidence and related information, including uncertainties in the evidence of associations between total blood Pb and neurocognitive effects in children, especially at the lowest blood Pb levels evaluated in such studies, as well as uncertainties in key parameters used in this evidence-based framework, including C–R functions and air-to-blood ratios. In addition, the Administrator recognizes that there are currently no commonly accepted guidelines or criteria within the public health community that would provide a clear basis for reaching a judgment as to the appropriate degree of public health protection that should be afforded to neurocognitive effects in sensitive populations, such as IQ loss in children.

The air-related IQ loss evidence-based framework considered by the Administrator focuses on quantitative relationships between air-related Pb and neurocognitive effects (e.g., IQ loss) in children, building on recommendations from CASAC to consider the body of evidence in a more quantitative manner. More specifically, this framework is premised on a public health goal of selecting a standard level that would prevent air-related IQ loss (and related effects) of a magnitude judged by the Administrator to be of concern in populations of children exposed to the level of the standard, taking into consideration uncertainties inherent in such estimates. In addition to this public health policy judgment regarding IQ loss, two other parameters are relevant to this framework—a C–R function for population IQ response associated with blood Pb level and an air-to-blood ratio. Based on the discussion of these parameters in section II.E.3.a above, the Administrator concludes that, in considering alternative standard levels below the level of the current standard, it is appropriate to take into account the same two sets of C–R functions, recognizing uncertainties in the related evidence, as was done in considering the adequacy of the current standard (as discussed above in section II.D). He notes that the first set of C–R functions reflects the evidence indicative of steeper slopes in relationships between blood Pb and IQ in children, and that the second set of C–R functions reflects relationships with shallower slopes between blood Pb and IQ in children. In addition, the Administrator concludes that it is appropriate to consider various air-to-blood ratios, again recognizing the uncertainties in the relevant evidence. He notes that an air-to-blood ratio of 1:5 is within the reasonable range of values that EPA considers to be generally supported by the available evidence, which includes ratios of 1:3 up to 1:7.

With regard to making a public health policy judgment as to the appropriate level of protection against air-related IQ loss and related effects, the Administrator first notes that ideally air-related (as well as other) exposures to environmental Pb would be reduced to the point that no IQ impact in children would occur. The Administrator recognizes, however, that in the case of setting a NAAQS, he is required to make a judgment as to what degree of protection is requisite to protect public health with an adequate margin of safety. The NAAQS must be sufficient but not more stringent than necessary to achieve that result, and does not require a zero-risk standard. Considering the advice of CASAC and public comments on this issue, notably including the comments of the American Academy of Pediatrics, the Administrator proposes to conclude that an air-related population mean IQ loss within the range of 1 to 2 points could be significant from a public health perspective, and that a standard level should be selected to provide protection from air-related population mean IQ loss in excess of this range.

The Administrator considered the application of this air-related IQ loss framework with this target degree of protection in mind, drawing from the information presented in Table 7 above in section II.E.3.a.ii that addresses a broad range of standard levels. In so doing, the Administrator first focused on the estimates associated with the first set of C–R functions in conjunction with the range of air-to-blood ratios considered by EPA in this framework. Specifically, using an air-to-blood ratio of 1:5, the Administrator notes that a standard level of 0.10 $\mu g/m^3$ would limit the estimated degree of impact on population mean IQ loss from air-related Pb to no more than 1.5 points, the mid-point of the proposed range of protection. Using the full range of air-to-blood ratios considered in this framework (1:3 to 1:7), he notes that a standard set at this level (0.10 $\mu g/m^3$) would limit the estimated degree of air-

related impact on population mean IQ loss to a range from less than 1 point to around 2 points. Again based on the first set of C–R functions, the Administrator notes that a standard level of 0.20 μg/m³ would also limit the estimated degree of air-related impact on population mean IQ loss to within the proposed range of protection based on using an air-to-blood ratio of 1:3.

In considering the use of the second set of C–R functions in conjunction with the range of air-to-blood ratios considered in this framework (1:3 to 1:7), the Administrator notes for example that a standard set within the range of 0.10 to 0.30 μg/m³ would limit the estimated degree of air-related impact on population mean IQ loss to a range from less than one-half point to just under 2 points. More specifically, based on using an air-to-blood ratio of 1:5 (the approximately central estimate) in conjunction with the second set of C–R functions, the Administrator notes that a standard level of 0.30 μg/m³ would limit the estimated degree of impact on population mean IQ loss from air-related Pb to just under 1.5 points, the mid-point of the proposed range of protection.

Taking these considerations into account, and based on the full range of information presented in Table 7 above on estimates of air-related IQ loss in children over a broad range of alternative standard levels, the Administrator concludes that it is appropriate to propose a range of standard levels, and that a range of levels from 0.10 to 0.30 μg/m³ is consistent with his target for protection from air-related IQ loss in children. In recognition of the uncertainties in these key parameters, the Administrator believes that the selection of a standard level from within this range is conditional on judgments as to the most appropriate parameter values to use in the context of this evidence-based framework. For example, he notes that placing more weight on the use of a C–R function with a relatively steeper slope would tend to support a standard level in the lower part of the proposed range, while placing more weight on a C–R function with a shallower slope would tend to support a level in the upper part of the proposed range. Similarly, placing more weight on a higher air-to-blood ratio would tend to support a standard level in the lower part of the proposed range, whereas placing more weight on a lower ratio would tend to support a level in the upper part of the range. In soliciting comment on a standard level within this proposed range, the Administrator specifically solicits comment on the appropriate values to use for these key parameters in the context of this evidence-based framework, reflecting that his proposal to revise the level of the primary Pb standard, defined in terms of the current Pb-TSP indicator, to within the range of 0.10 to 0.30 μg/m³ is conditional on judgments as to the appropriate values of key parameters to use in this context.

The Administrator has also considered the results of the exposure and risk assessments conducted for this review to provide some further perspective on the potential magnitude of air-related IQ loss. The Administrator finds that these quantitative assessments provide a useful perspective on the risk from air-related Pb. However, in light of the important uncertainties and limitations associated with these assessments, as discussed above in sections II.C and II.E.3.b, for purposes of evaluating potential new standards, the Administrator places less weight on the risk estimates than on the evidence-based assessments. Nonetheless, the Administrator finds that the risk estimates are roughly consistent with and generally supportive of the evidence-based air-related IQ loss estimates described above, as discussed above in section II.E.3.b. This lends support to the proposed range based on this evidence-based framework.

In the Administrator's view, the above considerations, taken together, provide no evidence- or risk-based bright line that indicates a single appropriate level. Instead, there is a collection of scientific evidence and judgments and other information, including information about the uncertainties inherent in many relevant factors, which needs to be considered together in making this public health policy judgment and in selecting a standard level from a range of reasonable values. Based on consideration of the entire body of evidence and information available at this time, as well as the recommendations of CASAC and public comments, the Administrator is proposing that a standard level within the range of 0.10 to 0.30 μg/m³ would be requisite to protect public health, including the health of sensitive groups, with an adequate margin of safety. He also recognizes that selection of a level from within this range is conditional on judgments as to what C–R function and what air-to-blood ratio are most appropriate to use within the context of the air-related IQ loss framework. The Administrator notes that this proposed range encompasses the specific level of 0.20 μg/m³, the upper end of the range recommended by CASAC and by many public commenters. The Administrator provisionally concludes that a standard level selected from within this range would reduce the risk of a variety of health effects associated with exposure to Pb, including effects indicated in the epidemiological studies at low blood Pb levels, particularly including neurological effects in children, and cardiovascular and renal effects in adults.

Because there is no bright line clearly directing the choice of level within this reasonable range, the choice of what is appropriate, considering the strengths and limitations of the evidence, and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments, is a public health policy judgment. To further inform this judgment, the Administrator solicits comment on the air-related IQ loss evidence-based framework considered by the Agency and on appropriate parameter values to be considered in the application of this framework. More specifically, we solicit comment on the appropriate C–R function and air-to-blood ratio to be used in the context of the air-related IQ loss framework. The Administrator also solicits comment on the degree of impact of air-related Pb on IQ loss and other related neurocognitive effects in children considered to be significant from a public health perspective, and on the use of this framework as a basis for selecting a standard level.

For the reasons discussed above, the Administrator proposes to revise the level of the primary Pb standard, defined in terms of the current Pb-TSP indicator, to within the range of 0.10 to 0.30 μg/m³, conditional on judgments as to the appropriate C–R functions and air-to-blood ratio to use in the context of the air-related IQ loss framework.

The Administrator notes that this framework indicates that for standard levels above 0.30 μg/m³ up to 0.50 μg/m³, the estimated degree of impact on population mean IQ loss from air-related Pb would range from approximately 2 points to 5 points or more with the use of the first set of C–R functions and the full range of air-to-blood ratios considered, and would extend from somewhere within the proposed range of 1 to 2 points IQ loss to above that range when using the second set of C–R functions and the full range of air-to-blood ratios considered. The Administrator proposes to conclude in light of his consideration of the evidence in the framework discussed above that the magnitude of air-related Pb effects at the higher blood Pb levels that would be allowed by standards above 0.30 up to 0.50 μg/m³ would be greater than what is requisite to protect

public health with an adequate margin of safety.

In addition, the Administrator notes that for standard levels below 0.10 μg/m^3, the estimated degree of impact on population mean IQ loss from air-related Pb would generally be somewhat to well below the proposed range of 1 to 2 points air-related population mean IQ loss regardless of which set of C–R functions or which air-to-blood ratio within the range of ratios considered are used. The Administrator proposes to conclude that the degree of public health protection that standards below 0.10 μg/m^3 would likely afford would be greater than what is requisite to protect public health with an adequate margin of safety.

Having reached this proposed decision based on the interpretation of the evidence, the evidence-based frameworks, the exposure/risk assessment, and the public health policy judgments described above, the Administrator recognizes that other interpretations, frameworks, assessments, and judgments are possible. There are also potential alternative views as to the range of values for relevant parameters (e.g., C–R function, air-to-blood ratio) in the evidence-based framework that might be considered supportable and the relative weight that might appropriately be placed on any specific value for these parameters within such ranges. In addition, the Administrator recognizes that there may be other views as to the appropriate degree of public health protection that should be afforded in terms of air-related population mean IQ loss in children that would provide support for alternative standard levels different from the proposed range. Further, there may be other views as to the appropriate weight and interpretation to give to the exposure/risk assessment conducted for this review. Consistent with the goal of soliciting comment on a wide array of issues, the Administrator solicits comment on these and other issues.

In particular, the Administrator solicits comment on alternative levels of a primary Pb-TSP standard of above 0.30 μg/m^3 up to 0.50 μg/m^3. In considering the air-related IQ loss framework and the case when the second set of C–R functions is used in conjunction with the lowest air-to-blood ratio considered in this framework (i.e., 1:3), a standard level as high as 0.50 μg/m^3 would still limit the estimated degree of impact on population mean IQ loss from air-related Pb to no more than 1.5 points, the mid-point of the proposed range of protection. Comment is solicited on levels within this range and the associated rationale for selecting such a level in terms of the appropriate weight to place on relevant parameter values that may extend to values outside the ranges of values considered by EPA, or in terms of alternative evidence- or risk-based frameworks that might support standard levels within this range.

In addition, the Administrator solicits comment on alternative levels below 0.10 μg/m^3. In considering the evidence-based framework discussed above, a standard level within this range would likely provide a degree of protection in terms of air-related population mean IQ loss that is greater than the proposed range based on the use of any of the relevant parameter values within the ranges considered by EPA. Comment is solicited on levels within this range and the associated rationale for selecting such a level in terms of the appropriate weight to place on relevant parameter values that may extend to values outside of the ranges considered by EPA, or alternative public health policy judgments as to the degree of protection that is warranted, or the appropriate weight to place on the results of the risk assessment.

More broadly, as discussed above, the Administrator recognizes that Pb can be considered a non-threshold pollutant.[152] In recognizing that no threshold has been identified below which we are scientifically confident that there is no risk of harm, EPA's views are consistent with the views of the CDC, the Federal agency that tracks children's blood Pb levels nationally and provides guidance on levels at which medical and environmental case management activities should be implemented (CDC, 2005a; ACCLPP, 2007). In 2005, CDC revised its statement on Preventing Lead Poisoning in Young Children, specifically recognizing the evidence of adverse health effects in children and the data demonstrating that no ''safe'' threshold for blood Pb had been identified (CDC, 2005a). EPA's views are also consistent with other organizations, including, for example, the American Academy of Pediatrics that recognized in commenting on the ANPR that ''[t]here is no known ''safe'' level of blood lead in children'' (AAP, 2008). In addition, the California Environmental Protection Agency, in a recent risk assessment report, recognizes that ''no safe level has been definitively established'' for effects of Pb in children (CalEPA, 2007, p. 1). Given the current state of scientific evidence, which does not resolve the question of whether or not there is a threshold, we recognize that there is no level below which we can say with scientific confidence that there is no risk of harm from exposure to ambient air related lead.

The Administrator also recognizes, as discussed in section I.A above, that the CAA does not require that NAAQS be established at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. In setting primary standards that are ''requisite'' to provide the this degree of public health protection, the Supreme Court has affirmed that EPA's task is to establish standards that are neither more nor less stringent than necessary for this purpose. The question then becomes how the Agency should reconcile these scientific and legal understandings in reviewing the Pb NAAQS.

As discussed above, EPA is proposing a range of levels for the primary Pb NAAQS, with the range extending down to 0.10 μg/m^3. This range reflects the Administrator's proposed conclusion that lower levels would be more than necessary to protect public health with an adequate margin of safety. This proposed conclusion is based in large part on EPA's evaluation of the evidence, recognizing important uncertainties in the scientific evidence and related assessments, and reflects the proposed public heath policy judgment of the Administrator on these issues. As discussed above, these uncertainties stem in part from the complexities of determining the health impact of air-related Pb given the multi-media exposure pathways for exposure to lead and the persistence of Pb in the environment. The major areas of uncertainty include the appropriate air-to-blood ratio; the apportionment of Pb between air-related and nonair Pb; the increasing uncertainty at lower blood Pb levels as to the existence, nature, and degree of health effects; and the uncertainty over the public health significance of smaller and smaller impacts on IQ or other similar neurocognitive metrics from exposure to air-related Pb. In recognition of such uncertainties, EPA is also soliciting comment on a lower range of standard levels below 0.10 μg/m^3.

In so doing, EPA fully recognizes that a standard set at the lowest proposed level of 0.10 μg/m^3, or any non-zero level, would not be a risk-free standard.

[152] Similarly, in the most recent reviews of the NAAQS for ozone and PM, EPA recognized that the available epidemiological evidence neither supports nor refutes the existence of thresholds at the population level, while noting uncertainties and limitations in studies that make discerning thresholds in populations difficult (e.g., 73 FR 16444, March 27, 2008; 71 FR 61158, October 17, 2006).

As in numerous prior NAAQS reviews, we recognize that the CAA does not require that EPA set a risk-free standard. Instead, EPA is to recognize and take risk into account, and set a standard that is requisite to protect public health with an adequate margin of safety based on the currently available information. This calls for a public health policy judgment informed by many factors, most notably the nature and severity of the health effects at issue, the size of the population(s) at risk, and the kind and degree of uncertainties involved. After considering all of these factors in this review, the Administrator's proposed judgment is that a standard set below 0.10 $\mu g/m^3$ would not satisfy this statutory directive.

The Administrator recognizes that the current state of the scientific evidence clearly indicates that health effects from Pb occur at much lower blood Pb levels than we understood in the past, and that the appropriate level for ambient air Pb is much lower than we thought in the past. Further the Administrator expects that, as time goes on, future scientific studies will continue to enhance our understanding of Pb, and anticipates that such studies might lead to a situation where there is very little, if any, remaining uncertainty about human health impacts from even extremely low levels of Pb in the ambient air. As noted above, this has the potential to raise fundamental questions as to how the Agency can continue to reconcile such evidence with the statutory provision calling for the NAAQS to be set at a level that is requisite to protect public health with an adequate margin of safety. Faced with scientific evidence that could reasonably be interpreted as demonstrating that any ambient Pb level above zero contributes to adverse health effects in at-risk populations, some might conclude that the only standard requisite to protect public health with an adequate margin of safety would be a standard set at zero. While EPA's proposed conclusions on the current scientific evidence and an appropriate standard based on that evidence and on its interpretation of the statute clearly differ from such a view, EPA nonetheless believes that inviting comment in this review on the views described above and the issues raised by such circumstances is appropriate.

More specifically, EPA invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. Comments on this question might address issues such as: The level of scientific certainty that would be needed to support such a decision; the level of harm, e.g., severity of health effect and size of affected population, that would be needed to support such a decision; and whether there are normative or quantitative criteria that could be applied in deciding whether, and if so, when it would be appropriate to set a standard at zero. EPA invites comment on how to reconcile the above issues in this and subsequent NAAQS reviews.

4. Level for a Pb NAAQS with a Pb-PM_{10} Indicator

EPA is requesting comment on the option of revising the indicator for the Pb NAAQS from Pb-TSP to Pb-PM_{10}, based on low-volume sample collection as discussed above in section II.E.1 and below in section V.A. In this section, we discuss considerations important to selection of a level for such a Pb-PM_{10}-based standard (section II.E.4.a) and CASAC's advice and public comments on this issue (section II.E.4.b). Approaches for adjusting the level of a Pb NAAQS with Pb-TSP indicator for a Pb-PM_{10}-based standard, and a range of levels for a Pb-PM_{10}-based standard, under consideration and on which EPA is soliciting comment are presented in II.E.4.c.

a. Considerations With Regard to Particles Not Captured by PM_{10}

In the course of deciding to propose the Pb-TSP indicator approach as described in section II.E.1 above, EPA has noted the important role of both respirable and non-respirable Pb particles in air-related Pb exposure of concern and the lesser capture of these particles by PM_{10} samplers compared to TSP samplers. We recognize that the health evidence indicates that Pb in all particle size fractions, not just respirable Pb, contributes to Pb in blood and to associated health effects. Further, the quantity of Pb in ambient particles with the potential to deposit (indoors and outdoors, leading to a role in ingestion pathways) is a key contributor to air-related exposure, and these particles include ultra-coarse mode particles that are not captured by PM_{10} samplers (as discussed in section II.E.1 above). In recognition of these considerations, both of the indicator options discussed in this notice recognize the need to consider use of an adjustment related to the use of PM_{10} measurements, either when considering the optional use of Pb-PM_{10} data for comparison with a Pb-TSP-based NAAQS, or when considering a level for a NAAQS based on a Pb-PM_{10} indicator.

Section II.E.1 above contains extensive discussion of the relationship between Pb-PM_{10} and Pb-TSP, including the fact that Pb-PM_{10}/Pb-TSP relationships vary from site to site and from time to time, but have a systematic variation with distance from emissions sources emitting particles larger than would be captured by Pb-PM_{10} samplers, such that generally there are larger differences between Pb-PM_{10} and Pb-TSP near sources. Section II.E.1 goes on to identify and solicit comment on two ranges from which scaling factors could be chosen that would be applied to the Pb-PM_{10} measurements to derive surrogate Pb-TSP concentrations for use in making comparisons to a Pb-TSP-based NAAQS. In recognition of the influence of proximity to sources on the relationship between Pb-TSP and Pb-PM_{10} measurements for source types with a high fraction of ultra-coarse particles containing Pb, different scaling factors are identified for source-oriented monitoring sites and nonsource-oriented monitoring sites (as described in section II.E.1). These ranges have been developed based on analyses of the available collocated Pb-TSP and Pb-PM_{10} data (Schmidt and Cavender, 2008) and recognition of variability and uncertainty inherent in this data set.

The data supporting the range for source-oriented scaling factors, as discussed in Schmidt and Cavender (2008), indicate the potential, in areas influenced by some types of sources (e.g., Pb smelters), for PM_{10} samplers to capture as little as approximately 50% of the Pb that is measured with Pb-TSP monitors. The data from 20 sites not known to be near Pb sources show a range of ratios between Pb-TSP and Pb-PM_{10} that vary from day to day and between sites. When rounded to one decimal place, these ratios of the multi-day mean concentration of Pb-TSP to the same statistic for Pb-PM_{10} at each site ranged from 1.0 to 1.9.[153] Eighty-five percent of the sites had ratios between 1.0 and 1.4, and slightly over one-half the sites had ratios between 1.0 and 1.2. This is consistent with the conceptual model that concentrations of ultra-coarse particles of Pb are quite low at sites not near the primary sources of such particles, such that Pb-PM_{10} monitors at such sites would tend to collect the large majority, but generally not all, of total airborne Pb.

In considering the need for and magnitude of a potential adjustment to derive a standard level for a Pb-PM_{10}-

[153] On individual days, the ratio between the two measures was sometimes below 1.0 or well over 2.0, which may be the result of sampler errors and data rounding particularly when concentrations of one or both measures were low. Accordingly, EPA considers the ratio of the multi-day mean concentration of Pb-TSP to the same statistic for Pb-PM_{10} at each site to be a better indicator of typical monitor behavior.

based NAAQS, we note the inherent variability in the TSP sampling methodology which will contribute variability to relationships derived between Pb-PM_{10} and Pb-TSP data. We also note the influence on such relationships of proximity to sources of Pb particles that would not be captured by PM_{10} samplers. This latter influence is evident in the difference between the two ranges of scaling factors proposed in section II.E.1 above.

We are also aware of the limitations of the dataset available on which to base these decisions, including those related to the quantity of collocated measurements and particularly the very limited number of source-influenced monitors for which such measurements are available, and the correspondingly limited number of types of sources represented. Moreover, the available collocated measurements suggesting the above-referenced 50% figure in a source-influenced location are from conditions in which ambient concentrations were above the current standard level and well above the proposed range of levels. If the contributing emissions sources had been controlled so that local concentrations were within or near the range proposed for the revised standard, it is unclear whether the relationship between Pb-PM_{10} and Pb-TSP data would have been different or not. The Pb-TSP concentrations at sites in the dataset analyzed that were not known to be source-influenced were well below the proposed range of standard levels, leaving uncertainty about typical proportions of ultra-coarse particles in nonsource areas with Pb-TSP concentrations near the proposed range of levels.

If EPA adopts a PM_{10} indicator, the approach of using two adjustment factors representing source-oriented and nonsource-oriented sites, or the approach of site-specific adjustment factors, would not be used in setting a standard level.[154] Rather, the complexity of the site-to-site variability in the Pb-TSP/Pb-PM_{10} relationship would have to be reflected in a decision about whether and how to adjust the level of the standard to account for the fact that a Pb-PM_{10} indicator would be less inclusive of Pb particles than would a Pb-TSP indicator.

b. CASAC Advice

As noted above, CASAC has described the use of an adjustment of the NAAQS level to accommodate the loss of the ultra-coarse Pb particles that are important contributions to Pb exposure but that are excluded by PM_{10} samplers (section II.E.1). For example, in discussion of the recommendation for the Agency to revise the Pb NAAQS indicator to Pb-PM_{10} (using low-volume samplers) in their February 2007 letter, the CASAC Pb Panel stated that ''Presumably a downward scaling of the level of the Lead NAAQS could accommodate the loss of very large coarse-mode lead particles * * *'' (Henderson, 2007a). With regard to the magnitude of such scaling, CASAC has recognized the usefulness of some ''short period of concurrent PM_{10} and TSP lead sampling'' to ''help develop site-specific scaling factors at sites with highest concentrations'' (Henderson, 2007a) and also indicated an expectation that, in general, Pb-PM_{10} will represent a large fraction of, and be highly correlated with TSP Pb (Henderson, 2007b). In their most recent letter, the Panel stated generally that ''it would be well within EPA's range of discretionary options to accept a slight loss of ultra-coarse lead at some monitoring sites by selecting an appropriately conservative level for the revised Pb NAAQS'' (Henderson, 2008). In summary, while the CASAC recognized the appropriateness of making an adjustment to the level for a Pb-PM_{10}-based NAAQS, they did not provide a quantitative value, but did note interest in sites with highest concentrations. Further, CASAC expressed the view that the overall health-related benefits from moving to a PM_{10}-based standard could outweigh a small loss in protection from exposure to ultra-coarse particles in some areas.

The Agency received few public comments with regard to a standard level for a revised indicator of Pb-PM_{10}. Of these, some generally agreed with CASAC that an adjustment to the level was appropriate, recognizing the difference in the two sampling methods. Some were concerned that the current data may not support the derivation of a single scaling or adjustment factor that would provide requisite protection for some communities near some large point source emitters of dust.

c. Approaches for Levels for a PM_{10}-Based Standard

For the reasons identified in the preceding section and in section II.E.1 above, EPA's consideration of a Pb-PM_{10} indicator is accompanied by consideration of an adjustment of the proposed level for the standard, in recognition of the importance for public health of those ultra-coarse dust contributions not captured by PM_{10} samplers.

In considering the appropriate level for a standard for which the indicator is Pb-PM_{10}, EPA recognizes the importance of all particle size fractions and the dominant role of the ingestion pathway in contributing to human exposures to air-related Pb. We also recognize that the proportion of Pb captured by TSP monitors that is not captured by PM_{10} monitors will vary, not only in reflection of the inherent greater variability of the TSP sampler (as compared to the PM_{10} sampler), but also based on proximity to sources emitting ultra-coarse Pb particles. An appreciably lower proportion of the Pb captured by TSP monitors will be captured by PM_{10} monitors in areas near such sources (e.g., Pb smelters).

However, we are also aware of the limitations with regard to the available Pb monitoring data on which to base a decision with regard to an adjustment that appropriately recognizes these considerations. EPA notes that at lower levels, there is increased uncertainty as to the appropriate scaling factor to use, particularly in light of the very limited data we have on which to base an analysis. Additionally, we take note of advice from CASAC and public comments with regard to considerations for a level to accompany a Pb-PM_{10} indicator.

Based on these and other considerations summarized above (II.E.1 and II.E.4.a), including the data indicating the proportion of Pb-TSP that may not be captured by PM_{10} samplers in some source-oriented locations, EPA requests comment on whether a level for a NAAQS with a Pb-PM_{10} indicator should be based on an adjustment to a lower level than the level for a NAAQS with a Pb-TSP indicator, and, if so, on the magnitude of the adjustment that would be appropriate. Taking into consideration uncertainties in the appropriate adjustment for a Pb-PM_{10} based level (due to the very limited collocated dataset with which to evaluate relationships between Pb-TSP and Pb-PM_{10}), and the appropriate policy responses based on the currently available information, EPA specifically solicits comment on the appropriate level for a Pb-PM_{10}-based primary standard within the full range of levels on which comment is being solicited for a Pb-TSP standard, i.e., levels up to 0.50 $\mu g/m^3$. Based on the comments received and the accompanying rationales, EPA may adopt standards within this broad range of alternative levels.

[154] As discussed below in sections IV and VI, however, EPA is soliciting comment on the potential use of Pb-TSP data for initial designations for Pb-PM_{10} standard and whether the associated use of scaling factors would be appropriate.

F. Proposed Decision on the Primary Standard

For the reasons discussed above, and taking into account information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and the public comments to date, the Administrator is proposing options for the revision of the various elements of the standard to provide increased protection for children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, including neurocognitive and neurobehavioral effects, in children. Specifically, with regard to the indicator and level of the standard, the Administrator proposes to revise the level of the standard to a level within the range of 0.10 to 0.30 $\mu g/m^3$ in conjunction with retaining the current indicator of Pb-TSP but with allowance for the use of Pb-PM_{10} data. The Administrator also solicits comment on alternative levels up to 0.50 $\mu g/m^3$ and down below 0.10 $\mu g/m^3$. With regard to the form and averaging time of the standard, the Administrator proposes two options: (1) To retain the current averaging time of a calendar quarter and the current not-to-be-exceeded form, to apply across a 3-year span, and (2) to revise the averaging time to a calendar month and the form to be the second-highest monthly average across a 3-year span.

Corresponding revisions to data handling conventions and the schedule for States to request exclusion of ambient Pb concentration data affected by exceptional events are specified in proposed revisions to Appendix R, as discussed in section IV below. Corresponding revisions to aspects of the ambient air monitoring and reporting requirements for Pb are discussed in section V below, including sampling and analysis methods (e.g., a new Federal reference method for monitoring Pb in PM_{10}, quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

In recognition of alternative views of the science and the exposure and risk assessments, the uncertainties inherent in this information, and the appropriate policy responses based on the currently available information, the Administrator also solicits comments on other options. More specifically, the Administrator solicits comment on revising the indicator to Pb-PM_{10} and on the same broad range of levels on which EPA is soliciting comment for the proposed Pb-TSP indicator, i.e., up to 0.50 $\mu g/m^3$. In addition, the Administrator invites comment on when, if ever, it would be appropriate to set a NAAQS for Pb at a level of zero. Based on the comments received and the accompanying rationales, the Administrator may adopt other standards within the range of the alternative levels identified above in lieu of the standards he is proposing today.

III. Rationale for Proposed Decision on the Secondary Standard

This section presents the rationale for the Administrator's proposed decision to revise the existing secondary NAAQS. In considering the currently available evidence on Pb-related welfare effects, the Staff Paper notes that there is much information linking Pb to potentially adverse effects on organisms and ecosystems. However, given the evaluation of this information in the Criteria Document and Staff Paper which highlighted the substantial limitations in the evidence, especially the lack of evidence linking various effects to specific levels of ambient Pb, the Administrator concludes that the available evidence supports revising the secondary standard but does not provide a sufficient basis for establishing a distinct secondary standard for Pb.

A. Welfare Effects Information

Welfare effects addressed by the secondary NAAQS include, but are not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being. A qualitative assessment of welfare effects evidence related to ambient Pb is summarized in this section, drawing from Chapter 6 of the Staff Paper. The presentation here first recognizes several key aspects of the welfare evidence for Pb. Lead is persistent in the environment and accumulates in soils, aquatic systems (including sediments), and some biological tissues of plants, animals, and other organisms, thereby providing long-term, multipathway exposures to organisms and ecosystems.

Additionally, EPA recognizes that there have been a number of uses of Pb, especially as an ingredient in automobile fuel but also in other products such as paint, lead-acid batteries, and some pesticides, which have significantly contributed to widespread increases in Pb concentrations in the environment, a portion of which remains today (e.g., CD, Chapters 2 and 3).

Ecosystems near smelters, mines, and other industrial sources of Pb have demonstrated a wide variety of adverse effects including decreases in species diversity, loss of vegetation, changes to community composition, decreased growth of vegetation, and increased number of invasive species. These sources may have multiple pathways for discharging Pb to ecosystems, and apportioning effects between air-related pathways and other pathways (e.g. discharges to water) in such cases is difficult. Likewise, apportioning these effects between Pb and other stressors is complicated because these point sources also emit a wide variety of other heavy metals and sulfur dioxide which may cause toxic effects. There are no field studies which have investigated effects of Pb additions alone but some studies near large point sources of Pb have found significantly reduced species composition and altered community structures. While these effects are significant, they are spatially limited: the majority of contamination occurs within 20 to 50 km of the emission source (CD, AX7.1.4.2).

By far, the majority of air-related Pb found in terrestrial ecosystems was deposited in the past during the use of Pb additives in gasoline. This gasoline-derived Pb was emitted predominantly in small size particles which were widely dispersed and transported across large distances. Many sites receiving Pb predominantly through such long-range transport have accumulated large amounts of Pb in soils (CD, p. AX7–98). There is little evidence that terrestrial sites exposed as a result of this long range transport of Pb have experienced significant effects on ecosystem structure or function (CD, AX7.1.4.2, p. AX7–98). Strong complexation of Pb by soil organic matter may explain why few ecological effects have been observed (CD, p. AX7–98). Studies have shown decreasing levels of Pb in vegetation which seems to correlate with decreases in atmospheric deposition of Pb resulting from the removal of Pb additives to gasoline (CD, AX 7.1.4.2).

Terrestrial ecosystems remain primarily sinks for Pb but amounts retained in various soil layers vary based on forest type, climate, and litter cycling (CD, section 7.1). Once in the soil, the migration and distribution of Pb is controlled by a multitude of factors including pH, precipitation, litter composition, and other factors which govern the rate at which Pb is bound to organic materials in the soil (CD, section 2.3.5).

Like most metals the solubility of Pb is increased at lower pH. However, the

reduction of pH may in turn decrease the solubility of dissolved organic material (DOM). Given the close association between Pb mobility and complexation with DOM, a reduced pH does not necessarily lead to increased movement of Pb through terrestrial systems and into surface waters. In areas with moderately acidic soil (i.e., pH of 4.5 to 5.5) and abundant DOM, there is no appreciable increase in the movement of Pb into surface waters compared to those areas with neutral soils (i.e., pH of approximately 7.0). This appears to support the theory that the movement of Pb in soils is limited by the solubilization and transport of DOM. In sandy soils without abundant DOM, moderate acidification appears likely to increase outputs of Pb to surface waters (CD, AX 7.1.4.1).

Lead exists in the environment in various forms which vary widely in their ability to cause adverse effects on ecosystems and organisms. Current levels of Pb in soil also vary widely depending on the source of Pb but in all ecosystems Pb concentrations exceed natural background levels. The deposition of gasoline-derived Pb into forest soils has produced a legacy of slow moving Pb that remains bound to organic materials despite the removal of Pb from most fuels and the resulting dramatic reductions in overall deposition rates. For areas influenced by point sources of air Pb, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms. Adverse effects associated with Pb include neurological, physiological, and behavioral effects which may influence ecosystem structure and functioning. Ecological soil screening levels (Eco-SSLs) have been developed for Superfund site characterizations to indicate concentrations of Pb in soils below which no adverse effects are expected to plants, soil invertebrates, birds, and mammals. Values like these may be used to identify areas in which there is the potential for adverse effects to any or all of these receptors based on current concentrations of Pb in soils.

Atmospheric Pb enters aquatic ecosystems primarily through the erosion and runoff of soils containing Pb and deposition (wet and dry). While overall deposition rates of atmospheric Pb have decreased dramatically since the removal of Pb additives from gasoline, Pb continues to accumulate and may be re-exposed in sediments and water bodies throughout the United States (CD, section 2.3.6).

Several physical and chemical factors govern the fate and bioavailability of Pb in aquatic systems. A significant portion of Pb remains bound to suspended particulate matter in the water column and eventually settles into the substrate. Species, pH, salinity, temperature, turbulence, and other factors govern the bioavailability of Pb in surface waters (CD, section 7.2.2).

Lead exists in the aquatic environment in various forms and under various chemical and physical parameters which determine the ability of Pb to cause adverse effects either from dissolved Pb in the water column or Pb in sediment. Current levels of Pb in water and sediment also vary widely depending on the source of Pb. Conditions exist in which adverse effects to organisms and thereby ecosystems may be anticipated given experimental results. It is unlikely that dissolved Pb in surface water constitutes a threat to ecosystems that are not directly influenced by point sources. For Pb in sediment, the evidence is less clear. It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The long residence time of Pb in sediment and its ability to be resuspended by turbulence make Pb likely to be a factor for the foreseeable future. Criteria have been developed to indicate concentrations of Pb in water and sediment below which no adverse effects are expected to aquatic organisms. These values may be used to identify areas in which there is the potential for adverse effects to receptors based on current concentrations of Pb in water and sediment.

B. Screening Level Ecological Risk Assessment

This section presents a brief summary of the screening-level ecological risk assessment conducted by EPA for this review. The assessment is described in detail in *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas, Pilot Phase* (ICF, 2006). Funding constraints have precluded performance of a full-scale ecological risk assessment. The discussion here is focused on the screening level assessment performed in the pilot phase (ICF, 2006) and takes into consideration CASAC recommendations with regard to interpretation of this assessment (Henderson, 2007a, b). The following summary focuses on key features of the approach used in the assessment and presents only a brief summary of the results of the assessment. A complete presentation of results is provided in the pilot phase Risk Assessment Report (ICF, 2006) and summarized in Chapter 6 of the Staff Paper.

1. Design Aspects of Assessment and Associated Uncertainties

The screening level risk assessment involved several location-specific case studies and a national-scale surface water and sediment screen. The case studies included areas surrounding a primary Pb smelter and a secondary Pb smelter, as well as a location near a nonurban roadway. An additional case study for an ecologically vulnerable location was identified and described (ICF, 2006), but resource constraints have precluded risk analysis for this location.

The case study analyses were designed to estimate the potential for ecological risks associated with exposures to Pb emitted into ambient air. Soil, surface water, and/or sediment concentrations were estimated from available monitoring data or modeling analysis, and then compared to ecological screening benchmarks to assess the potential for ecological impacts from Pb that was emitted into the air. Results of these comparisons are not definitive estimates of risk, but rather serve to identify those locations at which there is the greatest likelihood for adverse effect. Similarly, the national-scale screening assessment evaluated surface water and sediment monitoring locations across the United States for the potential for ecological impacts associated with atmospheric deposition of Pb. The reader is referred to the pilot phase Risk Assessment Report (ICF, 2006) for details on the use of this information and models in the screening assessment.

The measures of exposure for these analyses are total Pb concentrations in soil, dissolved Pb concentrations in fresh surface waters (water column), and total Pb concentrations in freshwater sediments. The hazard quotient (HQ) approach was then used to compare Pb media concentrations with ecological screening values. The exposure concentrations were estimated for the three case studies and the national-scale screening analyses as described below:

- For the primary Pb smelter case study, measured concentrations of total Pb in soil, dissolved Pb in surface waters, and total Pb in sediment were used to develop point estimates for sampling clusters thought to be associated with atmospheric Pb deposition, rather than Pb associated with nonair sources, such as runoff from waste storage piles.
- For the secondary Pb smelter case study, concentrations of Pb in soil were

estimated using fate and transport modeling based on EPA's MPE methodology (USEPA, 1998) and data available from similar locations.

• For the near roadway nonurban case study, measured soil concentration data collected from two interstate sampling locations, one with fairly high-density development (Corpus Christi, Texas) and another with medium-density development (Atlee, Virginia), were used to develop estimates of Pb in soils for each location.

• For the national-scale surface water and sediment screening analyses, measurements of dissolved Pb concentrations in surface water and total Pb in sediment for locations across the United States were compiled from available databases (USGS, 2004). Air emissions, surface water discharge, and land use data for the areas surrounding these locations were assessed to identify locations where atmospheric Pb deposition may be expected to contribute to potential ecological impacts. The exposure assessment focused on these locations.

The ecological screening values used in this assessment were developed from the Eco-SSLs methodology, EPA's recommended ambient water quality criteria, and sediment screening values developed by MacDonald and others (2000, 2003). Soil screening values were derived for this assessment using the Eco-SSL methodology with the toxicity reference values for Pb (USEPA, 2005d, 2005e) and consideration of the inputs on diet composition, food intake rates, incidental soil ingestion, and contaminant uptake by prey (details are presented in section 7.1.3.1 and Appendix L, of ICF, 2006). Hardness-specific surface water screening values were calculated for each site based on EPA's recommended ambient water quality criteria for Pb (USEPA, 1984). For sediment screening values, the assessment relied on sediment ''threshold effect concentrations'' and ''probable effect concentrations'' developed by MacDonald *et al* (2000). The methodology for these sediment criteria is described more fully in section 7.1.3.3 and Appendix M of the pilot phase Risk Assessment Report (ICF, 2006).

The HQ is calculated as the ratio of the media concentration to the ecotoxicity screening value, and represented by the following equation:

HQ = (estimated Pb media concentration)/(ecotoxicity screening value)

For each case study, HQ values were calculated for each location where either modeled or measured media concentrations were available. Separate soil HQ values were calculated for each ecological receptor group for which an ecotoxicity screening value has been developed (i.e., birds, mammals, soil invertebrates, and plants). HQ values less than 1.0 suggest that Pb concentrations in a specific medium are unlikely to pose significant risks to ecological receptors. HQ values greater than 1.0 indicate that the expected exposure exceeds the ecotoxicity screening value and that there is a potential for adverse effects.

There are several uncertainties that apply across case studies noted below:

• The ecological risk screen is limited to specific case study locations and other locations for which dissolved Pb data were available and evaluated in the national-scale surface water and sediment screens. In identifying sites for inclusion in the assessment, efforts were made to ensure that the Pb exposures assessed were attributable to airborne Pb and not dominated by nonair sources. However, there is uncertainty as to whether other sources might have actually contributed to the Pb exposure estimates.

• A limitation to using the selected ecotoxicity screening values is that they might not be sufficient to identify risks to some threatened or endangered species or unusually sensitive aquatic ecosystems (e.g., CD, p. AX7–110).

• The methods and database from which the surface water screening values (i.e., the AWQC for Pb) were derived is somewhat dated. New data and approaches (e.g., use of pH as indicator of bioavailability) may now be available to estimated the aquatic toxicity of Pb (CD, sections AX7.2.1.2 and AX7.2.1.3).

• No adjustments were made for sediment-specific characteristics that might affect the bioavailability of Pb in sediments in the derivation of the sediment quality criteria used for this ecological risk screen (CD, sections 7.2.1 and AX7.2.1.4; Appendix M, ICF, 2006). Similarly, characteristics of soils for the case study locations were not evaluated for measures of bioavailability.

• Although the screening value for birds used in this analysis is based on reasonable estimates for diet composition and assimilation efficiency parameters, it was based on a conservative estimate of the relative bioavailability of Pb in soil and natural diets compared with water soluble Pb added to an experimental pellet diet (Appendix L, ICF, 2006).

2. Summary of Results

The following is a brief summary of key observations related to the results of the screening-level ecological risk assessment. A more complete discussion of the results is provided in Chapter 6 of the Staff Paper and the complete presentation of the assessment and results is presented in the pilot phase Risk Assessment Report (ICF, 2006).

• The national-scale screen of surface water data initially identified some 42 sample locations of which 15 were then identified as unrelated to mining sites and having water column levels of dissolved Pb that were greater than hardness adjusted chronic criteria for the protection of aquatic life (with one location having a HQ of 15), indicating a potential for adverse effect if concentrations were persistent over chronic periods. Acute criteria were not exceeded at any of these locations. The extent to which air emissions of Pb have contributed to these surface water Pb concentrations is unclear.

• In the national-scale screen of sediment data associated with the 15 surface water sites described above, threshold effect concentration-based HQs at nine of these sites exceeded 1.0. Additionally, HQs based on probable effect concentrations exceeded 1.0 at five of the sites, indicating probable adverse effects to sediment dwelling organisms. Thus, sediment Pb concentrations at some sites are high enough that there is a likelihood that they would cause adverse effects to sediment dwelling organisms. However, the contribution of air emissions to these concentrations is unknown.

• In the primary Pb smelter case study, for which measurements were used to estimate nonair media concentrations, all three of the soil sampling clusters (including the ''reference areas'') had HQs that exceeded 1.0 for birds. Samples from one cluster also had HQs greater than 1.0 for plants and mammals. The surface water sampling clusters all had measurements below the detection limit of 3.0 µg/L. However, three sediment sample clusters had HQs greater than 1.0. In summary, the concentrations of Pb in soil and sediments exceed screening values for these media indicating potential for adverse effects to terrestrial organisms (plants, birds and mammals) and to sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources is not quantified, air emissions from this facility are substantial (Appendix D, USEPA 2007b; ICF 2006). Further, the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is unknown.

• In the secondary Pb smelter case study, the soil concentrations, developed from soil data for similar locations, resulted in avian HQs greater than 1.0 for all distance intervals evaluated. The soil concentrations within 1 km of the facility, scaled using a combination of measurements and modeling (as described in the Staff Paper, Chapter 6) also showed HQs greater than 1.0 for plants, birds, and mammals. These estimates indicate a potential for adverse effect to those receptor groups. We note that the contribution of nonair sources to these concentrations is unknown. Further, the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is also unknown.

• In the nonurban, near roadway case study, HQs for birds and mammals were greater than 1.0 at all but one of the distances from the road. Plant HQs were greater than 1.0 at the closest distance. In summary, HQs above one were estimated for plants, birds and mammals, indicating potential for adverse effect to these receptor groups. We note that the contribution of air Pb under the current NAAQS to these concentrations as compared to that prior to the current NAAQS is unknown.

C. The Secondary Standard

The NAAQS provisions of the Act require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that secondary standards be set to eliminate all risk of adverse welfare effects, but rather at a level requisite to protect public welfare from those effects that are judged by the Administrator to be adverse.

The following discussion starts with background information on the current standard (section III.C.1). The general approach for this current review is summarized in section III.C.2. Considerations and conclusions with regard to the adequacy of the current standard are discussed in section III.C.3, with evidence and exposure-risk-based considerations in sections III.C.3.a and b, respectively, followed by a summary of CASAC advice and recommendations (section III.C.3.c) and the Administrator's proposed conclusions (section III.C.3.d). Considerations, conclusions and the Administrator's proposed decision with regard to elements of the secondary standard are discussed in section III.C.4.

1. Background on the Current Standard

The current standard was set in 1978 to be identical to the primary standard (1.5 μg Pb/m^3, as a maximum arithmetic mean averaged over a calendar quarter), the basis for which is summarized in Section II.C.1. At the time the standard was set, the Agency concluded that the primary air quality standard would adequately protect against known and anticipated adverse effects on public welfare, as the Agency stated that it did not have evidence that a more restrictive secondary standard was justified. In the rationale for this conclusion, the Agency stated that the available evidence cited in the 1977 Criteria Document indicated that ''animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans'' (43 FR 46256). The Agency recognized that Pb may be deposited on the leaves of plants and present a hazard to grazing animals. With regard to plants, the Agency stated that Pb is absorbed but not accumulated to any great extent by plants from soil, and that although some plants may be susceptible to Pb, it is generally in a form that is largely nonavailable to them. Further the Agency stated that there was no evidence indicating that ambient levels of Pb result in significant damage to manmade materials and Pb effects on visibility and climate are minimal.

The secondary standard was subsequently considered during the 1980s in development of the 1986 Criteria Document (USEPA, 1986a) and the 1990 Staff Paper (USEPA, 1990). In summarizing OAQPS staff conclusions and recommendations at that time, the 1990 Staff Paper stated that a qualitative assessment of available field studies and animal toxicological data suggested that ''domestic animals and wildlife are as susceptible to the effects of lead as laboratory animals used to investigate human lead toxicity risks.'' Further, the 1990 Staff Paper highlighted concerns over potential ecosystem effects of Pb due to its persistence, but concluded that pending development of a stronger database that more accurately quantifies ecological effects of different Pb concentrations, consideration should be given to retaining a secondary standard at or below the level of the then-current secondary standard of 1.5 μg/m^3.

2. Approach for Current Review

In evaluating whether it is appropriate to retain the current secondary Pb standard, or whether revision is appropriate, the Administrator has considered the evidence and risk analyses presented in the Criteria Document, the Staff Paper, the ANPR and the associated technical support documents, [together with the associated uncertainties] and CASAC advice and public comment on these documents. The Staff Paper and ANPR recognize that the available welfare effects evidence generally reflects laboratory-based evidence of toxicological effects on specific organisms exposed to concentrations of Pb at which scientists generally agree that adverse effects are likely to occur. It is widely recognized, however, that environmental exposures are likely to be at lower concentrations and/or accompanied by significant confounding factors (e.g., other metals, acidification), which increases our uncertainty about the likelihood and magnitude of the organism and ecosystem response.

3. Conclusions on Adequacy of the Current Standard

a. Evidence-Based Considerations

In considering the welfare effects evidence with respect to the adequacy of the current standard, the Administrator considers not only the array of evidence newly assessed in the Criteria Document but also that assessed in the 1986 Criteria Document and summarized in the 1990 Staff Paper. As discussed extensively in the latter two documents, there was a significantly improved characterization of environmental effects of Pb in the ten years after the Pb NAAQS was set. And in the subsequent nearly 20 years, many additional studies on Pb effects in the environment are now available (2006 Criteria Document). Some of the more relevant aspects of the evidence available since the standard was set include the following:

• A more quantitative determination of the mobility, distribution, uptake, speciation, and fluxes of atmospherically delivered Pb in terrestrial ecosystems shows that the binding of Pb to organic materials in the soil slows its mobility through soil and may prevent uptake by plants (CD, Sections 7.1.2, 7.1.5, AX7.1.4.1, AX7.1.4.2, AX7.1.4.3 and AX7.1.2). Therefore, while atmospheric deposition of Pb has decreased, Pb may be more persistent in some ecosystems than others and may remain in the active zone of the soil, where exposure

may occur, for decades (CD, Sections 7.1.2, AX7.1.2 and AX7.1.4.3).

• Plant toxicity may occur at lower levels than previously identified as determined by data considered in development of Eco–SSLs (CD, pp. 7–11 to 7–12, AX7–16 and Section AX7.1.3.2), although the range of reported soil Pb effect levels is large (tens to thousands of mg/kg soil).

• Avian and mammalian toxicity may occur at lower levels than those previously identified, although the range of Pb effect levels is large (<1 to >1,000 mg Pb/kg bw-day) (CD, p. 7–12, Section AX7.1.3.3).

• There is an expanded understanding of the fate and effects of Pb in aquatic ecosystems and of the distribution and concentrations of Pb in surface waters throughout the United States (CD, Section AX7.2.2).

• New methods for assessing the toxicity of metals to water column and sediment-dwelling organisms and data collection efforts (CD, Sections 7.2.1, 7.2.2, AX7.2.2, and AX7.2.2.2) have improved our understanding of Pb aquatic toxicity and findings include an indication that in some estuarine systems Pb deposited during historic usage of leaded gasoline may remain in surface sediments for decades. (CD, p. 7–23).

• A larger dataset of aquatic species assessed with regard to Pb toxicity, and findings of lower effect levels for previously untested species (CD, p. AX7–176 and Section AX7.2.4.3).

• Currently available studies have also shown effects on community structure, function and primary productivity, although some confounders (such as co-occurring pollutants) have not been well addressed (CD, Section AX7.1.4.2).

• Evidence in ecological research generally indicates the value of a critical loads approach; however, current information on Pb critical loads is lacking for many processes and interactions involving Pb in the environment and work is ongoing (CD, Section 7.3).

Given the full body of current evidence, despite wide variations in Pb concentrations in soils throughout the country, Pb concentrations are likely in excess of concentrations expected from geologic or other non-anthropogenic forces. In particular, the deposition of gasoline-derived Pb into forest soils has produced a legacy of slow moving Pb that remains bound to organic materials despite the removal of Pb from most fuels and the resulting dramatic reductions in overall deposition rates (CD, Section AX7.1.4.3). For areas influenced by point sources of air Pb that meet the current standard, concentrations of Pb in soil may exceed by many orders of magnitude the concentrations which are considered harmful to laboratory organisms (CD, Section 3.2 and AX7.1.2.3).

There are several difficulties in quantifying the role of current ambient Pb in the environment: some Pb deposited before the standard was enacted is still present in soils and sediments; historic Pb from gasoline continues to move slowly through systems as does current Pb derived from both air and nonair sources. Additionally, the evidence of adversity in natural systems is very sparse due in no small part to the difficulty in determining the effects of confounding factors such as multiple metals or factors influencing bioavailability in field studies. However, the evidence summarized above and in Section 4.2 of the Staff Paper and described in detail in the Criteria Document informs our understanding of Pb in the environment today and evidence of environmental Pb exposures of potential concern.

Conditions exist in which Pb-associated adverse effects to aquatic organisms and thereby ecosystems may be anticipated given experimental results. While the evidence does not indicate that dissolved Pb in surface water constitutes a threat to those ecosystems that are not directly influenced by point sources, the evidence regarding Pb in sediment is less clear (CD, Sections AX7.2.2.2.2 and AX7.2.4). It is likely that some areas with long term historical deposition of Pb to sediment from a variety of sources as well as areas influenced by point sources have the potential for adverse effects to aquatic communities. The Staff Paper concluded based on looking to laboratory studies and current media concentrations in a wide range of areas, it seems likely that adverse effects are occurring, particularly near point sources, under the current standard. The long residence time of Pb in sediment and its ability to be resuspended by turbulence make Pb contamination likely to be a factor for the foreseeable future. Based on this information, the Staff Paper concluded that the evidence suggests that the environmental levels of Pb occurring under the current standard, set nearly thirty years ago, may pose risk of adverse environmental effect.

b. Risk-Based Considerations

In addition to the evidence-based considerations described in the previous section, the screening level ecological risk assessment is informative, taking into account key limitations and uncertainties associated with the analyses.

The screening level risk assessment involved a comparison of estimates of environmental media concentrations of Pb to ecological screening levels to assess the potential for ecological impacts from Pb that was emitted into the air. Results of these comparisons are not considered to be definite predictors of risk, but rather serve to identify those locations at which there is greatest likelihood for adverse effect. Similarly, the national-scale screening assessment evaluated the potential for ecological impacts associated with the atmospheric deposition of Pb released into ambient air at surface water and sediment monitoring locations across the United States.

The ecological screening levels employed in the screening level risk assessment for different media are drawn from different sources. Consequently there are somewhat different limitations and uncertainties associated with each. In general, their use here recognizes their strength in identifying media concentrations with the potential for adverse effect and their relative nonspecificity regarding the magnitude of risk of adverse effect.

As discussed in the previous section, as a result of its persistence, Pb emitted in the past remains today in aquatic and terrestrial ecosystems of the United States. Consideration of the environmental risks associated with the current standard is complicated by the environmental burden associated with air Pb concentrations that exceeded the current standard, predominantly in the past.

Concentrations of Pb in soil and sediments associated with the primary Pb smelter case study exceeded screening values for those media, indicating potential for adverse effect in terrestrial organisms (plants, birds, and mammals) and in sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources has not been quantified, air emissions from this facility are substantial (Appendix D, USEPA 2007b; ICF 2006). Additionally, estimates of Pb concentration in soils associated with the nonurban near roadway case study and the secondary Pb smelter case study were also associated with HQs above 1 for plants, birds and mammals, indicating potential for adverse effect to those receptor groups. The industrial facility in the secondary Pb smelter case study is much younger than the primary Pb smelter and apparently became active less than ten years prior to the establishment of the current standard.

The national-scale screens, which are not focused on particular point source locations, indicate the ubiquitous nature of Pb in aquatic systems of the United States today. Further, the magnitude of Pb concentrations in several aquatic systems exceeded screening values. In the case of the national-scale screen of surface water data, 15 locations were identified with water column levels of dissolved Pb that were greater than hardness-adjusted chronic criteria for the protection of aquatic life (with one location having a HQ as high as 15), indicating a potential for adverse effect if concentrations were persistent over chronic periods. Further, sediment Pb concentrations at some sites in the national-scale screen were high enough that the likelihood that they would cause adverse effects to sediment dwelling organisms may be considered ''probable''.

A complicating factor in interpreting the findings for the national-scale screening assessments is the lack of clear apportionment of Pb contributions from air as compared to nonair sources, such as industrial and municipal discharges. While the contribution of air emissions to the elevated concentrations has not been quantified, documentation of historical trends in the sediments of many water bodies has illustrated the sizeable contribution that airborne Pb can have on aquatic systems (e.g., Staff Paper, section 2.8.1). This documentation also indicates the greatly reduced contribution in many systems as compared to decades ago (presumably reflecting the banning of Pb-additives from gasoline used by cars and trucks). However, the timeframe for removal of Pb from surface sediments into deeper sediment varies across systems, such that Pb remains available to biological organisms in some systems for much longer than in others (Staff Paper, section 2.8; CD, pp. AX7–141 to AX7–145).

The case study locations included in the screening assessment, with the exception of the primary Pb smelter site, are currently meeting the current Pb standard, yet Pb occurs in some locations at concentrations, particularly in soil, and aquatic sediment above the screening levels, indicative of a potential for harm to some terrestrial and sediment dwelling organisms. While the role of airborne Pb in determining these Pb concentrations is unclear, the historical evidence indicates that airborne Pb can create such concentrations in sediments and soil. Further, environmental concentrations may be related to emissions prior to establishment of the current standard and such concentrations appear to indicate a potential for harm to ecological receptors today.

c. CASAC Advice and Recommendations

In the CASAC letter transmitting advice and recommendations pertaining to the review of the ANPR and final Staff Paper and Pb Exposure and Risk Assessments, the CASAC Pb panel provided recommendations regarding the need for a Pb NAAQS, and the adequacy of the current Pb NAAQS, as well as comments on the documents. With regard to the revision of the primary and secondary NAAQS, this CASAC letter (Henderson, 2008) said:

> The Committee unanimously and fully supports Agency staff's scientific analyses in recommending the need to substantially lower the level of the primary (public-health based) Lead NAAQS, to an upper bound of no higher than 0.2 $\mu g/m^3$ with a monthly averaging time. The CASAC is also unanimous in its recommendation that the secondary (public-welfare based) standard for lead needs to be substantially lowered to a level at least as low as the recommended primary NAAQS for Lead.

In earlier comments on the December 2006 draft documents, the CASAC Pb Panel concluded they presented ''compelling scientific evidence that current atmospheric Pb concentrations and deposition—combined with a large reservoir of historically deposited Pb in soils, sediments and surface waters—continue to cause adverse environmental effects in aquatic and/or terrestrial ecosystems, especially in the vicinity of large emissions sources.'' The Panel went on to state that ''These effects persist in some cases at locations where current airborne lead concentrations are below the level of the current primary and secondary lead standards'' and ''Thus, from an environmental perspective, there are convincing reasons to both retain lead as a regulated criteria air pollutant and to lower the level of the current secondary standard'' (Henderson, 2007a).

In making this recommendation, the CASAC Pb Panel also cites the persistence of Pb in the environment, the possibility of some of the large amount of historically deposited Pb becoming resuspended by natural events, and the expectation that humans are not uniquely sensitive among the many animal and plant species in the environment.

CASAC provided further advice and recommendations on the Agency's consideration of the secondary standard in this review in their letter of September 2007 (Henderson, 2007b). In that letter they recognized the role of the secondary standard in influencing the long-term environmental burden of Pb and a need for environmental monitoring to assess the success of the standard in this role.

Similarly, in CASAC's advice on the ANPR and final Staff Paper they concluded:

> [I]t is critical that the secondary Lead NAAQS be set at a sufficiently-stringent level so as to ensure that there is no reversal of the current downward trend in lead concentrations in the environment. Therefore, at a minimum, the level of the secondary Lead NAAQS should be at least as low as the level of the recommended primary lead standard. Moreover, the Agency needs to give greater priority to the monitoring of environmental lead in the ambient air.

However, CASAC also recognized that EPA ''lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level or form'' (Henderson, 2007a).

d. Administrator's Proposed Conclusions on Adequacy of Current Standard

In considering the adequacy of the current standard in providing requisite protection from Pb-related adverse effects on public welfare, the Administrator has considered the body of available evidence (briefly summarized above in Section III.A). Depending on the interpretation, the available data and evidence, primarily qualitative, suggests the potential for adverse environmental impacts under the current standard. Given the limited data on Pb effects in ecosystems, it is necessary to look at evidence of Pb effects on organisms and extrapolate to ecosystem effects. Therefore, taking into account the available evidence and current media concentrations in a wide range of areas, the Administrator concludes that there is potential for adverse effects occurring under the current standard, however there are insufficient data to provide a quantitative basis for setting a secondary standard different than the primary. While the role of current airborne emissions is difficult to apportion, it is conclusive that deposition of Pb from air sources is occurring and that this ambient Pb is likely to be persistent in the environment. Historically deposited Pb has persisted, although location-specific dynamics of Pb in soil result in differences in the timeframe during which Pb is retained in surface soils or sediments where it may be available to ecological receptors (USEPA, 2007b, section 2.3.3).

There is only very limited information available pertinent to assessing whether groups of organisms which influence ecosystem function are subject to similar effects as those in humans. The screening-level risk information, while limited and accompanied by various uncertainties, also suggests occurrences of environmental Pb concentrations existing under the current standard that could have adverse environmental effects. Environmental Pb levels today are associated with atmospheric Pb concentrations and deposition that have combined with a large reservoir of historically deposited Pb in environmental media.

In considering this evidence, as well as the views of CASAC, summarized above, the Staff Paper and associated support documents, and views of public commenters on the adequacy of the current standard, the Administrator proposes to conclude that the current secondary standard for Pb is not requisite to protect public welfare from known or anticipated adverse effects.

4. Conclusions and Proposed Decision on the Elements of the Secondary Standard

The secondary standard is defined in terms of four basic elements: indicator, averaging time, level and form, which serve to define the standard and must be considered collectively in evaluating the welfare protection afforded by the standards.

With regard to the pollutant indicator for use in a secondary NAAQS that provides protection for public welfare from exposure to Pb, EPA notes that Pb is a persistent pollutant to which ecological receptors are exposed via multiple pathways. While the evidence indicates that the environmental mobility and ecological toxicity of Pb are affected by various characteristics of its chemical form, and the media in which it occurs, information is insufficient to identify an indicator other than total Pb that would provide protection against adverse environmental effect in all ecosystems nationally. Thus, the same concerns regarding the relative advantages of TSP and PM_{10} as the basis for the indicator apply here as for the primary standard.

Lead is a cumulative pollutant with environmental effects that can last many decades. In considering the appropriate averaging time for a secondary standard for such a pollutant the concept of critical loads may be useful (CD, section 7.3). However, information is currently insufficient for such use in this review.

There is a general lack of data that would indicate the appropriate level of Pb in environmental media that may be associated with adverse effects. The EPA notes the influence of airborne Pb on Pb in aquatic systems and of changes in airborne Pb on aquatic systems, as demonstrated by historical patterns in sediment cores from lakes and Pb measurements (section 2.8.1; CD, section AX7.2.2; Yohn *et al.*, 2004; Boyle *et al.*, 2005), as well as the comments of the CASAC Pb panel that a significant change to current air concentrations (e.g., via a significant change to the standard) is likely to have significant beneficial effects on the magnitude of Pb exposures in the environment and Pb toxicity impacts on natural and managed terrestrial and aquatic ecosystems in various regions of the U.S., the Great Lakes and also U.S. territorial waters of the Atlantic Ocean (Henderson, 2007a, Appendix E). EPA concurs with CASAC's conclusion that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level or form. The Administrator concurs with CASAC's conclusion that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level, or form.

Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposes to revise the current secondary Pb standard by making it identical in all respects to the proposed primary Pb standard (described in section II.D.4 above).

IV. Proposed Appendix R—Interpretation of the NAAQS for Lead and Proposed Revisions to the Exceptional Events Rule

The EPA is proposing to add Appendix R, Interpretation of the National Ambient Air Quality Standards for Pb, to 40 CFR part 50 in order to provide data handling procedures for the proposed Pb standard. The proposed Appendix R would detail the computations necessary for determining when the proposed Pb NAAQS is met. The proposed appendix also would address data reporting; sampling frequency and data completeness considerations; the use of scaled Pb-PM_{10} data as a surrogate for Pb-TSP data (or vice versa), including associated scaling instructions; and rounding conventions. Although the Administrator is proposing one indicator and inviting comment on another, and proposing several possible combinations of different averaging times, forms, and levels, for simplicity the proposed data handling appendix text only directly addresses one combination: a Pb-TSP indicator with an option for using scaled Pb-PM_{10} data for NAAQS comparisons, an averaging time of monthly, a second maximum (over three years) form, and a level of 0.20 $\mu g/m^3$. The proposed appendix text indicates in brackets, as examples, the change that would be needed if the level of the standard is set at 0.10 or 0.30 $\mu g/m^3$ rather than at 0.20 $\mu g/m^3$. A decision to adopt Pb-PM_{10} as the indicator, to adopt a different indicator, averaging time, and/or form, or not to make use of surrogate data would require other differences in the text of the appendix; the proposed differences in the appendix text to accommodate such difference are described below, after the explanation of the proposed version of the appendix.

The EPA is also proposing Pb-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe has been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines now contained in 40 CFR 50.14 are generic, and are not always appropriate for Pb given the anticipated schedule for the designations of areas under the proposed Pb NAAQS.

A. Background

The purpose of a data interpretation guideline in general is to provide the practical details on how to make a comparison between multi-day, possibly multi-monitor, and (in the unique instance of this proposed Pb NAAQS) possibly multi-parameter (i.e., Pb-TSP and/or Pb-PM_{10}) ambient air concentration data to the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all. When data are insufficient, for example because of failure to collect valid ambient data on enough days in enough months (because of operator error or events beyond the control of the operator), then no determination of current compliance or violation is possible.

The regulatory language for the current Pb NAAQS, originally adopted in 1977, contains no data interpretation instructions. Because of that, the EPA

has issued various guidance documents and memoranda relevant to the topic. This situation contrasts with the situations for ozone, $PM_{2.5}$, and PM_{10} for which there are detailed data interpretation appendices in 40 CFR part 50. EPA has used its experience drafting and applying these other data interpretation appendices to develop the proposed text for appendix R.

An exceptional event is an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data affected by an exceptional event in certain specified ways may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS, subject to EPA review and concurrence. Section 50.14 contains both substantive criteria that an event and the associated air concentration data must meet in order to be excluded, and process steps and deadlines for a State to submit specified information to EPA. The key deadlines are that a State must initially notify EPA that data have been affected by an event and provide an initial description of the event by July 1 of the year after the data are collected, and that the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data, for example a designation action, is anticipated, the schedule is foreshortened and all information must be submitted to EPA no later than a year before the decision is to be made. This schedule presents problems when a NAAQS has been recently revised, as discussed below.

The Staff Paper did not address data interpretation details, and although the ANPR discussed data handling to a limited extent, there has been only limited comment by CASAC or the public to date (other than comments on the related issues of form and indicator for the standard, including scaling factor issues). Similarly, no comments were received on exceptional event issues.

B. Interpretation of the NAAQS for Lead

1. Interpretation of a Standard Based on Pb-TSP

The purpose of a data interpretation rule for the Pb NAAQS is to give effect to the form, level, averaging time, and indicator specified in the proposed regulatory text at 40 CFR 50.16, anticipating and resolving in advance various future situations that could occur. The proposed Appendix R, like the existing NAAQS interpretation appendices for ozone, $PM_{2.5}$, and PM_{10}, addresses the possible situation of there being less than 100% complete data available, which is an issue in common across NAAQS pollutants. It also addresses several issues which are specific to the proposed Pb NAAQS, as described below.

With regard to data completeness, the proposed Appendix follows past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the combination of NAAQS parameters addressed in the proposed text, the key air quality statistic is the mean concentration in an individual month, and so the 75% requirement is applied for that time period. With the proposed required sampling schedule of one day in three under a monthly mean form for the standard (section V), typically there will be 10 required sampling days so a monthly mean would be considered valid if there were data available for at least 8 of those days.[155] EPA invites comment on this proposed 75% requirement, recognizing that for the current NAAQS based on a quarterly mean concentration form with a required one-day-in-six schedule, the current EPA policy is effectively that there be at least 11 days of data in a quarterly mean.

The proposed rule text for Pb data interpretation, like the corresponding existing rule for $PM_{2.5}$, has two provisions that help a monitoring agency guard against a month ending up with data completeness below 75%. First, there is a provision to allow data from secondary, collocated samplers to substitute for data from a primary monitor on a day when the primary monitor for some reason fails to deliver valid data. There is also a provision which would allow a monitoring agency to make up a sampling day on which no valid data were collected, and to count the make-up sampling data in the assessment of data completeness. To help insure that sampling days are well distributed across the month and that a make-up day will generally fall within the same source emissions and meteorological regime as the missed sampling day, a number of specific restrictions are proposed on the number of make-up days per month and on how soon after the missed scheduled sampling day they must occur. These restrictions are stated in the proposed rule text, and are adapted from current practice for $PM_{2.5}$ with adaptations to fit the monthly form of the proposed Pb standard.

A monthly mean Pb concentration for Pb-TSP would be calculated from all available daily mean concentrations within that calendar month, including successfully completed sampling days, allowed make-up sampling days, and any other sampling days actually completed successfully by the primary monitor or by secondary monitors if there is no data from a primary monitor. These other sampling days would not be used in calculating data completeness, however; this follows the example of the current requirements for $PM_{2.5}$ data interpretation.

Recognizing that even allowing for make-up samples, there may be months with fewer than 75% complete data, the proposed text provides for two diagnostic tests which are intended to identify those cases with completeness less than 75% in which it nevertheless is very likely, if not virtually certain, that the monthly mean concentration would have been observed to be either above or below the level of the NAAQS if monitoring data had been complete. One test, to be applied if the mean of the incomplete data is above the NAAQS level, substitutes low hypothetical concentrations for as much of the missing data as needed to meet the 75% requirement; if the resulting mean is still above the NAAQS level, then the NAAQS level is considered to have been exceeded for the month. The hypothetical low values would be set equal to the lowest concentration observed in the same month over the 3-year period being evaluated, in effect giving the benefit of the doubt as to the actual concentrations on the days with missing data. If the monthly mean nevertheless is above the NAAQS, it is virtually certain that the mean of complete data would also have been above the NAAQS. The other test, to be applied if the mean of the incomplete data is below the NAAQS level, works similarly except that at most 50% of the scheduled data can be missing and all missing data is substituted with the highest value observed in the same month over the 3-year period, with the same rationale. If the monthly mean nevertheless is below the NAAQS, it is virtually certain that the mean of complete data would also have been

[155] Fewer than 10 days could be required, and fewer needed for the monthly average to be valid, for February at all sites and in all months for sites approved for only one-day-in-six sampling because they have a history of recording concentrations well below the level of the NAAQS. See Section V for more detail on required sampling schedules.

below the NAAQS. Data substitution tests similar to these are currently used for ozone and $PM_{2.5}$. It should be noted that one outcome of applying the substitution tests proposed for Pb is that a month with incomplete data may still be determined to not have a valid monthly mean and to be unusable in making NAAQS exceedance determinations for that monthly time period. In turn, this may make it impossible to make a determination of compliance or violation for the 3-year period, depending on the completeness and levels of the concentration data from the other months.

EPA invites comment on also incorporating into the final rule two other possible tests that could allow a NAAQS exceedance determination to be made on the basis of monthly data that is not at least 75% complete. EPA may incorporate a version of either or both of these additional tests into the final rule. The first additional test would allow use of the monthly mean based on data that is between 50% and 75% complete if that monthly mean were below some percentage (for example, 50%) the NAAQS, on the rationale that if the available daily values (typically there would be 5 values in a month with 50% complete data) have a mean below some sufficiently low limit, day-to-day variability at the site must be small and the actual concentrations on the days with missing data are very unlikely to have been high enough to make the true monthly mean exceed the NAAQS level.

The second additional test would be more statistically rigorous, yet will allow compliance determinations to be made on some smaller data sets by considering uncertainty bounds. The test would use the available data to create a two-sided statistical confidence interval around the calculated monthly mean concentration. A reduced minimum completeness percentage such as 50% would still be applied to ensure that there are enough sampling days that they could not all be from within a very short period of time. As expected, the uncertainty range about the monthly mean would increase as the number of samples decreases, and as there is more variability in the data that were collected (more high concentrations days mixed with low concentration days). If the prescribed two-sided confidence interval is entirely above the level of the NAAQS, then the NAAQS would be deemed to have been exceeded in that month. Note that the calculated monthly mean in this situation would also have been above the NAAQS level. If the confidence interval is entirely below the level of the NAAQS, then the NAAQS would be deemed to have not been exceeded in that month. EPA invites comment on the statistical assumptions that should be considered to create a confidence interval from the available data, for example the assumed distribution of the underlying ambient data and how the confidence intervals should be constructed. For example, the confidence interval could be constructed based on an assumption of a log-normal distribution for daily concentrations combined with the concept of a ''finite population correction factor,'' where means based on data with between 50 and 75% completeness would have an associated uncertainty range.[156] Any data that is at least 75% complete could be considered ''complete'' and would have no confidence interval. This approach would make the general completeness test and this statistical test yield the same result for a month with at least 75% completeness. EPA notes that such a statistical confidence interval approach is not presently used in data interpretation for any other NAAQS, but no other NAAQS involves the combination of an averaging period as short as a month with a sampling schedule as infrequent as one day in three.

Section V.C. contains provisions which interact with the proposed data completeness requirements described above. EPA invites comment on whether the proposed data completeness provisions taken together provide a good balance between avoiding situations in which no determination of attainment or nonattainment can be made until more data are collected during another calendar year, and avoiding erroneous determinations caused by reliance on small sample sizes affected by data variability. EPA also plans to explore this question prior to the final rule, by analyzing hypothetical cases reflecting the variability seen in historical monitoring data, and may make adjustments to the proposed provisions for the final rule.[157]

The proposed rule text would require that only a minimum of two valid monthly means be available over the 3-year period in order to determine that a site has violated the NAAQS, since if the NAAQS has been observed to be exceeded twice the concentrations in the other months would be irrelevant to a finding of NAAQS violation. Valid monthly means would be required for all 36 possible months in the 3-year period in order to make a finding that the NAAQS has been met. An exception would be allowed if there are 35 valid monthly means and none of them exceed the NAAQS, because in that case it is irrelevant whether the one month with incomplete data experienced an exceedance or not.

The proposed text of Appendix R has provisions to implement the proposal that Pb-PM_{10} data adjusted by the application of site-specific scaling factors be treated as surrogate Pb-TSP data. These provisions are somewhat complex, to be able to address various possible situations without ambiguity. These situations arise from the possibility that both Pb-TSP and Pb-PM_{10} monitoring might take place at a single site, with differences from day to day within the 3-year period as to which samplers were operating and yielded valid data for the day. The proposed approach is to consider all Pb-TSP and Pb-PM_{10} data that have been collected and submitted by the monitoring agency, *i.e.*, once Pb-PM_{10} data have been collected and submitted the monitoring agency could not choose to have them ignored.[158] However, where and when both types of data exist, the Pb-TSP data would be given first consideration. Specifically the proposed approach is to treat as separate questions whether the Pb-TSP monitor and the Pb-PM_{10} monitor have produced a valid monthly mean concentration, taking into account the provisions for make-up samples and data substitution from secondary monitors, but not mixing Pb-TSP and Pb-PM_{10} data within the month. If valid monthly means for both Pb-TSP and Pb-PM_{10} have been achieved, *i.e.*, the main or a supplemental data completeness test has been passed, the Pb-TSP data takes precedence and the Pb-PM_{10} data for

[156] See, for example, the explanation of the finite population correction factor approach at grants.nih.gov/grants/funding/modular/eval/Sample_MGAP.doc. Another useful reference is ''Sampling: Design and Analysis'', Lohr, Sharon L., Brooks/Cole Publishing Co., Pacific Grove, CA, 1999.

[157] This exploration will be somewhat similar to the work EPA did on data quality objectives for the $PM_{2.5}$ monitoring network, but likely will be more simplistic in light of the more limited available data. See ''Data Quality Objectives (DQOs) for $PM_{2.5}$,'' July 25, 2001, *http://www.epa.gov/ttn/amtic/files/ambient/pm25/qa/2001Dqo.pdf.*

[158] Section 3(a) of the proposed Appendix R has a more detailed statement of what ambient data will be considered when determining compliance with the NAAQS than is given in other data interpretation appendices to 40 CFR part 50. EPA invites comment on this codification of current practice. One new feature is a provision for the use of data collected before the promulgation of the proposed changes and additions to the FRM/FEM criteria, to make it clear that these changes and additions are in effect retroactive. FRM/FEM revisions and new FRM/FEM designations have not always been treated as retroactive but in the case of the revised Pb NAAQS EPA wishes to maximize the available data for making designations.

that month are ignored. However, across the 3-year period, monthly means for Pb-TSP and scaled Pb-PM_{10} can be considered together in determining whether more than one monthly mean Pb concentration has exceeded the level of the NAAQS. This allows for the possibility that a monitoring agency may have switched from one type of monitoring to the other during the 3 years, or that it has been more successful in getting complete Pb-TSP data in some months than in others.

The proposed Appendix R addresses the procedures and criteria for development and use of site-specific scaling factors for Pb-PM_{10} data. The scaling factor is the number that would multiply Pb-PM_{10} data to get a surrogate for Pb-TSP data. The proposal would require States to develop a site-specific scaling factor for each monitoring site at which the State wishes to use Pb-PM_{10} data as a surrogate for Pb-TSP data, either to allow it to only operate a Pb-PM_{10} monitor or to make a Pb-PM_{10} monitor eligible as a back-up source of Pb data for greater data completeness. The site-specific scaling factor would have to be based on at least a year of measurements of both types at the site in question. EPA invites comment on the detailed criteria for developing such local scaling factors, given in section 2(b) of the proposed Appendix.

The existing FRM for Pb-TSP, Appendix G of 40 CFR part 50, contains procedures for calculating Pb concentration data in micrograms per cubic meter at standard conditions of temperature and pressure (STP). The proposed FRM for low-volume Pb-PM_{10}, Appendix Q of 40 CFR part 50, requires reporting of concentration data at local conditions of temperature and pressure, for reasons explained in section V. For consistency going forward, we are proposing in the proposed appendix R that for monitoring conducted on or after January 1, 2009, Pb-TSP data should be reported at local conditions of temperature and pressure also. The first deadline for such reporting will be about June 30, 2009 (to be exact, 90 days from March 31, 2009) so monitoring agencies will have ample lead time to change their reporting procedures. However, EPA believes it would be an unnecessary burden to require monitoring agencies to re-submit pre-January 1, 2009 Pb-TSP data corrected to local conditions, given that the adjustment would in most cases be small. The proposed Appendix R would provide that pre-2009 Pb-TSP data reported in STP is to be compared directly to the level of the standard with no adjustment for the difference in reporting forms, but gives the monitoring agency the option of re-submitting the data corrected to local conditions. EPA invites comment on this approach.

Both FRM rules require reporting of daily Pb concentrations with three decimal places. When monthly means are calculated, they are to be rounded to two decimal places for purposes of comparing to the level of the NAAQS, which is expressed to two decimal places.

2. Interpretation of Alternative Elements

This section addresses changes that would be made to the proposed Appendix R as printed at the end of this notice, if the Administrator decides to adopt certain features which are being proposed today in the alternative to those described above, or on which comment is invited.

If a quarterly maximum mean form is adopted for the final standard, we propose that the basic period for assessing completeness would still be the month. An equation would be added for calculating a quarterly mean from three monthly means. The two supplemental diagnostic completeness tests would be changed so that the outcome depends on whether the quarterly mean with substituted data included for one or more incomplete months meets or exceeds the standard, rather than the monthly mean. The design value would be defined as the maximum quarterly mean concentration in the 3-year period. To be determined to violate the standard, at least one valid quarterly mean in the 3-year period would be required. To be determined to meet the standard, 12 valid quarterly means in the 3-year period would be required. EPA invites comment on the alternative of applying completeness tests only for whole calendar quarters rather than individual months, an approach that might allow attainment determinations to be made in some cases in which the by-month approach just described would prevent a determination.

As discussed in section II.E.1, EPA is inviting comment on the possibility of the final rule containing default scaling factors for adjusting Pb-PM_{10} data for use as a surrogate for Pb-TSP data. This would give States the option of using a default scaling factor rather than conducting the site-specific paired monitor testing required in the proposed text of Appendix R. If EPA adopts this approach in the final rule, Appendix R would be modified to provide the default scaling factor values and explain their application. The appropriate default scaling factor would be used in calculation formulas exactly as the proposed Appendix R text requires the use of a site-specific scaling factor; other provisions would be unaffected. Because TSP samplers collect a broader range of particle sizes than PM_{10} samplers, the scaling factor logically can not be less than 1.0. EPA is inviting comment on the selection of default scaling factors from within two ranges. The first range is 1.1 to 2.0 and would apply to Pb-PM_{10} data collected at source-oriented monitoring sites. The other range is 1.0 to 1.4 [159] and would apply to Pb-PM_{10} data collected at monitoring sites that are not source-oriented. These ranges are based on historical data from sites where the two types of monitors were operated on the same days, as explained in section II.E.1. Because there would be different default scaling factors for the two monitoring site types, a modification of the proposed Appendix R text would require for each monitoring agency to determine and designate, subject to EPA review, whether each Pb-PM_{10} site is in fact source-oriented and to document that determination in the Annual Monitoring Plan required by 40 CFR 58.10 (see section V for more information on the requirement for this plan and for designating sites as source-oriented or not).

As explained in section II.E, EPA is inviting comment on the possibility of revising the Pb indicator to be Pb-PM_{10}. If a Pb-PM_{10} indicator is adopted in the final rule, references to the two types of data would be reversed from the way they appear in the proposed text of Appendix R, so that Pb-PM_{10} data when available would have primacy over scaled Pb-TSP data. If Pb-PM_{10} is adopted as the indicator for the final standard, many areas may not have sufficient Pb-PM_{10} data to allow a determination of compliance or violation with the Pb standard within the two or three years allowed under the Clean Air Act for initial designations. EPA is inviting comment on an approach that would allow the use of Pb-TSP data, with adjustment(s), for comparing ambient concentrations of Pb to a Pb-PM_{10} NAAQS for the sole purpose of making initial designations. The scaling issues, relevant data, and possible approaches are similar to those described in section II.E.1. We invite comment on adding language to Appendix R restricting the use of scaled Pb-TSP data to determinations made for purposes of designations within three years of promulgation of the revised standard. (See section VI for discussion

[159] EPA is also soliciting comment on a broader range of 1.0 to 1.9 for nonsource-oriented sites as discussed in section II.E.1.

of the schedule for designations.) This generally would mean that scaling factors would be used only on 2007–2009 and possibly on earlier Pb-TSP data, because Pb-PM_{10} monitoring is proposed to be required to begin by January 1, 2010. Because scaling factors would need to be available for designations decisions which must be made within three years of promulgation of the NAAQS, there would be limited time for a State to do collocated testing to develop local scaling factors and then have them reviewed and approved by EPA. Requiring development of site-specific scaling factors might effectively prevent use of scaled Pb-TSP data in many States, resulting in more areas having to be designated unclassifiable initially. Therefore, we invite comment on removing the passages requiring the development of site-specific scaling factors from Appendix R and providing default scaling factors instead. Scaling factors would be 1.0 or less. EPA invites comment on the selection of appropriate default scaling factors for this situation.

C. Exceptional Events Information Submission Schedule

As explained above, 40 CFR 50.14 contains generic deadlines for a State to submit to EPA specified information about exceptional events and associated air concentration data. A State must initially notify EPA that data has been affected by an event by July 1 of the year after the data are collected; this is done by flagging the data in AQS. The State must also provide an initial description of the event by July 1. Also, the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected; however, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule for the full justification is foreshortened and all information must be submitted to EPA no later than a year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a revised NAAQS. One problem is that some of the deadlines, especially the deadlines for flagging data, can have already passed for some relevant data by the time the revised NAAQS is promulgated. However, until the level and form of the NAAQS have been promulgated a State does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day, so the only way a State can be sure to have flagged all data of concern and possible eligibility for exclusion by the deadline is to flag far more data than will eventually be eligible for exclusion. Another problem is that some of the data that may be used for final designations may not be collected and submitted to EPA until later than one year before the final designation decision, making it impossible to flag that data one year before the decision. When Section 50.14 was revised to add these deadlines in March 2007, EPA was mindful that designations were needed under the recently revised $PM_{2.5}$ NAAQS, and so exceptions to the generic deadline were included for $PM_{2.5}$ only.

The EPA was also mindful that similar issues would arise for subsequent new or revised NAAQS. The Exceptional Events Rule at section 51.14(c)(2)(v) indicates ''when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those NAAQS.'' For the specific case of Pb, EPA anticipates that designations under the revised NAAQS may be made in September 2011 based on 2008–2010 data (or possibly in September 2010 based on 2007–2009 data if sufficient data is available), and thus will depend in part on air quality data collected as late as December 2010 (or December 2009). (See Section VI below for more detailed discussion of the designation schedule and what data EPA intends to use.) There is no way for a State to flag and submit documentation regarding events that happen in October, November, and December 2010 (or 2009) by one year before designation decisions that are made in September 2011 (or 2010).

The proposed revisions to 40 CFR 50.14 involve only changes in submission dates for information regarding claimed exceptional events affecting Pb data. In the proposed rule text at the end of this notice, only the changes that would apply if designations are made three years after promulgation are shown; where a deadline would be different if designations were made at the two-year point, the difference in deadline is noted in the description immediately below. We propose to extend the generic deadline for flagging data (and providing a brief initial description of the event) of July 1 of the year following the data collection, to July 1, 2009 for data collected in 2006–2007. The extension includes 2006 and 2007 data because Governors' designation recommendations will consider 2006–2008 data, and possibly EPA will consider 2006–2008 or 2007–2009 data if complete data for 2008–2010 are not available at the time of final designations. EPA does not intend to use data prior to 2006 in making Pb designation decisions. The generic event flagging deadline in the Exceptional Events Rule would continue to apply to data from 2008, and would thus be July 1, 2009. This would allow a State time following the September 2008 promulgation of the revised Pb NAAQS to consider what data it wishes to flag and to submit those flags. The Governor of a State would be required to submit designation recommendations to EPA in September 2009, and would therefore know what 2008 data have been flagged when formulating those recommendations.

For data collected in 2010 (or 2009), we propose to move up the generic deadline of July 1 for data flagging to May 1, 2011 (or May 1, 2010) (which is also the applicable deadline for certifying data in AQS as being complete and accurate to the best knowledge of the responsible monitoring agency head). This would give a State less time, but EPA believes still sufficient time, to decide what 2010 (or 2009) data to flag, and would allow EPA to have access to the flags in time for EPA to develop its own proposed and final plans for designations.

Finally, EPA proposes to make the deadline for submission of detailed justifications for exclusion of data collected in 2006 through 2008 be September 15, 2010 for the three year designation schedule, or September 15, 2009 under the two year designation schedule. EPA generally does not anticipate data from 2006 and 2007 being used in final Pb designations. Under the three year designation schedule, for data collected in 2010, EPA proposes to make the deadline for submission of justifications be May 1, 2011. This is less than a year before the designation decisions would be made, but we believe it is a good compromise between giving a State a reasonable period to prepare the justifications and EPA a reasonable period to consider the information submitted by the State. Similarly, under the two year designation schedule, for data collected in 2009, EPA proposes to make the deadline for submission of justifications be May 1, 2010. Table 8 summarizes the proposed three year designation deadlines discussed in this section, and Table 9 summarizes the two year designation deadlines.

TABLE 8.—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN THREE YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009*	September 15, 2010*.
2007	July 1, 2009*	September 15, 2010.
2008	July 1, 2009	September 15, 2010*.
2009	July 1, 2010	September 15, 2010*.
2010	May 1, 2011*	May 1, 2011*.

* Indicates proposed change from generic schedule in 40 CFR 50.14.

TABLE 9.—PROPOSED SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION IF DESIGNATIONS PROMULGATED IN TWO YEARS

Air quality data collected for calendar year	Event flagging deadline	Detailed documentation submission deadline
2006	July 1, 2009*	September 15, 2009.
2007	July 1, 2009*	September 15, 2009*.
2008	July 1, 2009	September 15, 2009*.
2009	May 1, 2010*	May 1, 2010*.

* Indicates proposed change from generic schedule in 40 CFR 50.14.

EPA invites comment on these proposed changes in the exceptional event flagging and documentation submission deadlines.

V. Proposed Amendments to Ambient Monitoring and Reporting Requirements

As part of our proposal to revise and implement the Pb NAAQS, we are proposing several changes to the ambient air monitoring and reporting requirements for Pb. Ambient Pb monitoring data are used to determine whether an area is in violation of the Pb NAAQS. Ambient data are collected and reported by State, local, and Tribal monitoring agencies (''monitoring agencies'') according to the monitoring requirements contained in 40 CFR parts 50, 53, and 58. This section explains aspects of the existing Pb monitoring and reporting requirements as background and discusses the changes we are proposing to support the changes being proposed in the Pb NAAQS and other options for the NAAQS on which EPA is inviting comments, discussed above in section II.E. These aspects include the sampling and analysis methods (including quality assurance requirements), network design, sampling schedule, data reporting, and other miscellaneous requirements.

A. Sampling and Analysis Methods

We are proposing changes to the sampling and analysis methods for the Pb monitoring network. Specifically, we are proposing a new Federal Reference Method (FRM) for Pb in PM_{10} ($Pb\text{-}PM_{10}$) and revised Federal Equivalent Method (FEM) criteria. We are maintaining the current FRM for Pb in TSP (Pb-TSP) and lowering the Pb concentration range required during Pb-TSP and $Pb\text{-}PM_{10}$ candidate FEM comparability testing. The following sections provide background, rationale, and details for the proposed changes to the sampling and analysis methods.

1. Background

Lead monitoring data must be collected and analyzed using FRM or FEM methods in order to be comparable to the NAAQS. The current FRM for Pb sampling and analysis is based on the use of a high-volume TSP FRM sampler to collect the particulate matter sample and the use of atomic absorption (AA) spectrometry for the analysis of Pb in a nitric acid extract of the filter sample (40 CFR part 50, Appendix G). There are 21 FEMs currently approved for Pb-TSP [160]. All 21 FEMs are based on the use of high-volume TSP samplers and a variety of approved equivalent analysis methods.[161]

Concerns have been raised over the use of the high-volume TSP samplers to collect samples for subsequent Pb analysis. It is known that the high-volume TSP sampler's particulate matter capture efficiency varies as a function of wind speed and wind direction due to the non-symmetrical inlet design and the lack of an integral particle separator. Early evaluations of the high-volume TSP sampler demonstrated that the sampler's 50% collection efficiency cutpoint can vary between 25 and 50 μm depending on wind speed and direction (Wedding *et al.*, 1977, McFarland and Rodes, 1979). More recently, a study was conducted during the last Pb NAAQS review to evaluate the effect of wind speed and direction on sampler efficiency (Purdue, 1988). This study showed that despite the effect of wind speed and wind direction on the sampler's collection efficiency for larger particles, for particle distributions typical of those near industrial sources the overall Pb collection efficiency of the high-volume TSP sampler ranged from 80% to 90% over a wide range of wind speeds and directions.

CASAC commented in the context of their review of the Staff Paper that TSP samplers have poor precision, that the upper particle cut size of TSP samplers varies widely as a function of wind speed and direction, and that the spatial non-homogeneity of very coarse particles cannot be efficiently captured by a national monitoring network (Henderson, 2007a, Henderson, 2008). For these reasons, CASAC recommended considering a revision to the Pb reference method to allow sample collection using low-volume PM_{10} samplers.[162]

As part of preparing the ANPR for this rulemaking, we performed and reported in the ANPR the results of an analysis of the precision and bias of the high-volume TSP sampler based on Pb-TSP

[160] For a list of currently approved FRM/FEMs for Pb-TSP refer to: *http://www.epa.gov/ttn/amtic/criteria.html.*

[161] The 21 distinct approved FEMs represent less than 21 fundamentally different analysis methods, as some differ in only in minor aspects.

[162] PM_{10} can be measured with either a ''low-volume'' or a ''high-volume'' sampler. CASAC specifically recommended the low-volume sampler, for reasons explained here and in section II.E.1.

data reported to AQS for collocated samplers and the results of in-field sampler flow audits and laboratory audits for lead (Camalier and Rice, 2007). The average precision of the high-volume Pb-TSP sampler was approximately 12% with a standard deviation of 19% and average sampling bias (based on flow audits) was -0.7% with a standard deviation of 4.2%. The average bias for the lab analyses of Pb-spiked audit strips was −1.1% with a standard deviation of 5.5%. Total bias, which includes bias from both sampling and laboratory analysis, was estimated at −1.7% with a standard deviation of 3.4%. These findings are specific for the times and sites of the sampling, including the nature and total quantity of TSP and Pb-TSP that prevailed during the sampling, and may not be indicative of the TSP FRM performance in other places. Also, we did not investigate to determine whether the physical arrangement of the collocated samplers was such as to provide a good test of sensitivity to wind speed and wind direction.[163] However, we note that at face value these bias and precision results are not greatly different than has historically been considered acceptable for other criteria pollutants.

The CASAC and some public comments on the ANPR again stressed concerns with the use of the high-volume TSP sampler and a strong interest in moving to a low-volume Pb-PM_{10} sampler. The CASAC reiterated the disadvantages of retaining TSP and of utilizing it as the ''gold standard'' against which new and better technologies are compared (Henderson 2008). On March 25, 2008, the AAMM Subcommittee of CASAC and EPA staff conducted a consultation by conference call, at which the subcommittee members confirmed and elaborated on the views CASAC expressed in their comments on the ANPR. Public comments were also generally supportive of moving away from the current high-volume PM sampling technology and moving toward modern, sequential, low-volume PM_{10} monitors, especially if sampling frequencies are increased. On the other hand, several monitoring agencies cautioned against moving to Pb-PM_{10} as the indicator because samplers for Pb-PM_{10} would miss much of the Pb in the atmosphere especially near Pb sources.

[163] If the collocated TSP samplers were always oriented in the same direction, they would be exposed to the same wind speed and wind direction, and the appearance of good precision between them would not necessarily be indicative of the sensitivity of Pb-TSP measurements to wind speed and wind direction.

CASAC recommended that Pb-PM_{10} be measured with low-cost, multi-element analysis methods with improved detection limits (e.g., x-ray fluorescence, XRF) for measuring concentrations typical of today's ambient air. One public commenter suggested that the MDL be significantly reduced to enable measurement of average Pb levels of 0.08 $\mu g/m^3$ or below.

The current post-sampling FRM analysis method for Pb-TSP is atomic absorption (AA) spectrometry. A typical or nominal lower detectable limit (LDL) for Pb, for high-volume sample collection followed by AA analysis, stated in the FRM regulation in Appendix G to Part 50 for informational purposes only, is 0.07 $\mu g/m^3$. This value was calculated by doubling the between-laboratory standard deviation obtained for the lowest measurable lead concentration (Long 1979). This value can be considered a conservative (i.e., upper bound) estimate of the sensitivity for the AA method currently used by air monitoring laboratories, as evidence by the fact that data obtained from AQS includes reported locally determined MDL values for the AA FRM that are well below 0.07 $\mu g/m^3$ (typically 0.01 (g/m^3 or below).

One estimate of the method detection limit (MDL) for AA analysis of a low-volume sample of either Pb-PM_{10} or Pb-TSP, taking into account the nominal LDL of 0.07 $\mu g/m^3$ (or 140 $\mu g/L$), and the smaller sample volume, extraction volume, and filter size for low-volume sampling, is about 0.12 $\mu g/m^3$ (see Table 10). Assuming an LDL of 0.01 (g/m^3 for TSP sampling, the MDL for low-volume sampling would be about 0.02 (g/m^3. Other Pb-TSP FEM analysis methods currently used with the high-volume sampling method, such as XRF, inductively coupled plasma mass spectrometry (ICP/MS) and graphite furnace atomic absorption (GFAA) are more sensitive than AA analysis, and are clearly sensitive enough to support low-volume sampling and a reduced NAAQS level.

2. Proposed Changes

As discussed in Section II.E.3 of this preamble, after considering the CASAC and public comments on monitoring issues, we are proposing to retain Pb-TSP, as measured by the FRM method specified in 40 CFR part 50, appendix G (which cross references appendix B, the specification of the TSP FRM) as the indicator for the Pb standard, and to invite comment on a second option which would instead make Pb-PM_{10} measured by a low-volume monitor the indicator. We further propose that monitoring agencies should be given the option to use adjusted or scaled low-volume Pb-PM_{10} monitoring data as a surrogate for Pb-TSP data. Details on how this option would work are discussed in the data handling section of this preamble (section IV). Also, in section IV.B we are inviting comment on whether, if low-volume Pb-PM_{10} is selected as the indicator, Pb-TSP data with an adjustment should be useable as a surrogate for Pb-PM_{10} data for the specific purpose of initial designations under the revised standard. In this section, we discuss the Pb-TSP and Pb-PM_{10} sampling and analysis issues themselves and propose approaches for these issues, as these issues are relevant to the use of data from each method directly or as surrogates for the other.

a. TSP Sampling Method

If the final standard is based on Pb-TSP we believe it is appropriate to continue to allow, although perhaps not to encourage, the use of the current high-volume FRM for measuring Pb-TSP. The selection of Pb-TSP as the NAAQS indicator would depend on a conclusion that the precision, bias, and MDL (discussed above) of the TSP sampler is adequate for continued use in the Pb monitoring network, including a conclusion that although the TSP sampler's size selection performance is affected by wind speed and wind direction, we do not believe that this effect is so significant as to prevent the continued use of this sampler in the Pb network. EPA proposes to make several minor clarifying changes in Appendix G to correct long-standing errors in reference citations. We are not proposing any other substantive changes to Appendix G.

However, we also believe that low-volume Pb-TSP samplers might be superior to high-volume TSP samplers. Presently, a low-volume TSP sampler cannot obtain FRM status, because the FRM is specified in design terms that preclude designation of a low-volume sampler as a FRM. A low-volume Pb-TSP monitoring system (including an analytical method for Pb) can in principle be designated as a FEM Pb-TSP monitor, if side-by-side testing is performed as prescribed by 40 CFR 53.33. We are proposing amendments to this CFR section, described below, to make such testing more practical and to clarify that both high-volume and low-volume TSP methods may use this route to FEM status. Note that the terms of the revised FEM procedures can also be used to obtain FEM status for Pb-PM_{10} samplers.

b. PM_{10} Sampling Method

If the final standard is based on Pb-PM_{10}, or if the final rule for a standard based on Pb-TSP includes an option to monitor Pb-PM_{10} instead of Pb-TSP, we will need to promulgate both an FRM for measuring Pb-PM_{10} and an appropriate set of FEM criteria. Accordingly, we are proposing new FRM and FEM criteria for measuring Pb-PM_{10}. The proposed FRM for Pb-PM_{10} can be broken down into two parts: (1) the sampling method (i.e., the procedures and apparatus used for collecting PM_{10} on a filter) and (2) the analysis method (i.e., the procedures and apparatus used to analyze the collected particulate matter for Pb content).

Currently, the FRM specification for PM_{10} monitoring, Appendix J to 40 CFR Part 50, is based on a performance test and does not specify whether a sampler is high-volume or low-volume. Early commercialized samplers were high-volume, but more recently a number of low-volume PM_{10} samplers have received FRM approvals. To be certain that Pb-PM_{10} monitoring is conducted with low-volume samplers without specifying the use of particular sampler brands or models, it is necessary to establish a new FRM specification for low-volume PM_{10} samplers. There is a recently promulgated FRM for particulate matter with aerodynamic diameter between 2.5 and 10 microns ($PM_{10-2.5}$) (Appendix O to 40 CFR part 50) that is based on a pair of low-volume samplers for $PM_{2.5}$ and PM_{10} to provide a $PM_{10-2.5}$ concentration by difference. We are proposing to create a FRM for Pb-PM_{10} sampling by cross-referencing to the specification for the PM_{10} sampler in this paired FRM (referred to as the PM_{10C} sampler, where the ''C'' refers to the use of this PM_{10} sampler as part of a pair for measuring coarse PM). We are proposing to use the low-volume PM_{10C} sampler for the FRM for Pb-PM_{10} rather than the existing PM_{10} FRM specified by appendix J, for several reasons. Appendix J to part 50 has resulted in the designation of both high-volume and low-volume PM_{10} samplers as FRM for PM_{10}. We believe high-volume PM_{10} sampling should not be used to measure Pb-PM_{10} under a revised Pb standard. A low-volume PM_{10C} FRM sampler must meet more demanding performance criteria than is required for PM_{10} samplers in general in Appendix J. We note the current availability of samplers that meet these more demanding performance criteria (already in use for $PM_{2.5}$ and $PM_{10-2.5}$ sampling) that are equipped with sequential sampling capabilities (i.e., the ability to schedule multiple samples between operator visits, which is desirable if the proposed sampling frequency requirements are increased to support a monthly averaging form of Pb NAAQS). The geometry of commercial high-volume PM_{10} samplers makes sequential sampling with a single sampler impossible. The low-volume sampler also precisely maintains a constant sample flow rate corrected to actual conditions by actively sensing changes in temperature and pressure and regulating sampling flow rate. Use of a low-volume sampler for the Pb-PM_{10} FRM would also provide network efficiencies and operational consistencies with the samplers that are in widespread use for the $PM_{2.5}$ FRM network, and that are seeing growing use in the PM_{10} and $PM_{10-2.5}$ networks. Finally, the use of a low-volume sampler is consistent with the comments and recommendations from CASAC and members of CASAC's AAMM (Henderson 2007a, Henderson 2008, Russell 2008).

Low-volume Pb-PM_{10} samplers and the data systems that they connect to can be configured to report concentrations corrected to standard conditions of temperature and pressure or based on local conditions of temperature and pressure. We are proposing that the FRM for samplers used to collect Pb data specify reporting of concentrations based on local conditions, for a few reasons. The actual concentration of Pb in the atmosphere is a better indicator of the potential for deposition than the concentration based on standard pressure and temperature. In addition, there are practical advantages to moving to local conditions since the FRM for both $PM_{2.5}$ and $PM_{10-2.5}$ are also based on local conditions.

c. Analysis Method

There are several potential analysis methods for a Pb-PM_{10} FRM. Atomic absorption (AA) is the analysis method for the current Pb-TSP FRM. In addition, there are several other analysis methods (e.g., XRF, ICP/MS) approved as FEMs for the measurement of Pb-TSP. Table 10 summarizes the estimated MDLs for the analysis methods considered in developing the proposed FRM for Pb-PM_{10}. The estimated MDLs are based on published instrument detection limits and LDLs, which typically take into account only instrument signal-to-noise ratios and laboratory-related variability but not variability related to sample collection and handling. It is important to note that the MDLs in Table 10 are estimates and these values will vary as a function of the specific instrument used, detector age, instrument signal-to-noise level, etc., and therefore, MDLs must be determined for the specific instrument used.

TABLE 10.—SUMMARY OF CANDIDATE ANALYSIS METHOD DETECTION LIMITS FOR A PB-PM_{10} FRM OR FEM WITH LOW-VOLUME SAMPLE COLLECTION

Analysis method	Estimated DLs [a]	Estimated MDL [b] (μg/m³)
Atomic Absorption (AA)	0.07 μg/m³ [c]	0.12 [f]
	0.01 μg/m³ [d]	0.02 [f]
X-Ray Fluorescence (XRF)	1.5 ng/cm² [e]	0.001 [g]
Graphite Furnace Atomic Absorption (GFAA)	0.05 μg/L [h]	0.00004 [f]
Inductively Coupled Plasma/Mass Spectrometry (ICP/MS)	0.08 μg/L [e]	0.00006 [f]

[a] Detection limits (DLs) found in available literature as provided in footnotes below.

[b] Estimated MDLs determined using estimated DL, extraction volume, and sample volume as noted in footnotes provided.

[c] The lower detectable limit (LDL) for Pb-TSP taken from Appendix G to Part 50 based on 2400m³ sample volume, 0.10L extraction volume, and 12 strips per filter.

[d] Based on MDLs reported in AQS.

[e] DL expressed as nanogram per square centimeter of filter surface is taken from the Compendium of Methods for the Determination of Inorganic Compounds in Ambient Air (USEPA, 1999).

[f] Based on 46.2-mm filter extraction volume of 0.020 L and sample volume of 24 m³ of air.

[g] Based on 46.2-mm filter area of 11.86 cm² and sample volume of 24 m³ of air.

[h] Taken from the Perkin Elmer Guide to Atomic Spectroscopy Techniques and Applications (Perkin Elmer, 2000).

One disadvantage of the low-volume sampler is that the total mass of the PM_{10} sample collected is significantly lower than that of the high-volume sampler due to the lower volume of air sampled (24 m^3 per 24 hours for the low-volume sampler versus. over 1500 m^3 per 24 hours for a high-volume sampler). The lower mass of sample collected results in higher MDLs for any given analysis method when coupled with the low-volume sampler. As can be seen in Table 10, even assuming the smaller LDL reported to AQS for recent sampling, the estimated MDL for atomic absorption (the current FRM analysis method for Pb-TSP) when coupled with low-volume sampling is the highest (least sensitive) of all potential methods for use as an FRM/FEM method for Pb-PM_{10}.

AA, GFAA, and ICP/MS are destructive methods and require solvent extractions that possibly involve the use of strong acids to adequately extract Pb from the collected PM for analysis. The specific extraction solutions and methods are selected and optimized in order to meet the required extraction efficiency for a measurement program. Both methods are destructive, meaning that the sample collected on the filter is destroyed during analysis. These methods also have higher analysis costs relative to XRF.

While XRF, GFAA, and ICP/MS all have more than adequate MDLs to support a reduced NAAQS level, we believe that the XRF analysis method has several advantages which make it a desirable analysis method to specify as the FRM. XRF does not require sample preparation or extraction with acids prior to analysis. It is a non-destructive method; therefore, the sample is not destroyed during analysis and can be archived for future analysis or re-analysis if needed. XRF analysis is a cost-effective approach that could be used at the option of the monitoring agency to simultaneously analyze for many additional metals (e.g., arsenic, antimony, and iron) which may be useful in source apportionment. XRF is also the method used for the urban $PM_{2.5}$ speciation monitoring networks and for the mostly rural visibility monitoring program in Class I visibility areas, and is being considered for the $PM_{10-2.5}$ coarse speciation monitoring network that will be implemented by monitoring agencies as part of the NCore multi-pollutant network. The XRF analysis method should have acceptable precision, bias, and MDL for use as the FRM for Pb-PM_{10} when coupled with the low-volume PM_{10} sampler. Finally, CASAC recommended the use of XRF as a low-cost and sensitive analysis method for the FRM (Henderson 2007a, Henderson 2008). For these reasons, we are proposing to base the analysis method for the proposed Pb-PM_{10} FRM on XRF.

d. FEM Criteria

The FEM criteria provide for approval of candidate methods that employ an alternative analysis method for Pb, an alternative sampler, or both.

The proposed Pb-PM_{10} FRM is based on the low-volume PM_{10}c sampler and XRF analysis. Under the proposed revisions to 40 CFR 53.33, Pb-PM_{10} data from any candidate FEM using an alternative sampler would be compared to side-by-side data from the low-volume PM_{10c} FRM sampler. An FEM candidate using only an alternative analysis method would be evaluated by collecting paired filters from paired low-volume PM_{10c} FRM samplers, and analyzing one filter of each pair with XRF and the other filter with the candidate method.

As mentioned above, there are other analysis methods commonly used which are also expected to meet the precision, bias, and MDLs necessary to be used in the Pb surveillance monitoring network (e.g., GFAA and ICP/MS). These analysis methods would be compared to the proposed XRF method and would be approvable as FEMs through the performance testing requirements outlined in regulation § 53.33 of 40 CFR part 53, subpart C. Several of these requirements need revisions for consistency with a potentially lowered Pb NAAQS and for the potential addition of a Pb-PM_{10} FRM. The following paragraphs describe the aspects of the FEM criteria that we are proposing to revise.

The current FEM requirements state that the ambient Pb concentration range at which the FEM comparability testing must be conducted to be valid is 0.5 to 4.0 $\mu g/m^3$. Currently there are few locations in the United States where FEM testing can be conducted with assurance that the ambient concentrations during the time of the testing would exceed 0.5 $\mu g/m^3$. In addition, the Agency is proposing to lower the Pb NAAQS level to between 0.10 and 0.30 $\mu g/m^3$. As such, we are proposing to revise the Pb concentration requirements for candidate FEM testing to a range of 30% of the NAAQS to 250% of the NAAQS in $\mu g/m^3$. For example, if the level of the Pb NAAQS is finalized at 0.20 $\mu g/m^3$, the ambient concentrations that would be required for FEM testing would have to range between 0.06 $\mu g/m^3$ to 0.50 $\mu g/m^3$. The requirements were changed from actual concentration values to percentages of the NAAQS to allow the FEM text to remain appropriate if subsequent changes to NAAQS levels occur in the future.

The current FEM requirements state that the maximum precision and accuracy for candidate analytical methods must be 15% and 5% respectively. No changes are proposed for these requirements. Based on the results for the current high-volume Pb-TSP precision and bias (Camalier and Rice, 2007), these requirement seem reasonable for the proposed FEM requirements. The current FEM does not have a requirement for a maximum MDL. In order to ensure that candidate analytical methods have adequate sensitivity or MDLs, we are proposing to add a requirement that as part of the testing of a candidate FEM, the applicant must demonstrate that the MDL of the method is less than 1% of the level of Pb NAAQS. We believe this MDL requirement will ensure that FEM methods will have enough sensitivity to detect Pb concentrations much less than the proposed NAAQS level, but will not unnecessarily restrict methods which could be used to provide data sufficient for the purpose of determining compliance with the NAAQS. Subsequent users of a previously approved FEM would not be required to demonstrate the MDL of the method as implemented in their laboratories, but EPA plans to encourage them to do so periodically as a good quality assurance practice.

The existing FEM requirements require that audit samples (the known concentration or reference samples provided on request by EPA used to verify the accuracy with which a laboratory conducts the FRM analytical procedure before it may begin comparing the FRM to the candidate FEM) be analyzed at levels that are equal to 100, 300, and 750 µg per spiked filter strip (equivalent to 0.5, 1.5, and 3.75 $\mu g/m^3$ of sampled air). We are proposing to revise the levels of the audit concentrations to percentages (30%, 100% and 250%) of the Pb NAAQS to provide for reduced audit concentrations for a lowered NAAQS. These percentages are roughly equivalent to the percentages of the current NAAQS level (1.5 $\mu g/m^3$) used to set the spiked filter strip audit concentrations provided above in the original FEM regulation.

The existing FEM requirements are based on the high-volume TSP sampler, and as such, refer to ¾ x 8-inch glass fiber strips. In order to also accommodate the use of low-volume sample filters, we are proposing to add references to 46.2-mm sample filters

where appropriate. Pairs of these filters will be collected by a pair of FRM samplers, so that there is no need to cut the 46.2 mm filters into two parts before analysis.

e. Quality Assurance

Modifications are needed to the quality assurance (QA) requirements for Pb in 40 CFR part 58, Appendix A paragraph 3.3.4 in order to accommodate Pb-PM_{10} monitoring. Paragraph 3.3.4 specifies requirements for annual flow rate audits for TSP samplers used in Pb monitoring and Pb strip audits for laboratories performing analysis of TSP filters for Pb. Other QA requirements specified in paragraph 3.3.1 for all TSP samplers are also applicable to Pb-TSP samplers. As part of the overall Pb NAAQS review, it is appropriate to revise these requirements to consolidate all the QA requirements for Pb monitoring in paragraph 3.3.4, to add provisions specific for Pb-PM_{10} measurements and to eliminate cross references to the general TSP provisions. The following paragraphs detail the QA requirements we are proposing to change.

The collocation requirement for all TSP samplers (paragraph 3.3.1) applies to TSP samplers used for Pb-TSP monitoring. These requirements are the same for PM_{10} (paragraph 3.3.1); as such, no changes are needed to accommodate low-volume Pb-PM_{10}. However, to clarify that this requirement also applies to Pb monitoring we are proposing to add a reference to this requirement in paragraph 3.3.4.

The sampler flow rate verifications requirement (paragraph 3.3.2) for low-volume PM_{10} and for TSP are at different intervals. While this appears appropriate and no change is needed, to clarify that this requirement also applies to Pb monitoring we are proposing to add a reference to this requirement in paragraph 3.3.4.

Paragraph 3.3.4.1 has an error in the text that suggests an annual flow rate audit for Pb, but then includes reference in the text to semi-annual audits. The correct flow rate audit frequency is semi-annual. We are proposing to correct this error. Also, we are proposing to change the references to the Pb FRM to include the proposed Pb-PM_{10} FRM.

Paragraph 3.3.4.2 discusses the audit procedures for the lead analysis method. This section assumes the use of a high-volume TSP sampler, and we are proposing edits to account for the proposed Pb-PM_{10} FRM. In addition, the audit concentration ranges will not be appropriate if the NAAQS is lowered. We are proposing to lower the audit ranges for Pb-TSP from the current range of 0.5–1.5 $\mu g/m^3$ to a range from 30–100% of the proposed Pb NAAQS level for the low concentration audit and from 3.0–5.0 $\mu g/m^3$ to 200–300% of the proposed NAAQS for the higher concentration audit standard. The requirements would also be changed from specific concentration value-based ranges to ranges based on the percentages of the NAAQS to allow these QA requirements to remain appropriate if changes to NAAQS levels occur during future reviews.

Unlike the $PM_{2.5}$ and $PM_{10-2.5}$ Performance Evaluation Program (PEP), the existing QA program requirements for Pb monitoring do not include a requirement for the collection of data appropriate for making an independent estimate of the overall sampling and analysis bias. We are proposing to require one PEP-like audit at one site within each primary quality assurance organization (PQAO) once per year. We are also proposing that, for each quarter, one filter of a collocated sample filter pair from one site within each PQAO be sent to an independent laboratory for analysis. The independent measurement on one filter from each pair would be compared to the monitoring agency's regular laboratory's measurement on the other filter of the pair, to allow estimation of any bias in the regular laboratory's measurements. EPA believes that the combination of the PEP data and the independent collocation data will be enough to provide a reasonable assessment of overall bias and data comparability on a PQAO basis over the designation period. As currently is the case for PEP auditing of $PM_{2.5}$ and $PM_{10-2.5}$ monitoring sites, it would be the responsibility of each State to ensure that Pb PEP testing and collocation testing as described here is performed as required. EPA plans to consult with monitoring agencies after completion of this rulemaking as to whether a centrally run program managed by EPA and funded with State and Tribal Assistance Grant funds would be a more efficient and preferred alternative than individual State-managed programs.

B. Network Design

As a result of this Pb NAAQS review and the proposed tightening of the standards, EPA recognizes that the current network design requirements are inadequate to assess compliance and determine the extent of all the areas that may violate the revised NAAQS. As such, we are proposing new network design requirements for the Pb NAAQS surveillance network. The following sections provide background, rationale, and details for the proposed changes to the Pb network design requirements.

1. Background

The once large Pb surveillance network of FRM samplers for Pb-TSP has decreased substantially over the last few decades. In 1980 there were over 900 Pb surveillance sites. This number has been reduced to approximately 200 sites today. These reductions were made because of substantially reduced ambient Pb concentrations causing monitoring agencies to shift priorities to other criteria pollutants including $PM_{2.5}$ and ozone which were believed to pose a greater health risk. As a result of these reductions, many states currently have no ambient air Pb monitors resulting in large portions of the country with no data on current ambient Pb air concentrations. In addition, many of the largest Pb emitting sources in the country do not have nearby ambient Pb air monitors.

There is also a smaller network, the National Air Toxics Trends Stations network, of 27 monitoring sites measuring Pb-PM_{10}. Some of these use a high-volume PM_{10} sampler to collect the particulate matter and some use a low-volume PM_{10} sampler. Most are in urban areas.

The current network design requirements for Pb monitoring are given in 40 CFR part 58 appendix D section 4.5. The current minimum network design requirements are for two Federal Reference Method (FRM) or Federal Equivalent Method (FEM) sites in any area where Pb concentrations exceed or have exceeded the NAAQS in the most recent two years. These current minimum monitoring requirements cannot be relied upon to cause monitoring agencies to fill the existing gaps in the current network, and if they are not revised it will be difficult to develop the necessary network to properly evaluate ambient air concentrations during the designation process, especially if the NAAQS is finalized at a significantly lower level than the current standard.

For these reasons, EPA indicated in the Advanced Notice of Proposed Rulemaking (72 FR 71488) that the existing Pb NAAQS surveillance network may not be adequate for a lowered Pb NAAQS, and that if the NAAQS is substantially lowered as proposed additional monitoring sites would be needed to provide estimates of ambient Pb air concentrations near Pb emission sources and for characterizing ambient air concentrations in large urban areas. Comments received from CASAC and other public commenters

on the ANPR stated that the Pb surveillance network should be expanded in order to provide better coverage of Pb emission sources and to better understand population exposures to Pb from ambient air. After considering these comments and evaluating the existing network, EPA is proposing changes to the network as described below.

2. Proposed Changes

We are proposing to modify the existing network design requirements for the Pb surveillance monitoring network to achieve better understanding of ambient Pb air concentrations near Pb emission sources and to provide better information on population exposure to Pb in large urban areas. The following paragraphs provide the rationale and details for the proposed changes.

The primary objective of the Pb monitoring network is to provide data on the ambient Pb air concentrations in areas where there is the potential for a violation of the NAAQS. Ambient Pb concentrations have dropped dramatically in most urban areas due to the elimination of Pb in gasoline. However, based on our analysis of the ambient Pb data, relatively large sources of Pb continue to have the potential to cause ambient air concentrations in excess of the proposed NAAQS (EPA, 2007c). Furthermore, it appears, based on the limited network still operating, that violations of the proposed range for the revised NAAQS levels are likely to exist only near such sources of Pb emissions, with lower levels of Pb away from such sources. Accordingly, we are proposing to require monitoring near Pb emission sources such as Pb smelters, metallurgical operations, battery manufacturing, and other source categories that emit Pb. By implementing the NAAQS through a source-oriented monitoring network, Pb concentrations will be kept below the NAAQS level for those living near these sources and for those living farther away.

The 2002 National Emissions Inventory (NEI) lists over 13,000 sources of Pb, with emission rates from as low as 1 pound to nearly 60 tons per year (according to the NEI 90% of lead sources emit less than 0.1 tpy). It is not practical to conduct monitoring at every Pb emission source, nor is it likely that very small Pb emission sources will cause ambient concentrations to exceed the proposed NAAQS. Therefore, it is appropriate to limit the source oriented monitoring requirement to emission sources that may have the potential to result in ambient air concentrations in excess of the proposed NAAQS.

We are proposing that monitoring be presumptively required at sources that have Pb emissions (as identified in the latest NEI or by other scientifically justifiable methods and data) that exceed a Pb ''emissions threshold.'' This monitoring requirement would apply not only to existing industrial sources of lead, but also to fugitive sources of lead (e.g., mine tailing piles, closed industrial facilities) and airports where leaded aviation gas is used. In this context, the emissions threshold is the Pb emission rate for a source that may reasonably be expected to result in ambient air concentrations in excess of the proposed Pb NAAQS. We conducted an analysis to estimate the appropriate emission threshold (Cavender 2008b) which is available in the docket for this rulemaking. In this analysis, four different methods were used for calculating an appropriate threshold emissions rate based on the candidate NAAQS level. The arithmetic mean of the four methods suggests a maximum emission impact of 0.5 $\mu g/m^3$ per 1,000 kg Pb emitted per year. Using the results from this analysis, we propose that the emission threshold be set in the range of 200 kg–600 kg per year total Pb emissions (including point, area, and fugitive emissions and including Pb in all sizes of PM). We are proposing a range for the emission threshold since we are proposing a range for the level of the standard. If the final NAAQS is set at 0.10 $\mu g/m^3$, we would set the emission threshold at 200 kg per year. Conversely, if the final NAAQS is set at 0.30 $\mu g/m^3$, we would set the emission threshold at 600 kg per year. We solicit comments on the various methods for calculating emission rate thresholds, as well as using the arithmetic mean of these results in choosing the appropriate threshold for designing the monitoring network.

We recognize that a number of factors influence the actual impact a source of Pb has on ambient Pb concentrations (e.g., local meteorology, emission release characteristics, and terrain). As such, we are also proposing to allow monitoring agencies to petition the EPA Regional Administrator to waive this requirement for a source that emits less than 1 ton per year where it can be shown (by demonstrating actual emissions are less than the threshold, through modeling, historical monitoring data, or other means) that a source will not cause ambient air concentrations to exceed 50% of the NAAQS during a three year period. We are proposing that for facilities identified as emitting more than 1 tpy in the NEI, a waiver is possible only by demonstrating that actual emissions are less than the emissions threshold. By requiring every source actually emitting more than 1 tpy to be monitored, we will avoid the possibility that faulty or uncertain modeling demonstrations or past monitoring programs would be the basis for not monitoring sources that are the most likely to cause NAAQS violations.

We seek comments on the appropriateness of requiring monitoring near Pb emissions sources and the proposed emission rate threshold. We also seek comments on the appropriateness of allowing monitoring agencies to seek waivers from this requirement and the upper emission threshold level at which waivers should no longer be allowed.

The required source-oriented monitors shall be located at sites of maximum impact and will be classified primarily as microscale monitors representative of small hot-spot areas adjacent or nearly adjacent to facility fence-lines. EPA takes comment on this monitoring requirement and whether monitors should only be placed in areas which are population-oriented. In some cases, source-oriented monitors may be representative of somewhat bigger areas due to the orientation of sources with respect to areas with locations appropriate for ambient monitoring. In these cases, the source-oriented monitors may be classified as middle-scale, but should still represent the locations where maximum Pb concentrations around a facility are expected to occur, consistent with applicable siting regulations and the outputs of quantitative tools (e.g., dispersion modeling) used to determine maximum impacts.

We are proposing to require a small network of nonsource-oriented monitors in urban areas in addition to the source oriented monitors discussed above, in order to gather information on the general population exposure to Pb in ambient air. While it is expected that these nonsource-oriented monitors will show lower concentrations than source oriented monitors, data from these nonsource-oriented monitors will be helpful in understanding the risk posed by Pb to the general population. Data from these monitors will also be useful in determining impacts on Pb concentrations from re-entrained roadway dust, construction and demolition projects, other nonpoint area sources; and in determining the spatial variation in Pb concentrations between areas that are and are not source impacted. Such data on spatial variations within an urban area could assist with the determination of non-attainment boundaries.

We are proposing to require one nonsource-oriented monitor in each Core Base Statistical Area (CBSA, as defined by the Office of Management and Budget)[164] with a population of 1,000,000 people or more as determined in the most recent census estimates. Based on the most current census estimates, 50 CBSAs would be required to have nonsource-oriented population monitors. We request comments on the appropriateness of requiring nonsource-oriented monitors and the proposed population threshold of 1,000,000 people for this requirement.

Lead concentrations near roadways are not well understood at this time. The Pb critieria document discussed data for the South Coast Air Quality Management District where a modeling effort suggested that Pb deposited during the years when leaded gasoline was used could be a significant portion of their ambient Pb inventory. However, this work was conducted in an area of the country where quarterly average Pb-TSP concentrations are considerably less than 0.1 $\mu g/m^3$. We analyzed ambient air Pb concentrations near a number of large roadways (Cavender 2008). Based on this analysis it appears unlikely that roadways will result in ambient Pb air concentrations in excess of the lowest Pb NAAQS level being proposed in this action. In addition, members of the CASAC AAMM Subcommittee agreed that a separate monitoring requirement for roadways was unnecessary based on the results of this analysis. As such, the proposed regulatory text does not include a requirement for Pb monitoring near roadways. We do, however, propose to allow monitoring near roadways to satisfy the requirements of the nonsource-oriented monitoring requirement discussed above. For example, a monitoring agency could place a monitor in a CBSA with a population greater than one million and locate that monitor nearly adjacent to a major roadway in a populated area. That monitor would satisfy the nonsource-oriented requirements while also gathering data on possible roadway exposure. We request comments on the need for monitoring near roadways and the appropriateness of allowing near roadway monitoring to be used to satisfy the requirement for nonsource-oriented monitoring.

Monitoring agencies would need to install new Pb monitoring sites as a result of these proposed revisions to the Pb monitoring requirements. We are estimating that the size of the required Pb network will range from between approximately 160 and 500 sites, depending on the level of the final standard. If the size of the final network is on the order of 500 sites, we are proposing to allow monitoring agencies to stagger the installation of newly required sites over two years, with at least half the newly required Pb monitoring sites being installed and operating by January 1, 2010 (16 months after the court-ordered deadline for promulgation of the final Pb NAAQS revision) and the remaining newly required monitoring sites installed and operating by January 1, 2011. As proposed, monitors near the highest Pb emitting sources would need to be installed in the first year, with monitors near the lower Pb emitting sources and nonsource-oriented monitors being installed in the second year. The annual network plan due on July 1, 2009 would need to include the plan and schedule for installation and operation of the newly required Pb monitoring sites necessary to comply with these proposed requirements. We are also proposing to allow monitoring agencies one year following the release of updates to the NEI or an update to the census to add new monitors if these updates would trigger new monitoring requirements. Monitoring agencies would be required to identify and propose new Pb monitoring sites as part of their annual network plan required under 40 CFR 58.10. We invite comments on the need for a staggered network deployment.

The type of monitor that must be used at these required monitoring sites will depend on whether for a final revised NAAQS based on Pb-TSP scaled monitoring data for Pb-PM_{10} may be used as a surrogate. If cross-use of data is permitted, then either type of monitor could be used at a required monitoring site. EPA intends to encourage a relatively small number of sites to operate both types of monitors. The proposed appendix R (see section IV) explains how data would be selected for purposes of NAAQS compliance determinations if both types of monitors operate in the same month or quarter. One approach on which EPA is seeking comment would be to change the Pb indicator to Pb-PM_{10} and allow the use of Pb-TSP data only for the purpose of initial designations. If this approach is adopted, a Pb-TSP monitor could not be used in lieu of a Pb-PM_{10} sampler at a required monitoring site after the area containing the monitoring site had received its initial designation (see section VI for an explanation of the anticipated designation schedule).

If the final Pb standard is based on Pb-TSP, the July 1, 2009 monitoring plan would be required to designate which Pb-PM_{10} monitoring sites, if any, are source-oriented, so that this designation can be available for public comment and can be reviewed by the EPA Regional Administrator. This site designation information is needed to determine scaling factors for the Pb concentration data from these Pb-PM_{10} monitoring sites (see section IV). Sites that are counted towards meeting the required number of source-oriented monitoring sites should of course be designated as source-oriented. It may be appropriate to designate other sites as source-oriented also. Because sources may come and go, or be newly discovered, the revised 40 CFR 58.10 requires the monitoring agency to consider whether revisions in site designations are needed as part of the preparation of each year's monitoring plan.

C. Sampling Schedule

We are proposing to increase the sampling frequency if the final Pb NAAQS is based on a monthly averaging form. Specifically, we are proposing to increase the sampling frequency to require one 24-hour sample taken every 3 days (referred to as ''1 in 3 day sampling'') if the final Pb NAAQS is based on a monthly average. The remainder of this section provides background, rationale, and details for the proposed changes to the Pb sampling frequency.

1. Background

The current required sampling frequency requirement for Pb is one 24-hour sample every six days (40 CFR 58.12(b)). For the current form of the NAAQS that is based on a quarterly average, the 1-in-6 day sampling schedule yields 15 samples per quarter on average with 100% completeness, or 12 samples with 75% completeness. A change to a monthly averaging period would result in between 4 and 6 samples per month at the current sampling frequency with 100% completeness, or between 3 and 5 samples with 75% completeness.

In the ANPR, we indicated that if we changed the averaging time to a monthly average, we would need to consider increasing the required sampling frequency from 1-in-6 days since 3 to 5 samples would likely not result in a reasonably confident estimate of the actual air quality for the period. We suggested several alternatives which included increasing the sampling frequency to 1-in-3 day, or increasing

[164] For the complete definition of CBSA refer to: *http://www.census.gov/population/www/estimates/aboutmetro.html.*

the sampling frequency to 1-in-1 day sampling (i.e., every day sampling). In addition, we suggested an option that relates sampling frequency to recent ambient Pb-TSP concentrations, such that an increased sampling frequency is required as the recent ambient Pb-TSP concentration approaches the NAAQS level. In addition, we sought comments on several practices that would help to reduce the burden associated with more frequent sampling including:

- Increasing sampling time duration (e.g., changing from a 24-hour sampling time duration to a 48-hour or 72-hour sampling time duration),
- Allowing for compositing of samples (i.e., extracting and analyzing several sequential samples together), and
- Allowing for multiple samplers at one site.

In CASAC's comments on the ANPR, they recommended increasing the sampling frequency to 1-in-3 day sampling, or higher. They discouraged increasing the sample duration and the allowance for compositing of samples, as these practices would reduce the ability to use the samples in source apportionment techniques that may be useful in identifying what sources contributed to the ambient air Pb concentrations.

2. Proposed Changes

We propose increasing the sampling frequency to 1-in-3 day sampling if we change the form of the revised NAAQS to a monthly average in the final rule. A 1-in-3 day sampling frequency would yield 9 or 10 samples per month on average at 100% completeness. At 75% completeness, a 1-in-3 day sampling frequency would yield 7 or 8 samples per month at a minimum.

We recognize that at concentrations considerably below the level of the NAAQS there is less potential to misclassify an area due to the error resulting from less than complete sampling. We believe it is appropriate to allow for less frequent sampling in areas with low ambient air Pb concentrations relative to the level of the NAAQS. As such, we are proposing to allow monitoring agencies to request a reduction in the sampling frequency to 1-in-6 day sampling if the most recent 3-year design value is less than 70% of the NAAQS.

We request comment on the proposed change to 1-in-3 day sampling and the proposed option to reduce sampling to 1-in-6 day sampling in areas with low ambient Pb concentrations. We also seek comments on the need to increase sampling frequency further to 1-in-1 day sampling in areas with ambient air Pb concentrations near the level of the final NAAQS.

We are currently assessing how different sampling schedules could affect the confidence in the estimate of a mean monthly Pb concentration as part of developing Data Quality Objectives (DQOs) for Pb monitoring. This assessment will include evaluating temporal variability at current Pb monitoring sites (both Pb-TSP and Pb-PM_{10}) in order to provide uncertainty estimates associated with various sampling frequency scenarios. We will evaluate 1-in-1 day, 1-in-3 day, and 1-in-6 day sampling frequencies, at varying degrees of completion between 50% and 100%, and for each we plan to estimate the margin of error about a mean monthly estimate, focusing on sites assumed to be close to the proposed NAAQS. Based upon this assessment, expected to be complete in June of 2008, we will be able to better understand the uncertainties around a monthly estimate. We will use this better understanding and information provided in public comment to choose the final sampling frequency requirements.

D. Monitoring for the Secondary NAAQS

We are not proposing additional monitoring requirements for the secondary NAAQS because the proposed monitoring requirements for the primary NAAQS will be sufficient to demonstrate compliance with the secondary NAAQS. The remainder of this section provides background and rationale on our decision to not propose additional monitoring requirements for the secondary NAAQS.

1. Background

CASAC has recommended additional monitoring to gather information to better inform consideration of the secondary NAAQS in the next and future reviews. Specifically, CASAC stated that ''the EPA needs to initiate new measurement activities in rural areas—which quantify and track changes in lead concentrations in the ambient air, soils, deposition, surface waters, sediments and biota, along with other information as may be needed to calculate and apply a critical loads approach for assessing environmental lead exposures and risks in the next review cycle'' (Henderson, 2007b).

We currently monitor ambient Pb in $PM_{2.5}$ (Pb-$PM_{2.5}$) as part of the Interagency Monitoring of Protected Visual Environments (IMPROVE) network. There are 110 formally designated IMPROVE sites located in or near national parks and other Class I visibility areas, virtually all of these being rural. Approximately 80 additional sites at various urban and rural locations, requested and funded by various parties, are also informally treated as part of the IMPROVE network. While we believe it is not appropriate to rely on Pb-$PM_{2.5}$ monitoring to demonstrate compliance with a Pb-TSP NAAQS, we believe the Pb-$PM_{2.5}$ measurements provided by the IMPROVE network can be used as a useful indicator to temporal and spatial patterns in ambient Pb concentrations and resulting Pb deposition in rural areas that are not directly impacted by a nearby Pb emission source. In the ANPR, we suggested it might be desirable to augment the IMPROVE network with a small ''sentinel'' network of collocated Pb-TSP monitors for a period of time in order to develop a better understanding of how Pb-$PM_{2.5}$ and Pb-TSP relate in these rural areas. Alternatively, since it is likely that at rural locations nearly all ambient Pb is in the less than 10 μm size range, we suggested it might be possible to analyze the IMPROVE PM_{10} mass samples (which are already being collected) for Pb for a period of time to develop a better understanding of how Pb-$PM_{2.5}$ and Pb-PM_{10} relate in these rural areas.

The National Water-Quality Assessment (NAWQA), conducted by the United States Geological Survey, contains data on Pb concentrations in surface water, bed sediment, and animal tissue for more than 50 river basins and aquifers throughout the country (CD, AX7.2.2.2). NAWQA data are collected during long-term, cyclical investigations wherein study units undergo intensive sampling for 3 to 4 years, followed by low-intensity monitoring and assessment of trends every 10 years. Similarly, the USGS is collaborating with Canadian and Mexican government agencies on a multi-national project called ''Geochemical Landscapes'' that has as its long-term goal a soil geochemical survey of North America (*http://minerals.cr.usgs.gov/projects/geochemical_landscapes/index.html*). The Geochemical Landscapes project has the potential to fill the need for periodic Pb soil sampling. We note the value of the NAWQA and Geochemical Landscapes data in the assessment of trends in Pb concentrations in both soil and aquatic systems, and support the continued collection of this data by the USGS.

2. Proposed Changes

As discussed in Section III of this preamble, we are proposing to set the secondary NAAQS equal to the primary NAAQS. Based on our analysis of the

existing ambient Pb monitoring data (EPA 2007c), we do not expect there to be ambient air concentrations in excess of the proposed secondary NAAQS in rural areas that are not associated with a Pb emission source. As noted earlier in this section, we are proposing Pb surveillance monitoring requirements for Pb sources to demonstrate compliance with the primary NAAQS that will also be sufficient to determine compliance with the secondary NAAQS.

The Pb-$PM_{2.5}$ data collected as part of the IMPROVE program provides useful information on Pb concentrations in rural areas that can be used to track trends in ambient air Pb concentrations in rural areas and important ecosystems. These data are available through the VIEWS Web portal (*http://vista.cira.colostate.edu/views/*) and are also reported to AQS. While collection of a limited amount of collocated Pb-TSP or Pb-PM_{10} would be useful in understanding the relationship between Pb-$PM_{2.5}$ and Pb-TSP (or Pb-PM_{10}) in rural areas, we do not believe it is appropriate to establish a regulatory requirement for the collection of these data. Rather, we believe it is more appropriate to work with the monitoring agencies responsible for IMPROVE monitoring to encourage the collection of a limited amount of collocated Pb data from PM_{10} or TSP samplers. We seek comments on our decision to not require additional monitoring requirements for the proposed secondary Pb NAAQS.

E. Other Monitoring Regulation Changes

We are proposing to make two other minor changes to various aspects of the Pb monitoring regulations to make them consistent with the proposed NAAQS. The remainder of this section discusses the proposed changes.

1. Reporting of Average Pressure and Temperature

The high-volume FRM for Pb-TSP monitoring is based on standard pressure and temperature (25 degrees C, and 760 mmHg). We are not proposing to change this. As discussed in section II.E of this preamble, we are proposing to adopt a new FRM for low-volume Pb-PM_{10} monitoring with concentration reporting based on local temperature and pressure. We are proposing to specify reporting based on local temperature and pressure because the actual concentration of Pb in the atmosphere is a better indicator of the potential for deposition than the concentration based on standard pressure and temperature. In addition, there are practical advantages to moving to local conditions since both $PM_{2.5}$ and $PM_{10-2.5}$ are also based on local conditions. We are proposing to revise 40 CFR 58.16(a) to add a requirement that the monitoring agency report the average pressure and temperature during the time of sampling for both Pb-TSP monitoring and Pb-PM_{10} monitoring, consistent with the requirements for such reporting contained in the $PM_{2.5}$ and $PM_{10-2.5}$ FRMs. For low-volume Pb-PM_{10} monitors, this requirement is easily met because the monitors incorporate temperature and pressure sensors and the monitor software makes reporting these parameters automatic. High-volume TSP samplers do not incorporate these sensors, so more effort may be needed to report the data. We note that sampler-generated average daily temperature and pressure are already required to be reported to AQS from filter-based $PM_{2.5}$ FRM/FEM samplers, and that the current submission of these data would fulfill the temperature and pressure reporting requirements for any Pb-TSP sampling at the same site. Relevant measurements could also be obtained from nearby National Weather System (NWS) monitoring sites, nearby low-volume $PM_{2.5}$ or PM_{10} samplers, and other nearby meteorological measurements that undergo routine quality control checks and quality assurance; relying on one of these sources would mean that a separate data submission action would be needed to associate the data with the Pb-TSP monitoring site. The reporting of average pressure and temperature data would support the ability to investigate data quality and other data analysis questions that may be arise with regard to the Pb-TSP or Pb-PM_{10} monitors.

We seek comment on the requirement to report the average temperature and pressure recorded during Pb measurements and the usefulness of such data in supporting data analysis purposes.

2. Special Purpose Monitoring Exemption

According to 40 CFR 58.20(e) ''If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, SO_2, NO_2, Pb, or 24-hour PM_{10} NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.'' When this provision was added in the October 2006 revisions to the ambient monitoring regulations, we stated that the basis for finalizing a prohibition on the use of SPM data to designate an area as nonattainment for Pb (as well as CO, SO_2, NO_2, and PM_{10}) was EPA's discretion to not make a finding of nonattainment even though a SPM indicated a violation of the relevant NAAQS (see 71 FR 61252). We stated that even though the NAAQS for these pollutants have forms that allow a nonattainment finding based on less than 24 months of data, EPA does not have a mandatory duty to make nonattainment redesignations until such time as the NAAQS are revised. Since EPA is proposing to revise the Pb NAAQS, and the form of the proposed NAAQS would allow a nonattainment finding to be based on only 1 or 2 years of data, and such a NAAQS revision must be followed by a mandatory round of designations, we are proposing to revise 40 CFR Section 58.20(e) by removing the specific reference to Pb in the rule language.

VI. Implementation Considerations

This section of the proposal discusses the specific CAA requirements that must be addressed when implementing any new or revised Pb NAAQS based on the structure outlined in the CAA, existing rules, existing guidance, and in some cases proposed revised guidance. We intend the preamble to the final rule revising the Pb NAAQS to provide EPA's final implementation guidance.

The CAA assigns important roles to EPA, states, and Tribal governments in implementing NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain state measures necessary to achieve the air quality standards in each area. EPA provides assistance to states and Tribes by providing technical tools, assistance, and guidance, including information on the potential control measures.

A SIP is the compilation of regulations and control programs that a state uses to carry out its responsibilities under the CAA, including the attainment, maintenance, and enforcement of the NAAQS. States use the SIP development process to identify the emissions sources that contribute to the nonattainment problem in a particular area, and to select the emissions reduction measures most appropriate for the particular area in question. Under the CAA, SIPs must ensure that areas reach attainment as expeditiously as practicable.

Currently only two areas in the United States are designated as nonattainment and eleven areas are designated as maintenance areas for the current Pb NAAQS. If the Pb NAAQS is lowered to the range proposed, it is likely (based on a review of the current air quality monitoring data) that

additional areas would be designated as nonattainment. States determined to have lead nonattainment areas would be required to submit SIPs that identify and implement specific air pollution control measures to reduce the ambient concentrations of lead to meet the NAAQS.

The EPA's analysis of the available Pb monitoring data suggests that a large majority of recent exceedances of Pb levels in the range of 0.10 to $\mu g/m^3$ have occurred in locations with active or retired industrial sources of Pb. Accordingly, if this pattern also prevails for concentrations observed from new monitoring sites, many states may be able to attain the revised NAAQS by implementing air pollution control measures on lead emitting industrial sources only. These controls could include measures such as fabric filter particulate matter control measures and industrial fugitive dust control measures applied in plant buildings and on plant grounds. However, it may become necessary in some areas to also implement controls on non-industrial sources. Based on these considerations, EPA believes that some of the regulations and guidance being used to implement the current Pb NAAQS is still appropriate to implement any of the options being proposed in this rulemaking for a new or revised Pb NAAQS.

The regulations and guidance for implementing the current NAAQS for Pb are mainly provided in the following documents: (1) ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'', 57 FR 13549, April 16, 1992, (2) ''State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'', 58 FR 67748, December 22, 1993, and (3) regulations at 40 CFR 51.117. The aforementioned documents address requirements such as designating areas, setting nonattainment area boundaries, promulgating area classifications, nonattainment area SIP requirements such as Reasonably Available Control Measures (RACM), Reasonably Available Control Technology (RACT), New Source Review (NSR), Prevention of Significant Deterioration (PSD), and emissions inventory requirements. We have summarized the most relevant information from these documents below for your convenience. The EPA believes that there is sufficient guidance and regulations to fully implement the proposed revised Pb NAAQS, although EPA may review and revise or update as necessary, policies, guidance, and regulations for implementing the Pb NAAQS in the future. The EPA solicits comment on whether additional guidance is necessary for implementation of the revised Pb NAAQS.

A. Designations for the Lead NAAQS

After EPA establishes or revises a NAAQS, the CAA requires EPA and the states to begin taking steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. The CAA defines EPA's authority to designate areas that do not meet a new or revised NAAQS. Section 107(d)(1) provides that ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the state'' that designates those areas as nonattainment, attainment, or unclassifiable. Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.'' The term ''promulgation'' has been interpreted by the courts to be signature and dissemination of a rule.[165] By no later than 120 days prior to promulgating final designations, EPA is required to notify states or Tribes of any intended modifications to their boundaries as EPA may deem necessary. States and Tribes then have an opportunity to comment on EPA's tentative decision. Whether or not a state or a Tribe provides a recommendation, EPA must promulgate the designation that it deems appropriate.

Accordingly, Governors of states and Tribal leaders will be required to submit their initial designation recommendations to EPA no later than September 2009. The initial designation of areas for any new or revised NAAQS for lead must occur no later than September 2010, although that date may be extended by up to one year under the CAA (or no later than September 2011) if EPA has insufficient information to promulgate the designations. As discussed below, EPA is anticipating a designations schedule that provides the full 3 years allowed under the CAA, and is taking comment on issues related to the anticipated designation schedule.

1. Potential Schedule for Initial Designations of a Revised Lead NAAQS

As stated previously, section 107(d)(1)(B)(i) requires EPA to promulgate initial designations for all areas of the country for any new or revised NAAQS, as expeditiously as practicable, but in no case later than 3 years from the date of promulgation of the new or revised NAAQS. Two key considerations in establishing a schedule for designating areas are: (1) The advantages of promulgating all designations at the same time; and (2) the availability of a monitoring network and sufficient monitoring data to identify areas that may be violating the NAAQS.

EPA continues to believe, consistent with its past practice, that there are important advantages to promulgating designations for all areas at the same time. This practice provides helpful uniformity for the deadlines for SIP submissions and attainment. Moreover, since a key question for the designation process is delineating the boundaries of nonattainment areas, establishing appropriate nonattainment boundaries in a two-stage process is likely to generate significant issues. Thus, EPA intends to promulgate designations for all areas at the same time.

As discussed in section V.B, the existing Pb monitoring network is not adequate to evaluate attainment of the proposed revised Pb NAAQS at locations consistent with EPA's proposed new network siting criteria and data collection requirements. These new requirements would result in a more strategically targeted network that would begin to be in operation by January 1, 2010. Thus, taking the additional year provided under section 107(d)(1)(B)(1) of the CAA (which would allow up to 3 years to promulgate designations following the promulgate of a new NAAQS) would allow the first year of data from this network to be available. The EPA believes that, due to the updated network design requirements, this additional data would be of significant benefit for designating areas for a new NAAQS. If EPA completes the initial designations within 2 years of new NAAQS promulgation, it is likely that large areas of the country will be designated ''unclassifiable'' because the monitoring network will not be sufficient to make clear decisions. Even if EPA takes an extra year for final initial designation

[165] *American Petroleum Institute* v. *Costle,* 609 F.2d 20 (D.C. Cir. 1979).

decisions we recognize that some areas may still have to be designated as unclassifiable or attainment/unclassifiable because of the lack of a sufficient record of FRM (FEM) monitoring data.[166] If sufficient monitoring data become available for ''unclassifiable'' areas subsequent to the time EPA finalizes initial designations, EPA may use the discretion provided to the Administrator under the CAA pursuant to section 107(d)(3) to revise the initial designations for these areas.

Under the initial designation schedule described above, states (and Tribes) would be required to submit designation recommendations to EPA no later than September 2009 (i.e., one year following promulgation of a new NAAQS). States will be able to consider ambient data collected with FRM (FEM) samplers through the end of 2008 and part way through 2009 when formulating their recommendations. As stated previously, by no later than 120 days prior to promulgating designations, EPA is required to notify states or Tribes of any intended modifications to their recommended boundaries as EPA may deem necessary. This would occur no later than in May 2011. If EPA promulgates designations in September 2011, EPA will have access to Pb air quality data from 2010 which state monitoring officials have certified is complete and accurate, since the deadline for such certification is May 1, 2011. Under this schedule, EPA would consider data from calendar years 2008–2010 in formulating its proposed revisions, if any, to the designations recommended by states and Tribes. States and Tribes will then have an opportunity to comment on EPA's proposed modifications

As described above, EPA is currently anticipating that there will be insufficient information to promulgate designations in 2010. The EPA is soliciting comment on whether we have the authority to determine in the final rule that three years are necessary to promulgate designations based on the availability of appropriate information. EPA is also soliciting comment on whether designations should be made within the 2 year period provided under section 107(d)(1)(B)(i) utilizing all data available by that time.

2. Ambient Data For Designations

The proposed alternative forms of the NAAQS, maximum quarterly average concentration over three years and second maximum monthly concentration over three years, would both allow a nonattainment determination based on less than three years of data, if the monitoring data in a more limited time period includes a quarterly average above the level of the NAAQS or if it includes two monthly averages above the level of the NAAQS. In such a case, EPA intends to designate the affected area nonattainment even though less than three years of data are available. EPA would designate an area attainment only if three calendar years of data indicate the absence of a violation. As stated above, EPA anticipates that some areas will have to be designated as unclassifiable. If sufficient monitoring data become available for ''unclassifiable'' areas subsequent to the time EPA finalizes initial designations, EPA may use the discretion provided to the Administrator under the CAA pursuant to section 107(d)(3) to revise the initial designations for these areas.

B. Lead Nonattainment Area Boundaries

As stated previously, the process for initially designating areas following the promulgation of a new NAAQS is prescribed in section 107(d)(1) of the CAA. This section of the CAA provides each state Governor an opportunity to recommend initial designations of attainment, nonattainment, or unclassifiable for each area in the state. Section 107(d)(1) of the CAA also directs the state to provide the appropriate boundaries to EPA for each area of the state, and provides that EPA may make modifications to the boundaries submitted by the state as it deems necessary. A lead nonattainment area must consist of that area that does not meet (or contributes to ambient air quality in a nearby area that does not meet) the Pb NAAQS. Thus, a key factor in setting boundaries for nonattainment areas is determining the geographic extent of nearby source areas contributing to the nonattainment problem. For each monitor or group of monitors that exceed a standard, nonattainment boundaries must be set that include a sufficiently large enough area to include both the area judged to be violating the standard as well as the source areas that are determined to be contributing to these violations.

Historically, Pb NAAQS violations have been the result of lead emissions from large stationary sources and mobile sources that burn lead-based fuels. In some locations, a limited number of area sources have also contributed to violations. Since lead has been successfully phased out of motor vehicle gasoline, mobile sources are no longer a significant source of violations of the current Pb NAAQS. At the current standard level, EPA expects stationary sources to be the primary contributor to violations of the NAAQS. At the lower standard levels contemplated in this proposal, it is possible that fugitive dust emissions from area sources containing deposited lead will also contribute to violations of a revised Pb NAAQS. The location and dispersion characteristics of these sources of ambient lead concentrations are important factors in determining nonattainment area boundaries. The EPA is proposing that the county boundary be the presumptive boundary for lead nonattainment areas. However, we are also taking comment on whether urban-based Metropolitan Statistical Area (MSA) boundaries should be the presumptive boundaries for lead nonattainment areas.

The EPA is proposing to presumptively define the boundary for designating a nonattainment area as the perimeter of the county associated with the air quality monitor(s) which records a violation of the standard. This presumption is the existing EPA recommendation for defining the nonattainment boundaries for the current Pb NAAQS, and is described in the 1992 General Preamble (57 FR 13549). The EPA is also taking comment on an option to presumptively define the nonattainment boundary using the OMB-defined Metropolitan Statistical Area (MSA) associated with the violating monitor(s). This presumption is used, by CAA requirement, for the ozone and CO NAAQS nonattainment boundaries, and was recommended by EPA as the appropriate presumption for the 1997 $PM_{2.5}$ NAAQS nonattainment boundaries. Under either option, the state and/or EPA may conduct additional area-specific analyses that could lead EPA to depart from the presumptive boundary. Factors relevant to such an analysis are described below.

1. County-Based Boundaries

The option being proposed by EPA is that lead nonattainment boundaries would be presumptively defined by the perimeter of the county in which the ambient lead monitor(s) recording a violation of the NAAQS is located, unless area-specific information indicates that some other boundary is more appropriate. In addition, if the relevant air quality monitor measuring a violation(s) is located near another county, then EPA would presume that the contributing county should also be designated as nonattainment for the Pb NAAQS. In some instances, a boundary other than the county perimeter, that

[166] As discussed in Section IV of this notice, EPA is soliciting comment on the use of Pb-TSP monitoring data, with or without a scaling factor, as a surrogate for Pb-PM_{10} data where Pb-PM_{10} data are not available, particularly for initial designations.

addresses areas impacted by specific sources of lead, may also be appropriate.

For the new proposed Pb NAAQS, EPA is recommending that nonattainment area boundaries that deviate from presumptive county boundaries should be supported by an assessment of several factors, which are discussed below. The factors for determining nonattainment area boundaries for the Pb NAAQS under this recommendation closely resemble the factors identified in recent EPA guidance for the 1997 8-hour ozone NAAQS, the 1997 $PM_{2.5}$ NAAQS, and the 2006 $PM_{2.5}$ NAAQS nonattainment area boundaries. EPA intends to apply these factors in evaluating boundary modifications. For this particular option, EPA would consider the following factors in assessing whether to exclude portions of a county and whether to include additional nearby areas outside the county as part of the designated nonattainment area:

- Emissions in areas potentially included versus excluded from the nonattainment area,
- Air quality in potentially included versus excluded areas,
- Population density and degree of urbanization including commercial development in included versus excluded areas,
- Expected growth (including extent, pattern and rate of growth),
- Meteorology (weather/transport patterns),
- Geography/topography (mountain ranges or other air basin boundaries),
- Jurisdictional boundaries (e.g., counties, air districts, Reservations, etc.),
- Level of control of emission sources.

Analyses of these factors may suggest nonattainment boundaries that are either larger or smaller than the county. A demonstration supporting the designation of boundaries that are less than the full county must show both that violation(s) are not occurring in the excluded portions of the county and that the excluded portions are not source areas that contribute to the observed violations. Recommendations to designate a nonattainment area larger than the county should also be based on an analysis of these factors. EPA will consider these factors in evaluating state and tribal recommendations and assessing whether any modifications are appropriate.

Under previous Pb implementation guidance, EPA advised that Governors could choose to recommend lead nonattainment boundaries by using any one, or a combination of the following techniques, the results of which EPA would consider when making a decision as to whether and how to modify the Governors' recommendations: (1) Qualitative analysis, (2) spatial interpolation of air quality monitoring data, or (3) air quality simulation by dispersion modeling. These techniques are more fully described in ''Procedures for Estimating Probability of Nonattainment of a PM_{10} NAAQS Using Total Suspended Particulate or PM_{10} Data,'' December 1986 (see 57 FR 13549).

EPA solicits comments on the use of these factors and modeling techniques, and other approaches, for adjusting county boundaries in designating nonattainment areas.

2. MSA-Based Boundaries

The EPA is also taking comment on the alternative that lead nonattainment boundaries should be presumptively defined by the perimeter of a metropolitan area as defined by OMB's Metropolitan Statistical Areas (MSAs), or appropriate divisions thereof, within which a violating monitor(s) is located. The Metropolitan Statistical Area, as delineated by the Office of Management and Budget (OMB), provides a presumptive definition of the populated area associated with a core urban area. Accordingly, EPA is taking comment on the alternative option that the Metropolitan Statistical Area would provide the presumptive definition of the source area that contributes to a lead nonattainment problem. This presumption would take the view that, in the absence of evidence to the contrary, violations of the Pb NAAQS in urban-oriented areas may be presumed attributable, at least in part, to contributions from large sources of lead emissions distributed throughout the Metropolitan Area. The last revision to the OMB listing of MSAs was published November 20, 2007. As in the EPA's preferred proposed option, EPA would consider state, local, and tribal recommendations of nonattainment area boundaries based on the same set of factors listed in the previous subsection.

As stated previously, EPA is proposing that the county boundaries be used as the presumptive boundaries for any new or revised Pb NAAQS, but is also requesting comments the MSA boundaries being used as the presumptive boundaries for any new or revised Pb NAAQS.

C. Classifications

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purposes of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify lead nonattainment areas, but is not required to do so.

While section 172(a)(1)(A) provides a mechanism to classify nonattainment areas, section 172(a)(2)(D) provides that the attainment date extensions described in section 172(a)(2)(A) do not apply to nonatainment areas having specific attainment dates that are addressed under other provisions of the part D of the CAA. Section 192(a), of part D, specifically provides an attainment date for areas designated as nonattainment for the Pb NAAQS. Therefore, EPA has legal authority to classify lead nonattainment areas, but the 5 year attainment date under section 192(a) cannot be extended pursuant to section 172(a)(2)(D).

Based on this limitation, EPA is proposing not to establish classifications within the 5 year interval for attaining any new or revised NAAQS. This approach is consistent with EPA's previous classification decision in the 1992 General Preamble (See 57 FR 13549, April 16, 1992).

D. Section 110(a)(2) Lead NAAQS Infrastructure Requirements

Under section 110(a)(1) and (2) of the CAA, all states are required to submit plans to provide for the implementation, maintenance, and enforcement of any new or revised NAAQS. Section 110(a)(1) and (2) require states to address basic program elements, including requirements for emissions inventories, monitoring, and modeling, among other things. States are required to submit SIPs to EPA demonstrating these basic program elements within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M), of section 110(a)(2), set forth the elements that a state's program must contain in their SIP. The list below identifies the required program elements contained in section 110(a)(2).[167] The list of section 110(a)(2)

[167] Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. The elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

NAAQS implementation requirements are the following:

• *Ambient air quality monitoring/data system:* Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.

• *Program for enforcement of control measures:* Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation of new/modified (permitted) sources.

• *Interstate transport:* Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one State from contributing significantly to nonattainment in another State or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.

• *Adequate resources:* Section 110(a)(2)(E) requires States to provide adequate funding, personnel and legal authority for implementation of their SIPs.

• *Stationary source monitoring system:* Section 110(a)(2)(F) requires States to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.

• *Emergency power:* Section 110(a)(2)(G) requires States to provide for authority to implement the emergency episode provisions in their SIPs.

• *Provisions for SIP revision due to NAAQS changes or findings of inadequacies:* Section 110(a)(2)(H) requires States to revise their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.

• *Section 121 consultation with local and Federal government officials:* Section 110(a)(2)(J) requires States to meet applicable local and Federal government consultation requirements of section 121.

• *Section 127 public notification of NAAQS exceedances:* Section 110(a)(2)(J) requires States to meet applicable requirements of section 127 relating to public notification of violating NAAQS.

• *PSD and visibility protection:* Section 110(a)(2)(J) also requires States to meet applicable requirements of title I part C related to prevention of significant deterioration and visibility protection.

• *Air quality modeling/data:* Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions from any NAAQS pollutant and submission of data to EPA upon request.

• *Permitting fees:* Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.

• *Consultation/participation by affected local government:* Section 110(a)(2)(M) requires States to provide for consultation and participation by local political subdivisions affected by the SIP.

E. Attainment Dates

Generally, the date by which an area is required to attain the Pb NAAQS is determined by the effective date of the nonattainment designation for the area. For areas designated nonattainment for any new or revised primary Pb NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). So, for example, if final designations are effective in Fall 2011, then nonattainment areas must plan to attain the NAAQS by no later than Fall 2016. For an area with an attainment date of September 2016, EPA would determine whether it had attained the Pb NAAQS by evaluating air quality monitoring data from the 1, 2, or 3 previous calendar years (i.e., 2013, 2014, and 2015) as available.

F. Attainment Planning Requirements

Any state containing an area designated as nonattainment with respect to the Pb NAAQS must develop for submission, a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment (see sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the lead part D SIP must be submitted within 18 months of an areas nonattainment designation. So, for example, if final designations are effective in Fall 2011, the part D SIPs must be submitted by Spring 2013. Additional specific plan requirements for lead nonattainment areas are outlined in 40 CFR 51.117.

The general part D nonattainment plan requirements are set forth in section 172 of the CAA. Section 172(c) specifies that SIPs submitted to meet the part D requirements must, among other things, include Reasonably Available Control Measures (RACM) (which includes Reasonably Available Control Technology (RACT)), provide for Reasonable Further Progress (RFP), include an emissions inventory, require permits for the construction and operation of major new or modified stationary sources (see also section 173), contain contingency measures, and meet the applicable provisions of section 110(a)(2) of the CAA related to the general implementation of a new or revised NAAQS. It is important to note that lead nonattainment SIPs must meet all of the requirements related to part D of the CAA, including those specified in section 172(c), even if EPA does not provide separate specific guidance for each provision (e.g., applicable provisions of section 110(a)(2)).

1. RACM for Lead Nonattainment Areas

Lead nonattainment area SIPs must contain RACM (including RACT) that addresses sources of ambient lead concentrations. In general, as stated previously, EPA believes that lead nonattainment area issues are usually attributed to emissions from stationary sources, but some emissions may also be attributed to smaller area sources. As a general rule, the stationary sources in lead nonattainment areas tend to emit a relatively large amount of particulate matter containing lead. In EPA's 2002 National Emissions Inventory (NEI), there were 29 stationary sources in the country with lead emissions over 5 tons per year, and 239 sources over 1 ton of lead emissions per year.

At primary lead smelters, for example, the process of reducing concentrated ore to lead involves a series of steps, some of which are completed outside of buildings, or inside of buildings which are not totally enclosed. Over a period of time, emissions from these sources have been deposited in neighboring communities (e.g., on roadways, parking lots, yards, and off-plant property). This historically deposited lead, when disturbed, may be re-entrained into the ambient air and re-entrained fugitive lead bearing dust may contribute to violations of the Pb NAAQS in the affected area. There are also potential sources of lead that are under federal control. As a part of the Regulatory Impact Analysis for this rule, the EPA is reviewing the impact of these and other sources of lead emissions to assess their impact on any new or revised Pb NAAQS. States must also meet the requirements outlined in 40 CFR 51.117(a) related to control strategy demonstrations.

The first step in addressing RACM for lead is identifying potential control measures for sources of lead in the nonattainment area. A suggested starting point for specifying RACM in lead nonattainment area SIPs is outlined in appendix 1 of the guidance entitled

''State Implementation Plans for Lead Nonattainment Areas; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990, 58 FR 67752, December 22, 1993. If a state receives substantive public comments that demonstrate through appropriate documentation, that additional control measures may be reasonably available in a particular circumstance for an area, those measures should be added to the list of available measures for consideration in that particular area.

While EPA does not presume that these control measures are reasonably available in all areas, a reasoned justification for rejection of any available control measure should be prepared. If it can be shown that measures, considered both individually and as a group, are unreasonable because emissions from the affected sources are insignificant, those measures may be excluded from further consideration as they would not be representative of RACM for an area. The resulting control measures should then be evaluated for reasonableness, considering their technological feasibility and the cost of control in the area for which the SIP applies. In the case of public sector sources and control measures, this evaluation should consider the impact and reasonableness of the measures on the municipal, or other governmental entity that must assume the responsibility for their implementation. It is important to note that a state should consider the feasibility of implementing measures in part when full implementation would be infeasible. A reasoned justification for partial or full rejection of any available control measure, including those considered or presented during the state's public hearing process, should be prepared. The justification should contain an explanation, with appropriate documentation, as to why each rejected control measure is deemed infeasible or otherwise unreasonable for implementation.

Economic feasibility considers the cost of reducing emissions and the difference between the cost of the emissions reduction approach at the particular source in question and the costs of emissions reduction approaches that have been implemented at other similar sources. Absent other indications, EPA presumes that it is reasonable for similar sources to bear similar costs of emissions reduction. Economic feasibility for RACT purposes is largely determined by evidence that other sources in a source category have in fact applied the control technology or process change in question. EPA also encourages the development of innovative measures not previously employed which may also be technically and economically feasible.

The capital costs, annualized costs, and cost effectiveness of an emissions reduction technology should be considered in determining whether a potential control measure is reasonable for an area or state. One available reference for calculating costs is the EPA Air Pollution Control Cost Manual,[168] which describes the procedures EPA uses for determining these costs for stationary sources. The above costs should be determined for all technologically feasible emission reduction options. States may give substantial weight to cost effectiveness in evaluating the economic feasibility of an emission reduction technology. The cost effectiveness of a technology is its annualized cost ($/year) divided by the emissions reduced (i.e., tons/year) which yields a cost per amount of emission reduction ($/ton). Cost effectiveness provides a value for each emission reduction option that is comparable with other options and other facilities. With respect to a given pollutant, a measure is likely to be reasonable if it has a cost per ton similar to other measures previously employed for that pollutant. In addition, a measure is likely to be reasonable from a cost effectiveness standpoint if it has a cost per ton similar to that of other measures needed to achieve expeditious attainment in the area within the CAA's time frames.

The fact that a measure has been adopted or is in the process of being adopted by other states is an indicator (though not a definitive one) that the measure may be technically and economically feasible for another state. We anticipate that states may decide upon RACT and RACM controls that differ from state to state, based on the state's determination of the most effective strategies given the relevant mixture of sources and potential controls in the relevant nonattainment areas, and differences in difficulty of attaining expeditiously. Nevertheless, states should consider and address RACT and RACM measures developed for other areas or other states as part of a well reasoned RACT and RACM analysis. The EPA's own evaluation of SIPs for compliance with the RACT and RACM requirements will include comparison of measures considered or adopted by other states.

[168] *EPA Air Pollution Control Cost Manual—Sixth Edition* (EPA 452/B–02–001), EPA Office of Air Quality Planning and Standards, Research Triangle Park, NC, Jan 2002.

In considering what level of control is reasonable, EPA is not proposing a specific dollar per ton cost threshold for RACT. Areas with more serious air quality problems typically will need to obtain greater levels of emissions reductions from local sources than areas with less serious problems, and it would be expected that their residents could realize greater public health benefits from attaining the standard. For these reasons, we believe that it will be reasonable and appropriate for areas with more serious air quality problems and higher design values to impose emission reduction requirements with generally higher costs per ton of reduced emissions than the cost of emissions reductions in areas with lower design values. In addition, where essential reductions are more difficult to achieve (e.g., because many sources are already controlled), the cost per ton of control may necessarily be higher.

The EPA believes that in determining appropriate emission control levels, the state should consider the collective public health benefits that can be realized in the area due to projected improvements in air quality. Because EPA believes that RACT requirements will be met where the state demonstrates timely attainment, and areas with more severe air quality problems typically will need to adopt more stringent controls, RACT level controls in such areas will require controls at higher cost effectiveness levels ($/ton) than areas with less severe air quality problems.

In identifying the range of costs per ton that are reasonable, information on benefits per ton of emission reduction can be useful as one factor to consider. The Pb NAAQS RIA will provide information on the estimated benefits per ton of reducing Pb emissions from various emissions sources. It should be noted that such benefits estimates are subject to significant uncertainty, and that benefits per ton vary in different areas. Nonetheless this information could be used in a way that recognizes these uncertainties. If a per ton cost of implementing a measure is significantly less than the anticipated benefits per ton, this would be an indicator that the cost per ton is reasonable. If a source contends that a source-specific RACT level should be established because it cannot afford the technology that appears to be RACT for other sources in its source category, the source should support its claim by providing detailed and verified information regarding the impact of imposing RACT on:

- Fixed and variable production costs ($/unit),

- Product supply and demand elasticity,
- Product prices (cost absorption vs. cost pass-through),
- Expected costs incurred by competitors,
- Company profits, and
- Employment costs.

The technical guidance entitled ''Fugitive Dust Background Document and Technical Information Document for Best Available Control Measures'' (EPA–450/2–92–004, September 1992) provides an example for states on how to analyze control costs for a given area.

Once the process of determining RACM for an area is completed, the individual measures should then be converted into a legally enforceable vehicle (e.g., a regulation or permit program) (see section 172(c)(6) and section 110(a)(2)(A) of the CAA). The regulations or other measures submitted should meet EPA's criteria regarding the enforceability of SIPs and SIP revisions. These criteria were stated in a September 23, 1987 memorandum (with attachments) from J. Craig Potter, Assistant Administrator for Air and Radiation; Thomas L. Adams, Jr. Assistant Administrator for Enforcement and Compliance Monitoring; and S. Blake, General Counsel, Office of the General Counsel; entitled ''Review of State Implementation Plans and Revisions of Enforceability and Legal Sufficiency.'' As stated in this memorandum, SIPs and SIP revisions that fail to satisfy the enforceability criteria should not be forwarded for approval. If they are submitted, they will be disapproved if, in EPA's judgment, they fail to satisfy applicable statutory and regulatory requirements.

The EPA's historic definition of RACT is the lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility.[169] RACT applies to the ''existing sources'' of lead including stack emissions, industrial process fugitive emissions, and industrial fugitive dust emissions (e.g., on-site haul roads, unpaved staging areas at the facility, etc) (see section 172(c)(1)). EPA's most recent guidance for implementing the current Pb NAAQS recommends that stationary sources which actually emit a total of 5 tons per year of lead or lead compounds, measured as elemental lead, be the minimum starting point for RACT analysis (see 58 FR 67750, December 22, 1993). Further, EPA recommends that available control technology be applied to those existing sources in the nonattainment area that are reasonable to control in light of the attainment needs of the area and the feasibility of such controls. Thus a state's control technology analysis may need to include sources which actually emit less than 5 tons per year of lead or lead compounds in the area, or other sources in the area that are reasonable to control, in light of the attainment needs and feasibility of control for the area.

Given the proposal for promulgating a new or revised Pb NAAQS significantly lower than the current standard, EPA is seeking comment on an appropriate threshold for the minimum starting point for future Pb RACT analyses for stationary lead sources in nonattainment areas. In the monitoring section of today's proposal, EPA is taking comment on minimum network monitoring requirements based on emissions source sizes ranging from 200 kg/yr to 600 kg/yr. One possible approach for RACT is to recommend that RACT analyses for Pb sources be consistent with the monitoring requirements, such that all stationary sources above from 200 kg/yr to 600 kg/yr should undergo a RACT review. EPA is also taking comment on source monitoring for stationary sources that emit Pb emissions in amounts that have potential to cause ambient levels at least one-half the selected NAAQS level. This suggests another potential recommended starting point for RACT analysis. EPA is seeking comment on these ideas as well as any information commenters can provide that would help inform EPA recommendations on an appropriate emissions threshold for initiating RACT analyses.

2. Demonstration of Attainment for Lead Nonattainment Areas

The SIPs for lead nonattainment areas should provide for the implementation of control measures for point and area stationary sources of lead emissions which demonstrate attainment of the Pb NAAQS as expeditiously as practicable, but no later than the applicable statutory attainment date for the area (See also 40 CFR 51.117(a) for additional control strategy requirements). Therefore, if a state adopts less than all available measures in an area but demonstrates, adequately, that reasonable further progress (RFP), and attainment of the Pb NAAQS are assured, and application of all such available measures would not result in attainment any faster, then a plan which requires implementation of less than all technologically and economically available measures may be approved (see 44 FR 20375 (April 4, 1979) and 56 FR 5460 (February 11, 1991)). The EPA believes that it would be unreasonable to require that a plan which demonstrates attainment include all technologically and economically available control measures even though such measures would not expedite attainment. Thus, for some sources in areas which demonstrate attainment, it is possible that some available control measures may not be ''reasonably'' available because their implementation would not expedite attainment.

3. Reasonable Further Progress (RFP)

Part D SIPs must provide for RFP (see section 172(c)(2) of the CAA). Section 171 of the CAA defines RFP as ''such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date.'' Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions generally sufficient to maintain linear progress toward attainment by the applicable attainment date. Requiring linear emission reduction progress to maintain RFP may be appropriate where:

- Pollutants are emitted by numerous and diverse sources;
- The relationship between any individual source and the overall air quality is not explicitly quantified;
- There is a chemical transformation involved; and
- The emission control system utilized (*e.g.*, at major point sources) will result in swift and significant emission reductions.

The EPA believes that it may not be reasonable to require linear reductions in emissions in SIPs for lead nonattainment areas because the air quality problem is not usually due to a vast inventory of sources. However, this is not to suggest that generally it would be unreasonable for EPA to require annual incremental reductions in emissions in lead nonattainment areas. RFP for lead nonattainment areas should be met, at least in part, by ''adherence to an ambitious compliance schedule'' which is expected to periodically yield significant emission reductions, and as appropriate, linear

[169] See for example, 44 FR 53762 (September 17, 1979) and footnote 3 of that notice. Note that EPA's emissions trading policy statement has clarified that the RACT requirement may be satisfied by achieving ''RACT equivalent'' emission reductions in the aggregate from the full set of existing stationary sources in the area. See also EPA's economic incentive proposal which reflects the Agency's policy guidance with respect to emissions trading 58 FR 11110, February 23, 1993.

progress.[170] The EPA recommends that SIPs for lead nonattainment areas provide a detailed schedule for compliance of RACM (including RACT) in the areas and accurately indicate the corresponding annual emission reductions to be achieved. In reviewing the SIP, EPA believes that it is appropriate to expect early implementation of less technology-intensive control measures (e.g., controlling fugitive dust emissions at the stationary source, as well as required controls on area sources) while phasing in the more technology-intensive control measures, such as those involving the installation of new hardware. Finally, it should be noted that failure to implement the SIP provisions required to meet annual incremental reductions in emissions (i.e., RFP) in a particular area could result in the application of sanctions as described in sections 110(m) and 179(b) of the CAA (pursuant to a finding under section 179(a)(4)), and the implementation of contingency measures required by section 172(c)(9) of the CAA.

4. Contingency Measures

Section 172(c)(9) of the CAA defines contingency measures as measures in a SIP that are to be implemented if an area fails to achieve and maintain RFP, or fails to attain the NAAQS by the applicable attainment date. Contingency measures must be designed to become effective without further action by the state or the Administrator, upon determination by EPA that the area has failed to achieve or maintain reasonable further progress, or attain the Pb NAAQS by the applicable statutory attainment date. Contingency measures should consist of available control measures that are not already included in the primary control strategy for the affected area.

Contingency measures are important for lead nonattainment areas, which is generally due to emissions from stationary sources, for several reasons. First, process and fugitive emissions from these stationary sources, and the possible re-entrainment of historically deposited emissions, have historically been difficult to quantify. Therefore, the analytical tools for determining the relationship between reductions in emissions, and resulting air quality improvements, can be subject to some uncertainties. Second, emission estimates and attainment analysis can be influenced by overly-optimistic assumptions about fugitive emission control efficiency.

Examples of contingency measures for controlling area fugitive emissions may include stabilizing additional storage piles, etc. Examples of contingency measures for processed-related fugitive emissions include increasing the enclosure of buildings, increasing air flow in hoods, increasing operation and maintenance procedures, etc. Examples for contingency measures for stack sources include reducing hours of operation, changing the feed material to lower lead content, and reducing the occurrence of malfunctions by increasing operation and maintenance procedures, etc.

Section 172(c)(9) provides that contingency measures should be included in the SIP for a lead nonattainment area and shall ''take effect without further action by the state or the Administrator.'' The EPA interprets this requirement to mean that no further rulemaking actions by the state, or EPA, would be needed to implement the contingency measures (see generally 57 FR 12512 and 13543–13544). The EPA recognizes that certain actions, such as the notification of sources, modification of permits, etc., may be needed before a measure could be implemented. However, states must show that their contingency measures can be implemented with minimal further action on their part and with no additional rulemaking actions such as public hearings or legislative review. After EPA determines that a lead nonattainment area has failed to maintain RFP or timely attain the Pb NAAQS, EPA generally expects all actions needed to affect full implementation of the measures to occur within 60 days after EPA notifies the state of such failure. The state should ensure that the measures are fully implemented as expeditiously as practicable after the requirement takes effect.

5. Nonattainment New Source Review (NSR) and Prevention of Significant Deterioration (PSD) Requirements

The PSD and nonattainment NSR programs contained in parts C and D of title I of the CAA govern preconstruction review and permitting programs for any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator. EPA rules addressing these regulations can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S.

Areas designated as nonattainment for the Pb NAAQS must submit SIPs that address the requirements of nonattainment area NSR. Specifically, section 172(c)(5) of the CAA requires that States which have areas designated as nonattainment for the Pb NAAQS must submit, as a part of the nonattainment area SIP, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area, in accordance with the permit requirements pursuant to section 173 of the CAA.

Stationary sources that emit lead are currently subject to regulation under existing requirements for the preconstruction review and approval of new and modified stationary sources. The existing requirements, referred to collectively as the New Source Review (NSR) program, require any major and minor stationary sources of any air pollutant for which there is a NAAQS to undergo review and approval prior to the commencement of construction.[171] The NSR program is composed of three different permit programs:

The NSR program is composed of three different permit programs:

- Prevention of Significant Deterioration (PSD);
- Nonattainment NSR (NA NSR); and,
- Minor NSR.

The PSD program and nonattainment NSR programs, contained in parts C and D, respectively, of Title I of the CAA, are often referred to as the major NSR program because these programs regulate only major sources.

The PSD program applies when a major source, that is located in an area that is designated as attainment or unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.[172] The NA NSR program applies when a major source that is located in an area that is designated as nonattainment for any criteria pollutant is constructed or undergoes a major modification. The minor NSR program addresses both major and minor sources that underground construction or modification activities that do not qualify as major, and it applies regardless of the designation of the area in which a source is located.

The national regulations that apply to each of these programs are located in the CFR as shown below:

[170] As previously stated most of the lead nonattainment problems are caused by point sources. For this reason EPA believes that the RFP for Pb should parallel the RFP policy for SO2 (see General Preamble, 57 FR 13545, April 16, 1992).

[171] The terms ''major'' and ''minor'' define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not ''major.'' ''Major'' is defined by the applicable regulations—PSD or nonattainment NSR.

[172] In addition, the PSD program applies to most non-criteria regulated pollutants.

	Applications
PSD	40 CFR 52.21, 40 CFR 51.166, 40 CFR 51.165(b).
NA NSR	40 CFR 52.24, 40 CFR 51.165, 40 CFR part 51, Appendix S.
Minor NSR	40 CFR 51.160–164.

The PSD requirements include but are not limited to the following:

- Installation of Best Available Control Technology (BACT);
- Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
- Notification of Federal Land Manager of nearby Class I areas; and
- Public comment on permit.

Nonattainment NSR requirements include but are not limited to:

- Installation of Lowest Achievable Emissions Rate (LAER) control technology;
- Offsetting new emissions with creditable emissions reductions;
- A certification that all major sources owned and operated in the state by the same owner are in compliance with all applicable requirements under the CAA;
- An alternative citing analysis demonstrating that the benefits of proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
- Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires ''* * * regulation of the modification and construction of any stationary source * * * as necessary to assure that the [NAAQS] are achieved.''

Areas which are newly designated as nonattainment for the Pb NAAQS as a result of any changes made to the NAAQS will be required to adopt the NA NSR program to address major sources of lead where the program does not currently exist for the Pb NAAQS. Prior to adoption of the SIP revision addressing NSR for lead nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply.

6. Emissions Inventories

States must develop and periodically update a comprehensive, accurate, current inventory of actual emissions affecting ambient lead concentrations. The emissions inventory is used by states and EPA to determine the nature and extent of the specific control strategy necessary to help bring an area into attainment of the NAAQS. Emissions inventories should be based on measured emissions or documented emissions factors. Generally, the more comprehensive and accurate the inventory, the more effective the evaluation of possible control measures can be for the affected area (see section 172(c)(3) of the CAA).

Pursuant to its authority under section 110 of Title I of the CAA, EPA has long required states to submit emission inventories containing information regarding the emissions of criteria pollutants as well as their precursors. The EPA codified these requirements in 40 CFR part 51, subpart Q in 1979 and amended them in 1987. The 1990 Clean Air Act Amendments (CAAA) revised many of the provisions of the CAA related to attainment of the NAAQS. These revisions established new emission inventory requirements applicable to certain areas that were designated as nonattainment for certain pollutants. In the case of lead, the emission inventory provisions are in the general provisions pursuant to section 173(c)(3) of the CAA.

In June 2002, EPA promulgated the Consolidated Emissions Reporting Rule (CERR) (67 FR 39602, June 10, 2002). The CERR consolidates the various emissions reporting requirements that already exist into one place in the CFR, and establishes new requirements for the state wide reporting of area source and mobile source emissions. States should follow the requirements under the CERR as well as any new or revised guidance related to emissions inventories for criteria pollutants. The CERR establishes two types of required emissions inventories: (1) Annual inventories, and (2) 3-year cycle inventories. The annual inventory requirement is limited to reporting statewide emissions data from the larger point sources. For the 3-year cycle inventory, states will need to report data from all of their point sources plus all of the area and mobile sources on a statewide basis.

By merging emissions information from relevant point sources, area sources and mobile sources into a comprehensive emission inventory, the CERR allows state, local and tribal agencies to do the following:

- Set a baseline for SIP development.
- Measure their progress in reducing emissions.
- Answer the public's request for information.

The EPA uses the data submitted by the states to develop the National Emission Inventory (NEI). The NEI is used by EPA to show national emission trends, as modeling input for analysis of potential regulations, and other purposes.

Most importantly, states need these inventories to help in the development of control strategies and demonstrations to attain the Pb NAAQS. While the CERR sets forth requirements for data elements, EPA guidance complements these requirements and indicates how the data should be prepared for SIP submissions. Our regulations at 40 CFR 51.117(e) require states to include in the inventory all point sources that emit 5 or more tons of lead emissions per year. EPA is also considering whether revision to the recommended threshold for RACT analysis is appropriate in light of the proposed revision to the Pb NAAQS. In this proposed rulemaking we are taking comment on whether the recommended threshold for RACT analysis should be less than the current 5 tons/yr (see section VI.F.1). If EPA lowers the recommended threshold for RACT at the time of the final rulemaking, we propose also to revise, to be consistent, the emissions threshold for including sources in the inventory pursuant to 40 CFR 51.117. We solicit comment on the appropriate threshold for Pb point source inventory reporting requirements.

The SIP inventory must be approved by EPA as a SIP element and is subject to public hearing requirements, whereas the CERR is not. Because of the regulatory significance of the SIP inventory, EPA will need more documentation on how the SIP inventory was developed by the State as opposed to the documentation required for the CERR inventory. In addition, the geographic area encompassed by some aspects of the SIP submission inventory will be different from the statewide area covered by the CERR emissions inventory.

The EPA has proposed the Air Emissions Reporting Rule (AERR) at 71 FR 69 (Jan. 3, 2006). When finalized, the AERR would update the CERR reporting requirements by consolidating and harmonizing new emissions reporting requirements with pre-existing sets of reporting requirements under the Clean Air Interstate Rule (CAIR) and the NO_X SIP Call. At this time, EPA expects to finalize the AERR rulemaking in the Fall of calendar year 2008. The AERR is expected to be a means by which the Agency will implement additional data reporting requirements for the Pb NAAQS SIP emission inventories.

7. Modeling

The lead SIP regulations found at 40 CFR 51.117 require states to employ atmospheric dispersion modeling for the demonstration of attainment for areas in

the vicinity of point sources listed in 40 CFR 51.117(a)(1). To complete the necessary dispersion modeling, meteorological, and other data are necessary. Dispersion modeling should follow the procedures outlined in EPA's latest guidance document entitled ''Guideline on Air Quality Models''. This guideline indicates the types and historical records for data necessary for modeling demonstrations (e.g., on-site meteorological stations are used, 12 months of data are required in order to demonstrate attainment for the affected area).

G. General Conformity

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 *et seq.*), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. Section 176(c) of the CAA requires EPA to promulgate criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. For the purpose of summarizing the general conformity rule, it can be viewed as containing three major parts: applicability, procedure, and analysis. These are briefly described below.

The general conformity rule covers direct and indirect emissions of criteria pollutants or their precursors that are caused by a Federal action, are reasonably foreseeable, and can practicably be controlled by the Federal agency through its continuing program responsibility. The general conformity rule generally applies to Federal actions except: (1) Actions covered by the transportation conformity rule; (2) Actions with respect to associated emissions below specified de minimis levels; and (3) Certain other actions that are exempt or presumed to conform.

The general conformity rule also establishes procedural requirements. Federal agencies must make their conformity determinations available for public review. Notice of draft and final general conformity determinations must be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. Each Federal agency must determine that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment and maintenance areas with respect to the criteria pollutants under the CAA: [173] carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter ($P_{M-2.5}$ and PM_{10}), and sulfur dioxide (SO_2). The general conformity rule establishes procedural requirements for Federal agencies for actions related to all NAAQS pollutants, both nonattainment and maintenance areas and will apply one year following the promulgation of designations for any new or revised Pb NAAQS.[174]

H. Transition From the Current NAAQS to a Revised NAAQS for Lead

EPA is proposing to revise the level of the Pb NAAQS significantly, as well as changing the indicator and averaging time. The EPA believes that Congress's intent, as evidenced by section 110(l), 193, and section 172(e) of the CAA, was to ensure that continuous progress, in terms of public health protection, takes place in transitioning from a current NAAQS for a pollutant to a new or revised NAAQS. Therefore, in this section, EPA is proposing that the existing NAAQS will be revoked one year following the promulgation of designations for any new NAAQS, except that the existing NAAQS will not be revoked for any current nonattainment area until the affected area submits, and EPA approves, an attainment demonstration which addresses the attainment of the new Pb NAAQS.

The CAA contains a number of provisions that indicate Congress's intent to not allow states to alter or remove provisions from implementation plans if the plan revision would jeopardize the air quality protection being provided by the plan. For example, section 110(l) provides that EPA may not approve a SIP revision if it interferes with any applicable requirement concerning attainment and RFP, or any other applicable requirement under the CAA. In addition section 193 of the CAA prohibits the modification of a control, or a control requirement, in effect or required to be adopted as of November 15, 1990 (i.e., following the promulgation of the Clean Air Act Amendments (CAAA) of 1990), unless such a modification would ensure equivalent or greater emissions reductions. One other provision of the CAA provides additional insight into Congress's intent related to the need to continue progress towards meeting air quality standards during periods of transition from one standard to another. Section 172(e) of the CAA, related to future modifications of a standard, applies when EPA promulgates a new or revised NAAQS and makes it less stringent than the previous NAAQS. This provision of the CAA specifies that in such circumstances, States may not relax control obligations that apply in nonattainment area SIPs, or avoid adopting those controls that have not yet been adopted as required.

Because it is EPA's belief that Congress did not intend to permit states to remove control measures when EPA revises a standard until the new or revised standard is implemented, we believe that controls that are required under the current Pb NAAQS, or that are currently in place under the current Pb NAAQS, should remain in place until designations are promulgated and, for current nonattainment areas, attainment SIPs are approved for any new or revised standard. As a result, EPA is proposing that the current Pb NAAQS should stay in place for one year following the effective date of designations for any new or revised NAAQS before being revoked, except in current nonattainment areas, where the existing NAAQS will not be revoked until the affected area submits, and EPA approves, an attainment demonstration for the revised Pb NAAQS. Pursuant to CAA section 110(l), any proposed SIP revision being considered by EPA after the effective date of the revised Pb NAAQs would be evaluated for its potential to interfere with attainment or maintenance of the new standard. Unlike the transition from the 1-hour ozone standard to the 8-hour ozone standard, EPA believes that any area attaining the revised Pb NAAQS would also attain the existing Pb NAAQS, and thus reviewing proposed SIP revisions for interference with the new standard will be sufficient to prevent backsliding. Consequently, in light of the nature of the proposed revision of the Pb NAAQS, the lack of classifications (and mandatory controls associated with such classifications pursuant to the CAA), and the small number of nonattainment areas, EPA believes that retaining the current standard for a limited period of time until attainment SIPs are approved for the new standard

[173] Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

[174] Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that federally supported highway and transit project activities are consistent with (''conform to'') the purpose of the SIP. Transportation conformity applies to areas that are designated nonattainment, and those areas redesignated to attainment after 1990 (''maintenance areas'' with plans developed under CAA section 175A) for transportation-related criteria pollutants. In light of the elimination of Pb additives from gasoline transportation conformity does not apply to the Pb NAAQS.

in current nonattainment areas, or one year after designations in other areas, will adequately serve the anti-backsliding goals of the CAA. The EPA requests comment on this proposed approach for transitioning to the proposed revised Pb NAAQS.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–OAR–2006–0735). In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. A copy of the analysis is available in the RIA docket (EPA–HQ–OAR–2008–0253) and the analysis is briefly summarized here. The RIA estimates the costs and monetized human health and welfare benefits of attaining four alternative Pb NAAQS nationwide. Specifically, the RIA examines the alternatives of 0.30 $\mu g/m^3$, 0.20 $\mu g/m^3$, 0.10 $\mu g/m^3$ and 0.05 $\mu g/m^3$. The RIA contains illustrative analyses that consider a limited number of emissions control scenarios that States and Regional Planning Organizations might implement to achieve these alternative Pb NAAQS. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing this proposed rule.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA for these proposed revisions to part 58 has been assigned EPA ICR numbers 0940.21.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). While this proposed rule amends the requirements for Pb FRM and FEM determinations, they merely provide additional flexibility in meeting the FRM/FEM determination requirements. Furthermore, we do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with Pb FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0559.12). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystem impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for Pb monitoring sites, require the siting and operation of additional Pb ambient air monitors, and the reporting of the collected ambient Pb monitoring data to EPA's Air Quality System (AQS). Because this rulemaking includes a range of proposals for the level and averaging time, it is not possible accurately predict the size of the final network, and its associated burden. Rather we have estimated the upper range of burden possible based on the regulatory options being proposed which would result in a higher reporting burden (i.e., a final level for the standard of 0.1 $\mu g/m^3$ with a 2nd maximum monthly averaging form). Based on these assumptions, the annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) for 150 respondents is estimated to increase by a total of 90,434 labor hours per year with an increase of $6,599,653 per year. Burden is defined at 5 CFR 1320.3(b). State, local, and tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

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.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2006–0735. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after May 20, 2008, a comment to OMB is best assured of having its full effect if OMB receives it by June 19, 2008. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any

requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of Pb in ambient air as required by section 109 of the CAA. *American Trucking Ass'ns* v. *EPA,* 175 F. 3d 1027, 1044–45 (D.C. cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the proposed amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Unless otherwise prohibited by law, under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is required under section 202, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to 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 why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The revisions to the Pb NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the increased monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed $100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the Pb NAAQS.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the Pb NAAQS. In this proposed rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

However, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to

ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS. Thus, Executive Order 13175 does not apply to this rule. However, EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

This action is subject to Executive Order (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The proposed rule will establish uniform national ambient air quality standards for Pb; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because neurological effects in children are among if not the most sensitive health endpoints for Pb exposure. Because children are considered a sensitive population, we have carefully evaluated the environmental health effects of exposure to Pb pollution among children. These effects and the size of the population affected are summarized in chapters 6 and 8 of the Criteria Document and sections 3.3 and 3.4 of the Staff Paper, and the results of our evaluation of the effects of Pb pollution on children are discussed in sections II.B and II.C of this preamble.

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. The purpose of this rule is to establish revised NAAQS for Pb. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards 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 proposed rulemaking involves technical standards. EPA proposes to use low-volume PM_{10} samplers coupled with XRF analysis as the FRM for Pb-PM_{10} measurement. While EPA identified the ISO standard ''Determination of the particulate lead content of aerosols collected on filters'' (ISO 9855: 1993) as being potentially applicable, we do not propose to use it in this rule. The use of this voluntary consensus standard would be impractical because the analysis method does not provide for the method detection limits necessary to adequately characterize ambient Pb concentrations for the purpose of determining compliance with the proposed revisions to the Pb NAAQS.

EPA welcomes comments on this aspect of the proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The proposed rule will establish uniform national standards for Pb in ambient air.

EPA is continuing to assess the impact of Pb air pollution on minority and low-income populations, and plans to prepare a technical memo as part of its assessment to be placed in the docket by the date of publication of this proposed rule in the **Federal Register**. EPA solicits comment on environmental justice issues related to the proposed revision of the Pb NAAQS.

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List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 53

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: May 1, 2008.

Stephen L. Johnson,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for particulate matter (PM2.5) standards contained in §§ 50.7 and 50.13 and lead standards contained in § 50.16 shall be corrected to a reference temperature of 25 (deg) C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of $PM_{2.5}$ for purposes of comparison to the standards contained in §§ 50.7 and 50.13 and of lead for purposes of comparison to the standards contained in § 50.16 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

3. Section 50.12 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 50.12 National primary and secondary ambient air quality standards for lead.

* * * * *

(b) The standards set forth in this section will remain applicable to all areas notwithstanding the promulgation of lead national ambient air quality standards (NAAQS) in § 50.16. The lead NAAQS set forth in this section will no longer apply to an area one year after the effective date of the designation of that area, pursuant to section 107 of the Clean Air Act, for the lead NAAQS set forth in § 50.16; except that for areas designated nonattainment for the lead NAAQS set forth in this section as of the effective date of § 50.16, the lead NAAQS set forth in this section will apply until that area submits, pursuant to section 191 of the Clean Air Act, and EPA approves, an implementation plan providing for attainment of the lead NAAQS set forth in § 50.16.

4. Section 50.14 is amended by:

(a) Revising paragraph (a)(2);

(b) Revising paragraph (c)(2)(iii);

(c) Redesignating paragraph (c)(2)(v) as paragraph (c)(2)(vi) and adding a new paragraph (c)(2)(v); and

(d) Redesignating existing paragraphs (c)(3)(iii) and (c)(3)(iv) as paragraphs (c)(3)(iv) and (c)(3)(v), respectively, and adding paragraph (c)(3)(iii).

The additions and revisions read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(a) * * *

* * * * *

(2) Demonstration to justify data exclusion may include any reliable and accurate data, but must demonstrate a clear causal relationship between the measured exceedance or violation of such standard and the event in accordance with paragraph (c)(3)(iv) of this section.

(c) * * *

(2) * * *

(iii) Flags placed on data as being due to an exceptional event together with an initial description of the event shall be submitted to EPA not later than July 1st of the calendar year following the year in which the flagged measurement occurred, except as allowed under paragraph (c)(2)(iv) or (c)(2)(v) of this section.

* * * * *

(v) For lead (Pb) data collected during calendar years 2006–2008, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2009. For Pb data collected during calendar year 2009, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than July 1, 2010. For Pb data collected during calendar year 2010, that the State identifies as resulting from an exceptional event, the State must notify EPA of the flag and submit an initial description of the event no later than May 1, 2011.

* * * * *

(3) * * *

(iii) A State that flags Pb data collected during calendar years 2006–2009, pursuant to paragraph (c)(2)(v) of this section shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify exclusion of the data not later than September 15, 2010. A State that flags Pb data collected during calendar year 2010 shall, after notice and opportunity for public comment, submit to EPA a demonstration to justify the exclusion of the data not later than May 1, 2011. A state must submit the public comments it received along with its demonstration to EPA.

* * * * *

5. Section 50.16 is added to read as follows:

§ 50.16 National primary and secondary ambient air quality standards for lead.

(a) The national primary and secondary ambient air quality standards for lead (Pb) and its compounds is [0.10–0.30] micrograms per cubic meter (μ/m^3), [arithmetic mean concentration averaged over a calendar quarter or second highest arithmetic mean concentration averaged over a calendar month] measured in the ambient air as Pb either by:

(1) A reference method based on (Appendix G or Appendix Q of this part) and designated in accordance with part 53 of this chapter; or

(2) An equivalent method designated in accordance with part 53 of this chapter.

(b) The national primary and secondary ambient air quality standards for Pb are met when the [quarterly or second highest monthly] arithmetic mean concentration, as determined in accordance with Appendix R of this part, is less than or equal to [0.10–0.30] micrograms per cubic meter.

6. Appendix G is amended as follows:

a. In section 10.2 the definition of the term ''V_{STP}'' in the equation is revised; and

b. In section 14 reference 10 is added and reference 15 is revised.

Appendix G to Part 50—Reference Method for the Determination of Lead in Suspended Particulate Matter Collected From Ambient Air

* * * * *

10.2 * * *

V_{STP}= Air volume from section 10.1.

* * * * *

14. * * *

10. Intersociety Committee (1972). Methods of Air Sampling and Analysis. 1015 Eighteenth Street, NW., Washington, DC: American Public Health Association. 365–372.

* * *

15. Sharon J. Long, et. al., ''Lead Analysis of Ambient Air Particulates: Interlaboratory Evaluation of EPA Lead Reference Method,'' APCA Journal, 29, 28–31 (1979).

* * * * *

7. Appendix Q is added to read as follows:

Appendix Q to Part 50—Reference Method for the Determination of Lead in Particulate Matter as PM_{10} Collected From Ambient Air

This Federal Reference Method (FRM) draws heavily from the specific analytical protocols used by the U.S. EPA.

1. Applicability and Principle

1.1 This method provides for the measurement of the lead (Pb) concentration in particulate matter that is 10 micrometers or less (PM_{10}) in ambient air. PM_{10} is collected on a 46.2 mm diameter polytetrafluoroethylene (PTFE) filter for 24 hours using active sampling at local conditions with a low-volume air sampler. The low-volume sampler has an average flow rate of 16.7 liters per minute (Lpm) and total sampled volume of 24 cubic meters (m^3) of air. The analysis of Pb in PM_{10} is performed on each individual 24-hour sample. For the purpose of this method, PM_{10} is defined as particulate matter having an aerodynamic

diameter in the nominal range of 10 micrometers (10 μm) or less.

1.2 For this reference method, PM_{10} shall be collected with the PM_{10c} federal reference method (FRM) sampler as described in Appendix O to Part 50 using the same sample period, measurement procedures, and requirements specified in Appendix L of Part 50. The PM_{10c} sampler is also being used for measurement $PM_{10-2.5}$ mass by difference and as such, the PM_{10c} sampler must also meet all of the performance requirements specified for $PM_{2.5}$ in Appendix L. The concentration of Pb in the atmosphere is determined in the total volume of air sampled and expressed in micrograms per cubic meter (μg/m³) at local temperature and pressure conditions.

1.3 The FRM will serve as the basis for approving Federal Equivalent Methods (FEMs) as specified in 40 CFR part 53 (Reference and Equivalent Methods).

1.4 An electrically powered air sampler for PM_{10c} draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator, where the suspended particulate matter in the PM_{10} size range is separated for collection on a PTFE filter over the specified sampling period. The lead content of the PM_{10c} sample is analyzed by energy-dispersive X-ray fluorescence spectrometry (EDXRF). Energy-dispersive X-ray fluorescence spectrometry provides a means for identification of an element by measurement of its characteristic X-ray emission energy. The method allows for quantification of the element by measuring the emitted characteristic line intensity and then relating this intensity to the elemental concentration. The number or intensity of X-rays produced at a given energy provides a measure of the amount of the element present by comparisons with calibration standards. The X-rays are detected and the spectral signals are acquired and processed with a personal computer. EDXRF is commonly used as a non-destructive method for quantifying trace elements in PM. An EPA method for the EDXRF analysis of ambient particulate matter is described in reference 1 of section 8. A detailed explanation of quantitative X-ray spectrometry is described in references 2 and 3.

1.5 *Quality assurance* (QA) procedures for the collection of monitoring data are contained in Part 58, Appendix A.

2. *PM_{10c} Lead Measurement Range and Method Detection Limit.* The values given below in section 2.1 and 2.2 are typical of the method capabilities. Absolute values will vary for individual situations depending on the instrument, detector age, and operating conditions used. Data are typically reported in ng/m³ for ambient air samples; however, for this reference method, data will be reported in μg/m³ at local temperature and pressure conditions.

2.1 *EDXRF Measurement Range.* The typical ambient air measurement range is 0.001 to 30 μg Pb/m³, assuming an upper range calibration standard of about 60 μg Pb per square centimeter (cm²), a filter deposit area of 11.86 cm², and an air volume of 24-m³. The top range of the EDXRF instrument is much greater than what is stated here. The top measurement range of quantification is defined by the level of the high concentration calibration standard used and can be increased to expand the measurement range as needed.

2.2 *Method Detection Limit (MDL).* A typical one-sigma estimate of the method detection limit (MDL) is about 1.5 ng Pb/cm² or 0.001 μg Pb/m³, assuming a filter size of 46.2-mm (filter deposit area of 11.86 cm²) and a sample air volume of 24-m³. The MDL is an estimate of the lowest amount of lead that can be detected by the analytical instrument. The one-sigma detection limit for Pb is calculated as the average overall uncertainty or propagated error for Pb, determined from measurements on a series of blank filters. The sources of random error which are considered are calibration uncertainty; system stability; peak and background counting statistics; uncertainty in attenuation corrections; uncertainty in peak overlap corrections; and uncertainty in flow rate, but the dominating source is by far peak and background counting statistics. Laboratories are to estimate the MDLs using 40 CFR Part 136, Appendix B, ''Definition and Procedure for the Determination of the Method Detection Limit.'' (Reference 4).

3. Factors Affecting Bias and Precision of Lead Determination by EDXRF

3.1 *Filter Deposit.* Too much deposit material can be problematic because XRF analysis and data processing programs for aerosol samples are designed specifically for a thin film or thin layer of material to be analyzed. The X-ray spectra are subject to distortion if unusually heavy deposits are analyzed. This is the result of internal absorption of both primary and secondary X-rays within the sample. The optimum filter loading is about 150 μg/cm² or 1.6 mg/filter for a 46.2-mm filter. Too little deposit material can also be problematic due to low counting statistics and signal noise. The particle mass deposit should minimally be 15 μg/cm². A properly collected sample will have a uniform deposit over the entire collection area. Sample heterogeneity can lead to very large systematic errors. Samples with physical deformities (including a visually non-uniform deposit area) should not be quantitatively analyzed.

3.2 *Spectral Interferences and Spectral Overlap.* Spectral interference occurs when the entirety of the analyte spectral lines of two species are nearly 100% overlapped. There are only a few cases where this may occur and they are instrument specific: Si/Rb, Si/Ta, S/Mo, S/Tl, Al/Br, Al/Tm. These interferences are determined during instrument calibration and automatically corrected for by the XRF instrument software. Interferences need to be addressed when multi-elemental analysis is performed. The presence of arsenic (As) is a problematic interference for EDXRF systems which use the Pb Lα line exclusively to quantify the Pb concentration. This is because the Pb Lα line and the As Kα lines severely overlap. However, if the instrument software is able to use multiple Pb lines, including the Lβ and/or the Lγ lines for quantification, then the uncertainty in the Pb determination in the presence of As can be significantly reduced. There can be instances when lines partially overlap the Pb spectral lines, but with the energy resolution of most detectors, these overlaps are typically de-convoluted using standard spectral de-convolution software provided by the instrument vendor. An EDXRF protocol for Pb must define which Pb lines are used for quantification and where spectral overlaps occur. Some of the overlaps may be very small and some severe. A de-convolution protocol must be used to separate all the lines which overlap with Pb.

3.3 *Particle Size Effects and Attenuation Correction Factors.* X-ray attenuation is dependent on the X-ray energy, mass sample loading, composition, and particle size. In some cases, the excitation and fluorescent X-rays are attenuated as they pass through the sample. In order to relate the measured intensity of the X-rays to the thin-film calibration standards used, the magnitude of any attenuation present must be corrected for. The effect is especially significant and more complex for PM_{10} measurements, especially for the lighter elements that may also be measured. An average attenuation and uncertainty for each coarse particle element is based on a broad range of mineral compositions and is a one-time calculation that gives an attenuation factor for use in all subsequent particle analyses. See references 6, 7, and 8 of section 8 for more discussion on addressing this issue. Essentially no attenuation corrections are necessary for Pb in PM_{10}: both the incoming excitation X-rays used for analyzing lead and the fluoresced Pb X-rays are sufficiently energetic that for particles in this size range and for normal filter loadings, the Pb x-ray yield is not significantly impacted by attenuation. However, this issue must be addressed when doing multi-element analyses.

4. Precision

4.1 Measurement system precision is assessed according to the procedures set forth in Appendix A to part 58. Measurement method precision is assessed from collocated sampling and analysis. The goal for acceptable measurement uncertainty, as precision, is defined as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent.

5. Bias

5.1 Measurement system bias for monitoring data is assessed according to the procedures set forth in Appendix A of part 58. The bias is assessed through an audit using spiked filters. The goal for measurement bias is defined as an upper 95 percent confidence limit for the absolute bias of 10 percent.

6. Measurement of PTFE Filters by EDXRF

6.1 Sampling

6.1.1 *Low-Volume PM_{10c} Sampler.* The low-volume PM_{10c} sampler shall be used for sample collection and operated in accordance with the performance specifications described in Part 50, Appendix L.

6.1.2 *PTFE Filters and Filter Acceptance Testing.* The PTFE filters used for PM_{10c} sample collection shall meet the specifications provided in Part 50, Appendix L. The following requirements are similar to those currently specified for the acceptance of $PM_{2.5}$ filters that are tested for trace

elements by EDXRF. For large batches of filters (greater than 500 filters) randomly select 50 filters from a given batch. For small batches (less than 500 filters) a lesser number of filters may be taken. Analyze each filter separately and calculate the average lead concentration in ng/cm^2. Ninety percent, or 45 of the 50 filters, must have an average lead concentration that is less than 4.8 ng Pb/cm^2.

6.2 *Analysis.* The four main categories of random and systematic error encountered in X-ray fluorescence analysis include errors from sample collection, the X-ray source, the counting process, and inter-element effects. These errors are addressed through the calibration process and mathematical corrections in the instrument software.

6.2.1 *EDXRF Analysis Instrument.* An energy-dispersive XRF system is used. Energy-dispersive XRF systems are available from a number of commercial vendors including Thermo (*www.thermo.com*) and PANalytical (*www.panalytical.com*). Note the mention of commercial products does not imply endorsement by the U.S. Environmental Protection Agency. The analysis is performed at room temperature in either vacuum or in a helium atmosphere. The specific details of the corrections and calibration algorithms are typically included in commercial analytical instrument software routines for automated spectral acquisition and processing and vary by manufacturer. It is important for the analyst to understand the correction procedures and algorithms of the particular system used, to ensure that the necessary corrections are applied.

6.2.2 *Thin film standards.* Thin film standards are used for calibration because they most closely resemble the layer of particles on a filter. Thin films standards are typically deposited on Nuclepore substrates. The preparation of thin film standards is discussed in reference 6, and 9. Thin film standards are commercially available from MicroMatter Inc. (Arlington, WA).[1]

6.2.3 *Filter Preparation.* Filters used for sample collection are 46.2-mm PTFE filters with a pore size of 2 microns and filter deposit area 11.86 cm^2. Filters are typically archived in cold storage prior to analysis. Filters that are scheduled for XRF analysis are removed from storage and allowed to reach room temperature. All filter samples received for analysis are checked for any holes, tears, or a non-uniform deposit which would prevent quantitative analysis. A properly collected sample will have a uniform deposit over the entire collection area. Samples with physical deformities are not quantitatively analyzable. The filters are carefully removed with tweezers from the Petri dish and securely placed into the instrument-specific sampler holder for analysis. Care must be taken to protect filters to avoid contamination prior to analysis. Filters must be kept covered when not being analyzed. No other preparation of the samples is required.

6.2.4 *Calibration.* In general, calibration determines each element's sensitivity, *i.e.*, its response in X-ray counts/sec to each µg/cm^2 of a standard and an interference coefficient for each element that causes interference with another one (See section 3.2 above). The sensitivity can be determined by a linear plot of count rate versus concentration (µg/cm^2) in which the slope is the instrument's sensitivity for that element. A more precise way, which requires fewer standards, is to fit sensitivity versus atomic number. Calibration is a complex task in the operation of an XRF system. Two major functions accomplished by calibration are the production of reference spectra which are used for fitting and the determination of the elemental sensitivities. Included in the reference spectra (referred to as ''shapes'') are background-subtracted peak shapes of the elements to be analyzed, as well as peak shapes for interfering element energies and spectral backgrounds. Pure element thin film standards are used for the element peak shapes and clean filter blanks from the same lot as unknowns are used for the background. The analysis of PM filter deposits is based on the assumption that the thickness of the deposit is small with respect to the characteristic lead X-ray transmission thickness. Therefore, the concentration of lead in a sample is determined by first calibrating the spectrometer with thin film standards to determine sensitivity factors and then analyzing the unknown samples under identical excitation conditions as used to determine the calibration factors. Calibration is performed only when significant repairs occur or when a change in fluorescers, X-ray tubes, or detector is made. Calibration establishes the elemental sensitivity factors and the magnitude of interference or overlap coefficients. See reference 7 for more detailed discussion of calibration and analysis of shapes standards for background correction, coarse particle absorption corrections, and spectral overlap.

6.2.4.1 *Spectral Peak Fitting.* The EPA uses a library of pure element peak shapes (shape standards) to extract the elemental background-free peak areas from an unknown spectrum. It is also possible to fit spectra using peak stripping or analytically defined functions such as modified Gaussian functions. The EPA shape standards are generated from pure, mono-elemental thin film standards. The shape standards are acquired for sufficiently long times to provide a large number of counts in the peaks of interest. It is not necessary for the concentration of the standard to be known. A slight contaminant in the region of interest in a shape standard can have a significant and serious effect on the ability of the least squares fitting algorithm to fit the shapes to the unknown spectrum. It is these elemental shapes, that are fitted to the peaks in an unknown sample during spectral processing by the analyzer. In addition to this library of elemental shapes, there is also a background shape spectrum for the filter type used as discussed below in section 6.2.4.2 of this section.

6.2.4.2 *Background Measurement and Correction.* A background spectrum generated by the filter itself must be subtracted from the X-ray spectrum prior to extracting peak areas. The background shape standards which are used for background fitting are created at the time of calibration. About 20–30 clean blank filters are kept in a sealed container and are used exclusively for background measurement and correction. The spectra acquired on individual blank filters are added together to produce a single spectrum for each of the secondary targets or fluorescers used in the analysis of lead. Individual blank filter spectra which show contamination are excluded from the summed spectra. The summed spectra are fitted to the appropriate background during spectral processing. Background correction is automatically included during spectral processing of each sample.

7. Calculation.

7.1 The PM_{10} lead concentration in the atmosphere (µg/m^3) is calculated using the following equation:

$$M_{Pb} = \frac{C_{Pb} \times A}{V_{LC}}$$

Where,

M_{Pb} is the mass per unit volume for lead in µg/m^3;

C_{Pb} is the mass per unit area for lead in µg/cm^2 as provided by the XRF instrument software;

A is the filter deposit area in cm^2;

V_{LC} is the total volume of air sampled by the PM_{10c} sampler in actual volume units measured at local conditions of temperature and pressure, as provided by the sampler in m^3.

8. References

1. Inorganic Compendium Method IO–3.3; Determination of Metals in Ambient Particulate Matter Using X–Ray Fluorescence (XRF) Spectroscopy; U.S. Environmental Protection Agency, Cincinnati, OH 45268. EPA/625/R–96/010a. June 1999.

2. Jenkins, R., Gould, R.W., and Gedcke, D. Quantitative X-ray Spectrometry: Second Edition. Marcel Dekker, Inc., New York, NY. 1995.

3. Jenkins, R. X–Ray Fluorescence Spectrometry: Second Edition in Chemical Analysis, a Series of Monographs on Analytical Chemistry and Its Applications, Volume 152. Editor J.D.Winefordner; John Wiley & Sons, Inc. New York, NY. 1999.

4. Code of Federal Regulations (CFR) 40 part 136, Appendix B; Definition and Procedure for the Determination of the Method Detection Limit—Revision 1.11

5. Dzubay, T.G. X-ray Fluorescence Analysis of Environmental Samples, Ann Arbor Science Publishers Inc., 1977.

6. Drane, E.A, Rickel, D.G., and Courtney, W.J., ''Computer Code for Analysis X–Ray Fluorescence Spectra of Airborne Particulate Matter,'' in *Advances in X–Ray Analysis,* J.R. Rhodes, Ed., Plenum Publishing Corporation, New York, NY, p. 23 (1980).

7. Analysis of Energy-Dispersive X-ray Spectra of ambient Aerosols with Shapes Optimization, Guidance Document; TR–WDE–06–02; prepared under contract EP–D–05–065 for the U.S. Environmental Protection Agency, National Exposure Research Laboratory. March 2006.

8. Billiet, J., Dams, R., and Hoste, J. (1980) Multielement Thin Film Standards for XRF Analysis, X–Ray Spectrometry, 9(4): 206–211.

8. Appendix R is added to read as follows:

Appendix R to Part 50—Interpretation of the National Ambient Air Quality Standards for Lead

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary and secondary national ambient air quality standards (NAAQS) for lead (Pb) specified in § 50.16 are met. The NAAQS indicator for Pb is defined as: lead and its compounds, measured as elemental lead in total suspended particulate (Pb-TSP), sampled and analyzed by a Federal reference method (FRM) based on appendix G to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Although Pb-TSP is the lead NAAQS indicator, surrogate Pb-TSP concentrations shall also be used for NAAQS comparisons; specifically, valid surrogate Pb-TSP data are concentration data for lead and its compounds, measured as elemental lead, in particles with an aerodynamic size of 10 microns or less ($Pb\text{-}PM_{10}$), sampled and analyzed by an FRM based on appendix Q to this part or by an FEM designated in accordance with part 53 of this chapter, the resulting concentrations then multiplied by an appropriate site-specific scaling factor to represent Pb-TSP. Data handling and computation procedures to be used in making comparisons between reported and/or surrogate Pb-TSP concentrations and the level of the Pb NAAQS, including $Pb\text{-}PM_{10}$ to Pb-TSP scaling instructions, are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in §§ 50.1, 50.14, and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual monitoring plan refers to the plan required by section 58.10 of this chapter.

Creditable samples are samples that are given credit for data completeness. They include valid samples collected on required sampling days and valid ''make-up'' samples taken for missed or invalidated samples on required sampling days.

Daily values for Pb refers to the 24-hour mean concentrations of Pb (Pb-TSP or $Pb\text{-}PM_{10}$) measured from midnight to midnight (local standard time) that are used in NAAQS computations.

Design value is the site-level metric (i.e., statistic) that is compared to the NAAQS level to determine compliance; the design value for the Pb NAAQS is the second highest monthly mean Pb-TSP or surrogate Pb-TSP concentration for the most recent valid 3-year calendar period.

Extra samples are non-creditable samples. They are daily values that do not occur on scheduled sampling days and that can not be used as make-ups for missed or invalidated scheduled samples. Extra samples are used in mean calculations. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and $Pb\text{-}PM_{10}$ data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Make-up samples are samples taken to supplant missed or invalidated required scheduled samples. Make-ups can be made by either the primary or collocated (same size cut) instruments. Make-up samples are either taken before the next required sampling day or exactly one week after the missed (or voided) sampling day. Make-up samples can not span years; that is, if a scheduled sample for December is missed (or voided), it can not be made up in January. Make-up samples, however, may span months, for example a missed sample on January 31 may be made up on February 1, 2, or 6. Section 3(e) explains how such month-spanning make-up samples are to be treated for purposes of data completeness and monthly means. Only two make-up samples are permitted each calendar month; these are counted according to the month in which the miss and not the makeup occurred Also, to be considered a valid make-up, the sampling must be conducted with equipment and procedures that meet the requirements for scheduled sampling. For purposes of determining whether a sample must be treated as a make-up sample or an extra sample, Pb-TSP and $Pb\text{-}PM_{10}$ data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

Monthly mean refers to an arithmetic mean, as defined in section 4.3 of this appendix. Monthly means are one of two specific types, ''monthly parameter means'' or ''monthly site means''. Monthly means are computed at each monitoring site separately for Pb-TSP and $Pb\text{-}PM_{10}$ (i.e., by site-parameter-year-month); these parameter-specific means are referred to as monthly parameter means. Monthly parameter means are validated according to the criteria stated in section 4 of this appendix. A ''monthly site mean'' (i.e., one for a site-year-month level) will be the valid monthly Pb-TSP mean if available, or the valid $Pb\text{-}PM_{10}$ (scaled) monthly mean when it is available and a valid Pb-TSP monthly mean is not. If neither a valid Pb-TSP nor a valid $Pb\text{-}PM_{10}$ monthly (parameter) mean exists for a particular site-year-month then there will be no corresponding valid monthly site mean.

Parameter refers either to Pb-TSP or to $Pb\text{-}PM_{10}$.

Scheduled sampling day means a day on which sampling is scheduled based on the required sampling frequency for the monitoring site, as provided in section 58.12 of this chapter.

Year refers to a calendar year.

2. Monitoring Considerations for Use of Scaled $Pb\text{-}PM_{10}$ Data as Surrogate Pb-TSP Data

(a) Monitoring agencies are permitted to monitor for $Pb\text{-}PM_{10}$ at a required Pb monitoring site rather than monitoring for Pb-TSP, but only after the monitoring agency develops, and the Regional Administrator approves, a site-specific scaling factor to be used to adjust $Pb\text{-}PM_{10}$ data before comparison to the standard. The development of such a factor must meet the criteria stated below (in sections 2(b)(i) through 2(b)(iv)), and the factor and associated analysis must be documented in the monitoring agency's Annual Monitoring Network Plan. The site-specific scaling factor meeting all of these requirements shall take effect on January 1 following Regional Administrator approval of the Plan. The data criteria for establishing a site-specific alternative $Pb\text{-}PM_{10}$ to Pb-TSP scaling factor are:

(i) A scaling factor shall be based on a minimum of 12 consecutive months of collocated Pb-TSP and $Pb\text{-}PM_{10}$ FRM/FEM monitoring which produces at least 6 pairs of valid collocated measurements for each of at least 10 months of each period of 12 months.

(ii) Calculated Pearson correlation coefficients for the paired data shall equal or exceed 0.60 for each individual month of the evaluation period (for months containing at least 6 pairs), and a calculated overall (using all 10 or more months with at least 6 pairs of valid collocated measurements) Pearson correlation coefficient shall equal or exceed 0.80.

(iii) The site-specific scaling factor shall be equal to the mean of the ratios of monthly mean Pb-TSP concentration to monthly mean $Pb\text{-}PM_{10}$ concentration, using all 10 or more months with at least 6 pairs of valid collocated measurements and only using the days with valid collocated measurements. The scaling factor shall be rounded to two decimal places.

(iv) Each monthly ratio of Pb-TSP to $Pb\text{-}PM_{10}$ shall be within twenty percent of the 10-month (or more) mean ratio. Ratios shall be computed from unrounded means but monthly ratios shall be rounded to two decimal places before making the comparison.

3. Requirements for Data Used for Comparisons With the Pb NAAQS and Data Reporting Considerations

(a) All valid FRM/FEM Pb-TSP data and all valid FRM/FEM $Pb\text{-}PM_{10}$ data submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Pb-TSP and $Pb\text{-}PM_{10}$ data representing sample collection periods prior to January 1, 2009 (i.e., ''pre-rule'' data) will also be considered valid for NAAQS comparisons and related attainment/nonattainment determinations if the sampling and analysis methods that were utilized to collect that data were consistent with previous or newly designated FRMs or FEMs and with either the provisions of part 58 of this chapter including appendices A, C, and E that were in effect at the time of original sampling or that are in effect at the time of the attainment/nonattainment determination, and if such data are submitted to AQS prior to September 1, 2009.

(b) Pb-TSP and $Pb\text{-}PM_{10}$ measurement data shall be reported to AQS in units of micrograms per cubic meter ($\mu g/m^3$) at local conditions (local temperature and pressure, LC) to three decimal places, with additional digits to the right being truncated. $Pb\text{-}PM_{10}$ data shall be reported without application of a scaling factor. Pre-rule Pb-TSP and $Pb\text{-}PM_{10}$ concentration data that were reported in standard conditions (standard temperature

and standard pressure, STP) will not require a conversion to local conditions but rather, after truncating to three decimal places and processing as stated in this appendix, shall compared ''as is'' to the NAAQS (i.e., the LC to STP conversion factor will be assumed to be one). However, if the monitoring agency has retroactively resubmitted Pb-TSP or Pb-PM_{10} pre-rule data converted from STP to LC based on suitable meteorological data, only the LC data will be used.

(c) At each monitoring location (site), Pb-TSP and Pb-PM_{10} data are to be processed separately when selecting daily data by day (as specified in 3(d) below) and when aggregating daily data by month (per 4(2)(a) below), however, when deriving the design value for the three-year period, monthly means for the two data types may be combined; see section 4(e) below.

(d) Daily values for sites will be selected for a site on a size cut (Pb-TSP or Pb-PM_{10}, i.e., ''parameter'') basis; Pb-TSP concentrations and Pb-PM_{10} concentrations shall not be commingled in these determinations. Site level, parameter-specific daily values will be selected as follows:

(i) The starting dataset for a site-parameter shall consist of the measured daily concentrations recorded from the designated primary FRM/FEM monitor for that parameter. The primary monitor for each parameter shall be designated in the appropriate State or local agency annual Monitoring Network Plan. If no primary monitor is designated, the Administrator will select which monitor to treat as primary. All daily values produced by the primary sampler are considered part of the site-parameter composite record (i.e., that site-parameter's set of daily values); this includes all creditable samples and all extra samples.

(ii) Data for the primary monitor for each parameter shall be augmented as much as possible with data from collocated (same parameter) FRM/FEM monitors. If a valid 24-hour measurement is not produced from the primary monitor for a particular day (scheduled or otherwise), but a valid sample is generated by a collocated (same parameter) FRM/FEM instrument, then that collocated value shall be considered part of the site-parameter data record (i.e., that site-parameter's monthly set of daily values). If more than one valid collocated FRM/FEM value is available, the mean of those valid collocated values shall be used as the daily value.

(e) All daily values in the composite site-parameter record are used in monthly mean calculations. However, not all daily values are given credit towards data completeness requirements. Only ''creditable'' samples are given credit for data completeness. Creditable samples include valid samples on scheduled sampling days and valid make-up samples. All other types of daily values are referred to as ''extra'' samples. Make-up samples taken in the (first week of the) month after the one in which the miss/void occurred will be credited for data capture in the month of the miss/void but will be included in the month actually taken when computing monthly means.

4. Comparisons With the Pb NAAQS

(a) The Pb NAAQS is met at a monitoring site when the identified design value is valid and less than or equal to 0.20 [0.10, 0.30] micrograms per cubic meter ($\mu g/m^3$). A Pb design value of 0.20 [0.10, 0.30] $\mu g/m^3$ or less is valid if it encompasses 3 consecutive calendar years of valid monthly means (i.e., 36 valid monthly means). See 4(c) below for the definition of a valid monthly mean and 6(c) below for the definition of the design value. A Pb design value of 0.20 [0.10, 0.30] $\mu g/m^3$ or less will also be considered valid if it encompasses 35 valid monthly means (out of 36 possible over 3 consecutive calendar years) and the highest of the 35 is equal to or less than 0.20 [0.10, 0.30] $\mu g/m^3$.

(b) The Pb NAAQS is violated at a monitoring site when the identified design value is valid and is greater than 0.20 [0.10, 0.30] micrograms per cubic meter ($\mu g/m^3$). A Pb design value greater than 0.20 [0.10, 0.30] $\mu g/m^3$ is valid if it encompasses at least two valid monthly means. A site does not have to have valid monitoring data for three full calendar years in order to have a valid violating design value. For example, a site could start monitoring in November of a given calendar year and violate the NAAQS for any three-year period that includes that given calendar year, if the November and December means are valid and greater than 0.20 [0.10, 0.30] $\mu g/m^3$.

(c) (i) A monthly mean is considered valid (i.e., meets data completeness requirements) if for one or both of the Pb parameters measured at the site, the data capture rate is greater than or equal to 75 percent. Monthly data capture rates (expressed as a percentage) are specifically calculated as the number of creditable samples for the month (including any make-up samples taken the subsequent month for missed samples in the (previous) month in question) divided by the number of scheduled samples for the month, the result then multiplied by 100 and rounded to the nearest integer. As noted above, Pb-TSP and Pb-PM_{10} daily values are processed separately when calculating monthly means and data capture rates; a Pb-TSP value cannot be used as a make-up for a missing Pb-PM_{10} value or vice versa. For purposes of assessing data capture, Pb-TSP and Pb-PM_{10} data collected before January 1, 2009 will be treated with an assumed scheduled sampling frequency of every sixth day.

(ii) A monthly parameter mean that does not have at least 75 percent data capture and thus cannot be considered valid under 4(c)(1) shall still be considered valid (and complete) if it passes either of the two following ''data substitution'' tests, one such test for validating an above NAAQS-level mean (using actual ''low'' reported values from the site), and the second test for validating a below-NAAQS level mean (using actual ''high'' values reported for the site). Note that both tests are merely diagnostic in nature, intending to confirm that there is a very high likelihood if not certainty that that original mean (the one with less than 75% data capture) reflects the true over/under NAAQS-level status for that month; the result of these data substitution tests (i.e., the test means, as described below) is never considered the actual monthly parameter mean and shall not be used to determine the design value. For both types of data substitution, substitution is permitted only if there are a sufficient number of available data points from which to identify the high or low 3-year month-specific values, specifically if there are at least 10 data points total from at least two of the three possible year-months. Data substitution may only use data of the same parameter type. For Pb-PM_{10} data, the ''test'' monthly mean after data substitution shall be scaled using Equation 2 of section 6(b) before being compared to the level of the standard.

(A) The ''above NAAQS level'' test is as follows: If by substituting the lowest reported daily value for that month over the 3-year design value period in question (year non-specific; *e.g.*, for January) for missing scheduled data in the deficient months (substituting only enough to meet the 75 percent data capture minimum), the computation yields a recalculated test monthly parameter mean concentration above the level of the standard, then the month is deemed to have passed the diagnostic test and the level of the standard is deemed to have been exceeded in that month. As noted above, in such a case, the monthly parameter mean of the data actually reported, not the recalculated (''test'') result including the low values, shall be used to determine the design value.

(B) The ''below NAAQS level'' test is as follows: A monthly parameter mean that does not have at least 75 percent data capture but does have at least 50 percent data capture shall still be considered valid (and complete) if, by substituting the highest reported daily value for that month over the 3-year design value period in question, for all missing scheduled data in the deficient months (i.e., bringing the data capture rate up to 100%), the computation yields a recalculated monthly parameter mean concentration equal or less than the level of the standard, then the month is deemed to have passed the diagnostic test and the level of the standard is deemed not to have been exceeded in that month. As noted above, in such a case, the monthly parameter mean of the data actually reported, not the recalculated (''test'') result including the high values, shall be used to determine the design value.

(d) Months that do not meet the completeness criteria stated in 4(c)(i) or 4(c)(ii) above, and design values that do not meet the completeness criteria stated in 4(a) or 4(b) above, may also be considered valid (and complete) with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The site-level design value for a three calendar year period is identified from the available valid monthly parameter means. In a situation where there are valid monthly means for both parameters (Pb-TSP and Pb-PM_{10}), the mean originating from the reported Pb-TSP data will be the one deemed the site-level monthly mean and used in design value identifications. A monitoring site will have only one site-level monthly

mean per month; however, the set of site-level monthly means considered for design value identification (i.e., two to 36 site-level monthly means) can be a combination of Pb-TSP and scaled Pb-PM_{10} data.

(f) The procedures for calculating monthly means, scaling Pb-PM_{10} monthly means to a surrogate Pb-TSP basis, and identifying Pb design values are given in section 6 of this appendix.

5. Rounding Conventions

(a) Monthly means shall be rounded to the nearest hundredth µg/m^3 (0.xx). Decimals 0.xx5 and greater are rounded up, and any decimal lower than 0.xx5 is rounded down; e.g., a monthly mean of 0.104925 rounds to 0.10, and a monthly mean of .10500 rounds to 0.11.

(b) Because a Pb design value is simply a (second highest) monthly mean and because the NAAQS level is stated to two decimal places, no additional rounding beyond what is specified for monthly means is required before a design value is compared to the NAAQS.

6. Procedures and Equations for the Pb NAAQS.

(a) A monthly mean value for Pb-TSP (or Pb-PM_{10}) is determined by averaging the daily values of a calendar month using equation 1 of this appendix:

Equation 1

$$\bar{X}_{m,y,s} = \frac{1}{n_m}\sum_{i=1}^{n_m} X_{i,m,y,s}$$

Where:

$\bar{X}_{m,y,s}$ = the mean for quarter q of the year y for site s; and

n_m = the number of daily values in the month; and

$X_{i,m,y,s}$ = the i^{th} value in month m for year y for site s.

(b) Monthly means for reported Pb-PM_{10} data are scaled to a surrogate Pb-TSP basis using Equation 2 of this appendix.

Equation 2

$$\bar{Z}_{m,y,s} = \bar{X}_{m,y,s} \times F_{m,y,s}$$

Where:

$\bar{Z}_{m,y,s}$ = the surrogate Pb-TSP mean for month m of the year y for site s; and

$\bar{X}_{m,y,s}$ = the Pb-PM_{10} mean for month m of the year y for site s; and

$F_{m,y,s}$ = the scaling factor for year y and for site s determined through collocated testing in accordance with section 2.0(b).

(c) The site-level identified Pb design value is the second highest valid site-level monthly mean over the most recent 3-year period. Section 4 above explains when the identified design value is itself considered valid for purposes of determining that the NAAQS is met or violated at a site.

PART 53—AMBIENT AIR MONITORING REFERENCE AND EQUIVALENT METHODS

9. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. sec. 1857g(a)), as amended by sec. 15(c)(2) of Pub. L. 91–604, 84 Stat. 1713, unless otherwise noted.

Subpart C—[Amended]

10. Section 53.33 is revised to read as follows:

§ 53.33 Test Procedure for Methods for Lead (Pb).

(a) *General.* The reference method for collection of Pb in TSP includes two parts, the reference method for high-volume sampling of TSP as specified in 40 CFR part 50, appendix B and the analysis method for Pb in TSP as specified in 40 CFR part 50, appendix G. Correspondingly, the reference method for Pb in PM_{10} includes the reference method for low-volume sampling of PM_{10} in 40 CFR part 50, appendix O and the analysis method of Pb in PM_{10} as specified in 40 CFR part 50, appendix Q. This section explains the procedures for demonstrating the equivalence of either a candidate method for Pb in TSP to the high-volume reference methods, or a candidate method for Pb in PM_{10} to the low-volume reference methods.

(1) Pb in TSP—A candidate method for Pb in TSP specifies reporting of Pb concentrations in terms of standard temperature and pressure. Comparisons of candidate methods to the reference method in 40 CFR part 50, appendix G must be made in a consistent manner with regard to temperature and pressure.

(2) Pb in PM_{10}—A candidate method for Pb in PM_{10} must specify reporting of Pb concentrations in terms of local conditions of temperature and pressure, which will be compared to similarly reported concentrations from the reference method in 40 CFR part 50, appendix Q.

(b) *Comparability.* Comparability is shown for Pb methods when the differences between:

(1) Measurements made by a candidate method, and

(2) Measurements made by the reference method on simultaneously collected Pb samples (or the same sample, if applicable), are less than or equal to the values specified in table C–3 of this subpart.

(c) *Test measurements.* Test measurements may be made at any number of test sites. Augmentation of pollutant concentrations is not permitted, hence an appropriate test site or sites must be selected to provide Pb concentrations in the specified range.

(d) *Collocated samplers.* The ambient air intake points of all the candidate and reference method collocated samplers shall be positioned at the same height above the ground level, and between 2 meters (1 meter for samplers with flow rates less than 200 liters per minute (L/min)) and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(e) *Sample collection.* Collect simultaneous 24-hour samples (filters) of Pb at the test site or sites with both the reference and candidate methods until at least 10 filter pairs have been obtained. A candidate method for Pb in TSP which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, appendix B, but uses a different analytical procedure than specified in 40 CFR part 50, appendix G, may be tested by analyzing pairs of filter strips taken from a single TSP reference sampler operated according to the procedures specified by that reference method. A candidate method for Pb in PM_{10} which employs a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method in 40 CFR part 50, appendix O, but uses a different analytical procedure than specified in 40 CFR part 50, appendix Q, requires the use of two PM_{10} reference samplers because a single 46.2-mm filter from a reference sampler may not be divided prior to analysis.

(f) *Audit samples.* Three audit samples must be obtained from the address given in § 53.4(a). For Pb in TSP collected by the high-volume sampling method, the audit samples are ¾ × 8-inch glass fiber strips containing known amounts of Pb in micrograms per strip (µg/strip) equivalent to the following nominal percentages of the National Ambient Air Quality Standard (NAAQS): 30%, 100%, and 250%. For Pb in PM_{10} collected by the low-volume sampling method, the audit samples are 46.2-mm polytetrafluorethylene (PTFE) filters containing known amounts of Pb in micrograms per filter (µg/filter) equivalent to the same percentages of the NAAQS: 30%, 100%, and 250%. The true amount of Pb (Tqi), in total µg/strip (for TSP) or total µg/filter (for PM_{10}), will be provided with each audit sample.

(g) *Filter analysis.*

(1) For both the reference method samples and the audit samples, analyze each filter or filter extract three times in accordance with the reference method analytical procedure. This applies to both the Pb in TSP and Pb in PM_{10} methods. The analysis of replicates

should not be performed sequentially, i.e., a single sample should not be analyzed three times in sequence. Calculate the indicated Pb concentrations for the reference method samples in micrograms per cubic meter (μg/m³) for each analysis of each filter. Calculate the indicated total Pb amount for the audit samples in μg/strip for each analysis of each strip or μg/filter for each analysis of each audit filter. Label these test results as R_{1A}, R_{1B}, R_{1C}, R_{2A}, R_{2B}, * * *, Q_{1A}, Q_{1B}, Q_{1C}, * * *, where R denotes results from the reference method samples; Q denotes results from the audit samples; 1, 2, 3 indicate the filter number, and A, B, C indicate the first, second, and third analysis of each filter, respectively.

(2) For the candidate method samples, analyze each sample filter or filter extract three times and calculate, in accordance with the candidate method, the indicated Pb concentration in μg/m³ for each analysis of each filter. The analysis of replicates should not be performed sequentially. Label these test results as C_{1A}, C_{1B}, C_{2C}, * * *, where C denotes results from the candidate method. For candidate methods which provide a direct measurement of Pb concentrations without a separable procedure, $C_{1A} = C_{1B} = C_{1C}$, $C_{2A} = C_{2B} = C_{2C}$, etc.

(h) *Average Pb concentration.* For the reference method, calculate the average Pb concentration for each filter by averaging the concentrations calculated from the three analyses as described in paragraph (g)(1) of this section using equation 1 of this section:

Equation 1

$$R_{iave} = \frac{(R_{iA} + R_{iB} + R_{iC})}{3}$$

Where, i is the filter number.

(i) *Accuracy.*

(1)(*i*) For the audit samples, calculate the average Pb concentration for each strip or filter by averaging the concentrations calculated from the three analyses as described in (g)(1) using equation 2 of this section:

Equation 2

$$Q_{iave} = \frac{(Q_{iA} + Q_{iB} + Q_{iC})}{3}$$

Where, i is audit sample number.

(*ii*) Calculate the percent difference (D_q) between the indicated Pb concentration for each audit sample and the true Pb concentration (T_q) using equation 3 of this section:

Equation 3

$$D_{qi} = \frac{Q_{iave} - T_{qi}}{T_{qi}} \times 100$$

(2) If any difference value (D_{qi}) exceeds ±5 percent, the accuracy of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source of the error(s) (e.g., calibration standard discrepancies, extraction problems, etc.) and the reference method and audit sample determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(j) *Acceptable filter pairs.* Disregard all filter pairs for which the Pb concentration, as determined in paragraph (h) of this section by the average of the three reference method determinations, falls outside the range of 30% to 250% of the Pb NAAQS level in μg/m³ for Pb in both TSP and PM_{10}. All remaining filter pairs must be subjected to the tests for precision and comparability in paragraphs (k) and (l) of this section. At least five filter pairs must be within the specified concentration range for the tests to be valid.

(k) *Test for precision.*

(1) Calculate the precision (P) of the analysis (in percent) for each filter and for each method, as the maximum minus the minimum divided by the average of the three concentration values, using equation 4 or equation 5 of this section:

Equation 4

$$P_{Ri} = \frac{R_{i\,max} - R_{i\,min}}{R_{iave}} \times 100$$

or

Equation 5

$$P_{Ci} = \frac{C_{i\,max} - C_{i\,min}}{C_{iave}} \times 100$$

where, i indicates the filter number.

(2) If any reference method precision value (P_{Ri}) exceeds 15 percent, the precision of the reference method analytical procedure is out-of-control. Corrective action must be taken to determine the source(s) of imprecision, and the reference method determinations must be repeated according to paragraph (g) of this section, or the entire test procedure (starting with paragraph (e) of this section) must be repeated.

(3) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the candidate method fails the precision test.

(4) The candidate method passes this test if all precision values (i.e., all P_{Ri}'s and all P_{Ci}'s) are less than 15 percent.

(l) *Test for comparability.* (1) For each filter or analytical sample pair, calculate all nine possible percent differences (D) between the reference and candidate methods, using all nine possible combinations of the three determinations (A, B, and C) for each method using equation 6 of this section:

Equation 6

$$D_{in} = \frac{C_{ij} - R_{jk}}{R_{jk}} \times 100$$

where, i is the filter number, and n numbers from 1 to 9 for the nine possible difference combinations for the three determinations for each method (j = A, B, C, candidate; k = A, B, C, reference).

(2) If none of the percent differences (D) exceeds ±20 percent, the candidate method passes the test for comparability.

(3) If one or more of the percent differences (D) exceed ±20 percent, the candidate method fails the test for comparability.

(4) The candidate method must pass both the precision test (paragraph (k) of this section) and the comparability test (paragraph (l) of this section) to qualify for designation as an equivalent method.

(m) *Method Detection Limit (MDL).* Calculate the estimated MDL using the guidance provided in 40 CFR Part 136, Appendix B. It is essential that all sample processing steps of the analytical method be included in the determination of the method detection limit. Take a minimum of seven aliquots of the sample to be used to calculate the method detection limit and process each through the entire analytical method. Make all computations according to the defined method with the final results in μg/m³. The MDL must be equal to, or less than 1% of the level of the Pb NAAQS.

10a. Revise Table C–3 to Subpart C of Part 53 to read as follows:

TABLE C–3 TO SUBPART C OF PART 53.—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM_{10} METHODS

Concentration range equivalent to percentage of NAAQS in μg/m³.	30% to 250%.
Minimum number of 24-hr measurements.	5.
Maximum precision, P_R or P_C	≤15%.
Maximum analytical accuracy, D_q.	±5%
Maximum difference (D), percent of reference method.	±20%.

TABLE C–3 TO SUBPART C OF PART 53.—TEST SPECIFICATIONS FOR PB IN TSP AND PB IN PM_{10} METHODS—Continued

Estimated Method Detection Limit (MDL), μg/m³.	1% of NAAQS level.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

11. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart B—[Amended]

12. Section 58.10, is amended by adding paragraphs (a)(4) and (b)(9) to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(4) A plan for establishing Pb monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the EPA Regional Administrator by July 1, 2009. The plan shall provide for at least one half of the required Pb monitoring sites to be operational by January 1, 2010, and for all required Pb monitoring sites to be operational by January 1, 2011. Source oriented Pb monitoring sites for the highest emitting half of Pb sources shall be installed by January 1, 2010.

(b) * * *

(9) The designation of any Pb monitors as either source-oriented or non-source oriented according to appendix D to this part.

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13. Section 58.12 is amended by revising paragraph (b) to read as follows:

§ 58.12 Operating schedules.

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(b) For Pb manual methods, at least one 24-hour sample must be collected every 3 days except during periods or seasons exempted by the Regional Administrator. The Regional Administrator can allow a reduction in the sampling schedule to one 24-hour sample every 6 days if the Pb design value over the previous 3 years is less than 70% of the Pb NAAQS.

14. Section 58.13 is amended by revising paragraph (b) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(b) Not withstanding specific dates included in this part, beginning January 1, 2008, when existing networks are not in conformance with the minimum number of required monitors specified in this part, additional required monitors must be identified in the next applicable annual monitoring network plan, with monitoring operation beginning by January 1 of the following year. To allow sufficient time to prepare and comment on Annual Monitoring Network Plans, only monitoring requirements effective 120 days prior to the required submission date of the plan (i.e., 120 days prior to July 1 of each year) shall be included in that year's annual monitoring network plan.

15. Section 58.16 is amended by revising paragraph (a) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2; NO; NO_Y; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$ FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10-2.5}$ mass concentration; chemically speciated $PM_{10-2.5}$ mass concentration data; meteorological data from NCore and PAMS sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (*http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm*). Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

Subpart C—[Amended]

16. Section 58.20 is amended by revising paragraph (e) to read as follows:

§ 58.20 Special purpose monitors (SPM).

* * * * *

(e) If an SPM using an FRM, FEM, or ARM is discontinued within 24 months of start-up, the Administrator will not designate an area as nonattainment for the CO, SO_2, NO_2, or 24-hour PM_{10} NAAQS solely on the basis of data from the SPM. Such data are eligible for use in determinations of whether a nonattainment area has attained one of these NAAQS.

* * * * *

17. Appendix A to part 58 is amended by revising paragraph 3.3.4 and Table A–2.

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

3.3.4 Pb Methods.

3.3.4.1 *Flow Rates.* For the Pb Reference Methods (40 CFR part 50, appendix G and appendix Q) and associated FEMs, the flow rates of the Pb samplers shall be verified and audited using the same procedures described in sections 3.3.2 and 3.3.3 of this appendix.

3.3.4.2 *Pb Analysis Audits.* Each calendar quarter or sampling quarter (PSD), audit the Pb Reference Method analytical procedure using filters containing a known quantity of Pb. These audit filters are prepared by depositing a Pb solution on unexposed filters and allowing them to dry thoroughly. The audit samples must be prepared using batches of reagents different from those used to calibrate the Pb analytical equipment being audited. Prepare audit samples in the following concentration ranges:

Range	Equivalent ambient Pb concentration, μg/m³ [1]
1	30–100% of Pb NAAQS.
2	200–300% of Pb NAAQS.

[1] Equivalent ambient Pb concentration in μg/m³ is based on sampling at 1.7 m³/min for 24 hours on a 20.3 cm × 25.4 cm (8 inch × 10 inch) glass fiber filter.

(a) Audit samples must be extracted using the same extraction procedure used for exposed filters.

(b) Analyze three audit samples in each of the two ranges each quarter samples are analyzed. The audit sample analyses shall be distributed as much as possible over the entire calendar quarter.

(c) Report the audit concentrations (in μg Pb/filter or strip) and the corresponding measured concentrations (in μg Pb/filter or strip) using AQS unit code 077. The relative percent differences between the concentrations are used to calculate analytical accuracy as described in section 4.4.2 of this appendix.

(d) The audits of an equivalent Pb method are conducted and assessed in the same manner as for the reference method. The flow auditing device and Pb analysis audit samples must be compatible with the specific requirements of the equivalent method.

3.3.4.3 *Collocated Sampling.* The collocated sampling requirements for Pb-TSP and Pb-PM_{10} shall be determined using the same procedures described in sections 3.3.1 of this appendix.

3.3.4.4 *Pb Performance Evaluation Program (PEP) Procedures.* One performance evaluation audit, as described in section 3.2.7 of this appendix must be performed at one Pb site in each primary quality assurance organization each year. The calculations for evaluating bias between the primary monitor(s) and the performance evaluation monitors for Pb are the same as those for $PM_{10-2.5}$ which are described in section 4.1.3 of this appendix. In addition, for each

quarter, one half of a collocated sample pair (from the designated collocated sampler) from one site within each PQAO must sent to an independent laboratory for analysis.

* * * * *

TABLE A–2 OF APPENDIX A TO PART 58.—MINIMUM DATA ASSESSMENT REQUIREMENTS FOR SLAMS SITES

Method	Assessment method	Coverage	Minimum frequency	Parameters reported
Automated Methods				
1-Point QC for SO_2, NO_2, O_3, CO.	Response check at concentration 0.01–0.1 ppm SO_2, NO_2, O_3, and 1–10 ppm CO.	Each analyzer	Once per 2 weeks	Audit concentration[1] and measured concentration.[2]
Annual performance evaluation for SO_2, NO_2, O_3, CO.	See section 3.2.2 of this appendix.	Each analyzer	Once per year	Audit concentration[1] and measured concentration[2] for each level.
Flow rate verification PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$.	Check of sampler flow rate using independent standard.	Each sampler	Once every 6	Audit flow rate and measured flow rate indicated by the sampler.
Collocated sampling $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	15%	Every 12 days	Primary sampler concentration and duplicate sampler concentration
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤ 5 sites 2. 8 valid audits for primary QA orgs, with > 5 sites 3. All samplers in 6 years.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Manual Methods				
Collocated sampling PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Collocated samplers	15%	Every 12 days PSD—every 6 days.	Primary sampler concentration and duplicate sampler concentration.
Flow rate verification PM_{10} (low Vol), $PM_{10-2.5}$, $PM_{2.5}$, Pb-PM_{10}.	Check of sampler flow rate	Each sampler	Once every month	Audit flow rate and measured flow rate indicated by the sampler.
Flow rate verification PM_{10} (High-Vol), TSP, Pb-TSP.	Check of sampler flow rate	Each sampler	Once every quarter	Audit flow rate and measured flow rate indicated by the sampler.
Semi-annual flow rate audit PM_{10}, TSP, $PM_{10-2.5}$, $PM_{2.5}$, Pb-TSP, Pb-PM_{10}.	Check of sampler flow rate using independent standard.	Each sampler, all locations	Once every 6 months	Audit flow rate and measured flow rate indicated by the sampler.
Pb audit strips Pb-TSP, Pb-PM_{10}.	Check of analytical system with Pb audit strips.	Analytical	Each quarter	Actual concentration.
Performance evaluation program $PM_{2.5}$, $PM_{10-2.5}$.	Collocated samplers	1. 5 valid audits for primary QA orgs, with ≤ 5 sites 2. 8 valid audits for primary QA orgs, with ≥ 5 sites 3. All samplers in 6 years.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.
Performance evaluation program Pb-TSP, Pb-PM_{10}.	Collocated samplers	1 valid audit for primary QA orgs.	Over all 4 quarters	Primary sampler concentration and performance evaluation sampler concentration.

[1] Effective concentration for open path analyzers.
[2] Corrected concentration, if applicable, for open path analyzers.

* * * * *

18. Appendix D to part 58 is amended as by revising paragraph 4.5 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.5 *Lead (Pb) Design Criteria.* (a) State and, where appropriate, local agencies are required to conduct Pb monitoring near lead sources which emit more than [200 to 600] kilograms per year. At a minimum, there must be one source-oriented SLAMS site located (taking into account logistics and other limitations) to measure the maximum Pb concentration in ambient air resulting from the lead source.

(b) The Regional Administrator may waive the requirement in paragraph 4.5(a) for monitoring near Pb sources emitting less than 1000 kilograms if the State or, where appropriate, local agency can demonstrate (via historical monitoring data, modeling, or other means) that the Pb source will not contribute to a maximum Pb concentration in ambient air in excess of 50% of the NAAQS.

(c) State and, where appropriate, local agencies are required to conduct Pb

monitoring in each CBSA with a population greater than 1,000,000 people as determined based on the latest available census figures. At a minimum, there must be one nonsource-oriented SLAMS site located to estimate typical Pb concentrations in the urban area. Consideration should be given to locating these monitors in neighborhoods near heavily trafficked roadways.

(d) The most important spatial scales for source-oriented sites to effectively characterize the emissions from point sources are microscale and middle scale. The most important spatial scale for nonsource-oriented sites to characterize typical lead concentrations in urban areas is the neighborhood scale.

(1) Microscale—This scale would typify areas in close proximity to lead point sources. Emissions from point sources such as primary and secondary lead smelters, and primary copper smelters may under fumigation conditions likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale sites provide information for evaluating and developing ''hot-spot'' control measures.

(2) Middle scale—This scale generally represents Pb air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may for example, include schools and playgrounds in center city areas which are close to major Pb point sources. Pb monitors in such areas are desirable because of the higher sensitivity of children to exposures of elevated Pb concentrations (reference 3 of this appendix). Emissions from point sources frequently impact on areas at which single sites may be located to measure concentrations representing middle spatial scales.

(3) Neighborhood scale—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Sites of this scale would provide monitoring data in areas representing conditions where children live and play. Monitoring in such areas is important since this segment of the population is more susceptible to the effects of Pb. Where a neighborhood site is located away from immediate Pb sources, the site may be very useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(e) Pb monitoring required in paragraphs 4.5(a) and 4.5(c) can be conducted with either Pb-TSP or Pb-PM_{10}.

(f) Technical guidance is found in references 4 and 5 of this appendix. These documents provide additional guidance on locating sites to meet specific urban area monitoring objectives and should be used in locating new sites or evaluating the adequacy of existing sites.

* * * * *

[FR Doc. E8–10808 Filed 5–19–08; 8:45 am]

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Federal Register

Tuesday,
May 20, 2008

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Revised Designation of Critical Habitat for the Wintering Population of the Piping Plover (*Charadrius melodus*) in Texas; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R2–ES–2008–0055; 92210–1117–0000–FY08–B4]

RIN 1018–AV46

Endangered and Threatened Wildlife and Plants; Revised Designation of Critical Habitat for the Wintering Population of the Piping Plover (*Charadrius melodus*) in Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate revised critical habitat for the wintering population of the piping plover (*Charadrius melodus*) in 18 specific units in Texas under the Endangered Species Act of 1973, as amended (Act). In total, approximately 138,881 acres (ac) (56,206 hectares (ha)) fall within the boundaries of the proposed revised critical habitat designation. The proposed revised critical habitat is located in Cameron, Willacy, Kenedy, Kleberg, Nueces, Aransas, Calhoun, Matagorda, and Brazoria Counties, Texas. Other previously designated critical habitat for the wintering piping plover in Texas or elsewhere in the United States is unaffected by this proposal.

DATES: Send your comments on or before July 21, 2008. We must receive requests for public hearings, in writing, at the address shown in the **FOR FURTHER INFORMATION CONTACT** section by July 7, 2008.

ADDRESSES: You may submit comments by one of the followingmethods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R2–ES–2008–0055; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Allan Strand, Field Supervisor, U.S. Fish and Wildlife Service, Corpus Christi Ecological Services Office, 6300 Ocean Drive, TAMU–CC, Unit 5837, Corpus Christi, TX 78412–5837; telephone 361–994–9005; facsimile 361–994–8262. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we request comments or suggestions on this proposed rule. We particularly seek comments concerning:

(1) The reasons we should or should not designate habitat as ''critical habitat'' in the 19 court-vacated units and adjacent areas in Texas under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation such that the designation of critical habitat is not prudent.

(2) Specific information on:

- The amount and distribution of wintering piping plover habitat in the 19 court-vacated units and areas adjacent to those 19 units in Texas, and
- What areas occupied at the time of listing, but located within or adjacent to these specific units, are essential to the conservation of the species and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed amended critical habitat.

(4) Any foreseeable economic, national security, or other potential impacts resulting from the proposed designation and, in particular, any impacts on small entities, and the benefits of including or excluding areas that exhibit these impacts.

(5) The appropriateness of the possible exclusion of approximately 28,474 acres (ac) (11,523 hectares (ha)) of wintering piping plover habitat from the final designation based on the benefits to the conservation of the species and its habitat provided by the Comprehensive Conservation Plans (CCPs) being drafted for National Wildlife Refuge (NWR) lands (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). Specifically:

(a) The benefits to the conservation of the species provided by a CCP;

(b) How the CCPs address the physical and biological features in the absence of designated critical habitat;

(c) The specific conservation benefits to the wintering piping plover that would result from designation;

(d) The certainty of implementation of the CCPs; and

(e) The benefits of excluding from the critical habitat designation the areas covered by the CCPs.

We are particularly interested in knowing how existing or future NWR partnerships may be positively or negatively affected by a designation, or through exclusion from critical habitat;

(6) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

(7) Whether there are areas we previously designated, but are not proposing for revised designation here, that we should include in our critical habitat designation.

(8) The existence of any conservation or management plans being implemented by public or private land management agencies or owners on lands proposed for designation that we should consider in connection with possible exclusion of those lands from the designation under section 4(b)(2) of the Act. Please include information on any benefits (educational, regulatory, etc.) of including or excluding lands from this proposed designation. We are interested in knowing how partnerships may be positively or negatively affected by a designation, or through exclusion from critical habitat, and costs and other relevant impacts associated with the designation.

(9) Any foreseeable impacts on energy supplies, distribution, and use resulting from the proposed designation and, in particular, any impacts on seismic studies for oil and gas drilling, and the benefits of including or excluding areas that exhibit these impacts.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by e-mail or fax or to an address not listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we

used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Corpus Christi Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to designating revised critical habitat in this proposed rule. For more information on piping plover wintering critical habitat, refer to the final rule designating critical habitat for the wintering population of the piping plover published in the **Federal Register** on July 10, 2001 (66 FR 36038).

The piping plover is a small, pale-colored shorebird that breeds in three separate areas of North America: the Northern Great Plains, the Great Lakes, and the Atlantic Coast. The piping plover winters in coastal areas of the United States from North Carolina to Texas, along the coast of eastern Mexico, and on Caribbean islands from Barbados to Cuba and the Bahamas (Haig and Elliott-Smith 2004, p. 2). Information from observation of color-banded piping plovers indicates that the winter ranges of the breeding populations overlap to a significant degree. Therefore, we cannot determine the source breeding population of a given wintering individual in the field unless it has been banded or otherwise marked.

Piping plovers begin arriving on the wintering grounds in July, with some late-nesting birds arriving in September. A few individuals can be found on the wintering grounds throughout the year, but sightings are rare in late May, June, and early July. In late February, piping plovers begin leaving the wintering grounds to migrate back to breeding sites. Northward migration peaks in late March, and by late May most birds have left the wintering grounds (Haig and Elliott-Smith 2004, p. 4). Individual plovers tend to return to the same wintering sites year after year as evidenced by multi-year observations of uniquely marked individuals (Nicholls and Baldassarre 1990; Drake 1999a).

Wintering plovers are dependent on a mosaic of habitat patches, and move among these patches depending on local weather and tidal conditions. One study by Drake (1999a) monitored the movement of 48 piping plovers in south Texas for one season. She found that these birds had a mean home range of 3,117 ac (1,262 ha). Drake (1999a) also noted that the mean linear distance moved per individual bird was 2 miles (mi) (3.3 kilometer (km)) from the fall through the spring. A complete description of the biology and ecology of the piping plover can be found in Haig and Elliott-Smith (2004).

Previous Federal Actions

The piping plover was listed as endangered in the Great Lakes watershed and threatened elsewhere within its range on December 11, 1985 (50 FR 50726). All piping plovers on migratory routes outside of the Great Lakes watershed or on their wintering grounds are listed as threatened under the Act due to the difficulty of knowing where they bred or were hatched.

On July 10, 2001, we designated 137 areas along the coasts of North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas as critical habitat for the wintering population of the piping plover (66 FR 36038). This designation included approximately 1,798 mi (2,892 km) of mapped shoreline and approximately 165,211 ac (66,881 ha) of mapped areas along the Gulf and Atlantic coasts and along margins of interior bays, inlets, and lagoons.

In February 2003, Dare and Hyde Counties, North Carolina, and the Cape Hatteras Access Preservation Alliance challenged the designation of four critical habitat units on the Cape Hatteras National Seashore, North Carolina. A November 1, 2004, court opinion vacated and remanded these units for reconsideration (*Cape Hatteras Access Preservation Alliance* v. *U.S. Department of the Interior* (344 F.Supp.2d108(D.D.C. 2004)). On June 12, 2006, we published a proposed rule in the **Federal Register** (71 FR 33703) to amend the Service's critical habitat designation in North Carolina. We anticipate publishing a final designation in late 2008.

The Texas General Land Office (GLO) filed suit on March 20, 2006, challenging our designation of 19 units of critical habitat along the Texas coast (Units 3, 4, 7, 8, 9, 10, 14, 15, 16, 17, 18, 19, 22, 23, 27, 28, 31, 32, and 33). In a July 26, 2006, stipulated settlement agreement and court order, the court vacated and remanded the designation for these units to us for reconsideration (*Texas General Land Office* v. *U.S. Department of the Interior, et al.*, No. 06–cv–00032 (S.D. Tex.). This proposed rule addresses only those 19 court-vacated and remanded units (referenced above). It also addresses minor edits to the regulatory language found in 50 CFR 17.95(b). All other areas remain as designated in the July 10, 2001, final critical habitat rule (66 FR 36038), including Texas units 1, 2, 5, 6, 11, 12, 13, 20, 21, 24, 25, 26, 29, 30, 34, 35, 36, and 37.

For information on previous Federal actions concerning the piping plover, refer to the final listing rule published in the **Federal Register** on December 11, 1985 (50 FR 50726), or the final rule designating critical habitat for the wintering population of the piping plover published in the **Federal Register** on July 10, 2001 (66 FR 36038). We are proposing this action in accordance with section 4(b)(2) of the Act and in compliance with the above-mentioned settlement agreement and court order.

Critical Habitat

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical 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

(a) Essential to the conservation of the species and

(b) Which may require special management considerations or protections; and

(2) Specific areas outside the geographical 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, as defined under section 3 of the Act, means the use of all methods and procedures that are necessary to bring any endangered species or threatened species to the point at which the measures provided under the Act are no longer necessary.

Critical habitat receives protection under section 7 of the Act through the prohibition against Federal agencies carrying out, funding, or authorizing the destruction or adverse modification of critical habitat. Section 7 of the Act requires consultation on Federal actions that may affect critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by the landowner. Where the landowner seeks or requests Federal agency funding or authorization that may affect a listed species or critical habitat, the consultation requirements of section 7 would apply, but even in the event of a destruction or adverse modification finding, the landowner's obligation is not to restore or recover the species, but to implement reasonable and prudent

alternatives to avoid destruction or adverse modification of critical habitat.

For inclusion in a critical habitat designation, habitat within the geographical area occupied by the species at the time it was listed must contain features that are essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific data available, habitat areas that provide essential life cycle needs of the species (areas on which are found the primary constituent elements (PCEs), as defined at 50 CFR 424.12(b)), laid out in the appropriate spatial arrangement essential to the conservation of the species.

Occupied habitat that contains the features essential to the conservation of the species meets the definition of critical habitat only if those features may require special management considerations or protections. Under the Act, we can designate unoccupied areas as critical habitat only when we determine that the best available scientific data demonstrate that the designation of that area is essential to the conservation needs of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific and commercial data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be proposed as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, 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.

Habitat is often dynamic (shifting spatially over time) 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 we may eventually determine, based on scientific data not now available to the Service, are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant now or may not be required for recovery of the species in the future.

Areas that support populations, but are outside the critical habitat designation, will continue to be subject to conservation actions we implement under section 7(a)(1) of the Act. These areas are also subject to the regulatory protections afforded by the section 7(a)(2) jeopardy standard for Federal agency actions, as determined on the basis of the best available scientific information at the time of the agency action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may sometimes result in jeopardy findings. Similarly, if new information available to these projects and associated planning efforts calls for a different outcome, 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.

Methods

As required by section 4(b) of the Act, we used the best scientific data available in determining areas occupied at the time of listing that contain the physical or biological features essential to the conservation of the wintering population of the piping plover, areas unoccupied at the time of listing that are essential to the conservation of the wintering population of the piping plover, or both. We are not currently proposing any areas outside the geographical area presently occupied by the species because occupied areas are sufficient for the conservation of the species.

We have also reviewed available information that pertains to the habitat requirements of this species. These sources included, but were not limited to, data in reports submitted during section 7 consultations and by biologists holding section 10(a)(1)(A) recovery permits, research published in peer-reviewed articles and presented in academic theses and agency reports, and recovery plans. To determine the most current distribution of wintering piping plovers in Texas, we evaluated these areas using wintering piping plover occurrence data from 1991, 1996, 2001, and 2006 international piping plover winter population censuses. We considered these data along with other occurrence data (including presence or absence survey data), research published in peer-reviewed articles and presented in academic theses and agency reports, and information received during the development of the July 10, 2001, designation of critical habitat for the wintering population of the piping plover (see final rule at 66 FR 36038).

To map bayside areas containing physical and biological features determined to be essential to the conservation of the species (see Primary Constituent Elements for the Wintering Population of the Piping Plover section below), we used data on known piping plover wintering locations, 1992 National Wetlands Inventory (NWI) data (except for Unit TX–22 which had 2001 data available) fitted to 2005 National Agriculture Imagery Program (NAIP) aerial photographs, and regional Geographic Information System (GIS) coverages that defined shorelines. The NWI data allowed non-PCEs to be removed from critical habitat designation and PCEs to be delineated more precisely. Based on their NWI classification, 10 wetland habitats for the bayside areas met our definition of PCEs (see Primary Constituent Elements section below). Their codes and brief descriptions are provided here; for a more complete description of each wetland habitat, go to *http://www.fws.gov/nwi/mapcodes.htm.*

M2USN—Marine (gulfside) sandy coastline (beach), regularly inundated by tides

M2USP—Marine (gulfside) sandy coastline (beach), irregularly inundated by tides

E2AB1N—Estuarine (bayside) algal mud or sand flats, regularly inundated by tides

E2AB1P—Estuarine (bayside) algal mud or sand flats, irregularly inundated by tides

E2AB3M—Estuarine (bayside) grass flats of mud or sand, irregularly inundated by tides

E2USM—Estuarine (bayside) sandy shore (beach/sandbar), rarely exposed by tidal fluctuation

E2USN—Estuarine (bayside) sandy shore (beach/sandbar), regularly inundated by tides

E2USP—Estuarine (bayside) sandy shore (beach/sandbar), irregularly inundated by tides

L1UBKhs—Impounded, artificially flooded open water dredge spoil pit, greater than 20 ac (8 ha)

L2USKhs—Impounded, artificially flooded sandy bottom dredge spoil pit, greater than 20 ac (8 ha)

We are aware that wintering piping plovers in Texas also use a NWI wetland

habitat that is classified as subtidal with rooted vascular vegetation which is usually five or more species of seagrass. Although that habitat is classified as subtidal and appears in the NAIP aerial photographs as such, when portions of it are exposed at very low tides, wintering plovers forage in them. However, because we are unable to identify those exposed portions on the aerial photographs, we are unable to map them and, therefore, we are unable to propose them for critical habitat designation.

To map the gulfside, we used 2005 NAIP imagery as a base from which the vegetation and water lines were digitized at a scale of 1:5,000 (using ESRI ArcMap 9.2 software) to produce polygons of critical habitat. The mean lower low waterline (MLLW) was used as the lower limit of the intertidal habitat used by wintering piping plovers. Due to the dynamic nature of the gulfside shoreline, the MLLW vector data from the National Oceanic and Atmospheric Administration (NOAA) was often misaligned with the shoreline in the 2005 NAIP aerial photography. To correct misalignments, we worked with unit TX–3, which had a well-aligned MLLW line. In that unit, we measured the average distance from the well-aligned MLLW line to the shoreline in the 2005 NAIP aerial photographs. We took measurements every 328 feet (ft) (100 meters (m)) along unit TX–03, and averaged them. The 184 ft (56 m) average distance was then used as an estimated MLLW line that was applied in all coastal (gulfside) areas. The landward limit of the gulfside critical habitat units was usually defined by densely vegetated dunes, which do not provide habitat for piping plovers.

We measured the accuracy of the aerial photographs we used by gathering Global Positioning System (GPS) readings at 29 locations and plotting them over the photographs to determine how close those photo points were to actual locations. The offset distance ranged from 10 to 43 ft (3 to 13 m). This information is in the GIS metadata to document the data's horizontal accuracy.

We included those areas within or adjacent to the 19 court-vacated units that contain essential physical or biological features along bay and gulf shorelines for which occurrence data indicate a consistent use by piping plovers, with observations over two or more wintering seasons between 1997 and 2007. We have not included the area of Allyn's Bight (court-vacated unit TX–17) because the PCEs have been reduced to two small, disjunct fragments that are not of sufficient size and spatial arrangement for wintering plovers. Therefore, we do not consider the vacated unit to be suitable for critical habitat designation. Within the remaining 18 court-vacated units, we also did not include very small areas (generally less than 5 ac (2.0 ha)) and areas disjunct from larger polygons containing the PCEs. We are assuming that when these areas were included in our original designation in 2001, either there were PCEs present that connected them to the larger polygons of PCEs or they were included in error because our mapping methodology was not as precise as the methodology we are using for this proposed revised designation. As a consequence, some of the units are smaller than when we originally designated them. In contrast, we expanded the boundaries of some units to capture complete polygons of PCEs, which we believe have shifted outside the boundaries we designated originally due to storms or other natural events. By expanding some boundaries to capture larger polygons and shrinking other boundaries to remove small and disjunct polygons, we believe we have provided a sufficient quantity of critical habitat in the appropriate spatial arrangement for the wintering population of the piping plover in Texas.

Delineating specific locations for designation as critical habitat for the wintering population of the piping plover is difficult because the coastal areas they use are constantly changing due to storm surges, flood events, and other natural geophysical alterations of beaches and shoreline. To ensure that areas containing features considered essential to the piping plover are included in this proposed designation, the textual unit descriptions in the regulation, definitively determine whether an area is within the critical habitat boundary. Our textual descriptions of the boundaries of each unit use reference points (such as roads or channels), latitude/longitude coordinates, the edge of a PCE (such as the edge of a sand flat or mud flat), the MLLW line, or the edge of a management unit (such as a park or municipality). Within the described boundary for each unit, the unit itself is restricted to only those areas that are utilized by the piping plover and contain the physical and biological features needed (the PCEs). These proposed unit boundaries are static and will not move over time unless we re-designate the boundaries. Unit boundaries were drawn to exclude manmade structures, such as roads or cuts to allow boat traffic. However, bollards, which are small posts placed to preclude driving on the beach, are not PCEs and we propose to exclude them from the boundary of critical habitat, although they are too small to digitally delete from maps at the scale of 1:5,000 that we used to delineate the critical habitat boundaries. Although we are not publishing UTM coordinates for the boundaries of the proposed critical habitat units in this proposed rule, they will be included in the final rule.

Primary Constituent Elements (PCEs)

In accordance with section 3(5)(A)(i) of the Act and the regulations at 50 CFR 424.12, in determining which areas occupied by the species at the time of listing to propose as critical habitat, we consider the physical and biological features that are essential to the conservation of the species to be the primary constituent elements laid out in the appropriate spatial arrangement for conservation of the species. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historic, geographical, and ecological distributions of a species.

We derive the specific PCEs required for the wintering population of the piping plover from the biological needs of the species as described in the Background section of the final rule designating critical habitat for the wintering population of the piping plover published in the **Federal Register** on July 10, 2001 (66 FR 36038).

Space for Individual and Population Growth and for Normal Behavior

Behavioral observations of piping plovers on the wintering grounds suggest that they spend the majority of their time foraging (Nicholls and Baldassarre 1990; Drake 1999a, 1999b). When not foraging, plovers can be found roosting, preening, bathing, in aggressive encounters with other piping plovers and other shorebird species, and moving among available habitat locations (Zonick and Ryan 1996).

The habitats used by wintering birds support these behaviors and include beaches, mud flats, sand flats, algal flats, spits, and washover areas. The intertidal sand or mud flats are used by the plovers for foraging, bathing and

aggressive encounters and have no or very sparse emergent vegetation. In some cases, these flats may be covered or partially covered by a mat of blue-green algae or fine shell. Spits are small points of land, especially sand, surrounded by water; they are used by wintering plovers for feeding and roosting. Washover areas, also used for foraging and roosting, are broad, unvegetated areas on the back side of sand dunes with little or no topographic relief formed by breaks in the dunes that are caused and maintained by extreme wave actions. Unvegetated or sparsely vegetated sand, mud, or algal flats above high tide are also used, especially for roosting. These sites may have debris or detritus (decaying organic matter). Some of these components (sparse vegetation, little or no topographic relief) are mimicked in artificial habitat types, particularly dredge spoil sites. Although they are used less commonly by piping plovers, we proposed them for critical habitat designation when occupancy has been confirmed.

Wintering plovers are dependent on a mosaic of these habitat patches, and move among them depending on local weather and tidal conditions. The habitats are found in geologically dynamic coastal areas that support intertidal beaches and flats (between annual low tide and annual high tide) and associated dune systems and flats above annual high tide. The most dynamic of these areas are those that are on barrier islands or on mainland areas that are not protected by barrier islands; these areas are adjacent to the Gulf of Mexico. Areas that are on the barrier islands or mainland and adjacent to the bay between the barrier islands and mainland are less dynamic.

Food

Primary prey of wintering plovers include polychaete marine worms, various crustaceans, insects, and occasionally bivalve mollusks (Nicholls 1989; Zonick and Ryan 1996). Wintering piping plovers peck for prey from on top of or just beneath the surface. Foraging usually takes place on moist or wet sand or mud flats, or fine shell that covers the sand or mud. These substrates may sometimes contain surfcast algae or be covered by a mat of blue-green algae.

Cover or Shelter

Wintering piping plovers roost and take shelter from storms and cold weather in backbeach areas that are above mean high tide and seaward of the dune line, or in cases where no dunes exist, seaward of a delineating feature such as a vegetation line, structure, or road. These backbeach areas consist of unvegetated or sparsely vegetated sand, mud, or algal flats. These flats may have microtopographic relief (less than 20 in (50 cm) above the substrate surface), which offers important shelter from high winds, storms, and cold weather.

Primary Constituent Elements for the Wintering Population of the Piping Plover

Within the geographical area we know to be occupied by the wintering population of the piping plover, we must identify the primary constituent elements (PCEs) laid out in the spatial arrangement essential to the conservation of the species (*i.e.*, essential physical and biological features) that may require special management considerations or protections. All areas proposed as critical habitat units in Texas in this proposed revised rule are currently occupied and contain sufficient PCEs to support at least one life history function.

In *Cape Hatteras Access Preservation Alliance* v. *U.S. Dept of the Interior*, 344 F. Supp. 2d 108 (D.D.C. 2004), the Court upheld the PCEs identified in our July 10, 2001, final rule designating critical habitat for the wintering population of the piping plover (66 FR 36038). Thus, we are not changing PCEs previously identified which remain based on the best available scientific information. They constitute the features that are essential for the conservation of wintering piping plovers along the coasts of North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, and Texas. The PCEs in Texas are found in geologically dynamic coastal areas along the Gulf of Mexico and along the shores of bays linked to the Gulf.

Based on the above needs, our current knowledge of the life history, biology, and ecology of the species, and the habitat requirements for sustaining the essential life history functions of the species on its wintering grounds, we have determined that PCEs for the wintering population of the piping plover are:

(1) Intertidal sand beaches (including sand flats) or mud flats (between annual low tide and annual high tide) with no or very sparse emergent vegetation for feeding. In some cases, these flats may be covered or partially covered by a mat of blue-green algae.

(2) Unvegetated or sparsely vegetated sand, mud, or algal flats above annual high tide for roosting. Such sites may have debris or detritus and may have micro-topographic relief (less than 20 in (50 cm) above substrate surface) offering refuge from high winds and cold weather.

(3) Surf-cast algae for feeding.

(4) Sparsely vegetated backbeach, which is the beach area above mean high tide seaward of the dune line, or in cases where no dunes exist, seaward of a delineating feature such as a vegetation line, structure, or road. Backbeach is used by plovers for roosting and refuge during storms.

(5) Spits, especially sand, running into water for foraging and roosting.

(6) Salterns, or bare sand flats in the center of mangrove ecosystems that are found above mean high water and are only irregularly flushed with sea water.

(7) Unvegetated washover areas with little or no topographic relief for feeding and roosting. Washover areas are formed and maintained by the action of hurricanes, storm surges, or other extreme wave actions.

(8) Natural conditions of sparse vegetation and little or no topographic relief mimicked in artificial habitat types (*e.g.*, dredge spoil sites).

We have designed this proposed revised designation for the conservation of the PCEs necessary to support the life history functions of the species and the areas containing those PCEs in the appropriate spatial arrangement essential for the conservation of the species where it winters.

Because not all life history functions require all the PCEs, not all proposed revised critical habitat units in Texas will contain all the PCEs. We propose units for designation based on sufficient PCEs being present to support at least one of the species' wintering life history functions.

Special Management Considerations or Protections

When designating critical habitat, we assess whether the occupied areas contain features essential to the conservation of the species that may require special management considerations or protections.

Primary threats to the wintering population of piping plover that may require special management or protection are:

(1) Disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals;

(2) Predation, especially falcons, hawks, coyotes, bobcats and feral cats; and

(3) Modification and loss of habitat due to uncontrolled recreational access and beach stabilization efforts (*e.g.*, beach nourishment, beach maintenance, sediment dredging and disposal, inlet channelization, construction of jetties and other hard structures).

Foraging and roosting piping plovers may be disturbed by events that result in flushing birds or disrupting normal feeding or roosting times and causing excessive alertness or abandonment of the area. Such disturbance can be caused by humans carrying out recreational activities such as walking on the beach, flying kites, or shooting fireworks. Driving vehicles on the beach also can disturb foraging and roosting plovers, as can pets being allowed to run or roam freely on the beach. Predation rates on piping plovers may increase above normal because human activities attract predators thereby increasing their numbers. Wintering piping plover habitat can be modified or lost by uncontrolled recreational access, such as off-road vehicle (ORV) use, pedestrians, and domestic animals. Additionally, habitat modification and loss occurs with beach stabilization activities that prevent the natural transfer and erosion and accretion of sediments along the ocean shoreline. Beach stabilization efforts that threaten to impact wintering piping plover habitat include beach nourishment, beach maintenance, sediment dredging and disposal, inlet channelization, and construction on jetties and other hard structures. However, when these efforts, in particular sediment dredging and disposal, result in PCEs that mimic natural PCEs, habitat is created. To address the threats affecting the wintering population of the piping plover within each of the proposed critical habitat units, certain special management actions may be needed. For example, the high level of vehicle and pedestrian use of some areas may require managing access to piping plover foraging habitat and adjacent upland roosting habitat during migration and overwintering periods. Managing access to these foraging and roosting areas may assist in the protection of all of the PCEs and reduce piping plover disturbance and predation caused by vehicle use, pedestrians, and pets. Managing access might also improve the available habitats for conservation of piping plovers.

Criteria Used To Identify Critical Habitat

All proposed revised critical habitat units in Texas are within areas that we have determined were occupied at the time of listing, and that contain sufficient PCEs in the quantity and spatial arrangement to support life history functions essential for the conservation of the species where it winters. All units for which we are proposing to designate critical habitat have occurrence data that indicate a consistent use. That is, occupancy has been documented over more than one wintering season, which is the same criterion used in the original 2001 designation. We used the best scientific data available in determining areas that contain the features that are essential to the conservation of the wintering population of the piping plover, as discussed in the Methods section above.

The units were delineated by compiling existing relevant spatial data of the unit descriptions described in our 2001 final rule designating critical habitat for the wintering population of the piping plover (66 FR 36038), refining the existing descriptions using our National Wetlands Inventory data, and mapping in such a manner that the units contain the PCEs (as described) and do not contain any structures or other features that are not identified as PCEs. However, as described in the Methods section, bollards are excluded, but are too small to be removed digitally from our maps. We have no information indicating that bollards negatively affect piping plovers. To further ensure that no manmade features are included in critical habitat, bollards are expressly excluded by text in the proposed rule and are not proposed for designation as critical habitat. Using the information compiled above, GIS was used to analyze and integrate the relevant data layers for the areas of interest in order to determine those areas that include PCEs. See the Methods section above for additional discussion of mapping techniques.

We did not consider for designation areas that do not contain one or more of the PCEs or areas that: (1) Are highly degraded and may not be restorable; and (2) are small, highly fragmented, or isolated and may provide little or no long-term conservation value. We included areas containing one or more PCEs where occurrence data exist and where the area: (1) Provides a patchwork of the features essential for the conservation of the species; (2) offers dispersal capabilities or are in proximity to other wintering piping plover occurrences that would allow for survival and recolonization following major natural disturbance events (*e.g.*, hurricanes); (3) are of sufficient size to maintain the physical and biological features that support occurrences; and (4) are representative of the historic geographic distribution of occupied areas that will help prevent further range collapse of the species and will provide for the conservation of the species.

Within the areas (TX–3, TX–4, TX–7, TX–8, TX–9, TX–10, TX–14, TX–15, TX–16, TX–18, TX–19, TX–22, TX–23, TX–27, TX–28, TX–31, TX–32, and TX–33) vacated and remanded to the Service for reconsideration in *Texas General Land Office* v. *U.S. Department of the Interior, et al.*, No. 06-cv-00032 (S.D. Tex.), we had found no unoccupied areas that we considered essential to the conservation of the species. The 18 units in Texas we are considering for designation cover a small area relative to the total area used by wintering piping plovers along the coasts of the Gulf of Mexico, Atlantic Ocean and Caribbean islands. That total occupied wintering area is vast. In comparison, unoccupied areas along the Texas coast are relatively small. Thus, we do not consider unoccupied areas in Texas to be essential to the conservation of the species. Therefore, we propose no areas in Texas outside the geographical area occupied by the species at the time of listing. In vacated unit TX–17 the PCEs have been reduced to two small and disjunct fragments and it has not been observed to have been occupied since 1997. Therefore, we do not consider it suitable now for critical habitat designation. When it was originally designated in 2001, it had been occupied at least 2 of the previous 10 years, and the PCEs covered a larger, less fragmented area. We are proposing to designate critical habitat on lands that we have determined were occupied at the time of listing, are currently occupied, and contain sufficient PCEs to support life history functions essential for the conservation of the species.

Summary of Changes From Previously Designated Critical Habitat

The areas identified in this proposed rule constitute a proposed revision of the areas we designated as critical habitat for the wintering population of the piping plover on July 10, 2001 (66 FR 36038). The main differences include the following:

(1) The 2001 final rule used a more generalized methodology for delineating critical habitat, which resulted in the inclusion of non-PCEs within the 19 court-vacated critical habitat units for the wintering population of the piping plover in Texas. We based this proposed revised designation on a more specific methodology (see Methods section) that resulted in the proposal of 18 units, which are changed in size and configuration. It also resulted in the elimination of an additional unit (vacated unit TX–17). The boundaries of the proposed revised units exclude areas without PCEs. The exception is that we include areas with bollards, which are too small to detect at the mapping resolution we used (1:5,000), but which the text of the rule makes

clear are not part of the designation. Table 1 presents the size of the vacated and proposed units.

TABLE 1.—ACRES (HA) OF VACATED AND PROPOSED REVISED CRITICAL HABITAT UNITS FOR THE WINTERING POPULATION OF THE PIPING PLOVER IN TEXAS

Unit	Acres (Hectares)	
	Vacated	Proposed
TX–03	168,725 (68,281)	107,673 (43,574)
TX–04	38,641 (15,638)	17,218 (6,969)
TX–07	208 (84)	295 (120)
TX–08	478 (194)	620 (251)
TX–09	447 (181)	171 (69)
TX–10	683 (276)	344 (139)
TX–14	1,103 (446)	590 (239)
TX–15	1,778 (719)	805 (325)
TX–16	927 (375)	1,376 (557)
TX–17	161 (65)	N/A
TX–18	8,423 (3,408)	2,467 (999)
TX–19	1,957 (792)	2,419 (979)
TX–22	1,823 (738)	545 (221)
TX–23	1,537 (622)	1,808 (732)
TX–27	1,464 (593)	906 (367)
TX–28	648 (262)	478 (193)
TX–31	849 (344)	399 (161)
TX–32	658 (266)	555 (225)
TX–33	770 (312)	212 (86)
Total	231,280 (93,596)	138,881 (56,206)

By eliminating areas without PCEs we decreased the overall area and increased the area of ''islands'' of non-PCEs surrounded by proposed units for the following proposed units: TX–04, TX–09, TX–15, TX–18, TX–22, TX–27, TX–28, TX–31, TX–32, and TX–33. The overall area of proposed units TX–07, TX–08, TX–16, TX–19, and TX–23 increased from that originally designated in 2001 because, in addition to eliminating non-PCEs, we expanded boundaries to capture entire polygons of PCEs. Those polygons appeared in recent aerial photographs (see Methods section) to have shifted since the original designation in 2001 due to storm events.

(2) The area in unit TX–3 has been reduced to 68 percent of what was designated in our July 10, 2001, critical habitat designation (66 FR 36038), primarily due to a decrease in the size of subunit TX–3C. Approximately the northern one-third of what was originally designated no longer contains PCEs or the PCEs that remain have been reduced in size and are fragmented and disjunct from the large polygon that was originally designated. Based on our review of recent aerial photographs, we believe that the PCEs became lost or fragmented as a result of storm events.

(3) The area in unit TX 0910 has been reduced to 50 percent of what was designated in our July 10, 2001, critical habitat designation (66 FR 36038), primarily due to a decrease in the size of subunit TX 0910 C. Using revised mapping methodology (see Methods section), we expanded the boundaries of TX 0910C to include all PCEs surrounding a large lagoon. The entire polygon of each PCE was included within the boundary of the subunit unless we encountered a road. When that occurred, the boundary of the unit was the edge of the road. The lagoon itself does not contain PCEs and is not included within the boundaries of subunit TX 0910 C, although a large portion of it had been included in the original 2001 designation.

(4) The area in unit TX 0914 has been reduced to 54 percent of what was designated in our July 10, 2001, critical habitat designation (66 FR 36038). Approximately the western half of what was originally designated no longer contains PCEs or the PCEs that remain have been reduced in size and are fragmented and disjunct from the large polygon that was originally designated and remains in the eastern portion. We expanded the original northern and eastern boundary to capture complete polygons of PCEs that, based on our review of recent aerial photographs, appear to have shifted.

(5) The court-vacated unit TX 0917 is an island. When it was designated in 2001, it was relatively small (Table 1). When we eliminated the non-PCEs in evaluating whether a proposed revised designation was appropriate, only two polygons, each less than 4 ac (1.6 ha) and separated by 0.8 mi (1.3 km), remained. In addition, we had no records of recent occupancy by wintering piping plovers. Therefore, we concluded that it was no longer essential to the conservation of the species.

Proposed Revised Critical Habitat Designation

We are proposing 18 units as revised critical habitat in Texas for the wintering population of the piping plover. The critical habitat units we describe below constitute our current best assessment of areas that meet the definition of critical habitat for wintering piping plovers. We have retained the same unit and subunit numbers that were vacated by the court. Units that were not vacated and remain critical habitat are not described, and vacated unit TX 0917 is not described because. we are not proposing that it be designated. Table 2 shows the occupancy, ownership, and approximate size of the proposed revised units.

TABLE 2.—OCCUPANCY AND THREATS TO THE PROPOSED REVISED CRITICAL HABITAT UNITS FOR THE WINTERING POPULATION OF THE PIPING PLOVER IN TEXAS

Unit	Occupied at time of listing?	Currently occupied?	Threats requiring special management or protections
Subunit TX–3A: South Padre Island—Gulf of Mexico Shoreline.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and nourishment.
Subunit TX–3B: South Padre Island—Interior.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
Subunit TX–3C: North Padre Island—Interior.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
Subunit TX–3D: North Padre Island—Gulf of Mexico.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and nourishment.

TABLE 2.—OCCUPANCY AND THREATS TO THE PROPOSED REVISED CRITICAL HABITAT UNITS FOR THE WINTERING POPULATION OF THE PIPING PLOVER IN TEXAS—Continued

Unit	Occupied at time of listing?	Currently occupied?	Threats requiring special management or protections
Subunit TX–3E: Mesquite Rincon	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–4. Lower Laguna Madre Mainland	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–7. Newport Pass/Corpus Christi Beach.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and nourishment.
TX–8. Mustang Island Beach	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and nourishment.
TX–9. Fish Pass Lagoons	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
Subunit TX–10A: Shamrock Island	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
Subunit TX–10B: Mustang Island—Unnamed sand flat.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and rehabilitation.
Subunit TX–10C: Mustang Island—Lagoon Complex.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and stabilization.
TX–14. East Flats	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–15. North Pass	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and restoration.
TX–16. San Jose Beach	Yes	Yes	Domestic animal disturbance, predation, pedestrian recreational access.
TX–18. Cedar Bayou/Vinson Slough	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use; beach cleaning and nourishment.
TX–19. Matagorda Island Beach	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–22. Decros Point	Yes	Yes	Domestic animal disturbance, predation; pedestrian recreational use., sea turtle monitoring efforts.
TX–23. West Matagorda Peninsula Beach.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–27. East Matagorda Bay/Matagorda Peninsula Beach West.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–28. East Matagorda Bay/Matagorda Peninsula Beach East.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–31. San Bernard NWR Beach	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.
TX–32. Gulf Beach Between Brazos and San Bernard Rivers.	Yes	Yes	Domestic animal disturbance, predation, pedestrian recreational access.
TX–33. Bryan Beach and Adjacent Beach.	Yes	Yes	Human, vehicle and domestic animal disturbance; predation; uncontrolled recreational use.

The 24 areas we propose as revised critical habitat are: (1) Subunit TX–3A: South Padre Island—Gulf of Mexico Shoreline, (2) Subunit TX–3B: South Padre Island—Interior, (3) Subunit TX–3C: North Padre Island—Interior, (4) Subunit TX–3D: North Padre Island—Gulf of Mexico, (5) Subunit TX–3E: Mesquite Rincon, (6) Unit TX–4: Lower Laguna Madre Mainland, (7) Unit TX–7: Newport Pass/Corpus Christi Pass Beach, (8) Unit TX–8: Mustang Island Beach, (9) Unit TX–9: Fish Pass Lagoons, (10) Subunit TX–10A: Shamrock Island, (11), Subunit TX–10B: Mustang Island—Unnamed sand flat, (12) Subunit TX–10C: Mustang Island—Lagoon Complex, (13) Unit TX–14: East Flats, (14) Unit TX–15: North Pass, (15) Unit TX–16: San Jose Beach, (16) Unit TX–18: Cedar Bayou/Vinson Slough, (17) Unit TX–19: Matagorda Island Beach, (18) Unit TX–22: Decros Point, (19) Unit TX–23: West Matagorda Peninsula Beach, (20) Unit TX–27: East Matagorda Bay/Matagorda Peninsula Beach West, (21) Unit TX–28: East Matagorda Bay/Matagorda Peninsula Beach East, (22) Unit TX–31: San Bernard NWR Beach, (23) Unit TX–32: Gulf Beach Between Brazos and San Bernard Rivers, and (24) Unit TX–33: Bryan Beach and Adjacent Beach.

The approximate area encompassed within each critical habitat unit by ownership is shown in Table 3.

TABLE 3.—OWNERSHIP AND SIZE OF PROPOSED REVISED CRITICAL HABITAT FOR THE WINTERING POPULATION OF PIPING PLOVER IN TEXAS

Unit	Size of unit in acres (hectares)	Land ownership in acres (hectares)			
		Federal	State	County	Private
Subunit, TX–3A: South Padre Island—Gulf of Mexico Shoreline	2,888 (1,169)	728 (295)	287 (116)	28 (11)	1,845 (747)
Subunit, TX–3B: South Padre Island—Interior	44,083 (17,840)	18,778 (7,599)	16,583 (6,711)	.....	8,722 (3,530)

TABLE 3.—OWNERSHIP AND SIZE OF PROPOSED REVISED CRITICAL HABITAT FOR THE WINTERING POPULATION OF PIPING PLOVER IN TEXAS—Continued

Unit	Size of unit in acres (hectares)	Land ownership in acres (hectares)			
		Federal	State	County	Private
Subunit, TX–3C: North Padre Island—Interior	50,855 (20,580)	.....	46,027 (18,626)	.....	4,828 (1,954)
Subunit, TX–3D: North Padre Island—Gulf of Mexico	269 (109)	.....	212 (86)	.....	57 (23)
Subunit, TX–3E: Mesquite Rincon	9,578 (3,876)	.....	398 (161)	.....	9,180 (3,715)
TX–4. Lower Laguna Madre Mainland	17,218 (6,969)	6,300 (2,550)	8,576 (3,471)	.....	2,342 (948)
TX–7. Newport Pass/Corpus Christi Beach	295 (120)	.....	143 (58)	.....	152 (62)
TX–8. Mustang Island Beach	620 (251)	.....	367 (149)	5 (2)	248 (100)
TX–9. Fish Pass Lagoons	171 (69)	.....	169 (68)	.....	2 (0.8)
Subunit TX–10A: Shamrock Island	12 (5)	.....	8 (3)	.....	4 (1.6)
Subunit TX–10B: Mustang Island—Unnamed sand flat	3 (1)	.....	3 (1)	.....	.....
Subunit TX–10C: Mustang Island—Lagoon Complex	329 (133)	.....	237 (96)	.....	92 (37)
TX–14. East Flats	590 (239)	.....	12 (5)	.....	578 (234)
TX–15. North Pass	805 (325)	.....	154 (62)	.....	651 (263)
TX–16. San Jose Beach	1,376 (557)	15 (6)	691 (280)	.....	670 (271)
TX–18. Cedar Bayou/Vinson Slough	2,467 (999)	115 (47)	2 (0.8)	.....	2,350 (951)
TX–19. Matagorda Island Beach	2,419 (979)	2,135 (864)	284 (115)	.....	.....
TX–22. Decros Point	545 (221)	.....	325 (132)	.....	220 (89)
TX–23. West Matagorda Peninsula Beach	1,808 (732)	.....	877 (355)	.....	931 (377)
TX–27. East Matagorda Bay/Matagorda Peninsula Beach West	906 (367)	.....	481 (195)	.....	425 (172)
TX–28. East Matagorda Bay/Matagorda Peninsula Beach East	478 (193)	.....	146 (59)	.....	332 (134)
TX–31. San Bernard NWR Beach	399 (161)	119 (48)	193 (78)	.....	87 (35)
TX–32. Gulf Beach Between Brazos and San Bernard Rivers	555 (225)	.....	555 (225)	.....	.....
TX–33. Bryan Beach and Adjacent Beach	212 (86)	.....	212 (86)	.....	.....
Total	138,881 (56,206)	28,190 (11,409)	76,942 (31,139)	33 (13)	33,716 (13,645)

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the wintering population of the piping plover, below. Description information is summarized in Tables 1 and 2.

Unit TX–3: Padre Island

Subunit TX–3A: South Padre Island—Gulf of Mexico Shoreline. This subunit consists of 2,888 ac (1169 ha) in Cameron and Willacy Counties Texas. It is a beach 30.0 mi (48.2 km) in length on the gulfside of South Padre Island, which is a barrier island. The subunit is located within an area bounded on the south by the southern boundary of Andy Bowie County Park, and on the north by the south jetty of Mansfield Channel, which divides North and South Padre Islands. The jetty itself is outside the boundary of the subunit. The eastern boundary is the estimated MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW), and the western boundary is the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This subunit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used.

Approximately one quarter of the subunit is in Federal ownership and managed by the Service's Laguna Atascosa NWR, and approximately 64 percent is in private ownership. Ten percent is State land managed by the GLO, and a small portion at the southern end is County park land managed by Andy Bowie County Park (Table 3).

Subunit TX–3A is the southernmost unit of the proposed revised critical habitat for the wintering population of the piping plover. It was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this subunit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover, including sand flats with little or no emergent vegetation (PCE 1), surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and nourishment efforts. These threats are of greatest magnitude at the southern end of the subunit where housing developments are to the west of the subunit. Laguna Atascosa NWR is preparing a Comprehensive Conservation Plan (CCP) that will address the wintering population of the piping plover as well as other listed species. We are considering the possible exclusion of NWR land in subunit TX–3A from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being prepared and which will be released shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any additional management plans that address this species in this area.

Subunit TX–3B: South Padre Island—Laguna Madre side. This bayside subunit consists of 44,083 ac (17,840 ha) in Cameron and Willacy Counties, Texas. Its southern boundary extends from the Gulf of Mexico south of the

Laguna Madre west along latitude 26°09′19.00″ N, paralleling the existing anthropogenic (manmade) dike, to the edge of the intertidal mudflats bordering the eastern shore of the lower Laguna Madre. The dike is not within the boundary of the subunit. The northern boundary is the channel at Mansfield Channel. The eastern boundary is dense vegetation or, if there is no dense vegetation or dune, the boundary of subunit 3A. The western boundary is the western edge of the intertidal mudflats bordering the eastern shore of the lower Laguna Madre.

Approximately 42 percent of the land is Federally owned and managed by the Service's Laguna Atascosa NWR, and approximately 38 percent is State-owned and managed by the GLO (Table 3). The remainder is in private ownership.

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand and mud flats with no or very sparse emergent vegetation for feeding (PCE 1), unvegetated or sparsely vegetated sand and mud flats above high tide for roosting (PCE 2), and sand spits running into the Laguna for foraging and roosting (PCE 5). This subunit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. These threats, particularly vehicle access, are of greatest magnitude at the southern portion of the subunit where roads are near or adjacent to PCE 1. At this time, we are not aware of any management plans that address this species in this area.

Subunit TX–3C: North Padre Island—Laguna Madre side. This bayside unit consists of 50,855 ac (20,580 ha) in Kenedy and Kleberg Counties, Texas. It is along and within the Laguna Madre and extends from the western boundary of Padre Island National Seashore (PAIS) to the Gulf Intracoastal Waterway (GIWW). The northern boundary of the subunit is a line extending westward from the PAIS (at latitude 27° 4′ 29.9″ N), and its southern boundary is a line extending westward from the southern boundary of PAIS along the northern edge of the Mansfield Channel. The eastern boundary of this subunit is the western boundary of PAIS when the PCEs extend as far as PAIS or the eastern edge of the sand flats where the PCEs end. The portion of the western boundary north of longitude/latitude coordinate 26°48′38.2″ N, 97°28′11.6″ W is the eastern edge of the GIWW, and the portion of the western boundary south of the coordinate is the western edge of the intertidal mudflats bordering the eastern shore of the Laguna Madre. Most of the land is State-owned and managed by the GLO. A small portion is in private ownership (Table 3).

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand and mud flats with sparse emergent vegetation for feeding (PCE 1), unvegetated or sparsely vegetated sand, or mud flats above high tide for roosting (PCE 2), and sand spits running into the Laguna for foraging and roosting (PCE 5). This subunit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7). This subunit also contains sparse vegetation and little or no topographic relief mimicked in artificial habitat types (*e.g.*, dredge spoil sites) for feeding (PCE 8).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, the location of the subunit and the lack of roads near it tend to limit access to the PCEs for recreational use, particularly PCEs 1 and 2. At the north end, dredge disposal may threaten plover habitat. At this time we are not aware of any management plans that address this species in this area.

Subunit TX–3D: North Padre Island—Gulf of Mexico. This gulfside subunit consists of 269 ac (109 ha) of beach in Kleberg County, Texas. It extends along the gulf shore of North Padre Island from the northern boundary of PAIS northward 6.2 mi (10 km) to the Nueces County line. The southern boundary is the north boundary of the northeast section of the PAIS. The subunit extends eastward to the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW), and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This subunit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Most of the land is owned by the State and managed by the GLO. Approximately one-fifth is in private ownership (Table 3).

It was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this subunit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and nourishment efforts. These threats are of greater magnitude at the north end of the subunit where more roads provide easy access to the PCEs and the subunit is in close proximity to houses. At this time, we are not aware of any management plans that address this species in this area.

Subunit TX–3E: North Padre Island—Mesquite Rincon. This triangular bayside subunit of 9,578 acres (3,876 hectares) lies on the western shore of the lower Laguna Madre in Kleberg County, Texas. The subunit is generally bounded by Rincon de la Soledad on the southwestern side, Mesquite Rincon on the north, and the GIWW and Rincon de San Jose on the east. The southwestern boundary is an irregular line along the PCEs between the latitude/longitude coordinate points: 26°44′10.5″ N, 97° 28′ 04.5″ W at the southeastern point of Rincon de San Jose and 26°50′58.1″ N, 97°34′19.5″ W. The northern boundary is the line described between the latitude/longitude coordinate points: 26°51′24.2″ N, 97°33′25.8″ W and 26°51′24.2″ N, 97°27′52.7″ W. The northern portion of the eastern boundary is the western edge of the GIWW south to latitude/longitude coordinate point 26°48′52.7″ N,

97°28′12.9″ W. There the subunit curves westward and skirts a small horseshoe-shaped inlet in the Laguna Madre to the northeastern point of Rincon de San Jose at latitude/longitude coordinate point 26°48′43.9″ N, 97°29′4.7″ W. There it continues south in an irregular line along the edge of the PCEs to the southeastern point of Rincon San Jose. The southeastern portion of the triangle is a patchy mosaic of polygons that are not within the boundaries of the subunit because they do not contain the PCEs. They appear as islands surrounded by the subunit. Most of the land is in private ownership with a small portion that is State-owned and managed by the GLO (Table 3).

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand and mud flats with no or very sparse emergent vegetation for feeding (PCE 1), unvegetated or sparsely vegetated sand, or mud flats above high tide for roosting (PCE 2), and sand spits running into the Laguna for foraging and roosting (PCE 5). This subunit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7). This subunit also contains sparse vegetation and little or no topographic relief mimicked in artificial habitat types (*e.g.*, dredge spoil sites) for feeding (PCE 7).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, the location of the subunit and the lack of roads near it tend to limit access to the PCEs for recreational use, particularly PCEs 1 and 2. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–4: Lower Laguna Madre Mainland

This bayside unit consists of 17,218 ac (6,969 ha) in Cameron and Willacy Counties, Texas and lies along the western shoreline of the Lower Laguna Madre. The southern boundary is an east-west line at the northern tip of Barclay Island, approximately following latitude 26°14′42.2″ N. The northern boundary is an east-west line located near the northern tip of El Sauz Island, approximately 1.2 mi (1.9 km) south of the center of the city of Port Mansfield, Willacy County, Texas, and approximately following latitude 26°32′7.8″ N. The eastern boundary of the unit is the eastern edge of the line of dredge spoils that parallel the western side of the GIWW. The western boundary runs from southeast to northwest and is the western edge of sandy beach and mudflat habitat, approximately following the latitude/longitude coordinate points: latitude/longitude coordinate points: 26°14′42.45″ N, 97°19′32.75″ W; 26°17′15.54″ N, 97°20′47.31″ W; 26°20′10.17″ N, 97°21′10.94″ W; 26°21′31.54″ N, 97°22′48.10″ W; 26°24′26.64″ N, 97°23′53.27″ W; 26°26′8.55″ N, 97°25′13.33″ W; and 26°32′5.44″ N, 97°27′6.91″ W.

Approximately one-third of this unit is within the Service's Laguna Atascosa NWR. Approximately half is State-owned and managed by the GLO. The remainder is in private ownership (Table 3).

This unit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This unit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand and mud flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand or mud flats above high tide for roosting (PCE 2). This unit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7). This unit also contains sparse vegetation and little or no topographic relief mimicked in artificial habitat types (*e.g.*, dredge spoil sites) for feeding (PCE 8).

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, recreational access is limited due to a lack of roads, particularly for access to PCEs 1 and 2. The refuge is preparing a CCP that will address piping plover and other listed species. We are considering the possible exclusion of NWR land in unit TX–4 from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being prepared and which will be released shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any additional management plans that address this species in this area.

Unit TX–7: Newport Pass/Corpus Christi Pass Beach

This unit consists of 295 ac (120 ha) in Nueces County, Texas. It is a gulfside beach unit approximately 5.1 mi (8.2 km) long. The southern boundary is the gulfward extension of Saint Bartholomew Avenue, adjacent to the north end of the seawall. The northern boundary is the edge of the south jetty of the Fish Pass Structure at Mustang Island State Park. The eastern boundary is MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW), and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dune. Packery Channel cuts the beach approximately 0.3 mi (0.5 km) north of the south boundary. The seawall, jetty, bollards, and open water of Packery Channel are not within the boundaries of the unit. This unit is in State and private ownership (Table 3); the State portion is managed by the Mustang Island State Park.

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains PCEs in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and nourishment efforts. Due to its close proximity to Corpus Christi, this unit receives considerable recreational use and beach cleaning and nourishment. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–8: Mustang Island Beach

This unit consists of 620 ac (251 ha) in Nueces County, Texas. It is a gulfside beach unit approximately 12.5 mi (20.1

km) long. The southern boundary is the edge of the north jetty of the Fish Pass Structure at Mustang Island State Park. The northern boundary is the south side of the Horace Calder Pier in Port Aransas, Texas. The unit is bounded on the east by the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW) and on the west by the dune line where the habitat changes from lightly vegetated sandy beach to densely vegetated. The jetty and pier are not within the boundary of the unit. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. The unit is in State and private ownership with a small municipal park owned and managed by the City of Port Aransas (Table 3). The State land is managed by the GLO.

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and nourishment efforts. Due to its close proximity to Corpus Christi, this unit receives considerable recreational use and beach cleaning and nourishment. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–9: Fish Pass Lagoons

This bayside unit consists of 171 ac (69 ha) in Nueces County, Texas. This unit encompasses flats facing Corpus Christi Bay that extend 1.0 km (0.6 mi) on either side of Fish Pass. The inland boundary is a line of dense vegetation, and the bayside boundary is the northeast edge of the tidal sand flats that are a PCE. This unit includes all areas of habitat that contain PCEs 1, 2, 5, and 6 within the area described by a polygon with the following latitude/longitude coordinate points: 27°42′14.63″ N, 97°10′44.70″ W; 27°41′56.97″ N, 97°10′8.13″ W; 27°41′24.35″ N, 97°10′36.89″ W; 27°41′18.98″ N, 97°11′16.79″ W; 27°41′23.51″ N, 97°11′31.32″ W and 27°42′14.63″ N, 97°10′44.70″ W. Within that polygon, six moderate to large polygons from 5 to 64 ac (2 to 25 ha) each and two small polygons less than 1 ac (0.4 ha) each are PCEs and comprise the unit. Most of the unit is owned by the State and managed by the GLO (Table 3). A few acres are in private ownership.

This unit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This unit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand and/or mud flats with no or very sparse emergent vegetation for feeding (PCE 1), unvegetated or sparsely vegetated sand, or mud flats above high tide for roosting (PCE 2), and sand spits running into the bay for foraging and roosting (PCE 5). This unit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7).

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, recreational access is limited by a lack of road access, particularly to PCEs 1 and 2. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–10: Shamrock Island and Adjacent Mustang Island Flats

Subunit TX–10A: Shamrock Island. This 12 ac (5 ha) island in Nueces County, Texas, was a peninsula extending off of Mustang Island in Corpus Christi Bay until erosion separated the island from the mainland. Five small polygons of sand flats from 1.1 to 6.8 ac (0.4 to 2.7 ha) comprise the subunit. Most of the land is State-owned and managed by the GLO; the remainder is privately owned (Table 3).

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, a lack of road access limits recreational use and vehicle use. At this time, we are not aware of any management plans that address this species in this area.

Subunit TX–10B: Mustang Island: Unnamed sand flat. This 3 ac (1 ha) subunit in Nueces County, Texas, is a small, unnamed sand flat near the north edge of the mouth of Wilson's Cut in Corpus Christi Bay. The subunit is the western half of the island that is sand flats landward (easterly) to the western edge of tidal marsh. It is entirely State-owned (Table 3) and managed by the GLO.

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2), and sand spits running into the bay for foraging and roosting (PCE 5).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and restoration efforts. However, the location of the subunit and the configuration of the polygons of PCEs that comprise this subunit, limit recreational access, particularly by vehicles, to PCEs 1 and 2. At this time, we are not aware of any management plans that address this species in this area.

Subunit TX–10C: Mustang Island: Lagoon Complex. This 329 ac (133 ha) subunit in Nueces County, Texas, is an extensive lagoon complex that consists of 11 polygons within a larger polygon that extends 2.2 miles (3.5 kilometers) south of Wilson's Cut in Corpus Christi Bay. The southern boundary of the larger polygon begins at the western end

at latitude/longitude coordinate point 27°43′2,4″ N, 97°10′ 19.4″ W at the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. It follows the dune line southeast approximately 830 ft (253 m) to a road, then follows the road approximately 945 ft (288 m) to the edge of the tidal sand flat PCE. It follows the southeastern edge of the sand flat northeast to the western edge of a north-south road, where it follows the edge of the sand flat northward to the south edge of a road that runs east-west parallel to the southwestern edge of Wilson's Cut. The northern edge of the boundary is the south edge of the road or the northern extent of the sand flat when it does not reach the road. The western boundary follows the PCEs along their eastern edge at Corpus Christi Bay beginning 409 ft (125 m) southwest of the southwestern edge of Wilson's Cut to the coordinate point at the western edge of the southern boundary. A road transects the larger polygon described above forming two polygons that exclude the road. The PCEs within the two polygons comprise the subunit. The subunit consists of private and State-owned lands (Table 3).

This subunit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This subunit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2).

The PCEs in this subunit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access and beach cleaning and stabilization efforts. Road access to the PCEs is extensive. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–14: East Flats

This bayside unit consists of 590 ac (239 ha) in Nueces County, Texas. It is an irregularly shaped intertidal sand flat south of the Corpus Christi Ship Channel. The north boundary is the northern edge of the sand flat near or adjacent to dredge spoil areas bordering the south side of the Corpus Christi Ship Channel. The northwestern latitude/longitude coordinate is 27°49′54.49″ N, 97°6′14.28″ W, and the northeastern latitude/longitude coordinate is 27°49′55.29″ N, 97°5′12.86″ W. From there, the sand flat curves southward, and the southeastern edge of it forms a highly irregular line that ends in the southwest portion of the polygon at the eastern edge of a navigation channel from the Corpus Christi Ship Channel to Corpus Christi Bay at latitude/longitude coordinate 51.93″ N, 97°5′52.58″ W. The sand flat continues on the western edge of the navigation channel in a northwesterly direction to latitude/longitude coordinate 27°49′22.08″ N, 97°6′37.04″ W. It then curves northeasterly and across the cut to the northern edge at the northwest coordinate. On the east, it abuts the City of Port Aransas. There is a small marshland within the sand flat that bisects the sand flat that is not a PCE and is not included in the unit. The unit is mostly in private ownership with a small portion of State land managed by the GLO (Table 3).

This unit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This unit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover, including intertidal sand and mud flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2).

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. However, this unit does not attract heavy recreational use. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–15: North Pass

This bayside unit consists of 805 ac (325 ha) in Aransas County, Texas. The unit is bounded on the northeast by a line between latitude/longitude coordinates 27°54′8.70″ N, 97°0′36.97″ W and 27°54′54.53″ N, 97°1′18.17″ W, on the northwest and west by the edge of tidal sand flats in Aransas Bay, on the south by a line running east from coordinate 27°53′16.96″ N, 97°2′22.44″ W to unit TX–16, and on the southeast by the landward boundary of unit 16. The unit is all areas that contain the PCEs for the species within a larger area described by a polygon with the following sets of latitude/longitude coordinate points: 27°54′8.70″ N, 97°0′36.97″ W; 27°53′10.68″ N, 97°1′21.36″ W; 27°53′16.96″ N, 97°2′22.44″ W; 27°53′33.08″ N, 97°2′33.05″ W; 27°54′42.68″ N, 97°2′4.83″ W; 27°54′47.59″ N, 97°1′51.73″ W; 27°54′54.53″ N, 97°1′18.17″ W and 27°54′8.70″ N, 97°0′36.97″ W. This unit is a remnant of a hurricane washover on San Jose Island. Approximately 18 percent is State-owned and managed by the GLO; the remainder is in private ownership (Table 3).

This unit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This unit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand flats with no or very sparse emergent vegetation for feeding (PCE 1) and unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2). This subunit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7).

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation by raptors and wild mammals; and pedestrian recreational access. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–16: San Jose Beach

This unit consists of 1,376 ac (557 ha) in Aransas County, Texas. It is a gulfside beach unit approximately 19.8 mi (31.9 km) long. The southern boundary is the edge of the north jetty of Aransas Pass. The jetty is not within the boundary of the unit. The south edge of Cedar Bayou Pass is the northern boundary. The eastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW), and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. A small section is in Federal ownership and managed by the Service's Matagorda Island NWR. Approximately half of the unit is State-owned and managed by the GLO, and

nearly as much is in private ownership (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by domestic animals, predation by raptors and wild mammals, and pedestrian recreational access. The refuge is preparing a CCP that will address the wintering population of the piping plover as well as other listed species. We are considering the possible exclusion of NWR land in unit TX–16 from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being draft and will be released shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any management plans that address this species in this area.

Unit TX–18: Cedar Bayou/Vinson Slough

This bayside unit consists of 2467 ac (999 ha) in Aransas County, Texas. It is a remnant of a hurricane washover area and includes the highly dynamic area of Cedar Bayou, the pass that separates San Jose Island and Matagorda Island. Beginning at the confluence of Vinson Slough and Cedar Bayou, the boundary follows the shore of Spalding Cove to Long Reef, then continues along a line extending 2.5 miles southwest of Long Reef to the shore of San Jose Island, then along the shore of the island to the landward boundary of unit TX–16. Within that area, the unit consists of numerous polygons of PCEs; non-PCE polygons within the described area are not within the boundaries of the unit. The southern and southeastern boundary is described by a line with the following sets of latitude/longitude coordinate points: 28°1′21.76″ N, 96°57′51.24″ W; 28°1′12.77″ N, 96°57′31.18″ W; 28°2′3.07″ N, 96°56′45.84″ W; 28°2′15.92″ N, 96°56′25.10″ W; 28°2′30.32″ N, 96°56′11.97″ W; 28°3′15.62″ N, 96°54′20.01″ W; 28°3′58.58″ N, 96°53′24.65″ W; 28°4′1.15″ N, 96°52′14.65″ W; 28°3′31.74″ N, 96°51′38.29″ W and 28°3′17.69″ N, 96°51′38.47″ W. The specific northern boundary is described by a line with the following sets of latitude/longitude coordinate points: 28°5′44.24″ N, 96°54′8.16″ W; 28°5′13.23″ N, 96°52′44.85″ W; 28°4′33.99″ N, 96°50′46.55″ W; 28°4′38.92″ N, 96°50′40.79″ W and 28°4′22.98″ N, 96°50′22.94″ W. The eastern boundary at the northeastern end of the unit is units TX–16 and TX–19 on the gulfside. The western boundary is the western edge of tidal sand flats in Aransas Bay.

This area includes a small section of Federally owned land managed by the Service's Matagorda Island NWR and a small section of State-owned land. The remaining area is privately owned (Table 3).

This unit was occupied at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. This unit contains PCEs in the appropriate spatial arrangement essential to the conservation of the piping plover including intertidal sand flats with no or very sparse emergent vegetation for feeding (PCE 1), unvegetated or sparsely vegetated sand flats above high tide for roosting (PCE 2), and sand spits running into the bay for foraging and roosting (PCE 5). This unit also includes unvegetated washover areas with little or no topographic relief for feeding and roosting (PCE 7).

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. Vehicle use of the unit may be limited somewhat by accessibility. The refuge is preparing a CCP that will address the wintering population of the piping plover as well as other listed species. We are considering the possible exclusion of NWR land in unit TX–18 from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being draft and will be released shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any additional management plans that address this species in this area.

Unit TX–19: Matagorda Island Beach

This unit consists of 2,419 ac (979 ha) in Calhoun County, Texas. It is a gulfside beach unit approximately 37.1 mi (59.7 km) long. The southern boundary is the northern edge of Cedar Bayou Pass, and the northern boundary is the southern edge of Pass Cavallo. At Pass Cavallo, the unit curves from the eastern gulfside passing between the south edge of the pass and the north edge of the dunes to a small area on the bayside. The eastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW) and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. The Federally owned land in this unit is managed by the Service's Matagorda Island NWR (Table 3). This unit also includes a small section of land in State ownership.

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by domestic animals, predation by raptors and wild mammals, pedestrian recreational access, and access by refuge staff and others for sea turtle monitoring efforts. The refuge is preparing a CCP that will address the wintering population of the piping plover as well as other listed species. We are considering the possible exclusion of NWR land in unit TX–19 from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being prepared and which will be released

shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any additional management plans that address this species in this area.

Unit TX–22: Decros Point

This unit consists of 545 ac (221 ha) at the Matagorda/Calhoun County line, Texas. It is a gulfside beach unit approximately 4.8 mi (7.7 km) long. This unit was originally the southern tip of the Matagorda Peninsula. It was made into an island by the dredging of the Matagorda Ship Channel, the edge of which is the northern boundary of the unit. The unit is horseshoe in shape with the east side along the Gulf of Mexico and the west side along Matagorda Bay; the two are connected at their southern boundary by habitat from the north edge of Pass Cavallo northward to the dune line. Densely vegetated sand dunes run north to south in the center of the horseshoe and are not within the boundary of the critical habitat because they are not a PCE. The eastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW), and the western boundary is the western edge of tidal sand flats on the east side of Matagorda Bay. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Approximately 60 percent of the unit is in State ownership managed by the GLO. The remainder is privately owned (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach (PCE 4) for roosting and feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. Due to a lack of road access, this unit does not receive much recreational vehicle use. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–23: West Matagorda Peninsula Beach

This unit consists of 1,808 ac (732 ha) of shoreline in Matagorda County, Texas. It is a gulfside beach unit approximately 23.9 mi (38.5 km) long. The southern boundary is the northern jetty of the Matagorda Ship Channel. The northern boundary is the Old Colorado River channel. The MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW) is the eastern boundary, and the western boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Just under half of the unit is State-owned and managed by the GLO; the remainder is privately owned (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–27: East Matagorda Bay/Matagorda Peninsula Beach West

This unit consists of 906 ac (367 ha) of shoreline in Matagorda County, Texas. It is a gulfside beach unit approximately 14.1 mi (22.8 km) long. The southwestern boundary is the northeastern edge of the Old Colorado River channel. The unit runs along the beach 14 mi (23 km) to the northeastern boundary opposite Eidelbach Flats described by a line between the latitude/longitude coordinate points: 28°41′2.26″ N, 95°46′29.04″ W and 28°41′6.74″ N, 95°46′32.46″ W. The southeastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW). The northwestern boundary runs along the dune line where the habitat changes from lightly vegetated sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Just over half of the unit is State-owned and managed by the GLO; the remainder is privately owned (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–28: East Matagorda Bay/Matagorda Peninsula Beach East

This gulfside unit consists of 478 ac (193 ha) in Matagorda County, Texas. It extends along the Gulf beach southwest and northeast of Brown Cedar Cut. The cut is not within the boundary of the unit. This unit abuts with portions of the southeastern edges of units TX–29 and TX–30, which are on the East Matagorda Bay side. The southwestern boundary is approximately 4 mi (6.5 km) southwest of Brown Cedar Cut at a line described by the following sets of latitude/longitude coordinate points: 28°43′11.91″ N, 95°42′25.47″ W and 28°43′17.09″ N, 95°42′28.56″ W. The northeastern boundary is approximately 2.8 mi (4.5 km) northeast of Brown Cedar Cut to the point where Texas

Farm to Market Road 457 intersects the beach. The southeastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW). The northwestern boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat boundaries, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Approximately one-third is in State ownership and managed by the GLO; the remaining two-thirds is privately owned (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–31: San Bernard NWR Beach

This gulfside unit consists of 399 ac (161 ha) in Matagorda and Brazoria counties, Texas. It is a 6.2 mi (10 km) segment of beach on the Gulf of Mexico near the mouth of the San Bernard River. The northeastern boundary is at the southwestern edge of the mouth of the San Bernard River. The southwestern boundary follows a line described by the following sets of latitude/longitude coordinate points: 28°47′54.39″ N, 95°33′26.21″ W, and 28°47′57.69″ N, 95°33′27.75: W. The southeastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW). The northwestern boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. There is a cut through the beach from the Gulf of Mexico to a lake 3.5 mi (5.6 km) southwest of the San Bernard River, which is not within the unit. Bollards also are not within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. Approximately 30 percent of this unit is in Federal ownership and managed by the Service's San Bernard NWR. Approximately 48 percent is State-owned and managed by the GLO with the remaining area in private ownership (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. The Federally owned portion has pedestrian recreational access, but no vehicle access. The refuge is preparing a CCP that will address the wintering population of the piping plover as well as other listed species. We are considering the possible exclusion of NWR land in unit TX–31 from the final critical habitat designation based on benefits provided to wintering piping plover habitat under the CCP, a draft of which is being prepared and which will be released shortly for public comment (see the Areas Considered for Exclusion Under Section 4(b)(2) of the Act section for further discussion). At this time, we are not aware of any additional management plans that address this species in this area.

Unit TX–32: Gulf Beach Between Brazos and San Bernard Rivers

This gulfside unit consists of 555 ac (225 ha) of shoreline in Brazoria County, Texas. This unit is a 6.1 mi (9.8 km) segment of beach on the Gulf of Mexico between the mouths of the San Bernard and Brazos Rivers. The southwestern boundary is the northeastern edge of the mouth of the San Bernard River. The northeastern boundary is the western edge of the mouth of the Brazos River. The southeastern boundary is the MLLW of the Gulf of Mexico (see the Methods section for our derivation of MLLW). The northwestern boundary runs along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. It is entirely in State ownership and managed by the GLO (Table 3).

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by domestic animals, predation by raptors and wild mammals, and pedestrian recreational access. At this time, we are not aware of any management plans that address this species in this area.

Unit TX–33: Bryan Beach and Adjacent Beach

This unit consists of 212 ac (86 ha) in Brazoria County, Texas. It is gulfside beach approximately 3.5 mi (5.7 km) in length on the Gulf of Mexico near the mouth of the Brazos River. The southwestern boundary is the northeastern edge of the Brazos River. The northeastern boundary is Farm-to-Market Road 1495 (Bryan Beach Rd). The southeastern boundary is the MLLW (see the Methods section for our derivation of MLLW). The northwestern boundary follows along the dune line where the habitat changes from lightly vegetated, sandy beach to densely vegetated dunes. This unit does not include bollards within the critical habitat designation, although they may be present within the described area because they are too small to be detected with the mapping methodology used. The unit is entirely in State

ownership (Table 3) and managed by the Texas Department of Parks and Wildlife.

The unit was occupied by piping plovers at the time of listing and is currently occupied (Table 2). Occupancy has been confirmed by species experts at least 2 years out of the last 10 years. Habitat in this unit contains features in the appropriate spatial arrangement that are essential to the conservation of the wintering population of the piping plover including sand flats with little or no emergent vegetation (PCE 1) and surf-cast algae (PCE 3) for feeding, and unvegetated or sparsely vegetated sandy backbeach and washovers (PCEs 4 and 7) for roosting and sheltering and for feeding.

The PCEs in this unit may require special management considerations or protections to ameliorate the threats of disturbance of foraging and roosting plovers by humans, vehicles, and domestic animals; predation; and modification and loss of habitat due to uncontrolled recreational access. At this time, we are not aware of any management plans that address this species in this area.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. Decisions by the 5th and 9th Circuit Court of Appeals have invalidated our definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service et al.*, 378 F.3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.*, 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would remain functional (or retain the current ability for the PCEs to be functionally established) to serve its intended conservation role for the species.

If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the 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. As a result of this consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. We define ''Reasonable and prudent alternatives'' 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,
- Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,
- Are economically and technologically feasible, and
- Would in the Director's opinion, avoid jeopardizing the continued existence of the listed species or destroying or adversely modifying 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 we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies may sometimes need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Federal activities that may affect the wintering population of the piping plover or its designated critical habitat will require consultation under section 7 of the Act. Activities on State, Tribal, local or private lands requiring a Federal permit (such as a permit from the U. S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from us under section 10 of the Act) or involving some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency) are subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat, and actions on State, Tribal, local or private lands that are not federally funded, authorized, or permitted, do not require section 7 consultations.

Application of the Adverse Modification Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species, would retain the current ability for the physical and biological features to be functionally established. Activities that may destroy or adversely modify critical habitat are those that alter the physical and biological features to an extent that appreciably reduces the conservation value of critical habitat for the wintering piping plover. Generally, the conservation role of wintering piping plover critical habitat units is to support viable core area populations.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and therefore should result in consultation for the wintering population of the piping plover include, but are not limited to:

(1) Actions that would significantly and detrimentally alter the hydrology of tidal mud and sand flats.

(2) Actions that would significantly and detrimentally alter the input of sediments and nutrients necessary for the maintenance of geomorphic and biologic processes that ensure appropriately configured and productive beach systems.

(3) Actions that would introduce significant amounts of emergent vegetation.

(4) Actions that would significantly and detrimentally alter the topography of a site (such alteration may affect the hydrology of an area or may render an area unsuitable for roosting).

(5) Actions that would reduce the value of a site by significantly disturbing plovers from activities such as foraging and roosting.

(6) Actions that would significantly and detrimentally alter water quality, which may lead to decreased diversity or productivity of prey organisms or may have direct detrimental effects on piping plovers.

(7) Actions that would impede natural processes that create and maintain washover passes and sparsely vegetated intertidal feeding habitats.

These activities could eliminate or reduce the habitat necessary for foraging by eliminating or reducing the piping plovers' prey base; destroying or removing available upland habitats necessary for protection of the birds during storms or other harsh environmental conditions; increasing the amount of vegetation to levels that make foraging or roosting habitats unsuitable; and increasing recreational activities to such an extent that the amount of available undisturbed foraging or rooting habitat is reduced, with direct or cumulative adverse effects to individuals and completion of their life cycles.

We consider all of the units proposed as critical habitat to contain features essential to the conservation of the wintering population of the piping plover. All units are within the geographic range of the species, all were occupied by the species at the time of listing, and are likely to be used by the wintering population of the piping plover. Federal agencies already consult with us on activities in areas currently occupied by the wintering population of the piping plover, or if the species may be affected by the action, to ensure that their actions do not jeopardize the continued existence of the wintering population of the piping plover.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary must designate and revise critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the legislative history is clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give any factor.

Under section 4(b)(2) of the Act, in considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and determine whether the benefits of exclusion outweigh the benefits of inclusion. If based on this analysis, we make this determination, then we can exclude the area only if such exclusion would not result in the extinction of the species.

Areas Considered for Exclusion Under Section 4(b)(2) of the Act

Under section 4(b)(2) of the Act, we intend to consider the possible exclusion of Federally owned National Wildlife Refuge lands in units TX–3, TX–4, TX–16, TX–18, TX–19, and TX–31 from the final critical habitat designation, These lands are to be covered under CCPs that are currently being drafted. We will further consider the possible exclusion of the areas covered by the CCPs being drafted once the drafts are released and if they are released within a timeframe that is reasonable for us. We specifically solicit comments on the inclusion or exclusion of these areas.

Editorial Corrections

We revised the entry in 50 CFR 17.95(b) in the following ways: In paragraph 1., we made minor revisions to our descriptions of the PCEs and reformatted the PCEs for clarity. In paragraph 2., we clarified what is not a PCE. In paragraph 3., we revised the methods used to map and designate critical habitat units for certain units in Texas, and we revised the critical habitat unit descriptions and maps for those units.

Economics

We are preparing an analysis of the economic impacts of proposing revised critical habitat (Texas Units 3, 4, 7, 8, 9, 10, 14, 15, 16, 18, 19, 22, 23, 27, 28, 31, 32, and 33) for the wintering population of the piping plover. 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://www.regulations.gov,* or by contacting the Corpus Christi Ecological Services Office directly (see **FOR FURTHER INFORMATION CONTACT** section). We may exclude areas from the final rule based on the information in the economic analysis.

Peer Review

In accordance with our joint policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we are requesting the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our proposed critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these 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 we receive during this comment period on this proposed rule during our preparation of a final determination. Accordingly, our final decision may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if we receive any request for hearings. We must receive your request for a public hearing within 45 days after the date of this **Federal Register** publication. Send your request to the person named in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the first hearing.

Required Determinations

Regulatory Planning and Review

The Office of Management and Budget (OMB) has determined that this rule is not significant and has not reviewed this rule under Executive Order 12866 (E.O. 12866). OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other Federal agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency must 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 effects 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 the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended RFA to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

The economic analysis prepared for the July 10, 2001, critical habitat designation (66 FR 36038) identified six activities that may be affected by the designation of wintering critical habitat for the piping plover because they occur within or near critical habitat areas. These activities are: (1) Housing and commercial shoreline development; (2) dredging and disposal of dredged materials; (3) beach nourishment; (4) oil and gas exploration; (5) recreational visitation of shoreline; and (6) waterway operations. At this time, we lack the available economic information necessary to provide an adequate factual basis for the required RFA finding. Therefore, we defer the RFA finding until completion of the draft economic analysis prepared under section 4(b)(2) of the Act and E.O. 12866. This draft economic analysis will provide the required factual basis for the RFA finding. Upon completion of the draft economic analysis, we will announce availability of the draft economic analysis of the proposed designation in the **Federal Register** and reopen the public comment period for the proposed designation. We will include with this announcement, as appropriate, an initial regulatory flexibility analysis or a certification that the rule will not have a significant economic impact on a substantial number of small entities accompanied by the factual basis for that determination. We have concluded that deferring the RFA finding until completion of the draft economic analysis is necessary to meet the purposes and requirements of the RFA. Deferring the RFA finding in this manner will ensure that we make a sufficiently informed determination based on adequate economic information and provides the necessary opportunity for public comment.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(a) This proposed amended rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or [T]ribal governments,'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and [T]ribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or [T]ribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; AFDC work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(b) We do not believe that this rule will significantly or uniquely affect small governments because the proposed units do not occur within the jurisdiction of small governments. The government-owned lands being proposed for critical habitat designation are owned by the County of Cameron, the State of Texas, and the U.S. Fish and Wildlife Service. None of these government entities fit the definition of a ''small governmental'' jurisdiction. Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Takings

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the wintering population of the piping plover in Texas in a takings implications assessment. The takings implications assessment concludes that this designation of critical habitat for the wintering population of the piping plover in Texas does not pose significant takings implications for lands within or affected by the proposed revised designation. However, we will further evaluate this issue as we conduct our economic analysis and review and revise this assessment as warranted.

Federalism

In accordance with E.O. 13132 (Federalism), this proposed 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 proposed critical habitat designation with appropriate State resource agencies in Texas. Some critical habitat is still designated in Texas for the piping plover. The designation of critical habitat on lands currently occupied by the wintering population of the piping plover imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. This proposed 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 wintering population of the piping plover.

Paperwork Reduction Act of 1995

This proposed rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act

It is our position that, outside the jurisdiction of the Circuit Court of the United States for the Tenth Circuit, we do not need to prepare environmental analyses as defined by the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld by the Circuit Court of the United States for the Ninth Circuit (*Douglas County* v. *Babbitt*, 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)). However, the court ruling in *Cape Hatteras Access Preservation Alliance* v. *U.S. Department of Interior* (344 F. Supp. 2d 108 (D.D.C. 2004)) ordered us to revise the critical habitat designation for wintering piping plovers in North Carolina and to prepare an environmental analysis. To comply with that court's order, we prepared an environmental assessment for that action pursuant to NEPA, and, as an exercise of our discretion, have chosen to prepare an environmental assessment for critical habitat designation for the wintering population of the piping plover in Texas. We will notify the public when it is drafted and available for comment.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

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), E.O. 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that there are no Tribal lands occupied at the time of listing with features essential for the conservation, and no Tribal lands that are essential for the conservation, of the wintering population of the piping plover in Texas. Therefore, we have not proposed designation of critical habitat for the wintering population of the piping plover on Tribal lands.

Energy Supply, Distribution, or Use

On May 18, 2001, the President issued an Executive Order (E.O. 13211; Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) 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 to designate revised critical habitat for the wintering population of the piping plover in areas of Texas is not a significant regulatory action under Executive Order 12866, and we do not expect it to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. This action, however, may impact seismic studies for oil and gas drilling; we will further evaluate energy-related issues as we conduct our economic analysis, and review and revise this assessment as warranted.

References Cited

A complete list of all references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the Field Supervisor, Corpus Christi Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary author of this package is the staff of the Corpus Christi Ecological Services Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

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; Public Law 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.95(b), amend the entry for ''Piping Plover (*Charadrius melodus*) Wintering Habitat'' as follows:

a. In paragraph 1., revise the text as set forth below;

b. In paragraph 2., revise the text as set forth below;

c. Under paragraph 3., *Texas*, remove the words ''*Texas* (Maps were digitized using 1995 and 1996 DOQQs and National Oceanic and Atmospheric Administration's (NOAA) Medium Resolution Digital Vector Shoreline)'' and add in their place a new header, parenthetical text, and introductory text as set forth below;

d. Remove the critical habitat description for Unit TX–3 and add in its place a new critical habitat description for Unit TX–3 as set forth below;

e. Remove the critical habitat description for Unit TX–4 and add in its place a new critical habitat description for Unit TX–4 as set forth below;

f. Remove the critical habitat description for Unit TX–7 and add in its place a new critical habitat description for Unit TX–7 as set forth below;

g. Remove the critical habitat description for Unit TX–8 and add in its place a new critical habitat description for Unit TX–8 as set forth below;

h. Remove the critical habitat description for Unit TX–9 and add in its place a new critical habitat description for Unit TX–9 as set forth below;

i. Remove the critical habitat description for Unit TX–10 and add in its place a new critical habitat description for Unit TX–10 as set forth below;

j. Remove the critical habitat description for Unit TX–14 and add in its place a new critical habitat description for Unit TX–14 as set forth below;

k. Remove the critical habitat description for Unit TX–15 and add in its place a new critical habitat description for Unit TX–15 as set forth below;

l. Remove the critical habitat description for Unit TX–16 and add in its place a new critical habitat description for Unit TX–16 as set forth below;

m. Remove the critical habitat description for Unit TX–17;

n. Remove the critical habitat description for Unit TX–18 and add in its place a new critical habitat description for Unit TX–18 as set forth below;

o. Remove the critical habitat description for Unit TX–19 and add in its place a new critical habitat description for Unit TX–19 as set forth below;

p. Remove the critical habitat description for Unit TX–22 and add in its place a new critical habitat description for Unit TX–22 as set forth below;

q. Remove the critical habitat description for Unit TX–23 and add in its place a new critical habitat description for Unit TX–23 as set forth below;

r. Remove the critical habitat description for Unit TX–27 and add in its place a new critical habitat description for Unit TX–27 as set forth below;

s. Remove the critical habitat description for Unit TX–28 and add in its place a new critical habitat description for Unit TX–28 as set forth below;

t. Remove the critical habitat description for Unit TX–31 and add in its place a new critical habitat description for Unit TX–31 as set forth below;

u. Remove the critical habitat description for Unit TX–32 and add in its place a new critical habitat description for Unit TX–32 as set forth below;

v. Remove the critical habitat description for Unit TX–33 and add in its place a new critical habitat description for Unit TX–33 as set forth below;

w. Remove the map for ''Texas Units: 1, 2, 4 and southern 3'' and the map for ''Texas Units: 5 and northern 3'' and add in their place a new map ''Texas Units 1 to 5'' as set forth below;

x. Remove the map for ''Texas Units: 6 to 14'' and add in its place two new maps ''Texas Units 6 to 10 and 14'' and ''Texas Units 11 to 13'' as set forth below;

y. Remove the map for ''Texas Units: 15 to 21'' and add in its place a new map ''Texas Units 15, 16 and 18 to 21'' as set forth below;

z. Remove the map for ''Texas Units: 22, 23, 24, 25 and 26'' and add in its place a new map ''Texas Units 22 to 27'' as set forth below; and

aa. Remove the map for ''Texas Units: 26, 27, 28, 29 and 30'' and the seventh map for ''Texas Units 31, 32, 33, and 34'' and add in their place a new map ''Texas Units 28 to 34'' as set forth below.

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(b) *Birds.*

* * * * *

Piping Plover (Charadrius melodus) Wintering Habitat

1. The primary constituent elements essential for the conservation of the wintering population of the piping plover are those habitat components that support foraging, roosting, and sheltering and the physical features necessary for maintaining the natural processes that support these habitat components. The primary constituent elements are:

(i) Intertidal sand beaches (including sand flats) or mud flats (between annual low tide and annual high tide) with no or very sparse emergent vegetation for feeding. In some cases, these flats may be covered or partially covered by a mat of blue-green algae.

(ii) Unvegetated or sparsely vegetated sand, mud, or algal flats above annual high tide for roosting. Such sites may have debris or detritus and may have micro-topographic relief (less than 20 in (50 cm) above substrate surface) offering refuge from high winds and cold weather.

(iii) Surf-cast algae for feeding.

(iv) Sparsely vegetated backbeach, which is the beach area above mean high tide seaward of the dune line, or in cases where no dunes exist, seaward of a delineating feature such as a vegetation line, structure, or road. Backbeach is used by plovers for roosting and refuge during storms.

(v) Spits, especially sand, running into water for foraging and roosting.

(vi) Salterns, or bare sand flats in the center of mangrove ecosystems that are found above mean high water and are only irregularly flushed with sea water.

(vii) Unvegetated washover areas with little or no topographic relief for feeding and roosting. Washover areas are formed and maintained by the action of hurricanes, storm surges, or other extreme wave actions.

(viii) Natural conditions of sparse vegetation and little or no topographic relief mimicked in artificial habitat types (*e.g.*, dredge spoil sites).

2. Critical habitat does not include manmade structures (such as bridges, jetties, buildings, roads, and other paved areas) or their ancillary facilities (such as lawns or other maintained landscaped areas) and the land on which they are located existing on the effective date of this rule.

3. * * *

* * * * *

Texas (Maps for units 1, 2, 5, 6, 11, 12, 13, 20, 21, 24, 25, 26, 29, 30, 34, 35, 36, and 37 were digitized using 1995 and 1996 DOQQs and National Oceanic and Atmospheric Administration's (NOAA) Medium Resolution Digital Vector Shoreline. Data layers defining map units 3, 4, 7, 8, 9, 10, 14, 15, 16, 18, 19, 22, 23, 27, 28, 31, 32, and 33 were created for bayside areas using data on known piping plover wintering locations, 1992 National Wetlands Inventory (NWI) data (except for Unit TX–22 which had 2001 data available) fitted to 2005 National Agriculture Imagery Program (NAIP) aerial photographs, and regional shoreline-defining electronic files.) The primary constituent elements for the piping plover are closely associated with the following NWI classifications: M2USN (marine (gulfside) sandy coastline (beach), regularly inundated by tides), M2USP (marine (gulfside) sandy coastline (beach), irregularly inundated by tides), E2AB1N (estuarine (bayside) algal mud or sand flats, regularly inundated by tides), E2AB1P (estuarine (bayside) algal mud or sand flats, irregularly inundated by tides), E2AB3M (estuarine (bayside) grass flats of mud or sand, irregularly inundated by tides), E2USM (estuarine (bayside) sandy shore (beach/sandbar), rarely exposed by tidal fluctuation), E2USN (estuarine (bayside) sandy shore (beach/sandbar), regularly inundated by tides), E2USP (estuarine (bayside) sandy shore (beach/sandbar), irregularly inundated by tides), L1UBKhs (impounded, artificially flooded open water dredge spoil pit, greater than 20 ac (8 ha), L2USKhs (impounded, artificially flooded sandy bottom dredge spoil pit, greater than 20 ac (8 ha)). To map the gulfside, 2005 NAIP imagery was used as a base and heads up digitizing of vegetation and water lines at a scale of 1:5,000 was used to produce polygons of critical habitat. Mean lower low waterline (MLLW) vector data from the National Oceanic and Atmospheric Administration (NOAA) was averaged with 2005 NAIP aerial photographs to correct misalignments. Measurements were taken every 100 meters along Unit TX–3 to determine an average distance between the 2005 NAIP waterline and the NOAA MLLW line. This 184 ft (56 m) average distance was then used to get an estimated MLLW line that was applied in all coastal areas.

* * * * *

Unit TX–3: Padre Island. This unit consists of five subunits:

(1) Subunit TX–3A: South Padre Island—Gulf of Mexico Shoreline.

(2) Subunit TX–3B: South Padre Island—Laguna Madre side.

(3) Subunit TX–3C: North Padre Island—Laguna Madre side.

(4) Subunit TX–3D: North Padre Island—Gulf of Mexico.

(5) Subunit TX–3E: North Padre Island—Mesquite Rincon.

Unit TX–4: Lower Laguna Madre Mainland.

* * * * *

Unit TX–7: Newport Pass/Corpus Christi Pass Beach.

Unit TX–8: Mustang Island Beach.

Unit TX–9: Fish Pass Lagoons.

Unit TX–10: Shamrock Island and Adjacent Mustang Island Flats. This unit consists of three subunits:

(1) Subunit TX–10A: Shamrock Island.

(2) Subunit TX–10B: Mustang Island: Unnamed sand flat.

(3) Subunit TX–10C: Mustang Island: Lagoon Complex.

* * * * *

Unit TX–14: East Flats.

Unit TX–15: North Pass.

Unit TX–16: San Jose Beach.

Unit TX–18: Cedar Bayou/Vinson Slough.

Unit TX–19: Matagorda Island Beach.

* * * * *

Unit TX–22: Decros Point.

Unit TX–23: West Matagorda Peninsula Beach.

* * * * *

Unit TX–27: East Matagorda Bay/Matagorda Peninsula Beach West.

Unit TX–28: East Matagorda Bay/Matagorda Peninsula Beach East.

* * * * *

Unit TX–31: San Bernard NWR Beach.

Unit TX–32: Gulf Beach Between Brazos and San Bernard Rivers.

Unit TX–33: Bryan Beach and Adjacent Beach.

* * * * *

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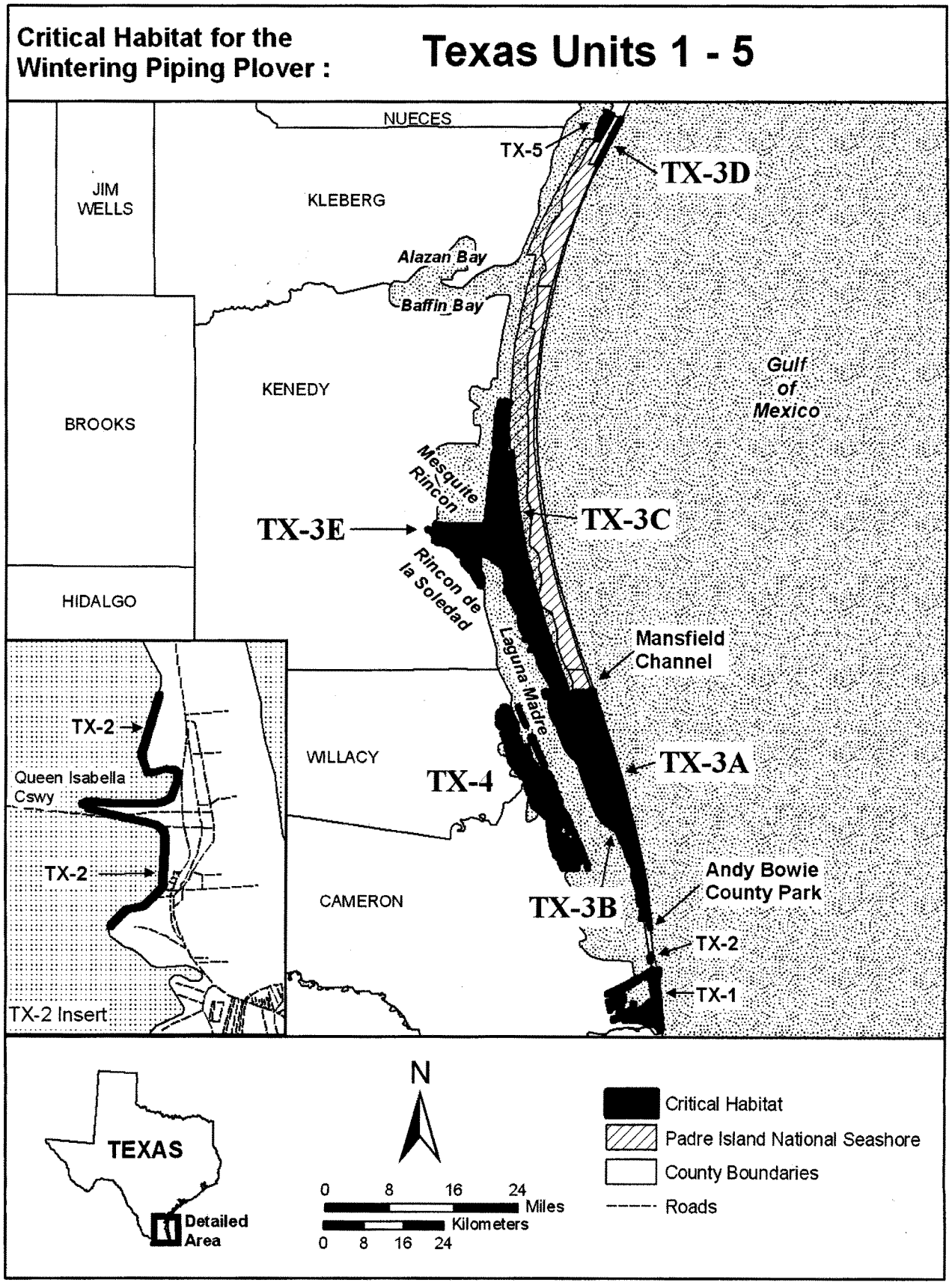
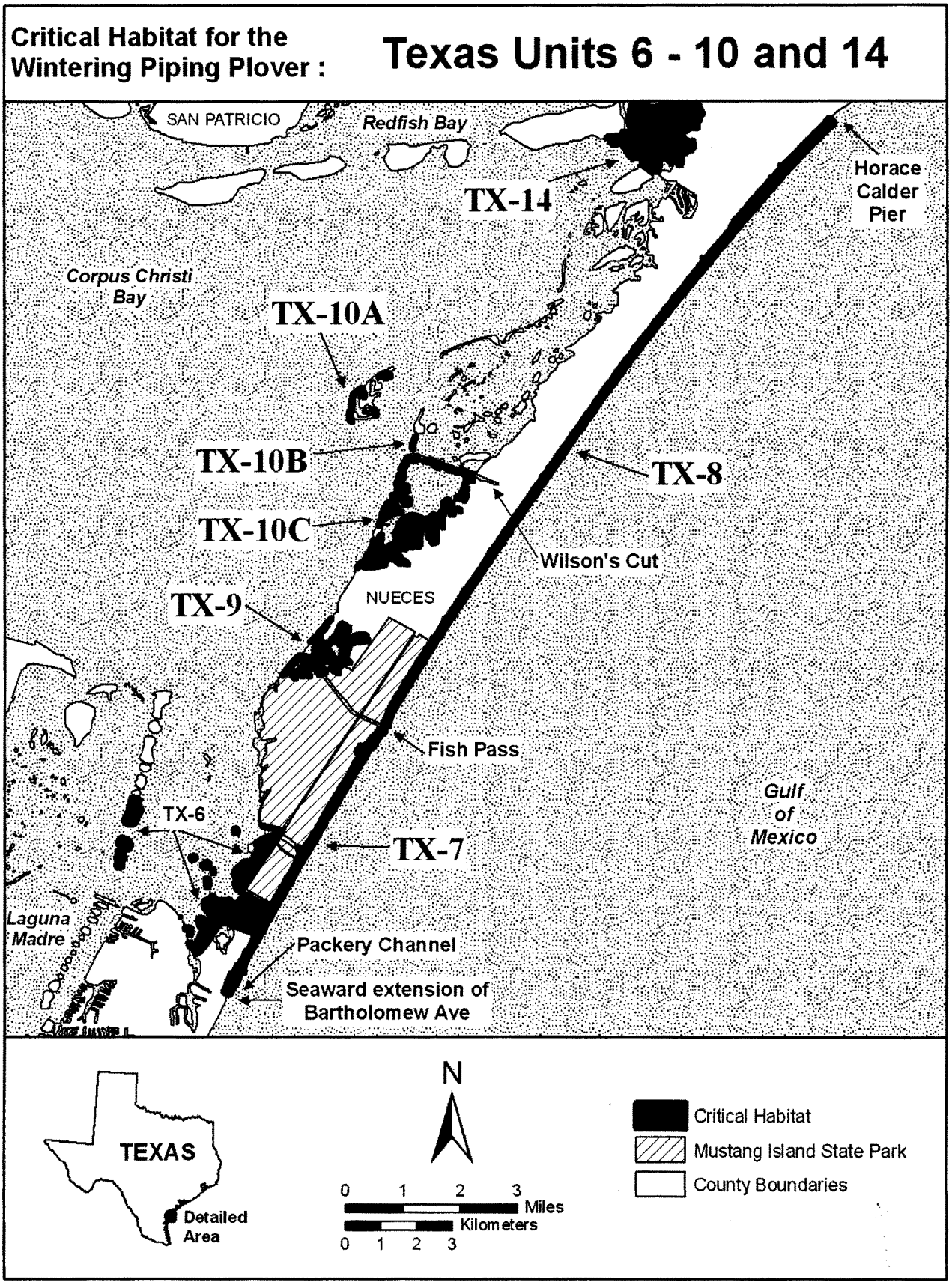

Critical Habitat for the Wintering Piping Plover :
Texas Units 1 - 5
NUECES
JIM WELLS
KLEBERG
KENEDY
BROOKS
HIDALGO
WILLACY
CAMERON
TX-5
TX-3D
Alazan Bay
Baffin Bay
Gulf of Mexico
Mesquite Rincon
TX-3E
TX-3C
Rincon de la Soledad
Laguna Madre
Mansfield Channel
TX-3A
TX-4
TX-3B
Andy Bowie County Park
TX-2
TX-1
TX-2 Insert
Queen Isabella Cswy
TEXAS
Detailed Area
N
0 8 16 24 Miles
0 8 16 24 Kilometers
Critical Habitat
Padre Island National Seashore
County Boundaries
Roads


Critical Habitat for the Wintering Piping Plover :
Texas Units 6 - 10 and 14
SAN PATRICIO
Redfish Bay
TX-14
Horace Calder Pier
Corpus Christi Bay
TX-10A
TX-10B
TX-8
TX-10C
Wilson's Cut
NUECES
TX-9
Fish Pass
Gulf of Mexico
TX-6
TX-7
Laguna Madre
Packery Channel
Seaward extension of Bartholomew Ave
TEXAS
Detailed Area
N
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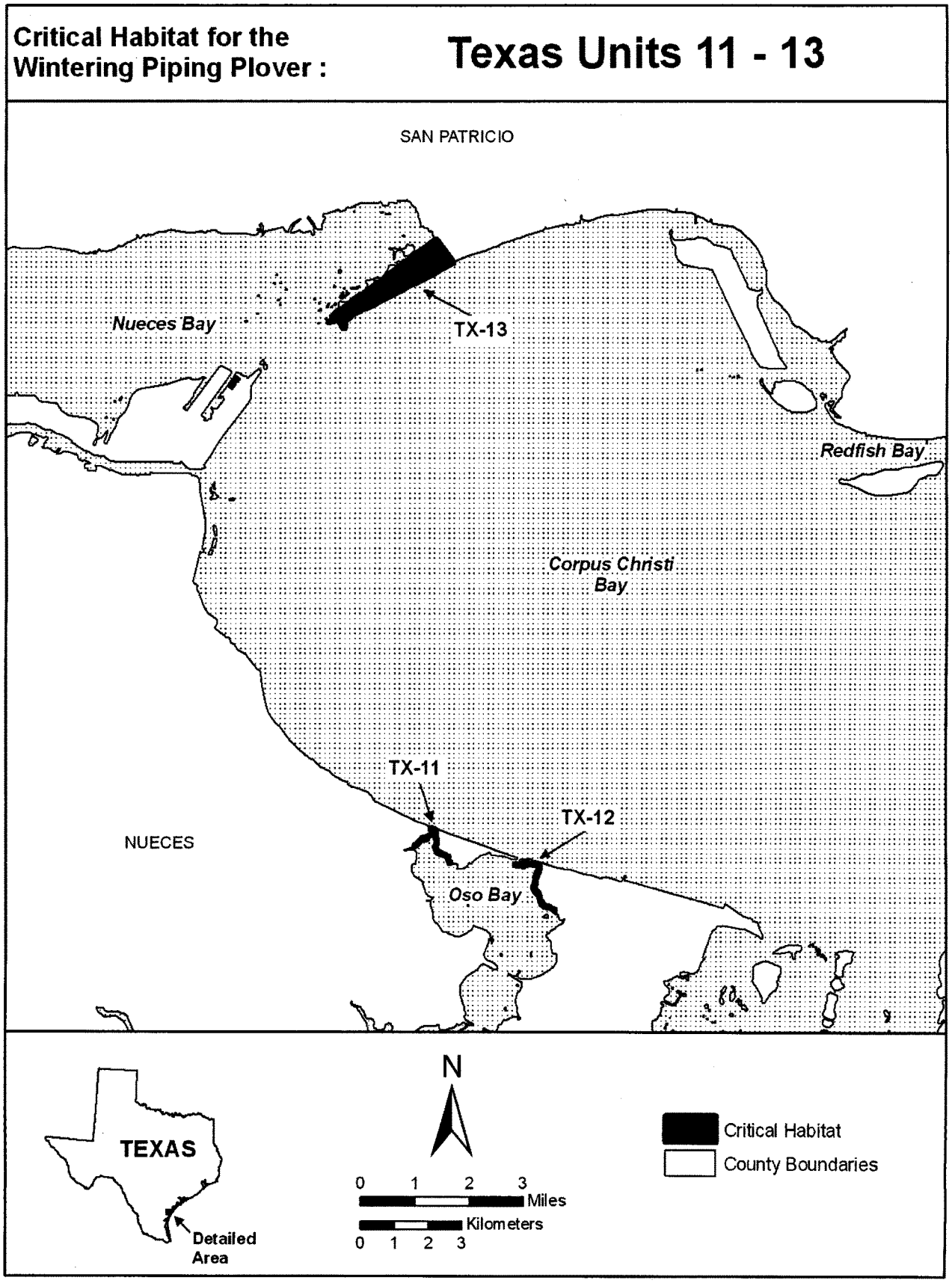
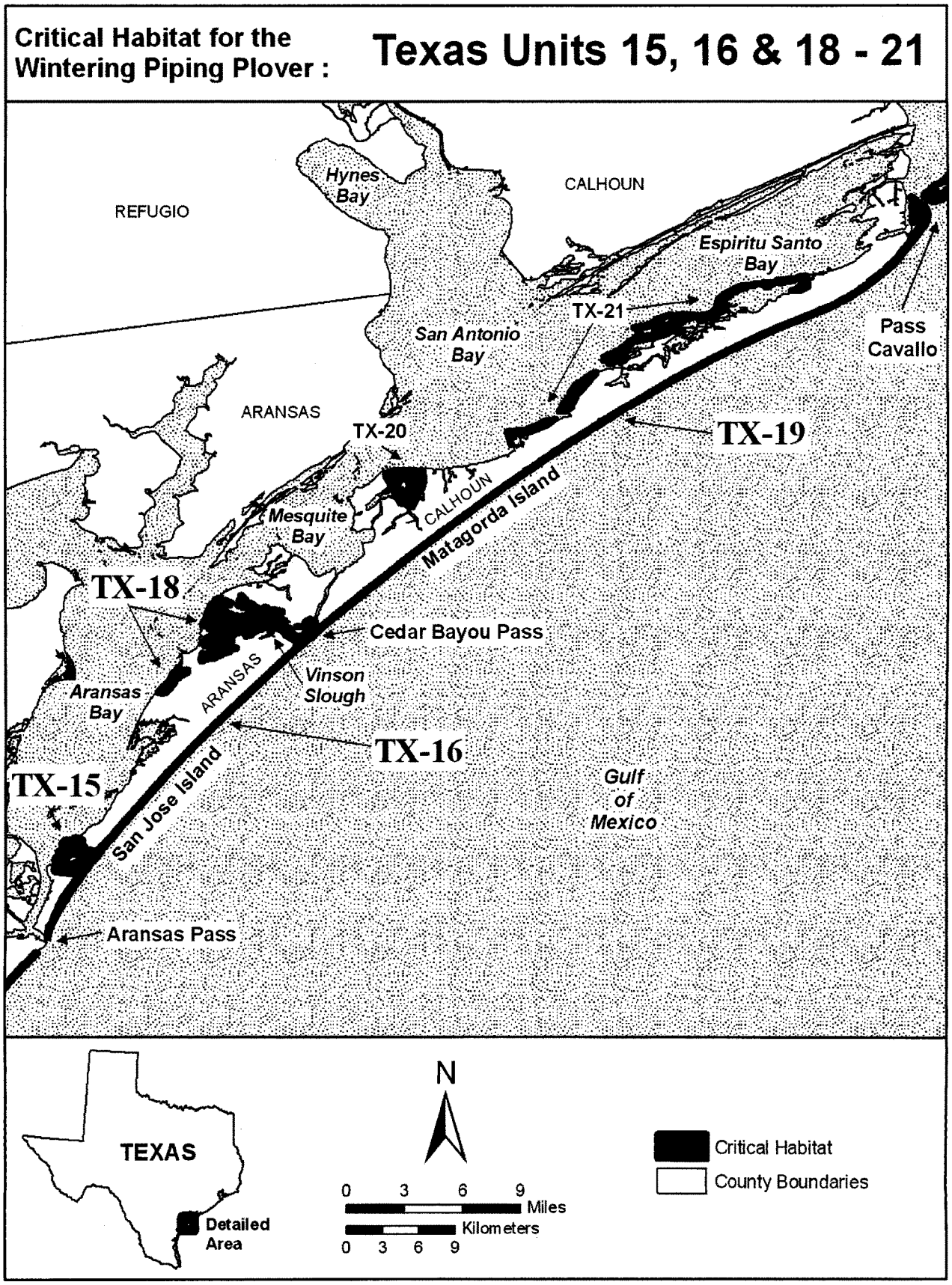
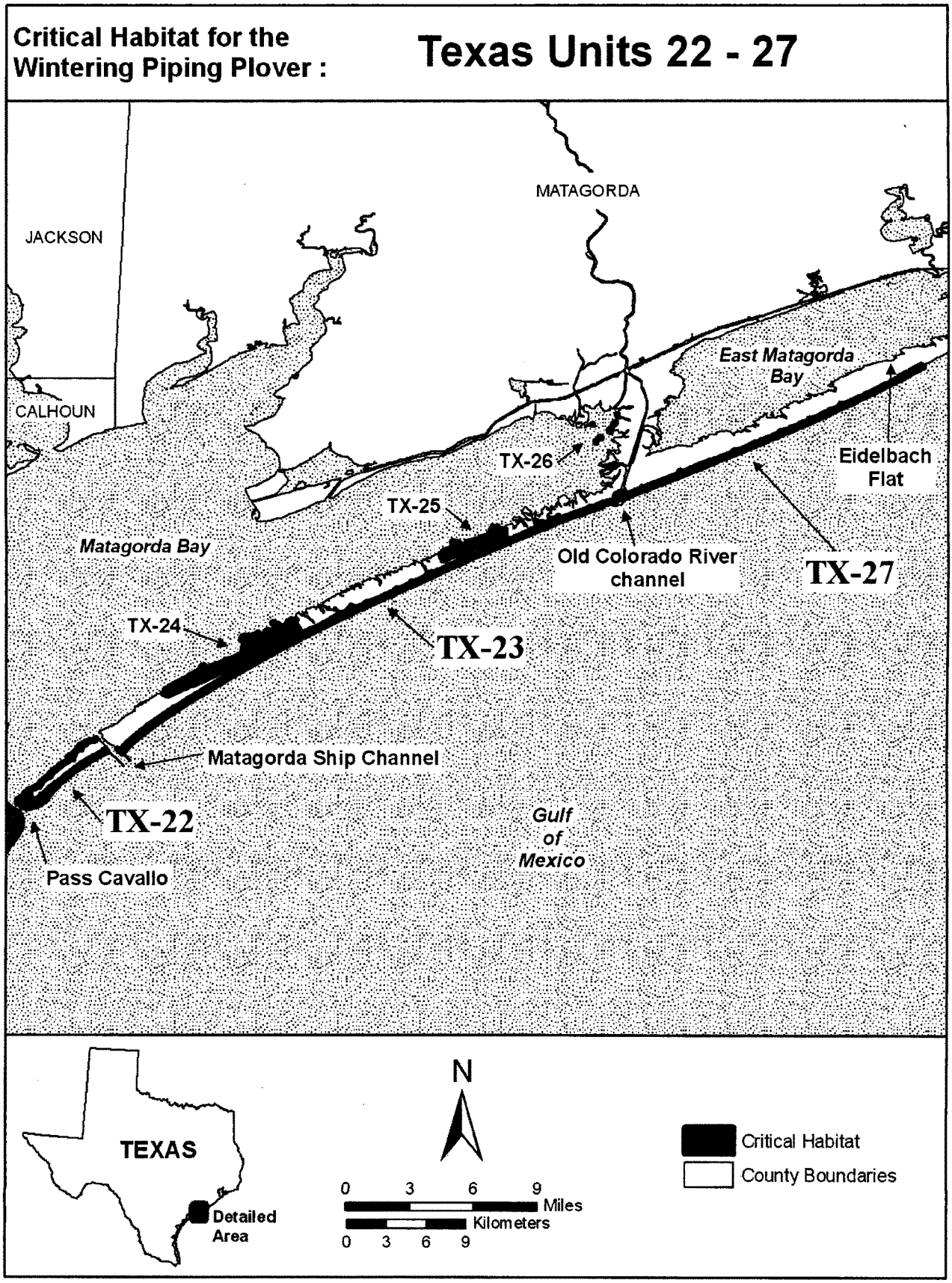
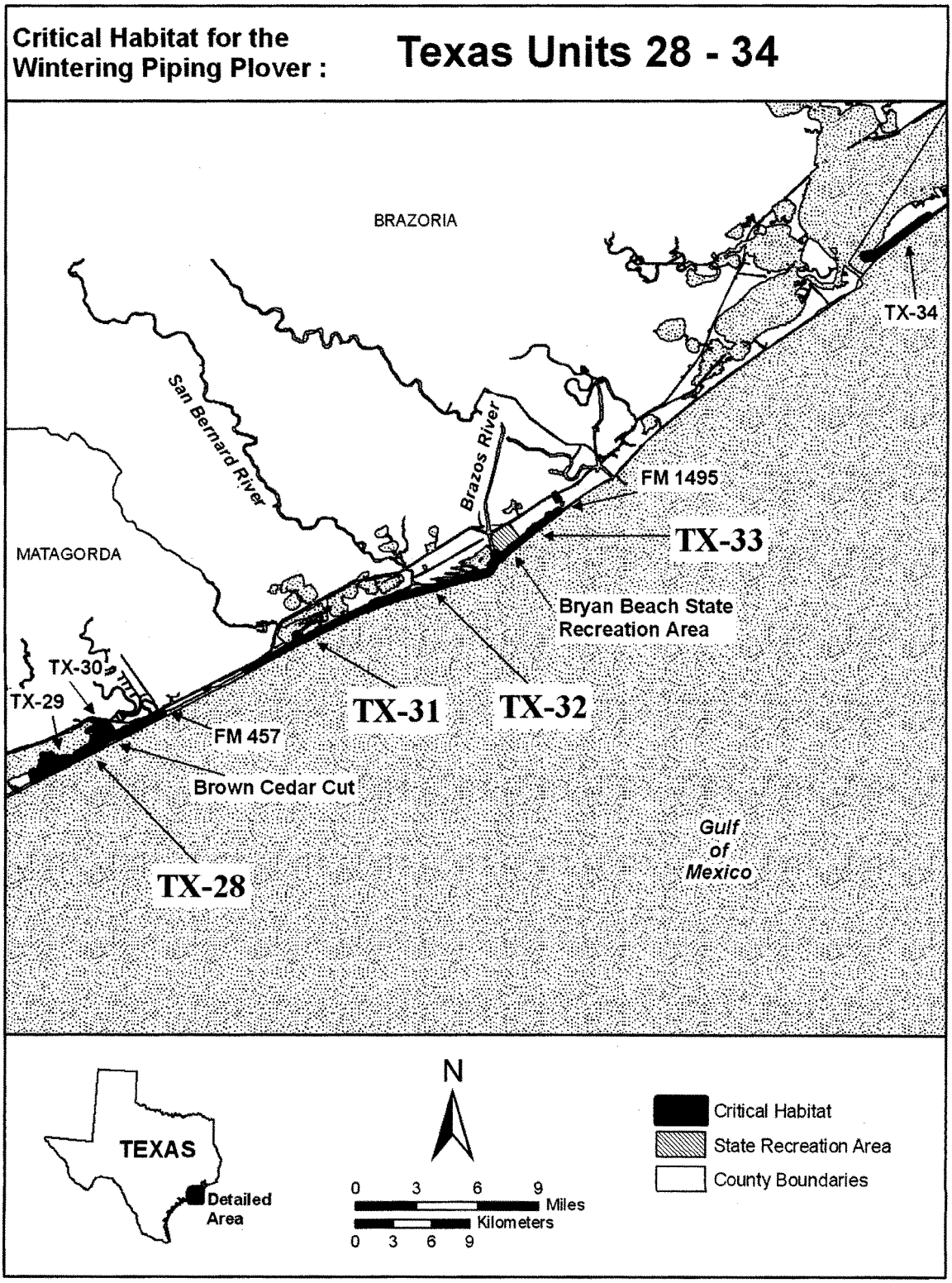
Miles
Kilometers
0 1 2 3
Critical Habitat
Mustang Island State Park
County Boundaries


Critical Habitat for the Wintering Piping Plover :
Texas Units 11 - 13
SAN PATRICIO
Nueces Bay
TX-13
Redfish Bay
Corpus Christi Bay
TX-11
TX-12
NUECES
Oso Bay
TEXAS
Detailed Area
N
0 1 2 3
Miles
0 1 2 3
Kilometers
Critical Habitat
County Boundaries


Critical Habitat for the Wintering Piping Plover :
Texas Units 15, 16 & 18 - 21
REFUGIO
Hynes Bay
CALHOUN
Espiritu Santo Bay
TX-21
Pass Cavallo
San Antonio Bay
ARANSAS
TX-20
TX-19
CALHOUN
Matagorda Island
Mesquite Bay
TX-18
Cedar Bayou Pass
Vinson Slough
Aransas Bay
ARANSAS
TX-16
TX-15
San Jose Island
Gulf of Mexico
Aransas Pass
TEXAS
Detailed Area
N
0 3 6 9
Miles
Kilometers
0 3 6 9
Critical Habitat
County Boundaries


Critical Habitat for the Wintering Piping Plover :
Texas Units 22 - 27
JACKSON
CALHOUN
MATAGORDA
East Matagorda Bay
Eidelbach Flat
TX-26
TX-25
Matagorda Bay
Old Colorado River channel
TX-27
TX-24
TX-23
Matagorda Ship Channel
TX-22
Gulf of Mexico
Pass Cavallo
TEXAS
Detailed Area
N
0 3 6 9
Miles
Kilometers
0 3 6 9
Critical Habitat
County Boundaries



* * * * *

Dated: May 8, 2008.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–10742 Filed 5–19–08; 8:45 am]

BILLING CODE 4310–55–C

Federal Register

Tuesday,
May 20, 2008

Part IV

Social Security Administration

20 CFR Part 411

Amendments to the Ticket To Work and Self-Sufficiency Program; Final Rule

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 411

[Docket No. SSA–2006–0092]

RIN 0960–AF89

Amendments to the Ticket To Work and Self-Sufficiency Program

AGENCY: Social Security Administration.

ACTION: Final Rules.

SUMMARY: We are revising our regulations for the Ticket to Work and Self-Sufficiency Program (Ticket to Work program), which was authorized by the Ticket to Work and Work Incentives Improvement Act of 1999. The Ticket to Work program provides Social Security Disability Insurance and disabled Supplemental Security Income beneficiaries expanded options for access to employment services, vocational rehabilitation services, and other support services. We are revising our prior rules to improve the overall effectiveness of the program to maximize the economic self-sufficiency of beneficiaries through work opportunities. We have based these revisions on our projections of the future direction of the Ticket to Work program, our experience using the prior rules, and recommendations made by commenters on the program.

DATES: These final rules are effective July 21, 2008.

FOR FURTHER INFORMATION CONTACT: Dan O'Brien, Office of Employment Support Programs, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, e-mail to *regulations@ssa.gov*, or telephone (410) 597–1632 for information about these rules. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*.

Background

These final rules amending the Ticket to Work program are based on Notices of Proposed Rulemaking (NPRM) published in the **Federal Register** on September 30, 2005 (70 FR 57222) and August 13, 2007 (72 FR 45191).

We explain the provisions of the final rules below. In the section ''Public Comments,'' we summarize the public comments and explain our reasons for adopting or not adopting the recommendations made by the commenters. The text of the final rules follows the Public Comments section.

What Programs Are Affected by These Final Rules?

These final rules affect the Ticket to Work program. In the Ticket to Work and Work Incentives Improvement Act of 1999 Congress explicitly recognized that, while many people who receive disability benefits from us want to work, and may have the potential to work, they face a number of significant barriers that may prevent them from reaching their goals. According to the authorizing legislation, Congress established the Ticket to Work program to provide disability beneficiaries a real choice in obtaining the services and technology that they need to find, enter, and maintain employment by expanding the universe of service providers. We published final regulations implementing the Ticket to Work program on December 28, 2001 (66 FR 67370).

Under the Ticket to Work program, the Commissioner of Social Security (the Commissioner) may issue tickets to Social Security disability beneficiaries and to disabled or blind Supplemental Security Income (SSI) beneficiaries under the programs under title II and title XVI of the Social Security Act (Act). In this voluntary program, each beneficiary who receives a ticket has the option of using his or her ticket to obtain services from a provider known as an employment network (EN) or from a State vocational rehabilitation (VR) agency. ENs may choose to whom they provide services. When the beneficiary and an EN or State VR agency agree to work together under the program, the EN or State VR agency, without charge to the beneficiary, will provide employment services, vocational rehabilitation services, and other support services to assist the beneficiary in obtaining or regaining and ultimately maintaining self-supporting permanent employment. If the beneficiary achieves certain work outcomes, we will pay the EN or State VR agency.

The title II and title XVI programs serve a diverse population of individuals with disabilities. Our beneficiaries are people from various age groups with different impairments, levels of education, work experience, and capacities for working. While many cannot work at all on a sustained basis, others may be able to work part-time or full-time with reasonable accommodations, ongoing supports, or both. This view is consistent with the assumptions underlying the Americans with Disabilities Act. As we develop our comprehensive work opportunity initiatives, we are also mindful that the unique needs of every beneficiary cannot be met by one program.

These projects advance the President's New Freedom Initiative and provide work incentives and opportunities earlier in the disability determination process. The Ticket to Work program is an important part of a comprehensive work opportunity initiative dedicated to helping people with disabilities who want to work do so to their fullest capabilities.

What Do We Mean by ''Final Rules'' and ''Prior Rules''?

Even though these rules will not go into effect until July 21, 2008, for clarity we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date of July 21, 2008. We will continue to use our prior rules until the effective date of these final rules. When these final rules become effective, we will apply them to both new cases and pending cases. In response to public comments on the September 30, 2005 NPRM, we explain in § 411.551 how we will apply the final rules on EN payment systems to cases still pending under our prior rules. In addition, we explain in § 411.226 how we will apply the final timely progress rules to individuals whose tickets were assigned under the prior rules.

Issues Addressed in These Final Rules

The Ticket legislation directs the Commissioner to periodically review EN payment systems to ensure that they provide adequate incentives for ENs to assist beneficiaries. Based in part on more than three years experience administering the program, we proposed a number of revisions to our prior rules in our September 30, 2005 NPRM and our August 13, 2007 NPRM that we believed would significantly enhance beneficiary choice and improve the likelihood that beneficiaries would receive the most effective support.

State Participation and Beneficiary Choice

Our rules for the Ticket to Work program provide that a State VR agency may participate in the program in one of two ways. On a case-by-case basis, with respect to beneficiaries who have

a ticket, the State VR agency may participate either as an EN or through the cost reimbursement payment system applicable under sections 222(d) and 1615(d) and (e) of the Act. Under our prior rules, if the State VR agency elects to be paid under the cost reimbursement payment system, the beneficiary's ticket must be assigned to the State VR agency in order for that agency to be paid through that system. The prior rules preclude further payment on the ticket if a State VR agency has been paid under the cost reimbursement payment system.

Before we published the September 30, 2005 NPRM, we received many comments that these policies under our prior rules do not allow beneficiaries to take advantage of the full potential of the Ticket to Work program. We agree with these comments and similar comments made in response to the September 30, 2005 NPRM. As a result, we are making changes in subparts B and F of our regulations to provide that a beneficiary's ticket will not be assigned to a State VR agency if that agency elects to be paid under the cost reimbursement payment system (the VR cost reimbursement option). We provide in §§ 411.135 and 411.140 of the final rules that, in this situation, the beneficiary may assign the ticket to a different provider of services after the State VR agency has closed his or her case.

We are making related changes in subpart C of our regulations to provide that, when a beneficiary is receiving services from a State VR agency that elects the VR cost reimbursement option, and has a ticket which would otherwise be available for assignment, the beneficiary will be considered to be ''using a ticket'' as described in that subpart if certain other requirements are met. This change will afford these beneficiaries protection from the initiation of a continuing disability review, irrespective of ticket assignment, provided all of the related provisions regarding timely progress are met. We explain in § 411.170(b) of the final rules when the period of ''using a ticket'' will begin for a beneficiary who has a ticket that would otherwise be available for assignment and who is receiving VR services pursuant to an individualized plan for employment (IPE) where the State VR agency has elected the VR cost reimbursement option. We explain that the period of ''using a ticket'' will begin on the effective date of the IPE or, if later, the first day the ticket would otherwise have been assignable if the beneficiary had not been receiving services from the State VR agency under the VR cost reimbursement option. We explain in final § 411.171 that, for a beneficiary for whom the State VR agency has elected the VR cost reimbursement option, whose ticket has not terminated and who continues to meet the timely progress requirements, the period of ''using a ticket'' will end with the close of the 90-day period following the date the State VR agency closes the beneficiary's VR case, unless the beneficiary assigns the ticket during this 90-day period.

In a change from the NPRMs, we are incorporating two new terms, ''VR cost reimbursement option'' and ''VR cost reimbursement status,'' in Subpart C of the final rules to better explain the rules on ''using a ticket'' that apply to a beneficiary with a ticket who receives VR services under an IPE from a State VR agency that has chosen the cost reimbursement payment system. We define these terms in final § 411.166, which contains a glossary of terms used in subpart C of our regulations. We explain that ''VR cost reimbursement option'' means an arrangement under which a beneficiary's ticket is not assigned to the State VR agency, but the beneficiary receives services under an IPE where the State VR agency has chosen to receive payment under the cost reimbursement payment system. We explain that the term ''VR cost reimbursement status'' means the status of the beneficiary's ticket under this arrangement. We also explain that this status begins when the period of using a ticket begins as described in final § 411.170(b) and this status ends when the State VR agency closes the beneficiary's case. We are defining these terms in the final rules to help simplify and clarify the provisions on using a ticket that relate to beneficiaries in these cases. Since we use the term ''VR cost reimbursement option'' in other subparts that we are amending in these final rules, we are also adding the definition of that term to § 411.115, which provides definitions of terms used in part 411.

We are also making changes in subpart F (State Vocational Rehabilitation Agencies' Participation). We removed the provisions of the prior rules which indicate that payment may not be made under both the cost reimbursement payment system and an EN payment system based on the same ticket. We have clarified in § 411.355(c) that a State VR agency can receive payment only under the cost reimbursement payment system when it serves a beneficiary who does not have a ticket that can be assigned pursuant to § 411.140. In other changes, we removed prior § 411.360 because it dealt with the phased implementation of the Ticket to Work program, which has been completed. We also are removing prior § 411.370, rather than revising it, as we proposed in our September 30, 2005 NPRM, because it would duplicate information included in final §§ 411.350 and 411.355. We have revised § 411.385(a)(1) to remove the reference to the beneficiary's decision to assign or reassign the ticket to the State VR agency. In a change from the September 30, 2005 NPRM, we are retaining in these final rules that part of prior § 411.385(a)(1) which requires that the information submitted to the program manager (PM) include a statement that an IPE has been agreed to and signed. In final § 411.390 and final § 411.510, we explain that for beneficiaries already receiving services from the State VR agency when they become eligible for a ticket, the State VR agency can receive payment only under the cost reimbursement payment system, unless both the beneficiary and the State VR agency agree to have the ticket assigned to the State VR agency.

We also are making related changes to § 411.585 that will allow for payment to an EN under an EN payment system and payment to a State VR agency under the VR cost reimbursement option with respect to the same beneficiary in certain circumstances. Section 411.585 of our prior rules provides that if we make payment to a State VR agency under the cost reimbursement payment system with respect to a ticket, that payment precludes payment under an EN payment system with respect to the same ticket. The prior rules also provide that if we make payment under an EN payment system, that payment precludes payment under the cost reimbursement payment system with respect to the same ticket. Final § 411.585(b) states that if a State VR agency is paid by us under the VR cost reimbursement option, such payment does not preclude payment by us to an EN or to another State VR agency acting as an EN under its elected EN payment system, and that a subsequent State VR agency also has the choice of being paid under the VR cost reimbursement option. In response to comments, new § 411.585(c) clarifies that if an EN or a State VR agency acting as an EN is paid by us under one of the EN payment systems, that does not preclude payment by us to a different State VR agency under the VR cost reimbursement option. It also clarifies that the subsequent State VR agency also has the choice of being paid under its elected EN payment system.

We believe that these changes will greatly expand beneficiary choice of

ENs and enable beneficiaries to take advantage of a more effective combination of services from both a State VR agency and an EN. For example, the State VR agency could provide the initial, intensive rehabilitation services, and an EN could follow up by providing the ongoing support many individuals need to maintain their work efforts. We will provide procedures regarding these issues in the Vocational Rehabilitation Providers Handbook (chapter 12, also known as Transmittal 17). This transmittal includes background information and procedures for State VR agencies to follow regarding the Ticket to Work program.

Employment Network Payment Systems

The rules for EN payment systems are set out in subpart H (Employment Network Payment Systems) (§§ 411.500 through 411.597). Section 411.597(a) of our prior rules states, ''We will periodically review the system of payments and their programmatic results to determine if they provide an adequate incentive for ENs to assist beneficiaries to enter the work force, while providing for appropriate economies.''

We studied extensively the question of whether the prior Ticket to Work program regulations provided an adequate incentive for ENs to assist beneficiaries. As we discussed in the proposed rules (70 FR at 57224), an evaluation of the Ticket to Work program by Mathematica Policy Research (MPR) in February 2004 found that despite aggressive marketing of the Ticket to Work program to over 50,000 organizations, only about 1,000 non-State providers had signed up as ENs and only a few hundred were actively participating in the Ticket to Work program. (*http://www.mathematica-mpr.com/publications/PDFs/TTWinitialrpt.pdf*). Over time, fewer organizations have joined the Ticket to Work program as service providers. The overall number of service providers in the program remains low, with retention a major challenge. The financial viability of some ENs remains uncertain as ENs report losing money on Ticket to Work operations. These problems reduce the number of organizations willing and able to serve as ENs and accept ticket assignments.

Accordingly, we made changes to subpart H in order to create a greater financial incentive for EN participation. We anticipate that these changes will increase the number of ENs actively accepting tickets. In response to public comments, we also added definitions of a ''transition case'' and a ''reconciliation payment'' as paragraphs (g) and (h) of § 411.500. Final § 411.525 provides that the total potential payment under the outcome-milestone payment system has been increased from 85% under the prior rules to 90% of the total potential payment under the outcome payment system under these final rules. By increasing the total potential payment, we believe that we will increase the incentive for small or undercapitalized providers to participate as ENs in the program. In addition, § 411.525 clarifies that milestone payments must occur before the beginning of the outcome period, and that once we begin making payments for a title XVI beneficiary we will continue using the title XVI payment rates even if the beneficiary later becomes eligible for disability insurance benefits under title II.

As we also discussed in the proposed rules (70 FR 57225), the Adequacy of Incentives (AOI) Advisory Group recommended a payment approach which recognizes that the steps leading to maximizing self-sufficiency are incremental and may be interrupted periodically. The link to the AOI report is: *http://www.dri.uiuc.edu/research/p03–08h/AOIFinal.pdf*. Final §§ 411.525 and 411.535 now provide a two-phased milestone payment system and outcome payments that parallel the steps beneficiaries take toward self-sufficiency.

Phase 1 is modeled on the nine-month trial work period (TWP) provided for title II beneficiaries. Four milestones at different points of employment retention will be paid when the beneficiary works for a period of time with gross earnings at or above the trial work earnings level. Phase 1 milestones are the only payments that will be the same for both title XVI and title II beneficiaries, and these payments will be based on the higher title II payment calculation base. This change addresses the concerns that the initial phase is the most expensive for the EN to provide services and that without equal payments title XVI beneficiaries would have difficulty accessing Phase 1 services. The trial work earnings requirement ($670/month in 2008) represents a significant work and earnings milestone for beneficiaries, as well as an attainable payment point for ENs. In response to public comments that we not narrow our focus to prior services from the State VR agency, we provide in § 411.535(a)(1)(ii) that work activity above the trial work earnings level in the 18 months prior to the first ticket assignment on each ticket may preclude us from paying some or all of the Phase 1 milestones. We also clarify in § 411.535(a)(1)(iii) the circumstances under which we will not pay Phase 1 milestones if a beneficiary received services from a State VR agency that elected the VR cost reimbursement option.

We also added a new rule, final § 411.536, which provides that we will pay an EN, or a State VR agency acting as an EN, for milestones that were unpaid because the beneficiary's outcome payment period begins.

Phase 2 requires a substantial achievement on the path toward full self-sufficiency. The employment outcome triggering a Phase 2 milestone payment is a month where the beneficiary's gross earnings equal or exceed the substantial gainful activity earnings level (in calendar year 2008, $940). During Phase 2, we will make a maximum of 11 monthly milestone payments with respect to a title II beneficiary and a maximum of 18 monthly milestone payments with respect to a title XVI beneficiary. We anticipate that some but not all beneficiaries will progress to Phase 2, increasing work hours and earnings to above the substantial gainful activity (SGA) level. As the AOI Advisory Group recommended, we are encouraging the use of work incentives during both Phase 1 and Phase 2 by making payments to ENs based on gross earnings before adjustments for work incentives. We have provided for a greater number of milestone payments with respect to title XVI beneficiaries as part of our overall effort to equalize the monetary value of the milestones payments that potentially can be made with respect to title II and title XVI beneficiaries. Under our prior rules, the total value of the four title XVI milestones is less than 60 percent of the total value of the four title II milestones. However, under these final rules, the total value of the title XVI milestones will be 98 percent of the total value of the title II milestones. We anticipate that this will provide an additional incentive for ENs to accept tickets from title XVI beneficiaries. Final § 411.540 provides the revised payment amounts for milestone payments. For both title II and title XVI beneficiaries, the payment amount for each milestone payment in Phase 1 will be 120 percent of the title II payment calculation base defined in § 411.500(a)(1). The payment amount for each milestone payment in Phase 2 will be 36 percent of the respective title II or title XVI payment calculation base. Final § 411.545 provides the revised payment amounts for outcome payments under the outcome-milestone payment system, which is 36 percent of the respective title II or title XVI payment calculation base. Final

§ 411.550 provides the revised payment rates for outcome payments under the outcome payment system, which is 67 percent of the respective title II or title XVI payment calculation base.

The final phase is the outcome payment period, during which beneficiaries are not receiving Social Security disability benefits or Federal SSI cash benefits because of work or earnings. Consistent with the discussion above about milestones, we are leaving the title XVI outcome period at 60 outcome payment months in order to equalize the monetary value of the outcome payments and the total amount of all payments that potentially can be made to an EN with respect to title II and title XVI beneficiaries. Final § 411.535(a)(3) provides that a reconciliation payment, as described above, will be made equal to the total amount of unpaid Phase 1 and Phase 2 milestones that had been available at first ticket assignment, if the beneficiary does not achieve all the Phase 1 and Phase 2 milestones prior to the beginning of the beneficiary's outcome payment period. As previously noted, in response to public comments on this provision, we added final § 411.536 to explain how this reconciliation payment will be made.

Finally, both the AOI Advisory Group in its *Final Report: Recommendations for Improving Implementation of the Ticket to Work and Self-Sufficiency Program (Regulatory and Administrative Changes*) and the Ticket to Work and Work Incentives Advisory Panel in its annual reports to the President and Congress expressed concerns (available at *http://www.dri.uiuc.edu/research/p03–08h/default.htm* and *http://www.ssa.gov/work/panel/panel_documents/reports.html*) that prior funding levels were inadequate to support the consumer-driven market-based employment service model that Congress envisioned in the Ticket legislation. The Ticket legislation established a maximum monthly outcome payment of 40% of the national average disability benefit payable under title II or title XVI, as appropriate, as the basis for EN payments under the Ticket to Work program. The Ticket legislation also requires us to periodically review this and other issues in order to determine whether, as relevant here, the percentage ''provides an adequate incentive for employment networks to assist beneficiaries to enter the workforce, while providing for appropriate economies.'' The 40% rate has proved inadequate to attract sufficient ENs to the marketplace to allow for adequate access to services and consumer choice. Therefore, consistent with our authority in section 1148(h)(5)(A) of the Act, final § 411.525 increases the overall percentage from 40% to 67% in the outcome payment system.

We believe that we will increase the financial incentives for small or undercapitalized providers to participate as ENs by offering a combination of: (1) Increasing the percent of the payment calculation base used to figure the payments; (2) reducing the differential between outcome and outcome-milestone payments; (3) equalizing funding for providing services to title II and title XVI beneficiaries; (4) increasing milestone payments; (5) making payments earlier in the return to work process; (6) recognizing that trial work level earnings constitute initial efforts at self-sufficiency for many beneficiaries; and (7) allowing beneficiaries to combine initial services provided by VR with ongoing support services from an EN. We also believe that the increased EN participation these changes will cause will improve beneficiary access to services and choice of quality providers. Final § 411.566 provides that an EN may use outcome or milestone payments to make payments to the beneficiary.

The revised payment rates are presented in charts I through III using the 2008 payment calculation base.

CHART I.—NEW OUTCOME-MILESTONE PAYMENT TABLE

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title II amount of payment	Title XVI amount of payment
Phase 1 (120% of Title II PCB)			
Milestone 1	$335/mo. $670/mo. x 3 mo. work in a 6-month period.	$1,177	$1,177
Milestone 2		$1,177	$1,177
Milestone 3	$670/mo. x 6 mo. work in a 12-month period.	$1,177	$1,177
Milestone 4	$670/mo. x 9 mo. work in an 18-month period.	$1,177	$1,177
Total Phase 1 milestones		$4,708	$4,708
Phase 2 (36% of PCB)	Gross Earnings>SGA.		
Title II milestones 1–11		$353 x 11 = $3,883	
Title XVI milestones 1–18			$203 x 18 = $3,654
Total Phase 1 + 2		$8,591	$8,362
Outcome payments (36% of PCB)			
Title II = 1–36	monthly cash benefit not payable due to SGA.	$353 x 36 = $12,708	
Title XVI = 1–60	Sufficient earnings for federal cash benefits =''0''.		203 x 60 = $12,180
Total milestone and outcome payments.		$21,299	$20,542

Definitions and amounts: Payment Calculation Base (PCB)—The average title II disability insurance benefit payable under section 223 of the Social Security Act for all beneficiaries for months during the preceding calendar

year; and the average payment of supplemental security income benefits based on disability payable under title XVI (excluding State supplementation) for months during the preceding calendar year to all beneficiaries who have attained 18 years of age but have not attained 65 years of age. (2008 title II = $981.17, title XVI = $563.35).

Gross earnings requirements for Phase 1 are based on Trial Work level amounts.

For Phase 1 milestones only, the payments are calculated for both title XVI and title II beneficiaries using the higher title II payment calculation base. All other payments are based on a percentage of the Payment Calculation Base (PCB) for the respective program (title XVI or title II). See § 411.535 for a discussion of the circumstances under which we will pay milestones.

Phase 1 milestones = 120% of PCB.

Phase 2 milestones = 36% of PCB.

Outcome payments (under the outcome-milestone payment system) = 36% of PCB.

Earnings used to meet the first, second, or third Phase 1 milestone may be counted again when determining if a later milestone is met, provided the earlier earnings fall within the relevant time period for meeting the later Phase 1 milestone (see 411.525(a)(2) for the relevant time period for each milestone).

CHART II.—NEW OUTCOME PAYMENT SYSTEM TABLE—TITLE II AND CONCURRENT

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title II amount of monthly payment	Title II total payments
Outcome payments 1–36 (67% of PCB)	Monthly cash benefit not payable due to SGA	$657.00	$23,652

CHART III.—NEW OUTCOME PAYMENT SYSTEM TABLE—TITLE XVI ONLY

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title XVI amount of monthly payment	Title XVI total payments
Outcome payments 1–60 (67% of PCB)	Earnings sufficient to ''0'' out Federal SSI cash benefits.	$377.00	$22,620

Note: Outcome payment (outcome payment system) = 67% of PCB. Individual payments are rounded to the nearest dollar amount.

2008 non-blind SGA level = $940.

2008 Blind SGA = $1570.

2008 TWP service amount = $670.

Ticket Eligibility for Beneficiaries Whose Conditions May Medically Improve

The Ticket to Work and Work Incentives Advisory Panel, in its July 26, 2001 report to the Commissioner, recommended that ''All SSI and SSDI adult disability beneficiaries, including those with a Medical Improvement Expected (MIE) designation, should be eligible to participate in the Ticket program.'' (Available at *http://www.ssa.gov/work/panel/panel_documents/reports.html*). (*Note:* The copy of the report at this link is not the official report, but a ''duplicate report'' that is ''similar'' to the original but which may contain ''small differences.'') We agree and are making changes to the ticket eligibility rules set out in § 411.125 under subpart B to allow beneficiaries with an MIE designation to be eligible for a ticket without first requiring a continuing disability review to be conducted.

''Using a Ticket'' and Related Timely Progress Rules

Subpart C (Suspension of Continuing Disability Reviews for Beneficiaries Who Are Using a Ticket) contains our rules on when a beneficiary will be considered to be ''using a ticket'' under the Ticket to Work program for the purpose of suspending the initiation of a medical continuing disability review (CDR) as provided under section 1148(i) of the Act. The rules in subpart C also describe the timely progress requirements which a beneficiary must meet to continue to be considered ''using a ticket'' under the program.

In final § 411.166, we explain that ''using a ticket'' means that a beneficiary has assigned a ticket to an EN or a State VR agency acting as an EN, or has a ticket in VR cost reimbursement status, and the beneficiary is making timely progress toward self-supporting employment. (As explained above, under these final rules, a beneficiary's ticket is in VR cost reimbursement status when the beneficiary has a ticket that would otherwise be available for assignment and is receiving VR services under an IPE from a State VR agency which has elected the VR cost reimbursement option.) Section 411.165 explains that we will not begin a CDR during the period in which a beneficiary is ''using a ticket.''

As in the prior rules, it is important that we continue to balance our desire to define ''using a ticket'' in a way that minimizes the disincentive for beneficiary participation that arises from the fear of having benefits terminated upon return to work because of a medical CDR, and our need to maintain the integrity of the disability programs by ensuring that beneficiaries who have medically improved do not continue to receive disability benefits for an undue length of time. We believe these final rules as described below maintain that balance.

In final § 411.180, we revised the timely progress guidelines contained in our prior rules. As we proposed in the August 13, 2007 NPRM, we added educational or technical training requirements to supplement the work requirements under the timely progress guidelines. We revised the work requirements under the guidelines and the documentation and other requirements for progress reviews to simplify the process for determining whether a beneficiary is making timely progress toward self-supporting employment. In addition, we eliminated the ''initial 24-month period'' after ticket assignment during which a beneficiary is considered to be making timely progress if actively participating in his or her employment plan. We

replaced this 24-month period with two successive 12-month progress certification periods during each of which the beneficiary must complete certain work requirements and/or educational or technical training requirements in order to be considered to be making timely progress until the next scheduled progress review.

We made changes from the guidelines proposed in the August 13, 2007 NPRM and included several important enhancements in final § 411.180. We extended the period for a beneficiary to complete a vocational or technical training program. In addition to the 4-year degree program, we added a 2-year degree or certification program to the guidelines. We also included obtaining a high school diploma or a General Education Development (GED) certificate in the first 12-month progress certification period as a part of the timely progress guidelines. In addition, we provide in the final rules that a beneficiary will be considered to have met the requirements for an applicable progress certification period if the beneficiary completes a certain percentage of the work requirement and a certain percentage of the post-secondary education requirement or vocational or technical training requirement for that progress certification period and the sum of the two percentages equals 100 or more. We also added a variance tolerance to provide a margin of flexibility in determining whether a beneficiary has met certain timely progress requirements. Under the variance tolerance, we will consider a beneficiary to have met the requirement for completing a specified amount of post-secondary credit hours in an educational degree or certification program or course requirements in a vocational or technical training program under § 411.180 in the applicable progress certification period if the beneficiary's completion of credit hours or course requirements in that period is within 10 percent of the specified goal.

As provided in final § 411.180, the timely progress guidelines for each 12-month progress certification period now reflect the following concrete, incrementally obtainable goals.

12-Month review period	Work requirement	High school diploma or GED	Degree or certification program	Technical, trade, or vocational program
1st*	3 out of 12 months with trial work period level earnings.	Obtained high school diploma or GED certificate.	Completed 60 percent of full time course load for 1 year.	Completed 60 percent of full time course load for 1 year.
2nd	6 out of 12 months with trial work period level earnings.		Completed 75 percent of full time course load for 1 year.	Completed 75 percent of full time course load for 1 year.
3rd	9 out of 12 months with substantial gainful activity level earnings.		Completed a 2-year program or, for a 4-year program, completed an additional academic year of full time study.	Completed the program.
4th	9 out of 12 months with substantial gainful activity level earnings.		Completed an additional academic year of full time study.	
5th	6 out of 12 months at level precluding Social Security and Federal SSI cash benefits.		Completed an additional academic year of full time study or completed 4-year degree program.	
6th	Work criteria are same for 5th and subsequent 12-month periods.		Completed 4-year degree program.	

In final § 411.166(b), we modified the definition of ''timely progress toward self-supporting employment'' to reflect that a high school diploma or GED certificate obtained in the first 12-month progress certification period counts as timely progress. In addition, we added a definition of ''variance tolerance'' in § 411.166(h).

In final § 411.171, we made several changes from the provisions of this section that were proposed in the September 30, 2005 NPRM. In final § 411.171(b), we deleted the references to prior §§ 411.190 and 411.195 since we are removing these sections of the regulations in these final rules. In final § 411.171(c), we changed the duration of the extension period from three months to 90 days to conform to the change in the duration of the extension period provided in final §§ 411.166 and 411.220, discussed below. This change to the duration of the extension period coincides with the 90-day period described in final § 411.150(b)(3) and incorporates the provision that was proposed in paragraph (d) of this section in the September 2005 NPRM, making the latter provision unnecessary. In paragraph (d) of final § 411.171, we explain when the period of using a ticket may end for a beneficiary receiving services from a State VR agency that has elected the VR cost reimbursement option. Based on a public comment, as well as the foregoing change in final paragraph (d), proposed paragraphs (e) and (f) of this section in the September 30, 2005 NPRM have been removed in these final rules. In a related change, cross-references to final § 411.155(a)(4) and (c)(8), on when the ticket terminates if an individual's outcome payment period ends, have been added in final § 411.171(a).

As we proposed in the August 13, 2007 NPRM, in final § 411.166 and paragraphs (a) and (d)(2) of final § 411.220, we changed the duration of the extension period from three months to 90 days.

We removed prior §§ 411.185, 411.190, 411.191, and 411.195. The changes we are making to subpart C in these final rules make these sections of the prior rules obsolete. In the final rules, we modified the section heading of § 411.192 and paragraph (a) of that section to provide that a beneficiary may place his or her ticket in inactive status if he or she is temporarily or otherwise unable to make timely progress toward self-supporting employment during a progress certification period.

In final § 411.225, we revised the prior rule to explain that any month during which a beneficiary's ticket is not assigned and is not in VR cost reimbursement status will not count

towards the time limitations for the timely progress guidelines. Final § 411.180(b) includes a similar provision. This change is necessary to take account of the situation provided for in these final rules, where a beneficiary's ticket is not assigned, but the beneficiary has a ticket that would otherwise be available for assignment and is receiving services under an IPE from a State VR agency which has elected the VR cost reimbursement option. As explained above, in this situation, the beneficiary's ticket is considered to be in VR cost reimbursement status.

In final § 411.226, we explain how we will apply the revised timely progress provisions to a beneficiary who assigned his or her ticket prior to the effective date of these final rules. We describe how we will determine which progress certification period a beneficiary is in as of the date these final rules become effective. We explain that we will not conduct a progress review at the end of that period, but will conduct a progress review at the end of the beneficiary's next 12-month progress certification period. In final § 411.226(b), we explain that we will notify the beneficiary regarding the specific timely progress requirements that will apply to him or her and when they will begin to apply. In § 411.226(d), we explain that tickets assigned under the prior rules to State VR agencies that have chosen to be paid for their services under the cost reimbursement payment system will no longer be considered assigned beginning on the effective date of these final rules. Instead, the ticket of a beneficiary in this situation will be considered to be in VR cost reimbursement status. We explain that a beneficiary in this situation may continue to be considered ''using a ticket'' under the final rules in subpart C for purposes of protection against the initiation of a continuing disability review. We explain that the beneficiary may assign his or her ticket after the State VR agency has closed his or her case.

Other Changes We Are Making

In subpart A, we are removing the prior § 411.110, which explains how we will implement the Ticket program, because we already have implemented the program on a nationwide basis.

In § 411.120, we clarify what information will be included on the Ticket To Work document.

We are making several changes in subpart B (Tickets Under the Ticket to Work Program). We revised § 411.130 to clarify that we will mail a ticket to the beneficiary when the beneficiary is eligible. In final § 411.140, we clarify in paragraph (a) that an individual with a ticket who has been receiving services under an IPE from a State VR agency which elected the VR cost reimbursement option may assign his or her ticket during the 90-day period after the State VR agency closes his or her case without having to meet the requirements of § 411.125(a)(2). The individual may assign his or her ticket after this 90-day period, but only if he or she meets the requirements of both paragraphs (a)(1) and (a)(2) of § 411.125. We are making this change in final § 411.140(a) to make this provision consistent with the similar rule for reassigning a ticket contained in final § 411.150(b)(3), discussed below.

We revised the section heading of § 411.145 to read ''When can my ticket be taken out of assignment?'', and revised the provisions of that section to indicate that, consistent with other sections of these final rules, a State VR agency will have a ticket assigned to it only if it elects to act as an EN. In a change from the September 30, 2005 NPRM, we added a provision to final § 411.145(a) to provide that if a beneficiary takes the ticket out of assignment, he or she will be sent a notice regarding the change. We changed § 411.150(a) to clarify that in all cases the ticket must be unassigned before it can be reassigned. We also revised § 411.150(b)(3) concerning the conditions under which a beneficiary may reassign a ticket even if the beneficiary does not meet certain requirements of § 411.125(a).

We also are making several changes in § 411.155. We are changing § 411.155(a)(2) to state that, if a beneficiary is entitled to widow's or widower's insurance benefits based on disability, the ticket terminates in the month in which the beneficiary attains full retirement age. We added §§ 411.155(a)(4) and (c)(8) to indicate that the ticket terminates in the month after the month in which the beneficiary's outcome payment period ends.

We are making changes to three sections in subpart E (Employment Networks). In § 411.310, we added new paragraph (d) to provide that one-stop delivery systems established under subtitle B of title I of the Workforce Investment Act of 1998 (29 U.S.C. 2811 *et seq.*) may participate in the Ticket to Work program as ENs without responding to our request for proposal (RFP). In response to public comments, we added new paragraph (e) to final § 411.310 to provide that organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities authorized under section 121 of part C of title I of the Rehabilitation Act of 1973, as amended (29 U.S.C. 441), also may participate as ENs without having to respond to our RFP. We explain that one-stop delivery systems and organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities must enter into an agreement with us to serve as an EN under the Ticket to Work program and must maintain compliance with the rules that apply to ENs. We made corresponding changes in final § 411.315. We added new paragraphs (e) and (f) to final § 411.315 to provide that one-stop delivery systems and organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities must still enter into an agreement with the Commissioner to be an EN and must maintain compliance with general and specific selection criteria of this section and § 411.305 to remain an EN.

In paragraph (a) of final § 411.325, we indicate that an EN must report to the PM in writing each time it accepts a ticket for assignment or no longer wants a ticket assigned to it.

In subpart F (State Vocational Rehabilitation Agencies' Participation), § 411.365(a) is revised to remove the reference to a letter we send to State VR agencies regarding implementation of the Ticket to Work program.

In subpart H (Employment Network Payment Systems), we are removing the prior § 411.530, which required that each outcome payment made to an EN under the outcome-milestone payment system be reduced by an amount equal to 1/60th of a milestone payment made to an EN with respect to the same individual. These final rules remove this requirement as one means of increasing the potential payment available to an EN and, as required by Ticket legislation, ensuring that these EN payment systems continue to provide adequate incentives for ENs to assist beneficiaries.

In addition, we made several additional changes in subpart H (Employment Network Payment Systems). We added a new § 411.552 to clarify that we will continue to make EN payments based on the title XVI payment structure once we authorize an outcome or milestone payment for a title XVI only beneficiary. If a title XVI beneficiary becomes entitled to title II disability benefits before we authorize an outcome or milestone payment we will make payments to the EN as if the individual were a title II beneficiary. By authorizing a payment we mean that we have performed the necessary actions to trigger a payment, whether or not the

Treasury Department has issued the payment or the EN has received the payment.

In final § 411.555, we eliminated the requirement in (b)(2) to adjust or recover an incorrect EN payment when the reason for the incorrect payment is because of a retroactive determination or decision SSA makes about an individual's right to benefits for the period of the payment. We made changes to § 411.555 to indicate that references to ENs refer to State VR agencies acting as EN as well. We also changed this section to reflect the difference in the number of outcome months for title XVI and title II beneficiaries.

Final § 411.575 explains that as primary evidence of the beneficiary's work and earnings we will require an original pay stub or an oral or written statement of monthly earnings from the employer or the employer's designated payroll preparer. It also explains that in lieu of primary evidence, we will accept two sources of secondary evidence, such as State unemployment insurance records and a signed beneficiary statement or federal or state tax returns. We also made two clarifications. We clarify in § 411.575(a)(2) that the request for each milestone payment must include evidence that the milestone was attained after ticket assignment and in § 411.575(b)(2) that as part of the payment request, we may require that the EN provide a summary of the services provided as described in the IWP/IPE.

New final § 411.581 explains the circumstances under which an EN can receive milestone and outcome payments for months after a beneficiary takes his or her ticket out of assignment.

Notice of Proposed Rulemaking

We issued two NPRMs proposing changes to our prior rules for the Ticket to Work program. We published an NPRM in the **Federal Register** on September 30, 2005 (70 FR 57222) and a second NPRM on August 13, 2007 (72 FR 45191). We provided the public 90 days in which to submit comments on the first NPRM and 60 days in which to submit comments on the second NPRM. The comment period for the first NPRM closed on December 29, 2005, and the comment period for the second NPRM closed on October 12, 2007.

We also held a series of town meetings in connection with the first NPRM to obtain additional input on the changes proposed in that NPRM. These meetings were open to the public and were announced in the **Federal Register** on October 19, 2005 (70 FR 60748) and November 1, 2005 (70 FR 65871). They were conducted in Irvine, California on November 4, 2005; in Miami, Florida on November 16, 2005; in Hartford, Connecticut on December 6, 2005; and in Des Moines, Iowa on December 14, 2005.

We received a combined total of 128 public comments on the September 30, 2005 NPRM and the August 13, 2007 NPRM. The public comments we received on the September 2005 NPRM are posted on our Internet site at: *https://s044a90.ssa.gov/apps10/erm/rules.nsf/5da82b031a6677dc85256b41006b7f8d/9fe46866babbb19b8525708c006d230a!OpenDocument*.

The public comments we received on the August 2007 NPRM are posted on the Federal eRulemaking Portal at: *http://www.regulations.gov*.

As we explain below, in these final regulations, we are making some changes from the proposed rules in response to public comments received on the NPRMs. We discuss the significant comments on the NPRMs and respond to these comments below under ''Public Comments.'' Although we condensed, summarized, or paraphrased the comments, we believe that we have expressed the views accurately and have responded to all of the significant issues raised by the commenters that are within the scope of the rulemaking.

In addition, some of the comments were about subjects that were outside the scope of the rulemaking. Except as noted below, we have not summarized and responded to these comments.

Public Comments

General

Many commenters endorsed the revision to § 411.125 to extend ticket eligibility to beneficiaries with an MIE designation. A number of commenters supported our proposal to provide a phased payment system that parallels the steps beneficiaries take toward self-sufficiency, which will expand an EN's ability to provide employment services to beneficiaries who have an initial goal to work part-time. Commenters also supported our other proposals to make other changes to the EN payment systems in order to increase EN participation, including increasing outcome payments under the outcome payment system from 40% of the payment calculation base to 67%, and increasing the total payment for ENs electing the outcome-milestone payment system to 90% of potential payments under the outcome payment system. Many commenters also supported our proposal to encourage partnerships between State VR agencies and ENs to provide long-term services to a beneficiary by permitting the beneficiary to assign a ticket to an EN after receiving VR services.

Other Models

Comment: A number of commenters suggested a model in which an EN composed of friends and family members might be formed to assist a beneficiary by making payments to service providers and coordinating service provisions. Other commenters recommended that we consider the feasibility of permitting the beneficiary to be his or her own EN without seeking third party assistance.

Response: We have not adopted these comments. Section 1148(f)(1) of the Act states that ENs serving under the Ticket to Work program shall consist of an agency or instrumentality of a State (or a political subdivision thereof) or a private entity, that assumes responsibility for the coordination and delivery of services under the program to individuals assigning tickets to the EN.

Retroactivity of These Revised Rules

Comment: A number of commenters recommended that these revised rules be effective retroactively, e.g., made effective for payments to ENs either from the date of their acceptance as an EN or from the beginning of calendar year 2005.

Response: An agency may not make its rules retroactive without appropriate legislative authority. The Act does not authorize us to make these rules retroactive.

Transitioning to These Revised Rules

Transition Rules for EN Payment Cases

Comment: Many commenters asked how we will make the transition to these new rules, i.e., how these new rules will apply to cases still pending on the effective date of the new rules. For example, one commenter noted that, if the new rules do not apply across the board to existing cases, ENs will delay ticket assignments or job placements, or otherwise jeopardize the benefits from this program for beneficiaries. Commenters asked specifically whether ENs will be given the opportunity to change their payment system election, in view of these revised rules, and how we would transition existing cases to the new EN payment systems.

Response: Final § 411.515 allows an EN to change its elected payment system once in each calendar year. We also added final § 411.551 to explain how we will move payment cases from

the prior EN payment system's schedule of payments and rates to the EN payment system's schedule of payments and rates in these final rules. We will process any EN payment requests received for milestones or outcomes that had been attained under our prior rules before we begin processing payments attained beginning with the effective date of the new rules. We will only accept payment requests for milestones or outcomes attained before the effective date of the new rules until March 31, 2009 or until the first payment is initiated under the new rules. Section 411.551 explains that milestones under our prior rules will be equated with Phase 1 milestones. For example, if a beneficiary has attained milestone 1 under our prior rules, then the next milestone to be achieved would be Phase 1 milestone 2 under the new rules (work in three months within a six-month period with gross earnings in each of the three months equal to a trial work period service month, i.e., $670 in 2008).

If the beneficiary has attained all of the milestones under the prior rules, the next milestone to be achieved would be the first Phase 2 milestone (a calendar month in which the beneficiary has worked and has gross earnings from employment or net earnings from self-employment that are more than the SGA earnings level).

The maximum number of outcome payments available to an EN for a transition case will be computed as follows.

When the EN requests a payment for a milestone or outcome attained in July 2008 or later, we will first compute the amount already paid or that can be paid on any particular ticket for milestones or outcomes attained before July 2008. Then, we will subtract this amount from the total value of the ticket under the new rules for 2008. The total value of the ticket is the sum of the payment amount of all payments available under the EN's chosen payment system for 2008. See the *Outcome Milestone Payment System Table* in § 411.545(c) and the *Outcome Payment System Tables* in § 411.550 for the value of the ticket in the year 2008 under each payment system for title II beneficiaries or title XVI beneficiaries or beneficiaries concurrently entitled under title II and title XVI. We then will divide this amount by the applicable outcome payment amount (whether title II or title XVI) payable for 2008 and round the result in accordance with customary rounding principles. The resulting number represents the number of outcome payments available on this ticket. In no case can this number exceed 60.

Timely Progress Transition Rules

Comment: Some commenters expressed concern that beneficiaries would receive a progress review using the new timely progress guidelines without having had advance notice of these guidelines and asked whether we would transition individuals with tickets assigned prior to the effective date of the final regulations to the new timely progress guidelines.

Response: In response to these comments, we made changes to § 411.226 in these final rules. We explain in the final rules that we will not conduct a progress review at the conclusion of the beneficiary's applicable 12-month progress certification period determined under § 411.226(a)(1) of these final rules. We explain that we will conduct a progress review using the provisions of these final rules at the conclusion of the beneficiary's next 12-month progress certification period. We also added a provision that we will send the beneficiary a notice explaining the specific timely progress requirements that will apply to the beneficiary and when they will begin to apply.

Subpart B—Tickets Under the Ticket to Work Program

General

Comment: One commenter recommended an ''overlap'' procedure under which ''ticket-in-use'' and ''ticket-assigned'' statuses could overlap. Under this proposal, once the VR client completed his or her individualized plan for employment (IPE), the State VR agency would advise the beneficiary that the ticket would be available for assignment to an EN for job development and placement, and the ''overlap'' period would begin with the State VR agency's approval, once the EN has advised the PM that the ticket is assigned. Once the EN has placed the beneficiary in a job, the 90 days required for case closure by the State VR agency would begin running. As the beneficiary works above SGA, the EN would subsequently become eligible for Phase 2 milestone payments, and the State VR agency would become eligible for cost reimbursement.

One commenter noted that often State VR agencies contract with a community-based organization to provide services at the outset of its relationship with a beneficiary, and recommended that the regulations recognize this by providing for a joint State VR agency/EN assignment. Under this proposal, with the individual's permission, the State VR agency and the community-based organization would be allowed to jointly submit an IPE that lays out the initial cost reimbursable services as well as the follow up services reimbursable to the EN by Phase 2 and outcome payments. This proposal would encourage the State VR agency and community-based organization to collaborate together in an efficient manner to plan out several years of service and support. In addition, this proposal would ensure that the VR client's supportive services can continue uninterrupted and in a consistent manner with the same service provider, if this is what the beneficiary chooses.

This commenter acknowledged that there may be some concern that such a process provides the community-based organizations that contract with State VR agencies an unfair advantage over other ENs in gaining access to beneficiaries with tickets who want to assign their tickets after working with a State VR agency who had chosen the cost reimbursement option. However, if the process is set up similar to the ''overlap'' system described above, all ENs could compete for a joint ticket assignment with the State VR agency. Those ENs who do not currently contract with a State VR agency could establish a working relationship with the State VR agency to create these joint plans for services, and this process may encourage new collaborations between the State VR agencies and the ENs. The individual would still be given the option to change service providers after the State VR agency closes the case. With this option, the individual's ability to choose service providers is protected, and those beneficiaries who choose to allow this joint submission process at the beginning will still have the same rights as those who did not choose this route.

Response: We agree that coordination of services between a State VR agency providing initial services and an EN providing ongoing support services would be beneficial. We do not believe that Congress intended the Ticket to Work program to make duplicate payments for services provided under the Rehabilitation Act. Therefore, when a beneficiary with a ticket receives VR services from a State VR agency which has elected the VR cost reimbursement option, these rules provide that the VR case must be closed by the State VR agency before the beneficiary may assign a ticket to an EN. We are, however, encouraging joint planning between the State VR agency and the EN selected by the consumer to provide ongoing support services as early as

possible. In this way, when the VR case is closed, the transition to ongoing supports under the Ticket to Work program will be seamless for the beneficiary.

Section 411.140 When may I assign my ticket and how?

Comment: A number of commenters asked how we would know that a person is a client of a State VR agency.

Response: We will use the procedures under § 411.385 for the State VR agency to notify the PM that an IPE has been signed so that we can record that the beneficiary's ticket is in use so that we can ensure that we will not initiate a continuing disability review.

Comment: One commenter recommended that the proposed rules be amended to require a State VR agency that has chosen the cost reimbursement payment system to notify a beneficiary upon case closure of his or her right to assign the ticket to an EN for follow-up services. Failure to provide this notice should constitute grounds for denying payment under the cost reimbursement payment system. The commenter indicated that the rules should also require the State VR agency to notify us of the case closure. We should also provide the beneficiary with a notice that his or her ticket is available for assignment, so that the beneficiary will be aware of and take advantage of this new process.

Response: We are not addressing the rules for the State VR Reimbursement program in this regulation. However, we are working out a process through which the State VR agency can efficiently inform the PM when it closes a case for beneficiaries participating in the program. We believe there are sufficient incentives built into the new payment system to encourage State VR agencies to facilitate the connection to an EN for ongoing support services. We also will publicize the provisions of these new rules so that beneficiaries are aware of their rights under these final rules.

Comment: A number of commenters suggested that it should be feasible to allow for simultaneous EN and State VR services in situations where the EN is not receiving any payments for services being provided by a State VR agency and the services provided by the State VR agency are not duplicating any services being provided by the EN.

Response: We do not agree. We do not believe that Congress intended to allow a beneficiary to be served simultaneously by a State VR agency and an EN under the Ticket to Work program. We believe that these final rules will provide incentives for beneficiaries to work with the State VR agency when they are developing the IPE to consider the expanded opportunities under the Ticket to Work program for receiving job retention and other support services from an EN after the close of VR services.

Comment: Another commenter noted that limiting the ability of State VR agencies to take a ticket as an EN after it has served a beneficiary and received cost reimbursement would seem to be an appropriate approach in many instances. However, there are situations where this may not be true. If there are no available ENs in an area and the State VR agency is willing to provide the long term follow up, then consideration should be given to allowing the State VR agency to function as an EN. There may also be situations where the State VR agency has unique expertise with certain populations that cannot be met by other ENs. In these circumstances, the commenter recommended that the VR agency should be permitted to function as an EN.

Response: We understand the concern expressed by this commenter and we will carefully monitor the availability of ENs in all regions of the country to ensure that we are not unduly restricting beneficiary choice. While we are confident that the new payment system should facilitate many additional ENs entering the program, we will make necessary changes to our rules if our evaluation shows that the Ticket to Work program is not serving our beneficiaries to the fullest extent possible.

Comment: A number of commenters noted that proposed § 411.140(a) stated that ''you may also assign your ticket during the 90-day period your ticket is considered in use after State VR services end'' and asked how we define ''end'' of VR services—after provision of direct cost services or after case closure?

Response: For purposes of these rules, we consider VR services to end when the VR case is closed by the State VR agency. We made changes in final §§ 411.140(a) and 411.171(d) to clarify that the 90-day period discussed in these sections begins after the date the beneficiary's case is closed by the State VR agency.

As we explain earlier in this preamble, we are also revising the provision in proposed § 411.140(a), referenced above, to indicate that an individual may assign his or her ticket during the 90-day period after his or her VR case is closed by a State VR agency that elected the cost reimbursement option, without having to meet the requirements of § 411.125(a)(2). We are making this change in the provision in these final rules to conform to the similar provision contained in final § 411.150(b)(3). Section 411.150(b)(3) provides that an individual whose ticket is no longer assigned to an EN or State VR agency acting as an EN, may reassign the ticket within 90 days of the effective date the ticket was no longer assigned, without meeting the requirements of § 411.125(a)(2).

Subpart C—Suspension of Continuing Disability Reviews for Beneficiaries Who Are Using a Ticket

General

We received many public comments regarding the proposed changes to the timely progress provisions described in the NPRM that was published in the **Federal Register** on August 13, 2007. Most of these comments concerned the educational requirements or the work requirements for making timely progress toward self-supporting employment. We also received comments on the changes to subpart C that were proposed in the September 30, 2005 NPRM.

Section 411.180 What is timely progress toward self-supporting employment?

Comment: The majority of commenters expressed support for the proposal to include educational or vocational or technical training requirements as part of the timely progress guidelines. However, based on the view that obtaining a high school diploma or its equivalent, such as a general education development (GED) certificate, increases an individual's ability to obtain and maintain self-supporting employment, some commenters suggested that we add language that incorporates a GED as part of the timely progress guidelines.

Response: We agree with the commenters' suggestion and have incorporated it in these final rules. We have expanded the timely progress requirements in § 411.180(c)(1) of the final rules to provide that an individual who obtains a high school diploma or a GED certificate during the first 12-month progress certification period will be considered to be making timely progress toward self-supporting employment for the purpose of the progress review conducted at the end of this 12-month period.

Comment: The majority of commenters suggested that we lower the educational and vocational or technical training requirements for making timely progress toward self-supporting employment. Some commenters asked that we allow flexibility to combine the achievement of work goals and

educational or vocational or technical training goals under the timely progress guidelines. Several commenters also asked that we provide beneficiaries with more time to complete educational or vocational or technical training requirements because of their disability and other factors that affect their ability to sustain heavy course loads.

Response: In response to these comments, we made changes in § 411.180 to lower the educational requirements and the vocational or technical training requirements from expecting the beneficiary to carry a full-time course load in the first two years to carrying 60 percent of a full-time course load in the first year and 75 percent in the second year. This has the effect of lengthening the amount of time a beneficiary has to complete a degree or certification program, or a vocational or technical training program. We also provide that if a beneficiary completes a certain percentage of the work requirement and a certain percentage of the post-secondary education requirement or vocational or technical training requirement in the applicable progress certification period, and the sum of the two percentages equals 100 or more, we will consider the beneficiary to have met the timely progress requirements for purposes of the progress review conducted at the end of the 12-month progress certification period. In addition, we included a variance tolerance of 10 percent to make the requirements for completing a specified amount of credit hours or course requirements easier to achieve. These measures will increase the flexibility of these provisions and give beneficiaries more time to gradually progress toward their work or educational goals.

Comment: A few commenters suggested that we give credit toward timely progress for Compensated Work Therapy, individuals in on-the-job, supported employment and specialized training in a community rehabilitation agency.

Response: We did not adopt this comment because the types of programs the commenters suggested may not be indicative of work that equates to trial work or SGA level earnings or training that typically leads directly to increased and sustained earnings at these levels. We will give credit for a post-secondary education program at an educational institution as defined in § 411.167, or for vocational or technical training at a technical, trade or vocational school as defined in § 411.167. We also will give credit for a high school diploma or a GED certificate obtained during the first 12-month progress certification period.

Comment: Some commenters suggested using the Individualized Plan for Employment (IPE) as a measure of timely progress and others suggested we retain the prior rules for timely progress during the initial 24-month period.

Response: We did not adopt these comments because they are inconsistent with the goals we are trying to accomplish with the revised timely progress guidelines. The IPE and IWP were essentially used to determine whether a beneficiary was making timely progress under the prior rules. We found that the initial 24-month period and the use of the IPE or IWP goals as a measure of timely progress did not always include specific enough rules to encourage the beneficiary to make concrete strides toward self-sufficiency early enough in the process. Furthermore, under the prior rules, the use of the IPE or IWP for progress reviews was administratively burdensome to service providers, who had to evaluate a beneficiary's goals and achievements under the IPE or IWP in order to provide the PM with their assessment as to whether the beneficiary was expected to meet the timely progress guidelines for the next progress review period.

Comment: A commenter requested clarification on the type of administrative records and educational documentation to be used to determine whether a beneficiary is meeting the timely progress guidelines.

Response: Social Security and SSI beneficiaries with disabilities are required to report their work and earnings to us. ENs and State VR agencies are also required to submit evidence of beneficiaries' earnings to support some types of payments under the Ticket to Work program. The administrative records referred to in § 411.200 are our records that contain this information, including any Program Manager (PM) records, which may include additional information such as certification of educational accomplishments.

Concerning the educational documentation, if our records do not show that the work or educational requirements have been met, we will send a letter to the beneficiary asking him or her to provide appropriate information about any work or educational progress made during the period. If the beneficiary does not respond, we will contact the EN or State VR agency. We plan to implement this part of the process in a way that should not be burdensome to ENs or State VR agencies. The PM will be accepting electronic notifications, and we will work to make the process as efficient as possible.

Section 411.192 What choices do I have if I am unable to make timely progress toward self-supporting employment?

Comment: Some commenters suggested that we allow beneficiaries with significant disabilities who do not expect that they will ever meet the timely progress requirements and whose medical conditions are not likely to improve, the choice of opting out of having their ticket being considered ''in-use'' with a VR agency. This would prevent the PM from requesting the beneficiary or the State VR agency to submit information for purposes of progress reviews in situations where the beneficiary isn't expected to meet the timely progress requirements and where a medical CDR is a non-issue because medical improvement is unlikely.

Response: In response to this comment, we modified § 411.192 to provide that a beneficiary may request to have his or her ticket placed in inactive status if the beneficiary is temporarily or otherwise unable to make timely progress toward self-supporting employment.

Comment: Some commenters requested that we clarify the role of the VR Agencies in providing evidence of tickets in-use under the cost reimbursement program and how to notify the PM when a beneficiary is receiving services under an IPE.

Response: In order to extend CDR protection to beneficiaries, State VR agencies will need to inform the PM when they initiate an IPE. In addition, we will need to know when cases are closed so that we can end the ''in-use'' period and make the ticket available for assignment. We intend to implement this part of the process in a way that will be least burdensome to State VR agencies. The PM will be accepting electronic notifications, and we will work to make the process as efficient as possible. State VR agencies can continue using SSA Form SSA–1365 if they are assigning a ticket and choosing to be paid under an EN payment system rather than the cost reimbursement payment method.

Comment: A few commenters suggested we extend the 90-day period for ticket assignment that begins after VR case closure by a State VR agency which elected the VR cost reimbursement option so the ticket can be available for assignment at any point after the VR case closure.

Response: The beneficiary can assign the ticket any time after the VR case closure. We clarified in § 411.140(a) of

the final rules that a beneficiary may assign the ticket during the 90-day period after his or her case is closed by a State VR agency that elected the VR cost reimbursement option, without meeting the requirements of § 411.125(a)(2). Also, if the beneficiary assigns the ticket within the 90-day period, the medical CDR protection does not lapse. Nevertheless, the beneficiary may assign the ticket at any time as long as he or she remains eligible to participate in the Ticket to Work program.

Section 411.171 When does the period of using a ticket end?

Comment: Proposed § 411.171(e)(1) and (f)(1) discussed when the period of using a ticket ended for a title II beneficiary (the 36th month for which an outcome payment is made to an EN) or title XVI beneficiary (the 60th month for which an outcome payment is made to an EN). One commenter noted that the language in paragraphs (e)(1) and (f)(1) of proposed § 411.171 was not about ''the period of using a ticket'' as much as it related to when the ticket actually terminated and was no longer available for use with anyone. Therefore, the commenter recommended that it was more appropriate to put the language of these paragraphs into § 411.155 (When does my ticket terminate?).

Response: In response to this comment, we removed proposed § 411.171(e) and (f) from these final rules. We have incorporated in final § 411.171(d) the discussion contained in proposed § 411.171(e)(2) and (f)(2) concerning when the period of using a ticket may end for a beneficiary receiving services from a State VR agency electing the VR cost reimbursement option.

Comment: One commenter recommended that the clock for ''timely progress'' be re-started to day 1 when the ticket-user assigns his or her ticket with an EN after receiving services from a State VR agency, because a beneficiary might find an EN unwilling to subsequently accept a ticket for assignment if the beneficiary has already used up a significant portion of the timely progress period during ''in-use'' status with the State VR agency.

Response: We do not agree. We believe the new payment options provide sufficient incentives for ENs to accept tickets regardless of where the beneficiary is in the progress certification period. Timely progress rules only limit CDR protections, not the assignability of the ticket.

Subpart E—Employment Networks

Section 411.310 How does an entity other than a State VR agency apply to be an EN and who will determine whether an entity qualifies as an EN?

Comment: Many commenters supported the decision to allow one-stop delivery systems to participate as ENs without responding to the RFP. While they supported making it easier for one-stop delivery systems to become ENs, they still had concerns about whether or not the one-stop delivery systems would be physically or programmatically accessible to people with disabilities.

One commenter also suggested we include the Vocational Rehabilitation Services Projects for American Indians with Disabilities authorized under section 121 of part C of title I of the Rehabilitation Act of 1973 in the Ticket to Work program which could benefit their communities.

Response: In order for a one-stop delivery system to operate as an EN and to remain an EN, they must enter into an agreement with us and must maintain compliance with both general and specific selection criteria found in § 411.305 and § 411.315. These sections require the EN to be physically and programmatically accessible to beneficiaries seeking services.

We amended final § 411.310(e) so that organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities authorized under section 121 of part C of title I of the Rehabilitation Act of 1973 may participate in the Ticket program without responding to the RFP. We made a corresponding change to final § 411.315(f) to indicate that they must enter into an agreement with us and must maintain compliance with both general and specific selection criteria found in §§ 411.305 and 411.315.

Comment: Some commenters suggested we allow veterans programs under title 38 of the U.S.C. to apply to become an EN.

Response: Section 1148(f)(1)(A) of the Act provides that an EN serving under the Ticket to Work program shall consist of an agency or instrumentality of a State (or a political subdivision thereof) or a private entity. Therefore, federally-operated veterans programs under title 38 of the U.S. Code are not eligible to participate as an EN. However, their contractors may qualify.

Subpart F—State Vocational Rehabilitation Agencies' Participation

Section 411.385 What does a State VR agency do if a beneficiary who is eligible for VR services has a ticket that is available for assignment or reassignment?

Comment: Noting that proposed § 411.385 continued to require that a State VR agency submit the information prescribed in proposed § 411.385(a) in order for us to consider a beneficiary to be ''using a ticket,'' a number of State VR agencies indicated that this requirement requires a substantial amount of time and resources, and asked if this process could be simplified. Another commenter suggested that we continue to use the form SSA–1365 (Agency Ticket Assignment Form), but amend it so that it does not require the beneficiary's signature and it indicates whether the form is being submitted for ''in use'' purposes or is a request for ticket assignment. Another commenter recommended that we give consideration to allowing State VR agencies to submit a monthly list of beneficiaries being served in lieu of providing a paper copy of the signed IPE, to reduce the burden of collecting and submitting these copies.

Response: While these final rules still require the submission of the information prescribed in § 411.385, we are considering ways to simplify the process under which State VR agencies will notify the PM when an IPE is signed and the State VR agency has elected the VR cost reimbursement option. The PM will accept electronic notifications. We will work out an efficient means to allow the State VR agencies to regularly provide the PM a listing of ticket holders who recently signed an IPE.

Subpart H—Employment Network Payment Systems

Comment: One commenter recommended simplification of the payment systems to only one system, in order to streamline the administration of the Ticket to Work program. The commenter suggested that the outcome-milestone system would appear to cover the widest range of possible employment situations.

Response: We are unable to limit the EN payment systems to payment under only one system, because the Ticket legislation specifies in section 1148(h) of the Act that the Ticket to Work program shall provide ENs with a choice to be paid under either the outcome payment system or the outcome-milestone payment system.

Comment: One commenter asked whether an EN could be compensated under the Ticket to Work program if the extended services provided following VR services are being funded from a different financial source.

Response: Section 1148(b)(4) of the Social Security Act and § 411.570 of our regulations prohibit an EN from requesting or receiving compensation from the beneficiary for the services of the EN. Otherwise, nothing in the Ticket to Work rules would preclude an EN from seeking financial support for services being provided to a beneficiary. We encourage ENs to seek financial support from other sources for services provided to beneficiaries.

Section 411.515 Can the EN change its elected payment system?

Comment: Section 411.515(b) provides the opportunity for an EN to make one change in its elected payment system at any time prior to the close of the 12th month following the month in which the EN first elects an EN payment system. One commenter noted that the 12-month period seems to be a minimal level of flexibility, given that State VR agencies can decide on a case-by-case basis whether to serve the beneficiary as an EN. Another commenter suggested that as a strategy to offer greater flexibility to ENs, we may want to consider allowing ENs the option of choosing the outcome or the outcome-milestone payment system on a case-by-case basis.

Response: We removed § 411.515(c), which says that after the year ends in which the beneficiary first elected a payment system, we will offer the opportunity for each EN to make a change in its elected payment system at least every 18 months. As revised, this section clarifies that after an EN elects a payment system, the EN can make one change in its elected payment system in each calendar year thereafter. We believe an annual opportunity to change the payment system election is reasonable and administratively prudent.

Section 411.525 What payments are available under each of the EN payment systems? and § 411.535 Under what circumstances will milestones be paid?

Comment: Proposed § 411.535(a)(3) provided that ''If the beneficiary does not achieve all Phase 1 and Phase 2 milestones prior to the beginning of the beneficiary's outcome period, then we will pay the EN (or State VR agency acting as an EN) the final milestone payment equal to the total amount of the remaining unpaid Phase 1 and Phase 2 milestones.'' A number of commenters expressed concern about this provision. They noted that there might be unintended consequences from providing this final milestone payment in a lump sum, which could result in a financial disincentive to continuing serving a beneficiary after the first year, if the lump sum was paid because the beneficiary went to work and immediately left the benefit rolls, or might provide an incentive for the State VR agency to choose the less-challenging milestone payment system over the cost reimbursement payment system. Another commenter noted that the proposed outcome-milestone payment system could result in shifting too much of the Ticket to Work program's value to the first couple months of employment, thus diminishing a beneficiary's ability to negotiate for needed service later in his or her efforts to return to work. The commenter recommended that we review the lump sum milestone payment provision to ensure that beneficiaries do not lose this protection. Commenters also recommended withholding the lump sum payment for anywhere from 6 to 18 months into the outcome period.

Response: In response to these comments, we added § 411.536 to explain how we will make the reconciliation payment if the beneficiary does not achieve all Phase 1 and Phase 2 milestones prior to the beginning of the beneficiary's outcome period.

We will make a reconciliation payment to the EN once the beneficiary achieves 12 outcome payment months. Congress intended that milestone payments should lead to permanent employment. The reconciliation payment will be equal to the total of all Phase 1 and 2 milestone payments which could have been payable with respect to a ticket but that were not paid prior to the beginning of the outcome payment period.

Comment: Proposed § 411.535(a)(4) provided that if the State VR agency already has received payment for services under the cost reimbursement payment system, we would not pay Phase 1 milestones to an EN. A number of commenters indicated that there are conditions under which an EN should be paid for Phase 1 milestones if the State VR Agency has received payment under cost reimbursement. They note that it is important that ENs and State VR agencies not be put in a position of ''competing for ticket holders.'' While understanding our fiscal concern about paying for the same service twice, they still do not want to discourage ENs from referring beneficiaries to the State VR agencies for services or vice versa. One commenter requested that we attempt to craft a rule that focuses on the beneficiary and the employment outcomes they have achieved prior to ticket assignment and is not VR-centric as in the NPRM.

Response: We agree that the rules in this regard should broadly consider work before ticket assignment and not focus exclusively on cases where a beneficiary received services from a State VR agency. The intent of the Phase 1 milestone payments is to support the high costs ENs frequently incur during the initial job acquisition phase of return to work, e.g., job development and on-the-job training and support. In developing these rules, we also wanted to address the concerns that the ticket should not pay for employment results that have recently been attained. We attempted to address this by revising § 411.535, ''Under what circumstances will milestones be paid?'' In that section we preclude payment of all Phase 1 milestones if the State VR agency services, under the cost reimbursement option, ended in an employment outcome before case closure. In addition, we limit payment of some or all of Phase 1 milestones when the beneficiary had significant work activity prior to ticket assignment.

Section 411.566 May an EN use outcome or milestone payments to make payments to the beneficiary?

Comment: Proposed § 411.566 provided that an EN could use outcome or milestone payments to pay bonuses to beneficiaries. A number of commenters expressed concern that this new section might lead to expectation that an EN must make these payments to beneficiaries. Beyond that, commenters noted a concern on how these bonus payments would affect a beneficiary's benefits, e.g., by counting as unearned income for title XVI beneficiaries.

Response: We changed the title of final § 411.566 to ''May an EN use outcome or milestone payments to make payments to the beneficiary?'' and revised this section to remove references to these payments as bonus payments. We must count income under our rules, but we have work incentives outreach efforts to help beneficiaries plan for how income affects them. In addition to work incentives specialist within SSA, § 1148 of the Act established Work Incentive Planning and Assistance Organizations in communities across the country that provide benefits planning and assistance to help beneficiaries anticipate and plan for the effect of work and earnings and other income,

such as the payments a beneficiary may receive from an EN, on their benefits.

Section 411.582 Can a State VR agency receive payment under the cost reimbursement system if a continuous 9-month period of substantial gainful activity is completed after the ticket is assigned to an EN?

Comment: A number of commenters provided the example of a case in which the State VR agency selects the traditional cost reimbursement payment system using the form SSA–1365 and provides services to the beneficiary that cost $25,000. In this example, the beneficiary completes the VR services and the case is closed. Three months later the beneficiary assigns his or her ticket to an EN which chooses the proposed outcome milestone payment and provides both job placement and supported employment. The beneficiary is successful and his or her SSI checks stop. The commenter asked if the State VR agency would get the reimbursement of the $25,000 plus administrative costs, and if the EN would have the potential to receive the full value of the ticket.

Response: The State VR agency can receive cost reimbursement and the EN can receive payments under its elected EN payment system with respect to the same ticket. After VR case closure an EN can receive Phase 2 milestone payments intended to support job retention and outcome payments. However, in the situation described by this commenter, the EN may be able to also receive Phase 1 milestones if the beneficiary did not achieve a successful employment outcome before the VR agency closed the case (see § 411.535).

Comment: One commenter noted that the citation to 34 CFR 361.12 in the proposed § 411.582 is incomplete, and should be cited as 34 CFR part 361 because VR services are provided pursuant to a number of sections in part 361.

Response: We agree, and corrected this citation in the final § 411.582.

Section 411.590 What can an EN do if the EN disagrees with our decision on a payment request?

Comment: One commenter noted that while we proposed to revise § 411.590(d), we also proposed to retain language commented on in the past, i.e., ''While an EN cannot appeal our determination about an individual's right to benefits, the EN may furnish any evidence the EN has which relates to the issue(s) to be decided on appeal if the individual appeals our determination.'' The commenter remains concerned that this sentence appears to encourage ENs to turn against beneficiaries if the ENs are unsuccessful in disputes with us over whether payments are due to the EN. The commenter believes that should an EN lose its dispute with us, the only alternative we have offered is for the EN to submit evidence against the beneficiary in the beneficiary's claim for cash benefits. The commenter believes this approach creates the potential for a serious conflict between the beneficiary and the EN in a contractual arrangement where the beneficiary needs to trust that the EN is working in the beneficiary's best interest in job preparation, placement, and follow-up.

Response: As we noted in response to this concern expressed by a number of commenters in the preamble to the prior regulations published on December 28, 2001 (66 FR 67370, 67416), we do not want to create an adversarial relationship between beneficiaries and ENs. For this reason, we clearly state in § 411.590(c) and (d) of the prior rules that an EN cannot appeal a determination we make about a beneficiary's right to benefits, but an EN may furnish evidence in support of the EN's claim for payment.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget and have determined that these final rules meet the criteria for an economically significant regulatory action under Executive Order 12866, as amended.

ESTIMATED INCREASES (+) AND DECREASES (−) IN OASDI BENEFITS AND FEDERAL SSI PAYMENTS DUE TO THE PROVISIONS OF THE FINAL RULE UNDER CONSIDERATION FOR THE TICKET TO WORK PROGRAM, FISCAL YEARS 2008–18

[In millions]

Provision	Fiscal year											Totals	
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2008–13	2008–18
Change due to proposed new EN payment structure (including State VR agencies):													
OASDI benefit payments	$1	$7	$29	$93	$154	$233	$290	$342	$376	$405	$421	$517	$2,351
Federal SSI payments	1	11	31	47	70	94	112	133	150	165	176	254	989
Subtotal, OASDI and SSI	2	19	60	140	224	326	403	474	525	570	597	771	3,340
Change due to deferral of CDRs:													
OASDI benefit payments	.....	.....	(1)\	2	5	12	21	32	44	58	76	20	251
Federal SSI payments	-	(1)\	1	2	3	4	5	5	5	6	5	10	36
Subtotal, OASDI and SSI	.....	(1)\	1	4	8	16	26	36	50	64	81	30	287
Change due to increase in work activity among OASDI and SSI beneficiaries:													
OASDI benefit payments	.....	.....	.....	−3	−26	−71	−123	−178	−247	−305	−363	−99	−1,315
Federal SSI payments	(2)\	−7	−28	−60	−75	−106	−128	−146	−176	−183	−185	−276	−1,093
Subtotal, OASDI and SSI	(2)\	−7	−28	−63	−101	−176	−251	−324	−422	−488	−548	−375	−2,408
Net total increase in outlays due to proposed rule changes:													
OASDI benefit payments	1	7	29	92	134	174	189	195	173	158	134	438	1,288
Federal SSI payments	1	5	4	−11	−3	−8	−11	−8	−20	−13	−4	−12	−68
Total, OASDI and SSI	2	12	33	81	131	166	178	187	153	146	130	426	1,219

[1] Increase of less than $500,000.
[2] Reduction of less than $500,000.

Notes:
1. See covering memorandum and table 1 for details of the proposed changes.
2. Above estimates are consistent with the assumptions underlying the President's FY 2009 Budget, and assume that a final regulation establishing the provisions of the proposed rule would become effective as of July 21, 2008.

3. Totals may not equal sum of rounded components.
4. SSI payments due on October 1st in fiscal years 2012, 2017 and 2018 are included in payments for the prior fiscal year.

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 2, we have prepared an accounting statement showing the annualized economic impact of implementing the Ticket to Work program. All estimated impacts are classified as transfers.

TABLE 2.—ACCOUNTING STATEMENT: ESTIMATED ECONOMIC IMPACT OF PROVISIONS TO ENHANCE THE TICKET TO WORK PROGRAM

[Fiscal years 2008–2018 in 2008 dollars]

Category	Transfers
Annualized Monetized Transfers	$98.8 million (7% discount rate). $102.6 million (3% discount rate).
From Whom To Whom?	From the Social Security trust funds and the general fund to SSA beneficiaries.

Regulatory Flexibility Act

We certify that these final rules would not have a significant economic impact on a substantial number of small entities because they would primarily affect only individuals, and those entities that voluntarily enter into a contractual agreement with us. Accordingly, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Federalism

We have reviewed these final rules under the threshold criteria of Executive Order 13132, ''Federalism,'' and determined that they do not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. These final rules will complement and enhance the existing State vocational rehabilitation program.

Paperwork Reduction Act

We are revising our regulations for the Ticket to Work and Self-Sufficiency Program (Ticket to Work program), which was authorized by the Ticket to Work and Work Incentives Improvement Act of 1999. The Ticket to Work program provides Social Security Disability Insurance and Supplemental Security Income beneficiaries expanded options for access to employment services, vocational rehabilitation services, and other support services. We are revising our prior rules to improve the overall effectiveness of the program to maximize the economic self-sufficiency of beneficiaries through work opportunities. We have based these revisions on our projections of the future direction of the Ticket to Work program, our experience using the prior rules, and recommendations made by a number of commenters on the program.

We published a Notice of Proposed Rulemaking on September 30, 2005 at 70 FR 57222 and solicited comments under the Paperwork Reduction Act (PRA) on the public reporting requirements in §§ 411.145(a), 411.190, 411.325(a), 411.140(d)(3), 411.365(a), 411.385, 411.390 and 411.575. We solicited comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. None of the comments submitted by the public on this regulation were related to these issues. On November 23, 2005 OMB filed comment on the NPRM in accordance with 5 CFR 1320. In response to the comment, we clarified the reporting requirement in § 411.325(a), ''What reporting requirements are placed on an EN as a participant in the Ticket to Work Program?''

We published a second Notice of Proposed Rulemaking on August 13, 2007 at 72 FR 45191 and solicited comments under the PRA on the public reporting requirements in §§ 411.192(b) and (c), 411.200(b), and 411.210. We solicited comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. None of the comments submitted by the public on this regulation were related to these issues.

As required by the PRA, we have submitted a clearance request to OMB for approval. We will publish the OMB number and expiration date upon approval. Requests for the Information Collection Request Package should be directed to SSA through the SSA Reports Clearance Officer at 410–965–0454 or to *OPLM.RCO@ssa.gov.*

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 411

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income, Public Assistance programs, Vocational Rehabilitation.

Dated: February 6, 2008.

Michael J. Astrue,

Commissioner of Social Security.

Editorial Note: This document was received at the Office of the Federal Register on May 12, 2008.

■ For the reasons set out in the preamble, we are amending subparts A, B, C, E, F and H of part 411 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 411—THE TICKET TO WORK AND SELF-SUFFICIENCY PROGRAM

■ 1. Revise the authority citation for part 411 to read as follows:

Authority: Secs. 702(a)(5) and 1148 of the Social Security Act (42 U.S.C. 902(a)(5) and 1320b–19); sec. 101(b)–(e), Public Law 106–170, 113 Stat. 1860, 1873 (42 U.S.C. 1320b–19 note).

Subpart A—[Amended]

§ 411.110 [Removed]

■ 2. Remove § 411.110.

■ 3. In § 411.115, redesignate paragraph (s) as paragraph (t) and add a new paragraph (s) to read as follows:

§ 411.115 Definitions of terms used in this part.

* * * * *

(s) *VR cost reimbursement option* means an arrangement under which your ticket is not assigned to the State VR agency but you do receive services pursuant to an individualized plan for employment where the State VR agency has chosen to receive payment under the cost reimbursement payment system.

* * * * *

Subpart B—[Amended]

■ 4. In § 411.120, revise paragraphs (b) and (c) to read as follows:

§ 411.120 What is a ticket under the Ticket to Work program?

* * * * *

(b) The left side of the ticket includes the beneficiary's name, ticket number, claim account number, and the date we issued the ticket. The ticket number is 12 characters and comprises the beneficiary's own social security number, the letters ''TW,'' and a number (1, 2, etc.) in the last position signifying that this is the first ticket, second ticket, etc., that the beneficiary has received.

(c) The right side of the ticket includes the signature of the Commissioner of Social Security and provides a description of the Ticket to Work program. The description of the program will tell you how you may offer the ticket to an EN or State VR agency. The description will also tell you how the EN provides services to you.

■ 5. In § 411.125, revise paragraphs (a)(1) and (a)(2)(ii)(C), and remove paragraph (a)(3) to read as follows:

§ 411.125 Who is eligible to receive a ticket under the Ticket to Work program?

(a) * * *

(1) You are age 18 or older and have not attained age 65; and

(2) * * *

(ii) * * *

(C) Your monthly Federal cash benefits based on disability or blindness under title XVI are not suspended (see subpart M of part 416 of this chapter for our rules on suspension of title XVI benefit payments).

* * * * *

■ 6. Revise § 411.130 to read as follows:

§ 411.130 How will we distribute tickets under the Ticket to Work program?

If you are eligible to receive a ticket under § 411.125, we will send a ticket to you by mail.

■ 7. Revise § 411.135 to read as follows:

§ 411.135 What do I do when I receive a ticket?

Your participation in the Ticket to Work program is voluntary. When you receive your ticket, you are free to choose when and whether to assign it (see § 411.140 for information on assigning your ticket). If you want to participate in the program, you can take your ticket to any EN you choose or to your State VR agency. You may choose either to assign your ticket to an EN by signing an individual work plan (see §§ 411.450 through 411.470) or receive services from your State VR agency by entering into and signing an individualized plan for employment. If the State VR agency provides services to you, it will decide whether to accept your ticket. If it accepts your ticket, you will have assigned your ticket to the State VR agency and it will receive payment as an EN. If the State VR agency decides to be paid under the cost reimbursement payment system, you have not assigned your ticket and you may assign your ticket after the State VR agency has closed your case.

■ 8. In § 411.140, revise the section heading, paragraph (a), the introductory text of paragraph (d), paragraph (d)(3), and the first sentence of paragraph (e) to read as follows:

§ 411.140 When may I assign my ticket and how?

(a) You may assign your ticket during a month in which you meet the requirements of § 411.125(a)(1) and (a)(2). You may assign your ticket during the 90-day period after your case is closed by a State VR agency that elected the VR cost reimbursement option (see § 411.171(d)), without meeting the requirements of § 411.125(a)(2). You may assign your ticket to any EN which is serving under the program and is willing to provide you with services, or you may assign your ticket to a State VR agency acting as an EN if you are eligible to receive VR services under 34 CFR 361.42. You may not assign your ticket to more than one provider of services (i.e., an EN or a State VR agency) at a time. You may not assign your ticket until after the State VR agency has closed your case if you are receiving VR services pursuant to an individualized plan for employment from a State VR agency which has elected the VR cost reimbursement option. You also may not assign your ticket to a State VR agency if that VR agency previously served you and elected the VR cost reimbursement option and closed your case.

* * * * *

(d) In order for you to assign your ticket to an EN or State VR agency acting as an EN, all of the following requirements must be met:

* * * * *

(3) A representative of the EN must submit a copy of the signed IWP to the PM, or a representative of the State VR agency, acting as an EN, must submit the completed and signed form (as described in § 411.385(a) and (b)) to the PM.

* * * * *

(e) If all of the requirements in paragraph (d) of this section are met, we will consider your ticket assigned to the EN or State VR agency acting as an EN.

* * *

■ 9. Revise § 411.145 to read as follows:

§ 411.145 When can my ticket be taken out of assignment?

(a) If you assigned your ticket to an EN or a State VR agency acting as an EN, you may take your ticket out of assignment for any reason. You must notify the PM in writing that you wish to take your ticket out of assignment. The ticket will be no longer assigned to that EN or State VR agency acting as an EN, effective with the first day of the month following the month in which you notify the PM in writing that you wish to take your ticket out of assignment. You will be sent a notice informing you that your ticket is no longer assigned to that EN or State VR agency. You may reassign your ticket under the rules in § 411.150.

(b) If your EN goes out of business or is no longer approved to participate as an EN in the Ticket to Work program, the PM will take your ticket out of assignment with that EN. The ticket will no longer be assigned to that EN effective on the first day of the month following the month in which the EN goes out of business or is no longer approved to participate in the Ticket to Work program. You will be sent a notice informing you that your ticket is no longer assigned to that EN. In addition, if your EN is no longer willing or able to provide you with services, or if your State VR agency acting as an EN stops providing services to you because you have been determined to be ineligible for VR services under 34 CFR 361.42, the EN or State VR agency acting as an EN may ask the PM to take your ticket out of assignment with that EN or State VR agency. The ticket will no longer be assigned to that EN or State VR agency acting as an EN effective on the first day of the month following the month in which the EN or State VR agency acting as an EN makes a request to the PM that the ticket be taken out of assignment.

You will be sent a notice informing you that your ticket is no longer assigned to that EN or State VR agency acting as an EN. You may reassign your ticket under the rules in § 411.150.

(c) For information about how taking a ticket out of assignment may affect medical reviews that we conduct to determine if you are still disabled under our rules, see §§ 411.171(c) and 411.220.

■ 10. In § 411.150, revise the section heading, and paragraphs (a) and (b)(3) to read as follows:

§ 411.150 Can I reassign my ticket?

(a) If you previously assigned your ticket and your ticket is no longer assigned (see § 411.145), you may reassign your ticket, unless you are receiving benefit payments under § 404.316(c), § 404.337(c), § 404.352(d) or § 404.1597a of this chapter, or you are receiving disability or blindness benefit payments under § 416.996 or § 416.1338 of this chapter (the provisions of paragraph (b)(3) of this section notwithstanding). If you previously assigned your ticket to an EN, you may reassign your ticket to a different EN which is serving under the program and is willing to provide you with services, or you may reassign your ticket to a State VR agency acting as an EN if you are eligible to receive VR services under 34 CFR 361.42. If you previously assigned your ticket to a State VR agency acting as an EN, you may reassign your ticket to an EN which is serving under the program and is willing to provide you with services, or to another State VR agency acting as an EN if you are eligible to receive VR services under 34 CFR 361.42.

(b) * * *

(3) You must meet the requirements of § 411.125(a)(1) and (2) on or after the day you and a representative of the new EN sign your IWP or you and a representative of the State VR agency sign your IPE and the required form. You may reassign your ticket within 90 days of the effective date your ticket was no longer assigned, without meeting the requirements of § 411.125(a)(2).

* * * * *

■ 11. In § 411.155, revise paragraphs (a)(2) and (a)(3), add a new paragraph (a)(4), remove the word ''or'' at the end of paragraph (c)(6), replace the period at the end of paragraph (c)(7) with ''; or'', and add a new paragraph (c)(8) to read as follows:

§ 411.155 When does my ticket terminate?

(a) * * *

(2) If you are entitled to widow's or widower's insurance benefits based on disability (see §§ 404.335 and 404.336 of this chapter), the month in which you attain full retirement age;

(3) If you are eligible for benefits under title XVI based on disability or blindness, the month following the month in which you attain age 65; or

(4) The month after the month in which your outcome payment period ends (see § 411.500(b)).

* * * * *

(c) * * *

(8) The month after the month in which your outcome payment period ends (see § 411.500(b)).

Subpart C—[Amended]

■ 12. In § 411.165, revise the section heading and the second sentence to read as follows:

§ 411.165 How does using a ticket under the Ticket to Work program affect my continuing disability reviews?

* * * However, we will not begin a continuing disability review during the period in which you are using a ticket. * * *

■ 13. Revise § 411.166 to read as follows:

§ 411.166 Glossary of terms used in this subpart.

(a) *Using a ticket* means you have assigned a ticket to an Employment Network (EN) or a State VR agency that has elected to serve you as an EN, and you are making timely progress toward self-supporting employment as defined in § 411.180; or you have a ticket that would otherwise be available for assignment and are receiving VR services pursuant to an individualized plan for employment (IPE) and the State VR agency has chosen to be paid for these services under the cost reimbursement payment system, and you are making timely progress toward self-supporting employment as defined in § 411.180. (See § 411.171 for when the period of using a ticket ends.)

(b) *Timely progress toward self-supporting employment* means you have completed the specified goals of work and earnings, or completed the specified post-secondary education credits at an educational institution (see § 411.167) in pursuit of a degree or certificate, or completed specified course requirements for a vocational or technical training program at an educational institution consisting of a technical, trade or vocational school (see § 411.167), or completed a certain percentage of the work requirement and a certain percentage of the post-secondary education requirement or vocational or technical training requirement and the sum of the two percentages equals 100 or more (see § 411.180(c)), or obtained a high school diploma or General Education Development (GED) certificate in the applicable progress certification period as described in § 411.180.

(c) *Timely progress guidelines* mean the guidelines we use to determine if you are making timely progress toward self-supporting employment (see § 411.180).

(d) *Progress certification period* means any 12-month progress certification period described in § 411.180(b).

(e) *Progress review* means the reviews the PM conducts to determine if you are meeting the timely progress guidelines described in § 411.180. We explain the method for conducting progress reviews in § 411.200.

(f) *Extension period* is a period of up to 90 days during which you may reassign a ticket without being subject to continuing disability reviews. You may be eligible for an extension period if the ticket is in use and no longer assigned to an EN or State VR agency acting as an EN (see § 411.220).

(g) *Inactive status* is a status in which you may place your ticket if you are temporarily or otherwise unable to make timely progress toward self-supporting employment during a progress certification period. See § 411.192 for the rules on placing your ticket in inactive status and on reactivating your ticket.

(h) *Variance tolerance* means the margin of flexibility whereby we will consider you to have met the requirement for completing a specified amount of post-secondary credit hours in an educational degree or certification program or the course requirements in a vocational or technical training program under § 411.180 in the applicable progress certification period if your completion of credit hours or course requirements in this period is within 10% of the goal. Figures representing the number of credit hours required for the first and second progress certification periods as described in § 411.180 will be rounded by dropping any fractions. Under the variance tolerance, we also will consider you to have met the requirements in an applicable progress certification period if you complete a certain percentage of the work requirement and a certain percentage of the post-secondary education requirement or vocational or technical training requirement in the period and the sum of the two percentages is within 10% of the goal. See § 411.180(a) and (c).

(i) *VR cost reimbursement option* means an arrangement under which your ticket is not assigned to the State VR agency but you do receive services pursuant to an individualized plan for employment where the State VR agency has chosen to receive payment under the cost reimbursement payment system.

(j) *VR cost reimbursement status* means the status of your ticket under the arrangement described in paragraph (i) of this section. The period during which your ticket is in VR cost reimbursement status begins on the date described in § 411.170(b) and ends on the date your case is closed by the State VR agency.

■ 14. Add § 411.167 to read as follows:

§ 411.167 What is an educational institution or a technical, trade or vocational school?

(a) *Educational institution* means a school (including a technical, trade, or vocational school), junior college, college or university that is: operated or directly supported by the United States; operated or directly supported by any State or local government or by a political subdivision of any State or local government; or approved by a State agency or subdivision of the State, or accredited by a State-recognized or nationally recognized accrediting body.

(b) *Technical, trade or vocational school* is an educational institution that is approved by a State agency or subdivision of the State or accredited by a State-recognized or nationally recognized accrediting body to provide technical, trade or vocational training.

(c) *State-recognized accrediting body* means an entity designated or recognized by a State as the proper authority for accrediting schools, colleges or universities.

(d) *Nationally recognized accrediting body* means an entity determined to be such by the U.S. Department of Education.

(e) *Approval by a State agency or subdivision of the State* includes approval of a school, college or university as an educational institution, or approval of one or more of the courses offered by a school, college or university.

■ 15. Remove the undesignated center heading before § 411.170.

■ 16. Revise § 411.170 to read as follows:

§ 411.170 When does the period of using a ticket begin?

(a) The period of using a ticket begins on the effective date of the assignment of your ticket to an EN or State VR agency under § 411.140.

(b) If you have a ticket that would otherwise be available for assignment and are receiving VR services pursuant to an individualized plan for employment (IPE) and the State VR agency has elected the VR cost reimbursement option, the period of using a ticket begins on the later of—

(1) The effective date of your IPE; or

(2) The first day your ticket would otherwise have been assignable if you had not been receiving services from a State VR agency that elected the VR cost reimbursement option.

■ 17. Revise § 411.171 to read as follows:

§ 411.171 When does the period of using a ticket end?

The period of using a ticket ends with the earliest of the following—

(a) The last day of the month before the month in which the ticket terminates as a result of one of the events listed in § 411.155 (see § 411.155(a)(4) and (c)(8) for when your ticket terminates if your outcome payment period ends);

(b) The day before the effective date of a decision under § 411.200 or § 411.205 that you are no longer making timely progress toward self-supporting employment;

(c) The last day of the 90-day extension period which begins with the first day of the first month in which your ticket is no longer assigned to an EN or State VR agency acting as an EN (see § 411.145), unless you reassign your ticket within the 90-day extension period (see § 411.220 for an explanation of the 90-day extension period); or

(d) If your ticket was in VR cost reimbursement status as described in § 411.166(j), the 90th day following the date the State VR agency closes your case, unless you assign your ticket during this 90-day period.

■ 18. In § 411.175, revise the section heading and the first and fourth sentences of paragraph (a) to read as follows:

§ 411.175 What if a continuing disability review is begun before my ticket is in use?

(a) If we begin a continuing disability review before the date on which your ticket is in use, you may still assign the ticket and receive services from an EN or a State VR agency acting as an EN under the Ticket to Work program, or you may still receive services from a State VR agency that elects the VR cost reimbursement option. * * * However, if your ticket was in use before we determined that you are no longer disabled, in certain circumstances you may continue to receive benefit payments (see §§ 404.316(c), 404.337(c), 404.352(d), and 416.1338 of this chapter). * * *

* * * * *

■ 19. Remove the undesignated center heading before § 411.180.

■ 20. Revise § 411.180 to read as follows:

§ 411.180 What is timely progress toward self-supporting employment?

(a) *General.* We consider you to be making timely progress toward self-supporting employment when you show progress as described below toward the ability to work at levels which will reduce your dependence on Social Security disability benefits or SSI benefits. We will also consider you to be making timely progress when you obtain a high school diploma or GED certificate in the first 12-month progress certification period, or if you show progress as described below toward obtaining an educational degree or certificate or vocational or technical training that will enhance your ability to return to work. In addition, if you complete a certain percentage of the work requirement and a certain percentage of the post-secondary education requirement or vocational or technical training requirement in the applicable progress certification period under the guidelines below, and the sum of the two percentages equals 100 or more, we will consider you to have met the timely progress requirements for purposes of the progress review conducted at the end of the 12-month progress certification period. For example, if you complete 33.3 percent of the work requirement during the first 12-month progress certification period as described in paragraph (c)(1)(i) of this section (i.e., one month of work with earnings equal to or greater than the amount representing a trial work service month), and complete 66.7 percent of the requisite credit hours in an educational program during this period as described in paragraph (c)(1)(iii) of this section (i.e., 40 percent of the post-secondary credit hours that are considered to represent an academic year of full-time study), we will consider you to have met the timely progress requirements for purposes of the progress review conducted at the end of the first 12-month progress certification period. In addition, we will apply the variance tolerance described in § 411.166(h) in determining whether you have met the requirements in paragraph (c)(1)(iii), (iv) or (v), paragraph (c)(2)(ii), (iii) or (iv), paragraph (c)(3)(iii) or (v), paragraph (c)(4)(ii) or (iii), or paragraph (c)(5)(ii) or (iii) of this section.

(b) *12-month progress certification periods.* The first 12-month progress certification period begins with the month following the month in which you first assigned your ticket, or with the month beginning after the date described in § 411.170(b) if you have a ticket that would otherwise be available for assignment and are receiving VR services under an IPE from a State VR agency which has chosen the VR cost reimbursement option. Any subsequent 12-month progress certification period will begin with the month following the end of the previous 12-month progress certification period. In computing any 12-month progress certification period, we do not count any month during which—

(1) Your ticket is not assigned to an EN or State VR agency acting as an EN and is not in VR cost reimbursement status (as described in § 411.166(j)); or

(2) Your ticket is in inactive status (see § 411.192).

(c) *Guidelines.* We will determine if you are making timely progress toward self-supporting employment by using the following guidelines:

(1) During the first 12-month progress certification period, you must be making timely progress as follows:

(i) You must have worked in at least three months within this 12-month period and have earnings in each of those three months that are equal to or greater than the amount representing a trial work service month (see § 404.1592(b) of this chapter); or

(ii) You must have obtained a high school diploma or GED certificate within this 12-month period; or

(iii) You must have been enrolled in a two- or four-year degree or certification program at an educational institution and have completed 60 percent of the post-secondary credit hours that are considered to represent an academic year of full-time study in the program by the end of this 12-month period; or

(iv) You must have been enrolled in a vocational or technical training program at an educational institution consisting of a technical, trade or vocational school and have completed 60 percent of the course requirements that are considered to represent a year of full-time study in the program by the end of this 12-month period; or

(v) You must have completed a percentage of the required number of months of work and earnings described in paragraph (c)(1)(i) of this section and a percentage of the specified amount of post-secondary credit hours or course requirements required under paragraph (c)(1)(iii) or (iv) of this section within this 12-month period so that the sum of the two percentages equals 100 or more.

(2) During the second 12-month progress certification period, at the conclusion of 24 months of ticket use, you must be making timely progress as follows:

(i) You must have worked in at least six months within this 12-month period and have earnings in each of those six months that are equal to or greater than the amount representing a trial work service month (see § 404.1592(b) of this chapter); or

(ii) You must have been enrolled in a two- or four-year degree or certification program at an educational institution and have completed an additional 75 percent of the post-secondary credit hours that are considered to represent an academic year of full-time study in the program by the end of this 12-month period; or

(iii) You must have been enrolled in a vocational or technical training program at an educational institution consisting of a technical, trade or vocational school and have completed an additional 75 percent of the course requirements that are considered to represent a year of full-time study in the program by the end of this 12-month period; or

(iv) You must have completed a percentage of the required number of months of work and earnings described in paragraph (c)(2)(i) of this section and a percentage of the specified amount of post-secondary credit hours or course requirements required under paragraph (c)(2)(ii) or (iii) of this section within this 12-month period so that the sum of the two percentages equals 100 or more.

(3) During the third 12-month progress certification period, at the conclusion of 36 months of ticket use, you must be making timely progress as follows:

(i) You must have worked in at least nine months within this 12-month period and have gross earnings from employment (or net earnings from self-employment as defined in § 404.1080 of this chapter) in each of those nine months that are more than the SGA threshold amount specified in § 404.1574(b)(2) of this chapter; or

(ii) You must have completed the course work and earned a degree or certificate from a two-year degree or certification program at an educational institution by the end of this 12-month period; or

(iii) You must have been enrolled in a four-year degree or certification program at an educational institution and completed additional post-secondary credit hours that are considered to represent an academic year of full-time study in the program by the end of this 12-month period; or

(iv) You must have been enrolled in a vocational or technical training program at an educational institution consisting of a technical, trade or vocational school and have completed the course requirements of the program by the end of this 12-month period; or

(v) You must have completed a percentage of the required number of months of work and earnings described in paragraph (c)(3)(i) of this section and a percentage of the specified amount of post-secondary credit hours required under paragraph (c)(3)(iii) of this section within this 12-month period so that the sum of the two percentages equals 100 or more.

(4) During the fourth 12-month progress certification period, at the conclusion of 48 months of ticket use, you must be making timely progress as follows:

(i) You must have worked in at least nine months within this 12-month period and have gross earnings from employment (or net earnings from self-employment as defined in § 404.1080 of this chapter) in each of those nine months that are more than the SGA threshold amount specified in § 404.1574(b)(2) of this chapter; or

(ii) You must have been enrolled in a four-year degree or certification program at an educational institution and completed additional post-secondary credit hours that are considered to represent an academic year of full-time study in the program by the end of this 12-month period; or

(iii) You must have completed a percentage of the required number of months of work and earnings described in paragraph (c)(4)(i) of this section and a percentage of the specified amount of post-secondary credit hours required under paragraph (c)(4)(ii) of this section within this 12-month period so that the sum of the two percentages equals 100 or more.

(5) During the fifth 12-month progress certification period, at the conclusion of 60 months of ticket use, you must be making timely progress as follows:

(i) You must have worked in at least six months within this 12-month period and have earnings in each of those six months that preclude payment of Social Security disability benefits and Federal SSI cash benefits; or

(ii) You must have been enrolled in a four-year degree or certification program at an educational institution and either completed additional post-secondary credit hours that are considered to represent an academic year of full-time study in the program or completed the course work and earned a degree or

certificate from the program by the end of this 12-month period; or

(iii) You must have completed a percentage of the required number of months of work and earnings described in paragraph (c)(5)(i) of this section and a percentage of the specified amount of post-secondary credit hours required under paragraph (c)(5)(ii) of this section within this 12-month period so that the sum of the two percentages equals 100 or more.

(6) During the sixth 12-month progress certification period, at the conclusion of 72 months of ticket use, you must be making timely progress as follows:

(i) You must have worked in at least six months within this 12-month period and have earnings in each of those six months that preclude payment of Social Security disability benefits and Federal SSI cash benefits; or

(ii) You must have completed the course work and earned a degree or certificate from a four-year degree or certification program at an educational institution by the end of this 12-month period.

(7) During all subsequent 12-month progress certification periods, you must have worked in at least six months within the 12-month period and have earnings in each of those six months that preclude payment of Social Security disability benefits and Federal SSI cash benefits.

§ 411.185 [Removed]

■ 21. Remove § 411.185.

§ 411.190 [Removed]

■ 22. Remove § 411.190.

§ 411.191 [Removed]

■ 23. Remove § 411.191.

■ 24. Add § 411.192 to read as follows:

§ 411.192 What choices do I have if I am unable to make timely progress toward self-supporting employment?

(a) If you report to the PM that you are temporarily or otherwise unable to make timely progress toward self-supporting employment during a progress certification period, the PM will give you the choice of placing your ticket in inactive status or, if applicable, taking your ticket out of assignment with the EN or State VR agency acting as an EN. The choice of placing your ticket in inactive status applies whether your ticket is assigned or in VR cost reimbursement status (as described in § 411.166(j)).

(b) You may place your ticket in inactive status at any time by submitting a written request to the PM asking that your ticket be placed in inactive status. Your ticket will be placed in inactive status beginning with the first day of the month following the month in which you make your request. You are not considered to be using a ticket during months in which your ticket is in inactive status. Therefore, you will be subject to continuing disability reviews during those months. The months in which your ticket is in inactive status do not count toward the time limitations for making timely progress toward self-supporting employment.

(c) You may reactivate your ticket and return to in-use status if your ticket is still assigned to an EN or State VR agency acting as an EN. You may also reactivate your ticket and return to in-use status if you have a ticket which would otherwise be available for assignment, you were receiving services under an IPE from a State VR agency which chose the VR cost reimbursement option, and your VR case has not been closed by the State VR agency. You may reactivate your ticket by submitting a written request to the PM. Your ticket will be reactivated beginning with the first day of the month following the month in which the PM receives your request. The progress certification period will resume counting from the last month of in-use status, and the next progress review will be due when the progress certification period has been completed. Earnings from work, obtaining a high school diploma or GED certificate, or completion of post-secondary education credits in a two- or four-year degree or certification program or course requirements in a vocational or technical training program, as described in § 411.180, during the period your ticket is in inactive status may be counted toward meeting the requirements for the next progress review.

(d) You may take your ticket out of assignment under § 411.145(a) at any time.

§ 411.195 [Removed]

■ 25. Remove § 411.195.

■ 26. Revise § 411.200 to read as follows:

§ 411.200 How will the PM conduct my progress reviews?

The PM will conduct a progress review at the end of each 12-month progress certification period.

(a) The PM will first review the available administrative records to determine if you completed the work requirements as specified in § 411.180 in the applicable progress certification period.

(b) If the administrative records do not indicate that you met the work requirements, the PM will contact either you or your EN or State VR agency to request additional information to determine if you completed the work requirements or have met the educational or training requirements as specified in § 411.180 in the applicable progress certification period.

(c) If the PM finds that you completed the work requirements or met the educational or training requirements as specified in § 411.180 in the applicable progress certification period, the PM will find that you are making timely progress toward self-supporting employment. On the basis of that finding, we will consider you to be making timely progress toward self-supporting employment until your next scheduled progress review.

(d) If the PM finds that you did not complete the work requirements or meet the educational or training requirements as specified in § 411.180 in the applicable progress certification period, the PM will find that you are not making timely progress toward self-supporting employment. If the PM makes such a finding, the PM will send a written notice of the decision to you at your last known address. This notice will explain the reasons for the decision and inform you of the right to ask us to review the decision. This decision will be effective 30 days after the date on which the PM sends the notice of the decision to you, unless you request that we review the decision under § 411.205.

■ 27. In § 411.210, revise paragraph (b), the heading of paragraph (c), and the fourth sentences of both paragraphs (c)(1) and (c)(2) to read as follows:

§ 411.210 What happens if I do not make timely progress toward self-supporting employment?

* * * * *

(b) *Re-entering in-use status.* If you failed to meet the timely progress guidelines for a 12-month progress certification period and you believe that you have now met the applicable requirements for that progress certification period as described in § 411.180, you may request that you be reinstated to in-use status. In order to do so, you must submit a written request to the PM asking that you be reinstated to in-use status and you must provide evidence showing that you have met the applicable requirements for the progress certification period. The PM will decide whether you have satisfied the applicable requirements for the progress certification period and may be reinstated to in-use status. If the PM determines you have met the applicable requirements for the progress certification period, you will be

reinstated to in-use status, provided that your ticket is assigned to an EN or State VR agency acting as an EN or in VR cost reimbursement status (as described in § 411.166(j)). See paragraph (c) of this section for when your reinstatement to in-use status will be effective. The month after you are reinstated to in-use status, your next 12-month progress certification period will begin.

(c) *Decisions on re-entering in-use status.* (1) * * * If the PM decides that you have satisfied the requirements for re-entering in-use status (including the requirement that your ticket be assigned to an EN or State VR agency acting as an EN or in VR cost reimbursement status), you will be reinstated to in-use status effective with the date on which the PM sends the notice of the decision to you. * * *

(2) * * * If we decide that you have satisfied the requirements for re-entering in-use status (including the requirement that your ticket be assigned to an EN or State VR agency acting as an EN or in VR cost reimbursement status), you will be reinstated to in-use status effective with the date on which we send the notice of the decision to you.

■ 28. In § 411.220, revise the first sentence of paragraph (a), revise paragraph (d)(2), remove paragraph (e), and redesignate paragraph (f) as paragraph (e) to read as follows:

§ 411.220 What if my ticket is no longer assigned to an EN or State VR agency?

(a) If your ticket was once assigned to an EN or State VR agency acting as an EN and is no longer assigned, you are eligible for an extension period of up to 90 days to reassign your ticket. * * *

* * * * *

(d) * * *

* * * * *

(2) Ends 90 days after it begins or when you assign your ticket to a new EN or State VR agency, whichever is sooner.

* * * * *

■ 29. In § 411.225, revise paragraphs (b) and (c), and remove paragraph (d) to read as follows:

§ 411.225 What if I reassign my ticket after the end of the extension period?

* * * * *

(b) *Time limitations for the timely progress guidelines.* Any month during which your ticket is not assigned and not in VR cost reimbursement status (as described in § 411.166(j)), either during or after the extension period, will not count toward the time limitations for the timely progress guidelines.

(c) *If you reassign your ticket after the end of the extension period.* If you reassign your ticket after the end of the extension period, the period comprising the remaining months in the applicable 12-month progress certification period will begin with the first month beginning after the day on which the reassignment of your ticket is effective under § 411.150(c).

■ 30. Add § 411.226 to read as follows:

§ 411.226 How will SSA determine if I am meeting the timely progress guidelines if I assign my ticket prior to July 21, 2008?

(a) If you assigned your ticket to an EN or State VR agency prior to July 21, 2008, we will determine which 12-month progress certification period in § 411.180 you are in as of July 21, 2008 using the rules in paragraph (a)(1) of this section. We will not conduct a progress review at the end of that progress certification period. We will conduct a progress review at the end of your next progress certification period as explained in paragraph (a)(2) of this section.

(1) We will consider you to be in the first or a subsequent 12-month progress certification period under § 411.180 as of July 21, 2008. We will determine your applicable 12-month progress certification period and the number of months remaining in that period as of July 21, 2008 by counting all months during which your ticket was assigned and in use during the period—

(i) Beginning with the month following the month in which you first assigned your ticket under the rules in effect prior to July 21, 2008; and

(ii) Ending with the close of June 2008.

(2) We will use the timely progress guidelines in § 411.180(c) beginning with your next 12-month progress certification period. At the conclusion of that progress certification period, we will conduct a progress review to determine whether you are making timely progress toward self-supporting employment using the guidelines in § 411.180(c) that apply in that period.

(b) Prior to the conclusion of your applicable 12-month progress certification period determined under paragraph (a)(1) of this section, we will send you a notice telling you that we will not conduct a progress review at the end of that progress certification period, and that we will conduct a progress review at the conclusion of your next 12-month progress certification period using the guidelines in § 411.180(c). We will tell you in the notice when this next 12-month progress certification period will begin and will describe the specific timely progress guidelines you must meet in this 12-month period.

(c) Subsequent 12-month progress certification periods will follow the rules in § 411.180.

(d) If, on June 30, 2008, your ticket is in use and assigned to a State VR agency which chose to be paid for services it provides to you under the cost reimbursement payment system, your period of using a ticket may continue under the rules in this subpart, including the rules in paragraphs (a), (b) and (c) of this section. While your ticket may still be considered in-use for the purpose of the suspension of continuing disability reviews, it will no longer be considered assigned to that State VR agency effective July 21, 2008. You may assign your ticket after the State VR agency has closed your case.

Subpart E—[Amended]

■ 31. In § 411.310, add paragraphs (d) and (e) to read as follows:

§ 411.310 How does an entity other than a State VR agency apply to be an EN and who will determine whether an entity qualifies as an EN?

* * * * *

(d) One-stop delivery systems established under subtitle B of title I of the Workforce Investment Act of 1998 (29 U.S.C. 2811 *et seq.*) may participate in the Ticket to Work program as ENs and do not need to respond to the RFP. However, in order to participate in the Ticket to Work program, the one-stop delivery system must enter into an agreement with the Commissioner to be an EN and must maintain compliance with general and specific selection criteria as described in § 411.315 in order to remain an EN.

(e) Organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities authorized under section 121 of part C of title I of the Rehabilitation Act of 1973, as amended (29 U.S.C. 741), may participate in the Ticket to Work program as ENs and do not need to respond to the RFP. However, in order to participate in the Ticket to Work program, the organization administering the project must enter into an agreement with the Commissioner to be an EN and must maintain compliance with general and specific selection criteria as described in § 411.315 in order to remain an EN.

■ 32. In § 411.315, add paragraphs (e) and (f) to read as follows:

§ 411.315 What are the minimum qualifications necessary to be an EN?

* * * * *

(e) One-stop delivery systems established under subtitle B of title I of the Workforce Investment Act of 1998

(29 U.S.C. 2811 *et seq.*) are qualified to be ENs. A one-stop delivery system must enter into an agreement with the Commissioner to be an EN and must maintain compliance with general and specific selection criteria of this section and § 411.305 in order to remain an EN.

(f) Organizations administering Vocational Rehabilitation Services Projects for American Indians with Disabilities authorized under section 121 of part C of title I of the Rehabilitation Act of 1973, as amended (29 U.S.C. 741), are qualified to be ENs. An organization administering such a project must enter into an agreement with the Commissioner to be an EN and must maintain compliance with general and specific selection criteria of this section and § 411.305 in order to remain an EN.

■ 33. In § 411.325, revise paragraph (a) to read as follows:

§ 411.325 What reporting requirements are placed on an EN as a participant in the Ticket to Work program?

* * * * *

(a) Report to the PM in writing each time the EN accepts a ticket for assignment or the EN no longer wants a ticket assigned to it;

* * * * *

Subpart F—[Amended]

■ 34. Revise § 411.350 to read as follows:

§ 411.350 Must a State VR agency participate in the Ticket to Work program?

A State VR agency may elect, but is not required, to participate in the Ticket to Work program as an EN. The State VR agency may elect on a case-by-case basis to participate in the Ticket to Work program as an EN, or it may elect to provide services to beneficiaries under the VR cost reimbursement option. (See § 411.115(s) for a definition of the VR cost reimbursement option.)

■ 35. In § 411.355, revise the section heading, the third sentence of the introductory text of paragraph (a), and the last sentence of paragraph (c), and remove paragraph (d) to read as follows:

§ 411.355 What payment options does a State VR agency have?

(a) * * * On a case-by-case basis, the State VR agency may participate either—

* * * * *

(c) * * * When serving a beneficiary who does not have a ticket that can be assigned pursuant to § 411.140, the State VR agency may seek payment only under the cost reimbursement payment system.

§ 411.360 [Removed]

■ 36. Remove § 411.360.

■ 37. In § 411.365, revise the section heading and paragraph (a) to read as follows:

§ 411.365 How does a State VR agency notify us about its choice of a payment system for use when functioning as an EN?

(a) The State VR agency must send us a letter telling us which EN payment system it will use when it functions as an EN with respect to a beneficiary who has a ticket.

* * * * *

§ 411.370 [Removed]

■ 38. Remove § 411.370.

■ 39. In § 411.385, revise the introductory text of paragraph (a) and paragraph (a)(1) to read as follows:

§ 411.385 What does a State VR agency do if a beneficiary who is eligible for VR services has a ticket that is available for assignment or reassignment?

(a) Once the State VR agency determines that a beneficiary is eligible for VR services, the beneficiary and a representative of the State VR agency must agree to and sign the individualized plan for employment (IPE) required under section 102(b) of the Rehabilitation Act of 1973, as amended (29 U.S.C. 722(b)). The State VR agency must submit the following information to the PM in order for the beneficiary's ticket to be considered in use:

(1) A statement that an IPE has been agreed to and signed by both the beneficiary and a representative of the State VR agency;

* * * * *

■ 40. Revise § 411.390 to read as follows:

§ 411.390 What does a State VR agency do if a beneficiary to whom it is already providing services has a ticket that is available for assignment?

If a beneficiary who is receiving services from the State VR agency under an existing IPE becomes eligible for a ticket that is available for assignment, the State VR agency must submit the information required in § 411.385(a) to the PM. We require this information in order for the beneficiary's ticket to be considered in use. If a beneficiary who is receiving services from the State VR agency under an existing IPE becomes eligible for a ticket that is available for assignment, the State VR agency is limited to the cost reimbursement payment system, unless both the beneficiary and the State VR agency agree to have the ticket assigned to the State VR agency.

Subpart H—[Amended]

■ 41. In § 411.500, revise paragraphs (b), (c), (e), and (f) and add paragraphs (g) and (h) to read as follows:

§ 411.500 Definitions of terms used in this subpart.

* * * * *

(b) *Outcome Payment Period* means a period of 36 months for a title II disability beneficiary or a period of 60 months for a title XVI disability beneficiary who is not concurrently a title II disability beneficiary, not necessarily consecutive, for which Social Security disability benefits and Federal SSI cash benefits are not payable to the beneficiary because of the performance of substantial gainful activity (SGA) or by reason of earnings from work activity. The outcome payment period begins with the first month, ending after the date on which the ticket was first assigned to an EN (or to a State VR agency acting as an EN), for which such benefits are not payable to the beneficiary because of SGA or by reason of earnings from work activity. The outcome payment period ends as follows:

(1) For a title II disability beneficiary (including a concurrent title II/title XVI disability beneficiary), the outcome payment period ends with the 36th month, consecutive or otherwise, ending after the date on which the ticket was first assigned to an EN (or to a State VR agency acting as an EN), for which Social Security disability benefits and Federal SSI cash benefits are not payable to the beneficiary because of earnings from work activity (except as provided for in § 411.551).

(2) For a title XVI disability beneficiary who is not concurrently a title II disability beneficiary, the outcome payment period ends with the 60th month, consecutive or otherwise, ending after the date on which the ticket was first assigned to an EN (or to a State VR agency acting as an EN), for which Federal SSI cash benefits are not payable to the beneficiary by reason of earnings from work activity (except as provided for in § 411.551).

(c) *Outcome Payment System* is a system providing a schedule of payments to an EN (or a State VR agency acting as an EN) for each month, during an individual's outcome payment period, for which Social Security disability benefits and Federal SSI cash benefits are not payable to the individual because of work or earnings.

* * * * *

(e) *Outcome Payment Month* means a month, during the beneficiary's outcome payment period, for which Social

Security disability benefits and Federal SSI cash benefits are not payable to the beneficiary because of work or earnings.

(f) *Outcome-Milestone Payment System* is a system providing a schedule of payments to an EN (or State VR agency acting as an EN) that includes, in addition to any outcome payments which may be made during the individual's outcome payment period, payments for completion by a title II or title XVI disability beneficiary of up to four Phase 1 milestones; and up to eleven Phase 2 milestones for a title II disability beneficiary or a concurrent beneficiary or up to eighteen Phase 2 milestones for a title XVI disability beneficiary who is not a concurrent title II disability beneficiary.

(1) *Phase 1 milestones* are based on the beneficiary achieving a level of earnings that reflects initial efforts at self-supporting employment. They are based on the earnings threshold that we use to establish a trial work period service month as defined in § 404.1592(b) of this chapter. We use this threshold amount as defined in § 404.1592(b) of this chapter in order to measure whether the beneficiary's earnings level meets the milestone objective.

(2) *Phase 2 milestones* are based on the beneficiary achieving a level of earnings that reflects substantial efforts at self-supporting employment. They are based on the earnings threshold that we use to determine if work activity is SGA. We use the SGA earnings threshold amount in § 404.1574(b)(2) of this chapter. We use the SGA threshold amounts in order to measure whether the beneficiary's gross earnings level meets the milestone objective.

(g) *Transition case* is a case where milestones or outcomes had been attained before July 21, 2008 (that is, the work required to meet such a milestone or outcome had been completed by that date). Section 411.551 explains how subsequent payments will be made to the EN (or State VR agency acting as an EN) on a transition case.

(h) *Reconciliation payment* is a final payment equal to the milestone payments that are unpaid when the beneficiary enters the outcome payment period before all the milestone payments are paid (see §§ 411.525(c) and 411.536).

■ 42. Revise § 411.505 to read as follows:

§ 411.505 How is an EN paid?

An EN (including a State VR agency acting as an EN) can elect to be paid under either the outcome payment system or the outcome-milestone payment system. The EN will elect a payment system at the time the EN enters into an agreement with us. (For State VR agencies, see § 411.365.) The EN (or State VR agency) may periodically change its elected EN payment system as described in § 411.515.

■ 43. In § 411.510, revise paragraph (c) to read as follows:

§ 411.510 How is the State VR agency paid under the Ticket to Work program?

* * * * *

(c) If a beneficiary who is receiving services from the State VR agency under an existing IPE becomes eligible for a ticket that is available for assignment, the State VR agency is limited to the cost reimbursement payment system, unless both the beneficiary and the State VR agency agree to have the ticket assigned to the State VR agency (see § 411.390).

■ 44. In § 411.515, revise paragraph (b) and remove paragraph (c) to read as follows:

§ 411.515 Can the EN change its elected payment system?

* * * * *

(b) After an EN (or a State VR agency) first elects an EN payment system, the EN (or State VR agency) can choose to make one change in its elected payment system in each calendar year (January–December) thereafter. The first EN payment system election constitutes the only election an EN may make for that calendar year.

■ 45. In § 411.525, revise the section heading, paragraphs (a)(1)(i), (a)(2), (b) and (c), and add paragraphs (d) and (e), to read as follows:

§ 411.525 What payments are available under each of the EN payment systems?

(a) * * *

(1)(i) Under the outcome payment system, we can pay up to 36 outcome payments to the EN (or State VR agency acting as an EN) for a title II disability beneficiary (including a concurrent title II/title XVI disability beneficiary). We can pay up to 60 outcome payments to the EN (or State VR agency acting as an EN) for a title XVI disability beneficiary who is not concurrently a title II disability beneficiary. For each month during the beneficiary's outcome payment period for which Social Security disability benefits and Federal SSI cash benefits are not payable to the beneficiary because of the performance of SGA or by reason of earnings from work activity, the EN (or the State VR agency acting as an EN) is eligible for a monthly outcome payment. Payment for an outcome payment month under the outcome payment system is equal to 67% of the payment calculation base for the calendar year in which such month occurs, rounded to the nearest whole dollar (see § 411.550).

* * * * *

(2) Under the outcome-milestone payment system:

(i) We can pay the EN (or State VR agency acting as an EN) for up to four Phase 1 milestones attained within the required earnings period for a title II or title XVI disability beneficiary who has assigned his or her ticket to the EN (or State VR agency acting as an EN). The first Phase 1 milestone is met when a beneficiary has worked in a month and earned at least 50% of the amount of earnings considered to represent a trial work period service month as defined in § 404.1592(b) of this chapter. The second Phase 1 milestone is met after a beneficiary has worked for three months within a six-month period and has gross earnings in each of those three months equal to or greater than a trial work period service amount as defined in § 404.1592(b) of this chapter. The third Phase 1 milestone is met after a beneficiary has worked for a total of six months within a twelve-month period and had gross earnings in each of those six months equal to a trial work period service amount as defined in § 404.1592(b) of this chapter. The fourth Phase 1 milestone is met after a beneficiary has worked a total of nine months within an 18-month period and had gross earnings in each of those nine months equal to a trial work period service amount as defined in § 404.1592(b) of this chapter and the EN has substantially completed the services agreed to in the IWP/IPE, including any amendments. Earnings used to meet the first, second or third Phase 1 milestone may be counted again when determining if a later Phase 1 milestone is met, provided the earlier earnings fall within the relevant time period for meeting the later milestone.

(ii) We can also pay the EN (or State VR agency acting as an EN) up to eleven Phase 2 milestones achieved by a title II disability beneficiary (including a concurrent title II/title XVI disability beneficiary) or up to eighteen Phase 2 milestones achieved by a title XVI disability beneficiary (who is not concurrently a title II disability beneficiary) who has assigned his or her ticket to the EN (or State VR agency acting as an EN). A Phase 2 milestone is met for each calendar month in which the beneficiary has worked and has gross earnings from employment (or net earnings from self-employment as defined in § 404.1080 of this chapter) in that month that are more than the SGA

threshold amount as defined in § 404.1574 of this chapter.

(iii) We pay available milestone payments in sequence except when the beneficiary's outcome period begins before the beneficiary has achieved all Phase 1 and Phase 2 milestones. Example: The individual, in the first month of employment after assigning the ticket, earns above the SGA level. Despite having exceeded trial work period level earnings and earned above the SGA level as required for Phase 2 payments in paragraph (a)(2)(ii) of this section, based on the individual's earning we would pay the EN the sequentially available milestone, which in this case would be Phase 1, milestone 1.

(iv) In addition to the milestone payments, monthly outcome payments can be paid to the EN (or State VR agency acting as an EN) during the outcome payment period.

(b) The outcome-milestone payment system is designed so that the total payments to the EN (or the State VR agency acting as an EN) for a beneficiary are less than the total amount that would have been paid if the EN were paid under the outcome payment system. Under the outcome-milestone payment system, the total payment to the EN (or the State VR agency acting as an EN) is about 90% of the total that would have been potentially payable under the outcome payment system for the same beneficiary.

(c) Except as provided in § 411.536 (reconciliation payments) the milestones for which payments may be made must occur prior to the beginning of the beneficiary's outcome payment period.

(d) We will pay an EN (or State VR agency acting as an EN) to which the beneficiary has assigned a ticket for milestones or outcomes achieved only in months prior to the month in which the ticket terminates (see § 411.155). We will not pay a milestone or outcome payment to an EN (or State VR agency acting as an EN) based on a beneficiary's work or earnings activity in or after the month in which the ticket terminates.

(e) If a title XVI disability beneficiary becomes entitled to title II benefits after we authorize the first milestone or outcome payment, we will continue to calculate the EN payments using title XVI payment calculation base under the outcome payment system on the basis of paragraph (a)(1)(i) and under the outcome-milestone payment system on the basis of paragraph (a)(2). This applies even if the title XVI eligibility is subsequently terminated and the person becomes only a title II beneficiary.

§ 411.530 [Removed]

■ 46. Remove § 411.530.

■ 47. In § 411.535, revise the section heading and paragraph (a) to read as follows:

§ 411.535 Under what circumstances will milestones be paid?

(a)(1)(i) Under the outcome-milestone payment system, an EN (or a State VR agency acting as an EN) can earn up to four Phase 1 milestone payments for serving beneficiaries whose gross earnings were less than the trial work level in each of the 18 months before the ticket was first assigned to an EN. All work and earnings counted toward reaching the four Phase 1 milestones must occur after the ticket is assigned and before the beginning of the beneficiary's outcome payment period (see § 411.500(f)) except as provided in § 411.536 (reconciliation payments).

(ii) Significant work activity prior to ticket assignment will limit the availability of Phase 1 milestone payments. The PM will make this assessment of work activity prior to the first ticket assignment on each ticket, irrespective of the EN's chosen payment system, in order to determine how many milestone payments may be available for serving an individual in the Ticket to Work program. The first Phase 1 milestone payment is not available to be made to an EN if the beneficiary has worked above the trial work level in the calendar month prior to the first ticket assignment on each ticket in the Ticket to Work program. The second Phase 1 milestone payment is not available if the beneficiary has worked above the trial work level in three of the six months prior to the first ticket assignment on each ticket in the Ticket to Work program. The third Phase 1 milestone is not available if the beneficiary has worked above the trial work level in six of the twelve months prior to the first ticket assignment on each ticket in the Ticket to Work program. The fourth Phase 1 milestone is not available if the beneficiary has worked above the trial work level in nine of the 18 months prior to the first ticket assignment on each ticket in the Ticket to Work program.

(iii) If a beneficiary had a ticket that otherwise was available for assignment and chose to receive services under an IPE from a State VR agency that elected the VR cost reimbursement option, payment of Phase 1 milestones to an EN or a different VR agency acting as an EN with respect to the same ticket is precluded if the State VR Agency that elected the VR cost reimbursement option achieved an employment outcome (as described in 34 CFR 361.56) before case closure. An EN or a different VR agency acting as an EN can be paid Phase 2 milestones as described in paragraph (2) of this section with respect to this ticket.

(2) Under the outcome-milestone payment system, an EN can receive up to eleven Phase 2 milestone payments for work by a title II disability beneficiary (including a concurrent title II/title XVI disability beneficiary), or up to eighteen Phase 2 milestone payments for work by a title XVI disability beneficiary. Earnings prior to the first assignment of the ticket in the Ticket to Work program are not taken into account when determining whether sufficient earnings exist for payment of Phase 2 milestones.

(3) If the beneficiary's outcome payment period begins before the beneficiary has achieved all Phase 1 and Phase 2 milestones, then we will pay the EN a final payment in accordance with § 411.536 (reconciliation payments) to account for unpaid milestone payments that had been available when the ticket was first assigned.

* * * * *

■ 48. Add § 411.536 to read as follows:

§ 411.536 Under what circumstances can we make a reconciliation payment under the outcome-milestone payment system?

When the beneficiary's outcome payment period begins before the beneficiary has attained all Phase 1 and Phase 2 milestones, we will pay the EN (or a State VR agency acting as an EN) a reconciliation payment. The reconciliation payment will equal the total amount of the milestone payments that were available with respect to that ticket, when the ticket was first assigned, but that have not yet been paid. The reconciliation payment will be based on the payment calculation base for the calendar year in which the first month of the beneficiary's outcome period occurs, rounded to the nearest whole dollar. The payment will be made after an EN has qualified for 12 outcome payments. Where multiple ENs had the ticket assigned at some time, the PM will apply the rule under § 411.560 to determine the allocation of the reconciliation payment.

■ 49. Revise § 411.540 to read as follows:

§ 411.540 How are the payment amounts calculated for each of the milestones?

(a) For both title II disability beneficiaries and title XVI disability beneficiaries, the payment amount for each of the Phase 1 milestone payments is equal to 120% of the payment

calculation base for title II (as defined in § 411.500(a)(1)) for the calendar year in which the month of attainment of the milestone occurs, rounded to the nearest whole dollar.

(b) The payment amount for each of the Phase 2 milestones:

(1) For title II disability beneficiaries (including concurrent title II/title XVI disability beneficiaries) is equal to 36% of the payment calculation base as defined in § 411.500(a)(1) for the calendar year in which the month of attainment of the milestone occurs, rounded to the nearest whole dollar;

(2) For title XVI beneficiaries (who are not concurrently title II disability beneficiaries) is equal to 36% of the payment calculation base as defined in § 411.500(a)(2) for the calendar year in which the month of attainment of the milestone occurs, rounded to the nearest whole dollar.

■ 50. Revise § 411.545 to read as follows:

§ 411.545 How are the outcome payments calculated under the outcome-milestone payment system?

The amount of each monthly outcome payment under the outcome-milestone payment system is calculated as follows:

(a) For title II disability beneficiaries (including concurrent title II/title XVI disability beneficiaries), an outcome payment is equal to 36 percent of the payment calculation base as defined in § 411.500(a)(1) for the calendar year in which the month occurs, rounded to the nearest whole dollar;

(b) For title XVI disability beneficiaries (who are not concurrently title II/title XVI disability beneficiaries), an outcome payment is equal to 36% of the payment calculation base as defined in § 411.500(a)(2) for the calendar year in which the month occurs, rounded to the nearest whole dollar.

(c) The following chart provides an example of how an EN could receive milestone and outcome payments:

OUTCOME-MILESTONE PAYMENT TABLE

CHART I—NEW OUTCOME-MILESTONE PAYMENT TABLE

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title II amount of payment	Title XVI amount of payment
Phase 1 (120% of Title II PCB)			
Milestone 1	$335/mo. $670/mo. × 3 mo. work in a 6-month period.	$1,177	$1,177
Milestone 2		$1,177	$1,177
Milestone 3	$670/mo. × 6 mo. work in a 12-month period	$1,177	$1,177
Milestone 4	$670/mo. × 9 mo. work in an 18-month period	$1,177	$1,177
Total Phase 1 milestones		$4,708	$4,708
Phase 2 (36% of PCB)	Gross Earnings>SGA		
Title II milestones 1–11		$353 × 11=$3,883	
Title XVI milestones 1–18			$203 × 18 = $3,654
Total Phase 1 + 2		$8,591	$8,362
	Outcome payments (36% of PCB).		
Title II = 1–36	Monthly cash benefit not payable due to SGA	$353 × 36 = $12,708	
Title XVI = 1–60	Sufficient earnings for federal cash benefits = "0".	203 × 60 = $12,180.	
Total milestone and outcome payments.		$21,299	$20,542

Definitions and amounts: Payment Calculation Base (PCB)—The average title II disability insurance benefit payable under section 223 of the Social Security Act for all beneficiaries for months during the preceding calendar year; and the average payment of supplemental security income benefits based on disability payable under title XVI (excluding State supplementation) for months during the preceding calendar year to all beneficiaries who have attained 18 years of age but have not attained 65 years of age. (2008 title II = $981.17, title XVI = $563.35).

Gross earnings requirements for Phase 1 are based on Trial Work level amounts.

For Phase 1 milestones only, the payments are calculated for both title XVI and title II beneficiaries using the higher title II payment calculation base. All other payments are based on a percentage of the Payment Calculation Base (PCB) for the respective program (title XVI or title II). See § 411.535 for a discussion of the circumstances under which we will pay milestones.

Phase 1 milestones = 120% of PCB.

Phase 2 milestones = 36% of PCB.

Outcome payments (under the outcome-milestone payment system) = 36% of PCB Earnings used to meet the first, second, or third Phase 1 milestone may be counted again when determining if a later milestone is met, provided the earlier earnings fall within the relevant time period for meeting the later Phase 1 milestone (see 411.525(a)(2) for the relevant time period for each milestone).

■ 51. Revise § 411.550 to read as follows:

§ 411.550 How are the outcome payments calculated under the outcome payment system?

The amount of each monthly outcome payment under the outcome payment system is calculated as follows:

(1) For title II disability beneficiaries (including concurrent title II/title XVI disability beneficiaries), an outcome payment is equal to 67% of the payment calculation base as defined in § 411.500(a)(1) for the calendar year in which the month occurs, rounded to the nearest whole dollar;

(2) For title XVI disability beneficiaries (who are not concurrently title II/title XVI disability beneficiaries), an outcome payment is equal to 67% of the payment calculation base as defined

in § 411.500(a)(2) for the calendar year in which the month occurs, rounded to the nearest whole dollar.

CHART II.—NEW OUTCOME PAYMENT SYSTEM TABLE—TITLE II AND CONCURRENT

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title II amount of monthly outcome payment	Title II total outcome payments
Outcome payments 1–36 (67% of PCB)	Monthly cash benefit not payable due to SGA	$657.00	$23,652

CHART III.—NEW OUTCOME PAYMENT SYSTEM TABLE—TITLE XVI ONLY

[2008 figures for illustration only]

Payment type	Beneficiary earnings	Title XVI amount of monthly outcome payment	Title XVI total outcome payments
Outcome payments 1–60 (67% of PCB)	Earnings sufficient to ''0'' out Federal SSI cash benefits.	$377.00	$22,620

Note: Outcome payment (outcome payment system) = 67% of PCB Individual payments are rounded to the nearest dollar amount.
2008 non-blind SGA level = $940.
2008 Blind SGA = $1570.
2008 TWP service amount = $670.

■ 52. Add § 411.551 to read as follows:

§ 411.551 How are EN payments calculated for transition cases pending on July 21, 2008?

A Transition case is a case where a ticket had been assigned and milestones or outcomes had been attained as of June 30, 2008 (that is, the individual has completed the necessary work to trigger a milestone or outcome payment before July 21, 2008 regardless of whether the payment has actually been made). We will pay outcome and milestone payments at the rate in effect when the work leading to such outcome or milestone is attained. Since milestone and outcome payments are numbered and attained in sequence, the EN must request the final payment for which it expects payment under the prior rules before we can determine the number of the milestone or outcome payment that represents the first payment after July 21, 2008. In addition, for cases on which an EN has attained an outcome payment before July 21, 2008 we must know the sum of the amount paid on the ticket before we can determine the remaining amount that can be paid in outcome payments on the ticket. Therefore, with respect to a ticket, we will only accept payment requests for milestones or outcomes attained under the prior rules until March 31, 2009 or until we make the first payment on the ticket under § 411.525. Payments to an EN (or State VR agency acting as an EN) after July 21, 2008 on a transition case will be made as follows:

(a) The four milestones under the prior rules will be equated with the four Phase 1 milestones available under the rules after July 21, 2008. For example, if a beneficiary had attained milestone 1 under our prior rules (1 month above the gross SGA level, *e.g.*, $940 in 2008), then the next milestone to be achieved would be Phase 1 milestone 2 under these rules (work in three months with gross earnings in each of these months equal to a trial work period service month, *e.g.*, $670 in 2008).

(b) If the beneficiary had attained all four of the milestones under the prior rules, the next milestone to be achieved would be the first Phase 2 milestone (a calendar month in which the beneficiary has worked and has gross earnings from employment or net earnings from self-employment that are more than the substantial gainful activity threshold level, *e.g.*, $900 in 2007).

(c) The maximum number of outcome payments available to an EN with respect to a ticket for a transition case will be computed as follows:

(1) First, we will compute the total dollar amount already paid or payable with respect to a ticket, including all outcome and milestone payments.

(2) Then, we will subtract the total dollar amount already paid from the total value of the ticket under the new rules for the year when these rules take effect. The total value of the ticket will be calculated based on the elected payment system for the beneficiary, *i.e.*, the outcome or the outcome-milestone payment system, and on the appropriate payment calculation base for either a title II disability beneficiary (including a concurrent title II and title XVI disability) or a title XVI disability beneficiary (see §§ 411.500 and 411.505). For accounting purposes, we will use the payment calculation base for 2008 and assume that all payments could be earned in that year in calculating the total value of the ticket.

(3) We then will divide this amount by the applicable outcome payment amount (whether title II or title XVI) payable for 2008 and round the result in accordance with customary rounding principles. The resulting number represents the number of outcome payments available to be paid with respect to the ticket. In no case can this number exceed 60.

■ 53. Add § 411.552 to read as follows:

§ 411.552 What effect will the subsequent entitlement to title II benefits have on EN payments for title XVI beneficiaries after they assign their ticket?

If a beneficiary is only eligible for title XVI benefits when we authorize the first milestone or outcome for which an EN can be paid, but the beneficiary later becomes entitled to title II benefits, we will continue to make payments as though the beneficiary were only a title XVI beneficiary, up to the maximum number of milestone and outcome payments payable for that ticket for title XVI beneficiaries. If a beneficiary who is eligible for title XVI disability benefits becomes entitled to title II disability benefits before we authorize the first milestone or outcome payment, we will make payments to the EN pursuant to the rate, payment calculation base and number of payments available for title II beneficiaries, as described in this subpart.

■ 54. Revise § 411.555 to read as follows:

§ 411.555 Can the EN keep the milestone and outcome payments even if the beneficiary does not achieve all outcome months?

(a) Yes. The EN (or State VR agency acting as an EN) can keep each milestone and outcome payment for which the EN (or State VR agency acting as an EN) is eligible, even though the title II beneficiary does not achieve all 36 outcome months or the title XVI beneficiary does not achieve all 60 outcome months.

(b) Except as provided in paragraph (c) of this section, payments which we make or deny to an EN (or a State VR agency acting as an EN) may be subject to adjustment (including recovery, as appropriate) if we determine that more or less than the correct amount was paid. This may happen, for example, because we determine that the payment determination was in error or because of an allocation of payment under § 411.560.

(c) If we determine that an overpayment or underpayment to an EN has occurred, we will notify the EN (or State VR agency acting as an EN) of the adjustment. We will not seek an adjustment if a determination or decision about a beneficiary's right to benefits causes an overpayment to the EN. Any dispute which the EN (or State VR agency) has regarding the adjustment may be resolved under the rules in § 411.590(a) and (b).

■ 55. Revise § 411.560 to read as follows:

§ 411.560 Is it possible to pay a milestone or outcome payment to more than one EN?

It is possible for more than one EN (including a State VR agency acting as an EN) to receive payment based on the same milestone or outcome. If the beneficiary has assigned the ticket to more than one EN (or State VR agency acting as an EN) at different times, and more than one EN (or State VR agency) requests payment for the same milestone, outcome or reconciliation payment under its elected payment system, the PM will make a determination of the allocation of payment to each EN (or State VR agency acting as an EN). The PM will make this determination based upon the contribution of the services provided by each EN (or State VR agency acting as an EN) toward the achievement of the outcomes or milestones. Outcome and milestone payments will not be increased because the payments are shared between two or more ENs (including a State VR agency acting as an EN).

■ 56. Revise § 411.565 to read as follows:

§ 411.565 What happens if two or more ENs qualify for payment on the same ticket but have elected different EN payment systems?

We will pay each EN (or State VR agency acting as an EN) according to its elected EN payment system in effect at the time the beneficiary assigned the ticket to the EN (or the State VR agency acting as an EN).

■ 57. Add § 411.566 to read as follows:

§ 411.566 May an EN use outcome or milestone payments to make payments to the beneficiary?

Yes, an EN may use milestone or outcome payments to make payments to a beneficiary.

■ 58. In § 411.575, revise the introductory text; paragraph (a)(1) introductory text; and paragraphs (a)(1)(i), (a)(2), (b)(1) introductory text, (b)(1)(ii), and (b)(2); and add paragraph (c) to read as follows:

§ 411.575 How does the EN request payment for milestone or outcome payment months achieved by a beneficiary who assigned a ticket to the EN?

The EN (or State VR agency acting as an EN) will send its request for payment, evidence of the beneficiary's work or earnings, and other information to the PM. In addition, we or the PM may require a summary of the services provided as described in the IWP/IPE.

(a) *Milestone payments.* (1) We will pay the EN (or State VR agency acting as an EN) for milestones only if—

(i) The outcome-milestone payment system was the EN's (or State VR agency's) elected payment system in effect at the time the beneficiary assigned a ticket to the EN (or the State VR agency acting as an EN);

* * * * *

(2) The EN (or State VR agency acting as an EN) must request payment for each milestone attained by a beneficiary who has assigned a ticket to the EN (or State VR agency acting as an EN). The request must include evidence that the milestone was attained after ticket assignment and other information as we may require to evaluate the EN's (or State VR agency's) request. If the EN is requesting payment for months after the ticket is no longer assigned to it, the payment request shall include evidence that the services agreed to in the IWP/IPE were provided and those services contributed to the employment milestones or outcomes that the beneficiary attained in months after the ticket had been assigned to the EN. We do not have to stop monthly benefit payments to the beneficiary before we can pay the EN (or State VR agency acting as an EN) for milestones attained by the beneficiary.

(b) *Outcome payments.* (1) We will pay an EN (or State VR agency acting as an EN) an outcome payment for a month if—

* * * * *

(ii) We have not already paid for 36 outcome payment months for a title II disability beneficiary (or a concurrent title II/title XVI disability beneficiary), or paid for 60 outcome payment months for a title XVI disability beneficiary who is not concurrently a title II disability beneficiary, on the same ticket; and

* * * * *

(2) The EN (or State VR agency acting as an EN) must request payment for outcome payment months. In its initial request, the EN (or State VR agency acting as an EN) must submit evidence of the beneficiary's work or earnings (e.g., a statement of monthly earnings from the employer or the employer's designated payroll preparer, or an unaltered copy of the beneficiary's pay stub). After we have started paying outcome payments to an EN (or State VR agency acting as an EN) based on evidence of the beneficiary's earnings, the EN (or State VR agency) must provide documentation of the beneficiary's continued work or earnings in such a manner or form and at such time or times as we may require. Exception: If the EN (or State VR agency) does not currently hold the ticket because it is assigned to another EN (or State VR agency), the EN (or State VR agency) must request payment, but is not required to submit evidence of the beneficiary's work or earnings. However, if the payment request is for work the beneficiary attained in a month in which the EN no longer held the ticket, the payment request should include evidence that the services agreed to in the IWP/IPE were provided and those services contributed to the beneficiary's work.

(c) *Evidence requirements for payment.* As primary evidence, we require original pay slips, or oral or written statements from an employer or the employer's designated payroll preparer. In lieu of primary evidence, we accept two sources of secondary evidence, such as photocopies of pay slips, a signed beneficiary statement, State unemployment records or federal/state tax returns. The evidence must be clear and legible and include the beneficiary's name, gross earnings or net earnings from self employment, pay date and pay period of wages or monthly net earnings of self-employment earnings.

■ 59. Revise § 411.580 to read as follows:

§ 411.580 Can an EN receive payments for milestones or outcome payment months that occur before the beneficiary assigns a ticket to the EN?

No. An EN (or State VR agency acting as an EN) may be paid only for milestones or outcome payment months that are achieved after the month in which the ticket is assigned to the EN or State VR agency acting as an EN (except as provided for in § 411.536).

■ 60. Add a new § 411.581 to read as follows:

§ 411.581 Can an EN receive milestone and outcome payments for months after a beneficiary takes his or her ticket out of assignment?

Yes. If an individual whose ticket is assigned to an EN (or State VR agency acting as an EN) takes his or her ticket out of assignment (see § 411.145), the EN (or State VR agency) can receive payments under its elected payment system for milestones or outcome payment months that occur after the ticket is taken out of assignment, provided the ticket has not terminated for any of the reasons listed in § 411.155. The PM will make a determination about eligibility for a payment based upon the contribution of services provided by an EN toward the achievement of the outcome or milestones. See § 411.560 for situations in which payment may be made to more than one EN or State VR agency based on the same milestone or outcome.

■ 61. Add a new § 411.582 to read as follows:

§ 411.582 Can a State VR agency receive payment under the cost reimbursement payment system if a continuous 9-month period of substantial gainful activity is completed after the ticket is assigned to an EN?

Yes. If a State VR agency provides services to a beneficiary under 34 CFR part 361, and elects payment under the cost reimbursement payment system under subpart V of part 404 (or subpart V of part 416) of this chapter, the State VR agency can receive payment under the cost reimbursement payment system for services provided to the beneficiary if all the requirements under subpart V of part 404 (or subpart V of part 416) of this chapter and § 411.585 are met even when these requirements are met after the ticket has been assigned to the EN. The EN can be paid during this period in accordance with §§ 411.525 and §§ 411.535.

■ 62. Revise § 411.585 to read as follows:

§ 411.585 Can a State VR agency and an EN both receive payment for serving the same beneficiary?

Yes. A State VR agency and an EN can both receive payment for serving the same beneficiary, but the ticket can only be assigned to one EN, including a State VR agency acting as an EN, at a time. It also cannot be assigned to an EN and placed in the VR cost reimbursement status at the same time.

(a) A State VR agency may act as an EN and serve a beneficiary. In this case, both the State VR agency acting as an EN and another EN may be eligible for payment based on the same ticket (see § 411.560).

(b) If a State VR agency is paid by us under the VR cost reimbursement option, such payment does not preclude payment by us to an EN or to another State VR agency acting as an EN under its elected EN payment system. A subsequent VR agency also may choose to be paid under the VR cost reimbursement option.

(c) If an EN or a State VR agency acting as an EN is paid by us under one of the EN payment systems, that does not preclude payment by us to a different State VR agency under the VR cost reimbursement option. The subsequent State VR agency also may choose to be paid under its elected EN payment system.

§ 411.587 [Removed]

■ 63. Remove § 411.587.

■ 64. In § 411.590, revise paragraph (d) to read as follows:

§ 411.590 What can an EN do if the EN disagrees with our decision on a payment request?

* * * * *

(d) Determinations or decisions we make about a beneficiary's right to benefits may cause payments we have already made to an EN (or denial of payment to an EN) to be incorrect, resulting in an underpayment or overpayment to the EN. If this happens, we will make any necessary adjustments to future payments (see § 411.555). See § 411.555(c) for when we will not make an adjustment in a case in which an overpayment results from a determination or decision we make about a beneficiary's right to benefits.) While an EN cannot appeal our determination about an individual's right to benefits, the EN may furnish any evidence the EN has which relates to the issue(s) to be decided on appeal if the individual appeals our determination.

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Part V

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Bureau of Indian Affairs

25 CFR Part 292

Gaming on Trust Lands Acquired After October 17, 1988; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 292

RIN 1076–AE81

Gaming on Trust Lands Acquired After October 17, 1988

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is publishing regulations implementing section 2719 of the Indian Gaming Regulatory Act (IGRA). IGRA allows Indian tribes to conduct class II and class III gaming activities on land acquired after October 17, 1988, only if the land meets certain exceptions. This rule articulates standards that the BIA will follow in interpreting the various exceptions to the gaming prohibitions contained in section 2719 of IGRA. It also establishes a process for submitting and considering applications from Indian tribes seeking to conduct class II or class III gaming activities on lands acquired in trust after October 17, 1988.

DATES: Effective Date: June 19, 2008.

FOR FURTHER INFORMATION CONTACT: George Skibine, Director, Office of Indian Gaming, (202) 219–4066.

SUPPLEMENTARY INFORMATION: The authority to issue this document is vested in the Secretary of the Interior by 5 U.S.C. 301 and 25 U.S.C. 2, 9, and 2719. The Secretary has delegated this authority to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

Background

The Indian Gaming Regulatory Act (IGRA), 25 U.S.C. 2701–2721, was signed into law on October 17, 1988. 25 U.S.C. 2719 (a/k/a section 20 of IGRA) prohibits gaming on lands that the Secretary of the Interior acquires in trust for an Indian tribe after October 17, 1988, unless the land qualifies under at least one of the exceptions contained in that section. If none of the exceptions in section 2719 applies, section 2719(b)(1)(A) of IGRA provides that gaming can still occur on the lands if:

(1) The Secretary consults with the Indian tribe and appropriate State and local officials, including officials of other nearby tribes;

(2) After consultation, the Secretary determines that a gaming establishment on newly acquired lands would be in the best interest of the Indian tribe and its members, and would not be detrimental to the surrounding community; and

(3) The Governor of the State in which the gaming activity is to be conducted concurs in the Secretary's determination.

On September 28, 1994, the BIA issued to all Regional Directors a Checklist for Gaming Acquisitions and Two-Part Determinations under section 20 of IGRA. This Checklist was revised and replaced on February 18, 1997. On November 9, 2001, an October 2001 Checklist was issued revising the February 18, 1997 Checklist to include gaming related acquisitions. On March 7, 2005 a new Checklist was issued to all Regional Directors replacing the October 2001 Checklist. On September 21, 2007 the Checklist was revised and issued to all Regional Directors replacing the March 2005 Checklist.

The regulations implement section 2719 of IGRA by articulating standards that the Department will follow in interpreting the various exceptions to the gaming prohibition on after-acquired trust lands contained in section 2719 of IGRA. Subpart A of the regulations define key terms contained in section 2719 or used in the regulation. Subpart B delineates how the Department will interpret the ''settlement of a land claim'' exception contained in section 2719(b)(1)(B)(i) of IGRA. This subpart clarifies that, in almost all instances, Congress must enact the settlement into law before the land can qualify under the exception. Subpart B also delineates what criteria must be met for a parcel of land to qualify under the ''initial reservation'' exception contained in section 2719(b)(1)(B)(ii) of IGRA. The regulation sets forth that the tribe must have present and historical connections to the land, and that the land must be proclaimed to be a new reservation pursuant to 25 U.S.C. 467 before the land can qualify under this exception. Finally, subpart B articulates what criteria must be met for a parcel of land to qualify under the ''restored land for a restored tribe'' exception contained section 2719(b)(1)(B)(iii) of IGRA. The regulation sets forth the criteria for a tribe to qualify as a ''restored tribe'' and articulates the requirement for the parcel to qualify as ''restored lands.'' Essentially, the regulation requires the tribe to have modern connections to the land, historical connections to the area where the land is located, and requires a temporal connection between the acquisition of the land and the tribe's restoration. Subpart C sets forth how the Department will evaluate tribal applications for a two-part Secretarial Determination under section 2719(b)(1)(A) of IGRA. Under this exception, gaming can occur on off-reservation trust lands if the Secretary, after consultation with appropriate State and local officials, including officials of nearby tribes, makes a determination that a gaming establishment would be in the best interest of the tribe and its members and would not be detrimental to the surrounding community. The Governor of the State must concur in any Secretarial two-part determination. The regulation sets forth how consultation with local officials and nearby tribes will be conducted and articulates the factors the Department will consider in making the two-part determination. The regulation also gives the State Governor up to one year to concur in a Secretarial two-part determination, with an additional 180 days extension at the request of either the Governor or the applicant tribe. Subpart D clarifies that the regulations do not disturb existing decisions made by the BIA or the National Indian Gaming Commission (NIGC).

Previous Rulemaking Activity

On September 14, 2000, we published proposed regulations in the **Federal Register** (65 FR 55471) to establish procedures that an Indian tribe must follow in seeking a Secretarial Determination that a gaming establishment would be in the best interest of the Indian tribe and its members and would not be detrimental to the surrounding community. The comment period closed on November 13, 2000. On December 27, 2001 (66 FR 66847), we reopened the comment period to allow consideration of comments received after November 13, 2000, and to allow additional time for comment on the proposed rule. The comment period ended on March 27, 2002. On January 28, 2002 we published a notice in the **Federal Register** (67 FR 3846) to correct the effective date section which incorrectly stated that the deadline for receipt of comments was February 25, 2002 and was corrected to read ''Comments must be received on or before March 27, 2002.'' No further action was taken to publish the final rule.

On October 5, 2006, we published a new proposed rule in the **Federal Register** (71 FR 58769) because we have determined that the rule should address not only the exception contained in section 2719(b)(1)(A) of IGRA (Secretarial Determination), but also the other exceptions contained in section 2719, in order to explain to the public how the Department interprets these exceptions. The comment period ended on December 5, 2006. On December 4, 2006, we published a notice in the **Federal Register** (71 FR 70335) to extend the comment period and make

corrections. The comment period ended on December 19, 2006. On January 17, 2007, we published a notice in the **Federal Register** (72 FR 1954) to reopen the comment period to allow for consideration of comments received after December 19, 2006. Comments received during the comment period ending December 5, 2006, and February 1, 2007, were considered in the drafting of this final rule.

Review of Public Comments

Stylistic and conforming changes were made to the proposed regulations and are reflected throughout the final regulations. Substantive changes, if any, are addressed in the comments and responses below:

Subpart A—General Provisions

Section 292.1 What is the purpose of this part?

One comment regarded the applicability of section 2719 of IGRA to restricted fee lands and suggested a change in § 292.1. Another comment regarded the applicability of section 2719 to trust or restricted lands of individual Indians.

Response: The recommendation to modify § 292.1 was not adopted, because section 2719(a) refers only to lands acquired in trust after October 17, 1988. The omission of restricted fee from section 2719(a) is considered purposeful, because Congress referred to restricted fee lands elsewhere in IGRA, including at sections 2719(a)(2)(A)(ii) and 2703(4)(B). Section 292.1 was not amended to include land taken in trust after October 17, 1988 for individual Indians, nor land acquired after October 17, 1988 in restricted fee by individual Indians, because the language in section 2719 of IGRA is limited to Indian tribes. Also, it is important to note that the final regulations do not address any restrictions on tribally owned fee land within reservation boundaries, because even though such lands are ''Indian lands'' pursuant to section 2703(4), they are not encompassed by the prohibition in section 2719. In addition, tribally owned fee land outside of reservation boundaries is not encompassed by section 2703(4) unless a Federal law, other than 25 U.S.C. 177, directly imposes such limitations on the land, and the Indian tribe exercises governmental power over them.

Several comments regarded whether the regulations for section 2719 should include the requirements of ''governmental powers'' referenced in section 2703(4), and ''jurisdiction'' referenced in section 2710.

Response: Section 2719 does not specifically reference the ''governmental powers'' and ''jurisdictional'' requirements that are referenced in other sections of IGRA. Therefore, the final regulations do not include references to these requirements. The governmental powers and jurisdictional analysis is not required for the specific purpose of determining whether newly acquired lands are otherwise exempt from the general prohibition for lands acquired after October 17, 1988. The governmental powers and jurisdictional requirements are, however, a necessary element for determining whether gaming may be conducted on newly acquired lands. Therefore, depending on the nature of the application or request, the governmental powers and jurisdictional elements may be part of the analysis.

Section 292.2 How are key terms defined in this part?

Appropriate State and Local Officials

Several comments suggested that the 25-mile radius is too narrow and either recommended that the regulation include a larger mile limit or no mile limit at all.

Response: These recommendations were not adopted. From the Department's prior experience implementing section 2719, the 25-mile radius allows for the adequate representation of local officials when conducting an analysis under section 2719(b)(1)(A). *See* discussion of the term ''surrounding community'' below.

A few comments suggested that the regulation is too broad as it applies to ''local officials'' and suggested that the regulation qualify the term ''local officials'' by using examples. A few other comments suggested that the term ''local officials'' was too vague and similarly suggested that the regulation qualify the term by using examples.

Response: These recommendations were not adopted. The term ''local officials'' is adequate. Because governmental organization varies from community to community, it is not practical to qualify the term ''local officials'' in either an effort to broaden or limit its applicability.

One comment suggested that the definition should be broadened to include other State officials or the Attorney General.

Response: This recommendation was not adopted. The only State official recognized under the definition is the Governor. However, the regulation does not limit the Governor from consulting with other State officials.

One comment suggested that the definition should apply to appropriate State and local officials in other States if within the 25-mile radius.

Response: The definition includes local officials from other States if they are within the 25-mile radius. However, the definition only recognizes the Governor of the State in which the proposed gaming establishment is located.

Section 292.2 How are key terms defined in this part?

Contiguous

Several comments related to the definition of contiguous. One comment suggested removing the definition from the section. A few other comments suggested keeping the definition, but removing the second sentence that specifies that contiguous includes parcels divided by non-navigable waters or a public road or right-of-way. A few comments suggested including both navigable and non-navigable waters in the definition. Many comments regarded the concept of ''corner contiguity.'' Some comments suggested including the concept, which would allow parcels that only touch at one point, in the definition. Other comments suggested that the definition exclude parcels that only touch at a point.

Response: The recommendation to remove the definition was not adopted. Likewise, the recommendation to remove the qualifying language pertaining to non-navigable waters, public roads or right-of-ways was not adopted. Additionally, the suggestion to include navigable waters was not adopted. The concept of ''corner contiguity'' was included in the definition. However, to avoid confusion over this term of art, the definition uses the language ''parcels that touch at a point.''

Section 292.2 How are key terms defined in this part?

Federal recognition or federally recognized:

A few comments suggested modifying the definition to follow the Department of the Interior (DOI) and NIGC definitions of Indian tribe in 25 CFR 290.2 and 502.13.

Response: This recommendation was adopted in part. We maintained the reference to the list of recognized tribes as it provides notice to the public. In response to comments indicating confusion caused by separate definitions of ''tribe'' and ''Federal recognition or federally recognized,'' the Department deleted the separate definitions and included a single definition of ''Indian tribe or tribe.''

Section 292.2 How are key terms defined in this part?

Former reservation:

One comment suggested deleting the word ''last'' in the definition.

Response: This recommendation was not adopted because the definition clarifies that the last reservation be in Oklahoma, which is consistent with the language of the statute.

Section 292.2 How are key terms defined in this part?

Land claim:

One comment suggested striking the words ''any claim'' and adding the words ''a legal action seeking title or possession of land.''

Response: This recommendation was not adopted because a land claim does not have to be filed in court in order to fall under the definition; the land claim does have to allege that the subject land was held in trust or subject to a prohibition against alienation on or before October 17, 1988. IGRA's date of enactment was added to clarify that claims accruing after its enactment are not included within its scope.

One comment suggested modifying paragraph (1) to read, ''or a constitutional, common law, statutory or treaty-based right to be protected from government taking of Indian lands.''

Response: This recommendation was adopted in part. The words ''the Constitution'' were added to paragraph (1), but the recommendation to qualify the cause of action to a takings claim was not adopted.

One comment suggested including State law claims in the definition.

Response: The recommendation was not adopted because the land claims within the meaning of IGRA arise under Federal statute, Federal common law, the U.S. Constitution or a treaty and jurisdiction lies in Federal, not State court.

One comment suggested adding language in paragraph (1) that reads, ''for the determination of title to lands,'' and language in paragraph (2) that reads, ''or the United States.''

Response: The recommendation to modify paragraph (1) was not adopted because it is too narrow; not all claims brought under the definition are for the determination of title to lands—sometimes they are brought for compensation. The recommendation regarding adding the words ''or the United States'' was not adopted because the United States is included in the word ''governmental.''

A few comments suggested various modifications to paragraph (1) regarding the words ''Indian'' or ''Indian lands'' in order to remove confusion with the definition of Indian lands in IGRA.

Response: These recommendations were adopted and the references to Indian and Indian lands were removed.

Section 292.2 How are key terms defined in this part?

Legislative termination:

One comment suggested deleting the brackets around ''and/or its members'' in order to be consistent with § 292.9(b) and § 292.10(c).

Response: This recommendation was adopted.

Section 292.2 How are key terms defined in this part?

Nearby Indian tribe:

A number of comments regarded the 25-mile radius limitation. Some comments suggested the definition include no mile limitation while others offered various extensions of the mile limitation based on whether the area is urban or rural.

Response: These recommendations were not adopted. The 25-mile radius is consistent throughout the regulations and provides uniformity for all the parties involved in the Secretarial Determination process.

One comment suggested that the definition include a tribe's Federal agency service area.

Response: This recommendation was not adopted because a tribe's service area is too difficult to define for purposes of applying a limitation to nearby Indian tribes.

One comment suggested striking the reference to 25 U.S.C. 2703(4).

Response: This recommendation was adopted.

A few comments suggested that the definition should include any tribes with significant cultural or historical ties to the proposed site. One comment suggested that the definition include any tribe within the same county as the proposed gaming site, and another comment suggested that the definition include any tribe within the same State.

Response: These recommendations were not adopted because they are beyond the scope of the regulations and inconsistent with IGRA. The statute specifically uses the word nearby. Therefore, ''any'' tribe cannot be included in the definition.

One comment suggested that the definition should include tribes whose on-reservation economic interest may be detrimentally affected by the proposed gaming site. Another comment suggested creating a standard for ''detrimental impact on nearby tribe.''

Response: These recommendations were not adopted. The definition qualifies a ''nearby tribe'' in terms of distance to a proposed gaming establishment. Thus, if an Indian tribe qualifies as a nearby Indian tribe under the distance requirements of the definition, the detrimental effects to the tribe's on-reservation economic interests will be considered. If the tribe is outside of the definition, the effects will not be considered. The Department will consider detrimental impacts on a case-by-case basis, so it is unnecessary to include a standard. The definition of ''nearby Indian tribe'' is made consistent with the definition of ''surrounding community'' because we believe that the purpose of consulting with nearby Indian tribes is to determine whether a proposed gaming establishment will have detrimental impacts on a nearby Indian tribe that is part of the surrounding community under section 20(b)(1)(A) of IGRA. *See* discussion of the term ''surrounding community'' below.

Section 292.2 How are key terms defined in this part?

Newly acquired lands:

Several comments inquired as to the applicability of section 2719 to restricted fee lands, and to trust or restricted lands of individual Indians.

Response: In response to these inquiries, a definition of ''newly acquired lands'' was added to the regulations. It encompasses lands the Secretary takes in trust for the benefit of an Indian tribe after October 17, 1988. It does not encompass lands acquired by a tribe in restricted fee after October 17, 1988 as discussed above in a response in § 292.1. It does not include land taken in trust after October 17, 1988 for individual Indians, nor land acquired after October 17, 1988 in restricted fee by individual Indians, because the language in section 2719 of IGRA is limited to Indian tribes.

Section 292.2 How are key terms defined in this part?

Reservation:

In response to comments, the definition of reservation is clarified and amended to include four paragraphs. The definition now specifically includes land acquired by a tribe from a sovereign, such as pueblo grant lands, acknowledged by the United States. Such grants occurred prior to the land coming under the jurisdiction of the United States, and is a closed set. The definition also specifically includes land set aside by the United States for Indian colonies and rancherias for the permanent settlement of the tribe, which were encompassed in part by the prior reference to ''judicial

determination, or court-approved stipulated entry of judgment to which the United States is a party.'' Both pueblo grant lands and rancherias are treated as reservations under existing Indian lands opinions.

One comment objected that land acquired under the Indian Reorganization Act (IRA), for purposes of reorganizing the half-bloods residing thereon, would not fall within the meaning of reservation as defined in the proposed rule.

Response: This recommendation was adopted and such land is now specifically included in the definition. If such land was proclaimed a reservation by the Secretary, it would be encompassed with the definition of reservation under both paragraphs (1) and (3). If that land was not proclaimed a reservation, it would nevertheless fall within paragraph (3) of the revised definition, as land acquired by the United States to reorganize adult Indians pursuant to statute.

One comment questioned whether the definition of reservation could be interpreted as including a disestablished reservation, or the area of a reservation that was ceded, leaving a diminished reservation.

Response: Reservation within these regulations does not include a disestablished reservation. Reservation does not include land ceded from the reservation that resulted in a diminished reservation. In addition, because the term ''reservation'' has different meanings under different statutes, the reference to ''judicial determination, or court-approved stipulated entry of judgment to which the United States is a party'' was deleted as overly broad and likely inconsistent with both the purposes of IGRA and the distinction in IGRA between ''reservation'' and ''trust land.''

One comment suggested that the term ''reservation'' in IGRA be the same as Indian Country in 25 U.S.C. 1151.

Response: We did not adopt this comment because Congress in enacting IGRA chose to use the concept of Indian lands instead of Indian Country. Moreover, Congress in IGRA distinguishes between trust lands and reservations in section 2719. Therefore for the purposes of these regulations that interpret section 2719 of IGRA, ''reservation'' for purposes of gaming on after acquired lands is limited to the four delineated categories in the definition of reservation and not lands that could be Indian Country for other purposes. Thus for the purposes of determining whether gaming can occur pursuant to section 2719, reservation does not include all property held in trust, as IGRA distinguishes reservation from trust lands in its definitions.

Section 292.2 How are key terms defined in this part?

Surrounding community:

Several comments related to the requirement that local governments and nearby Indian tribes be within 25 miles of the site of the proposed gaming establishment. Some comments suggested a greater distance, for example 50 miles; others urged no limit and instead recommended alternate factors, for example the community as defined by the National Environmental Policy Act (NEPA). One comment suggested that the surrounding community include any tribe in the State where the gaming facility is located.

Response: These recommendations were not adopted. The definition was modified so it is consistent with the rest of the regulations and the word radius was added. The 25-mile radius is consistent throughout the regulations and provides uniformity for all parties involved in the Secretarial Determination process. There is no legislative history informing Congressional intent in defining how the term ''surrounding community'' in section 20(b)(1)(A) of IGRA should be interpreted. However, it is reasonable to assume that Congress did not intend that all possible communities be consulted, no matter how distant, because Congress was concerned with how a proposed gaming establishment would affect those individuals and entities living in close proximity to the gaming establishment, or those located within commuting distance of the gaming establishment. The ''surrounding community'' is defined in order for the Secretary to determine whether a proposed gaming establishment would be detrimental to the ''surrounding community.'' Since 1994, the BIA has published a ''Checklist'' to guide agency officials in implementing section 20 of IGRA. The ''surrounding community'' was first defined to include local governments within 30 miles of the proposed gaming establishment, and nearby Indian tribes within 100 miles of the proposed gaming establishment. The Checklist was subsequently modified in 1997 to include only those local governments whose jurisdiction includes or borders the land, and nearby Indian tribes located within 50 miles of the proposed gaming establishment because our experience with the 1994 standard was that it included communities that were not impacted by the gaming establishment. In addition, this modification was made so that the term ''surrounding community'' would be similar to the consulted community under 25 CFR part 151. In 2005 the Checklist modified the term ''surrounding community'' to include local governments within ten miles of the proposed gaming establishment. The 2005 modification was made because the purpose of the consultation with State and local officials is to assess detriment to the surrounding community, and our experience in limiting the consultation to those local governments with jurisdiction over the land or adjacent to the land was too narrow. Ultimately, our objective in the regulation is to identify a reasonable and consistent standard to define the term ''surrounding community'' and we believe that it is reasonable to define the surrounding community as the geographical area located within a 25-mile radius from the proposed gaming establishment. Based on our experience, a 25-mile radius best reflects those communities whose governmental functions, infrastructure or services may be affected by the potential impacts of a gaming establishment. The 25-mile radius provides a uniform standard that is necessary for the term ''surrounding community'' to be defined in a consistent manner. We have, however, included a rebuttable presumption to the 25-mile radius. A local government or nearby Indian tribe located beyond the 25-mile radius may petition for consultation if it can establish that its governmental functions, infrastructure or services will be directly, immediately and significantly impacted by the proposed gaming establishment.

One comment suggested changing the definition to ''surrounding governmental entities'' because it would limit the consultation process to a government-to-government basis.

Response: This recommendation was not adopted because IGRA uses ''surrounding community.''

One comment suggested that the definition be limited to local governments and nearby Indian tribes within the State of the applicant tribe's jurisdiction.

Response: This recommendation was not adopted. The definition includes local governments and nearby tribes located in other States if they are within a 25-mile radius.

Section 292.2 How are key terms defined in this part?

Tribe:

Several comments requested a more elaborate definition of tribe. One comment suggested that all references of ''Indian tribe'' be changed to ''tribe.''

Response: The comments recommending a more elaborate definition of Indian tribe were adopted. The definition was renamed ''Indian tribe or tribe.'' It is unnecessary to change all references of ''Indian tribe'' to ''tribe'' because they are now both defined.

Section 292.2 How are key terms defined in this part?

General comments regarding § 292.2:

One comment suggested adding a definition of trust land.

Response: This recommendation was adopted in part and is addressed in the definition of ''newly acquired lands.''

One comment suggested adding a definition of ''gaming'' that includes ancillary structures such as hotels and parking.

Response: This recommendation was not adopted because it is outside the scope of the regulations and inconsistent with IGRA.

One comment suggested adding a definition of ''State or States.''

Response: This recommendation was adopted in part. The statutory term ''State or States'' along with some defining language was inserted in §§ 292.4, 292.6 and 292.12 in order to add clarity.

Subpart B—Exceptions to Prohibitions on Gaming on Newly Acquired Lands

Section 292.3 When can a tribe conduct gaming activities on trust lands?

The Department received a few comments on this section; mostly related to structure. Additionally, a few comments suggested that this section is an appropriate section to add a paragraph discussing the applicability of these regulations to applications for Secretarial Determinations and requests for lands opinions that tribes submitted before the effective date of these regulations; for those both acted upon and those that are pending.

Response: The recommendation regarding pending and acted upon Secretarial Determinations and requests for lands opinions was adopted and addressed in new § 292.26. The comments related to structure were not adopted because the section was deleted in its entirety and replaced with new § 292.3: ''How does a tribe seek an opinion on whether its newly acquired lands meet, or will meet, one of the exceptions in this subpart?'' The former section did not offer anything that is not covered in other parts of the regulation. Therefore, in response to comments requesting guidance on the process for seeking opinions under section 2719, the Department added the new section. Paragraph (a) allows a tribe to submit a request for an Indian lands opinion to either the NIGC or to the Office of Indian Gaming (OIG). As a general matter under this paragraph, a tribe should submit the request to NIGC when newly acquired lands are already in trust and, for example, there is a pending gaming ordinance or management contract before the NIGC Chairman or there is a question whether NIGC has, or would have, regulatory jurisdiction under IGRA. The tribe should submit the request to OIG if the request concerns reservation boundaries or reservation status. Paragraph (b) requires the tribe to submit a request for an Indian lands opinion to the OIG if the tribe must also request a land-into-trust application in order to game on the newly acquired lands or the request concerns whether a specific area of land is a reservation. An opinion provided in response to a request under paragraphs (a) or (b) is not, per se, a final agency action under the Administrative Procedures Act (APA). Final agency action only occurs when agency officials act on a determination pursuant to powers granted them by Congress. Communications from administrative agencies thus range ''from obvious agency action, such as adjudications and regulation, to informal pronouncements, such as opinion letters,'' which are not ?nal agency actions. *See, e.g., Sabella* v. *United States,* 863 F. Supp. 1, 4 (D.D.C. 1994). *Cheyenne-Arapaho Gaming Commission* v. *NIGC,* 214 F. Supp. 2d 1155, 1158 (N.D. Okla. 2002); *Sabella,* 863 F. Supp. at 5.

Section 292.4 What criteria must trust land meet for gaming to be allowed under the exceptions listed in 25 U.S.C. 2719(a) of IGRA?

This section was renamed ''What criteria must newly acquired lands meet under the exceptions regarding tribes with and without a reservation?''

For clarity, the references to ''trust lands'' in this subpart were changed to ''newly acquired lands.''

One comment suggested a rule in this section that precludes structures and activities that support or are ancillary to gaming operations on contiguous lands.

Response: This recommendation was not adopted because section 2719 of IGRA is concerned with lands on which gaming will occur. Support or ancillary operations to gaming facilities do not play a part in the analysis as to whether gaming will be permitted under this section.

One comment objected to any requirement that would limit a tribe to acquiring new lands for gaming that are ''adjacent'' to their original reservation.

Response: The requirement that limits a tribe to contiguous lands for gaming purposes is already written into law and these regulations cannot make a substantive change to that law.

A few comments suggested a substantial revision of this section so that it would eliminate inaccuracies, conform to the statute and add clarity.

Response: The suggestions were adopted in part and the section was revised in order to address the concerns and more closely mirror the statute.

''Settlement of a Land Claim'' Exception

Section 292.5 What must be demonstrated to meet the ''settlement of a land claim'' exception?

This section was renamed ''When can gaming occur on newly acquired lands under a settlement of a land claim?''

Comments on paragraph (a):

One comment suggested that the rule should require that, along with the State, the affected local governments also must approve a settlement if it is to qualify for the exception.

Response: This recommendation was not adopted because the regulations can neither dictate the language of Congressional legislation nor the parties to a particular settlement agreement; whether it is a final order or some other enforceable agreement. If a local government is a party in a matter concerning a settlement of a land claim, then its approval would be necessary.

One comment suggested that the rule should require that a tribe have a demonstrable historical connection to the site chosen.

Response: This recommendation was not adopted because the regulations can neither dictate the requirements of Congressional legislation nor the terms to a particular settlement agreement; whether it is a final order or some other enforceable agreement.

One comment suggested the following insertion at paragraph (a)(2): ''Has been resolved by congressional enactment; or.''

Response: This recommendation was addressed through the changes to paragraph (a).

One comment suggested adding a new paragraph (a)(3) as follows: ''Relates to the acquisition, transfer or exchange of land to compensate for or replace land within a reservation that is damaged or otherwise rendered uninhabitable by a natural disaster, catastrophic event, or other action.''

Response: This recommendation was not adopted because it is unnecessary to either include or exclude, in the

regulations, claims based on particular sets of facts and circumstances.

A few comments suggested that under paragraph (a)(1), the rule should state that land would not be eligible for gaming if the claim is dismissed on procedural grounds.

Response: This recommendation was not adopted because a dismissal on procedural grounds, i.e., laches, does not necessarily mean that a claim lacks merit and may not resolve other issues related to impairment of title or loss of possession.

One comment was concerned that under paragraph (a)(1), the language ''has not been dismissed on substantive grounds'' is vague and another comment suggested dropping the clause altogether.

Response: This recommendation was adopted.

One comment suggested that paragraph (a)(1) should include actions filed in State court.

Response: The recommendation was not adopted because the land claims within the meaning of IGRA arise under Federal statute, Federal common law, the U.S. Constitution or a treaty and jurisdiction lies in Federal, not State court.

One comment suggested that under paragraph (a)(1), language be added as follows: ''wherein the relief sought is (A) return of land, (B) conveyance of replacement land, or (C) monetary and Congress enacts legislation to mandate that a portion of the monetary recovery (i.e., the judgment funds) be used to purchase real property.''

Response: The recommendation was not adopted because the regulations cannot dictate the terms of a settlement or the relief a tribe may seek. While the language of the regulation does not specifically address the scenarios addressed in the comment, when a particular land claim otherwise meets the definition, whether for example the legal basis involves the impairment of title or other real property interest such as a lease, and the relief includes the return of land, conveyance of replacement land, or money for the purchase of other real property, the land claim may meet the requirements of this section as long as it is either subject to Congressional enactment or returns to the tribe all of the lands claimed by the tribe.

One comment suggested paragraph (a)(2) be replaced with the following language: ''Is a legal claim of a tribe that has not been filed in Federal or State court.''

Response: The recommendation was not adopted; however, the definition and regulation allow for a land claim that is not filed in court.

One comment suggested adding a new paragraph (a)(3) to read: ''Has been the subject of Federal legislation which allows for acquisition of land.''

Response: The recommendation was adopted in part and is in included in paragraph (a) of the reorganized section.

One comment suggested replacing in paragraph (a)(2) ''included'' with ''identified.''

Response: Due to a reorganization of this section, the suggestion is no longer relevant.

Comments on paragraph (b):

One comment suggested replacing in paragraph (b) ''must be covered by'' with ''must have been acquired pursuant to.''

Response: Due to a reorganization of this section, the suggestion is no longer relevant.

One comment suggested the following edits in paragraph (b)(1): ''States that the tribe is relinquishing its legal land claim to some or all of the lands claimed by the tribe as part of the settlement, results in the alienation or transfer of title to tribal some or all of the lands claimed by the tribe within the meaning of 25 U.S.C. 177, and has been enacted into law by the United States Congress; or''

Response: Due to reorganization of this section, the suggestion is no longer relevant, but the concepts behind the edits were adopted in part, and incorporated into the reorganized section.

One comment suggested the following edits in paragraph (b)(2): ''Returns to the tribe lands identical to the entirety of the exact lands claimed by the tribe, does not involve an alienation or transfer of title to tribal lands claimed by the tribe that is prohibited under 25 U.S.C. 177, and is either:''

Response: Due to a reorganization of this section, the suggestion is no longer relevant.

One comment suggested deleting the following language under paragraph (b)(1): ''results in the alienation or transfer of title to tribal lands within the meaning of 25 U.S.C. 177, and has been enacted into law by the United States Congress.''

Response: This recommendation was adopted in part as it pertains to 25 U.S.C. 177.

One comment suggested replacing paragraph (b)(2) with ''Returns to the tribe lands or allows acquisition of lands that the tribe has a historical connection to and is either * * *''

Response: This recommendation was not adopted because the regulations cannot dictate the terms of the settlement.

One comment suggested modifying the language in paragraph (b)(2)(i) to include both Federal and [S]tate court.''

Response: This recommendation was not adopted. The definition precludes actions filed in State court because land claims, within the meaning of IGRA, are based on Federal law. In addition, comments revealed that the proposed regulations could be read to identify settlements between a tribe and State without the involvement of the Federal Government. The final regulations clarify that the U.S. must be a party to the settlement.

One comment suggested adding a new paragraph (b)(2)(iii) that reads: ''Acquired pursuant to Federal legislation.''

Response: This recommendation was adopted in part and reflected in the reorganized section.

One comment suggested that the exception should be amended to apply to an out-of-court settlement that is approved by the United States and that only requires the non-Indian party to voluntarily vacate the premises, pay damages, or allows the settlement agreement to be implemented through Secretarial approval of some form of conveyance of interest in Indian land under existing law.

Response: The recommendation to amend the exception to apply under the exact scenario described by the comment was not adopted; however, to the extent that the United States is a party, the scenario would fit under the exception.

One comment suggested replacing the introduction with ''Under this section, class II or class III gaming may be conducted on trust lands only if the criteria of both (a) and (b) are met.''

Response: This recommendation was not adopted. The section was reorganized and the recommendation is no longer relevant.

A few comments suggested that the rule should require a settlement to be ratified either by Congress or consented to by the affected local government.

Response: This recommendation was adopted to the extent that it relates to Congressionally enacted settlements and to the extent an affected local government is a party to a particular settlement agreement, whether it is a final order or some other enforceable agreement.

''Initial Reservation'' Exception

Section 292.6 What must be demonstrated to meet the ''initial reservation'' exception?

One comment suggested that § 292.6(a) inappropriately restricts the scope of the ''Federal acknowledgment process'' to the regulatory procedures in 25 CFR part 83.

Response: The Department does not accept the recommendation to apply these regulations more broadly to recognition by means other than that through 25 CFR part 83. The plain meaning of the statute suggests that it applies to tribes acknowledged by this process and no others.

Comments on paragraph (b):

Several comments suggested deleting paragraph (b). One comment stated that there is no mention of location with respect to tribal members or tribal government in IGRA and that it is unfair to tribes with widely dispersed populations due to allotment and termination. One comment fundamentally disagreed with and recommended eliminating the 50-mile majority membership requirement.

Response: These recommendations were adopted in part. While a so-called ''modern connections'' requirement was not eliminated entirely, the paragraph was modified in response to a number of comments that suggested that the requirement encompass a wider range of criteria. The 50-mile majority requirement was eliminated and the paragraph was amended to reference a significant number of tribal members or other factors that demonstrate the tribe's current connection to the land. The inclusion of a modern connections requirement provides an element of notice to the surrounding community yet the elimination of the 50-mile majority requirement recognizes that the standard is too difficult to apply in today's mobile work related environment.

A few comments suggested reducing the 50-mile majority requirement to 25 miles so the mileage requirements are the same for both the ''tribal majority test'' and the ''headquarters test'' in paragraph (b). Another comment suggested making the ''50-mile majority test'' and the ''headquarters test'' conjunctive instead of disjunctive, for example; making the ''or'' an ''and.''

Response: These recommendations were not adopted because the purpose of the exception is to assist newly recognized tribes in economic development. As long as the tribe has a modern connection to the land, the surrounding community has notice of the tribal presence.

Several comments suggested that the ''headquarters test'' is easily manipulated and should not be included. Some comments suggested increasing the 25-mile limit.

Response: The recommendations to remove the headquarters test and to alter the 25-mile radius were not adopted because the headquarters test is a useful means of determining whether a tribe has a modern connection to the newly acquired land and the 25-mile radius is both useful and consistent. (The word radius was added to the regulation to provide clarity.) Nonetheless, the concerns raised by these comments are legitimate because the version of the headquarters test in the proposed regulations could be construed as being open to manipulation. Therefore, the qualifier was added in the final regulations that the tribe's headquarters or other tribal governmental facilities be in existence at that location for at least two years at the time of the application for land-into-trust. The addition of ''other tribal governmental facilities'' was necessary due to concerns that tribes often operate out of more than one headquarters or facility.

One comment suggested that the ''headquarters test'' is not in the best interest of the tribe because it may separate a headquarters from a tribal population center.

Response: This concern was addressed through the modification of paragraph (b). A tribe may show a modern connection through not only a nearby headquarters but also through other tribal governmental facilities.

Comments on paragraph (c):

A few comments suggested deleting the reference to ''cultural connection'' because it is essentially a subset of historical connections and adds redundancy and confusion to the regulation.

Response: This recommendation was adopted.

One comment suggested adding specific examples of significant historical and cultural connections in paragraph (c), for example, ''designated in a treaty, whether ratified or not.'' Another comment stated that the term ''significant historical connection'' is too vague to offer any protection to tribes or citizens and that the regulation should not allow gaming on lands to which a tribe has only a transient connection. Several comments specifically suggested a definition for ''significant historical connections.''

Response: This recommendation was adopted in part through the addition of the new definition ''significant historical connections.''

One comment suggested deleting (c).

Response: This recommendation was not adopted. The significant historical connection requirement insures that the tribe has a preexisting connection to the newly acquired lands proposed to be its initial reservation. Furthermore, the Department does not believe it is good policy to create an initial reservation in an area where the tribe has no preexisting connection.

One comment suggested that the word ''area,'' as it relates to the term ''significant historical connection,'' is too broad. The comment suggested that gaming should be limited to ancestral homelands and that language should be inserted to reference 25 CFR 151.11(b) so that as distance from homeland increases—nearby local officials, State officials and tribe's input gains greater weight.

Response: This recommendation was not adopted because the actual land to which a tribe has significant historical connection may not be available. Additionally, input from nearby local officials, State officials and other tribes is not part of the Initial Reservation analysis in section 2719.

One comment suggested that the significant historical connection requirement should be uninterrupted connection. Another comment suggested that the requirement should show historically exclusive use.

Response: These recommendations were not adopted. They would create too large a barrier to tribes in acquiring lands and they are beyond the scope of the regulations and inconsistent with IGRA.

General comments on § 292.6:

One comment noted that there is nothing in the ''Initial reservation'' section of the regulations regarding process so the public has an opportunity to comment.

Response: Unlike the exception in IGRA section 2719(b)(1)(A), the exceptions in section 2719(b)(1)(B) do not reference an opportunity for public comment. Because the section 2719(b)(1)(B) exceptions do not require public comment and since they present a fact-based inquiry, it is unnecessary to include a requirement for public comment in the regulations. Nonetheless, there are opportunities for public comment in other parts of the administrative process—for example, in the process to take the land in trust and during the NEPA review process. Although the regulations do not provide a formal opportunity for public comment under subpart B of these regulations, the public may submit written comments that are specific to a particular lands opinion. Submissions

may be sent to the appropriate agency that is identified in § 292.3.

One comment suggested that the regulations include the process by which the BIA will make their decisions. Another comment suggested that the regulations need to include standards by which the Secretary will make a decision.

Response: These recommendations were adopted in part. If the tribe does not have a proclaimed reservation on the effective date of these regulations, § 292.6(d) provides standards that the tribe must demonstrate in order to be proclaimed a reservation under the initial reservation exception.

One comment suggested that the regulations add a section that provides that lands far removed from historical territory shall not be taken into trust for gaming.

Response: This recommendation was not adopted because the comment raises issues pertaining to 25 CFR part 151—Land Acquisitions.

One comment suggested that the tribes should be required to analyze sites that are close to aboriginal homelands.

Response: This recommendation was not adopted. Newly acquired lands with significant historical and cultural connections may or may not include those that are close to aboriginal homelands.

A few comments suggested striking all of paragraphs (b) and (d) along with a large amount of (c) and (e) so that this paragraph would limit ''initial reservation'' to a tribe acknowledged under part 83 and the condition that ''the land is located within the external boundaries of the first reservation of lands set aside for the tribe.''

Response: This recommendation was not adopted, as it does not take into account the present circumstances of the tribe's location.

One comment suggested cross-referencing ''significant historical connections'' in the section to § 292.12(b).

Response: The intent of this recommendation was adopted through adding a definition of significant historical connections to the definition section.

One comment suggested that the request for an opinion should include the distance of the land from the location where the tribe maintains core governmental functions.

Response: The recommendation was not adopted because the distance from the tribal headquarters or other governmental facility is just one of three methods by which a tribe can meet the modern connections requirement and is therefore not always necessary. Additionally, it is not within the scope of IGRA to restrict such analysis to locations with ''core'' governmental functions.

One comment suggested that the regulations require a tribe to provide information about the tribe's ancestral ties to the land.

Response: The recommendation was not adopted; however, ancestral ties would be part of the significant historical connection analysis.

One comment suggested that the regulations use only one test for both the ''initial reservation'' exception and the ''restored lands'' exception; the test being that a majority of tribal members live within 50 miles of the proposed gaming site.

Response: This recommendation was not adopted. The regulations articulate a ''modern connections'' test for both the ''initial reservation'' and ''restored lands'' exceptions but the 50-mile majority requirement was eliminated from each for the reasons discussed under the comments for paragraph (b).

One comment noted that the BIA does not define what uses can be made of an initial reservation. The commenter was concerned about an initial reservation established solely for casino development.

Response: An initial reservation may be used solely for the establishment of a casino.

One comment suggested a ''contemporary ties'' test instead of using the ''modern connections test'' as set forth in the proposed regulations.

Response: This recommendation was adopted in part. The term ''contemporary ties'' was not used, but the modern connections test as set forth in the proposed regulations was modified using some of the suggestions that were given in relation to the ''contemporary ties'' test.

One comment suggested striking (e) and replacing it with ''the tribe has not conducted gaming on any other lands proclaimed to be a reservation under 25 U.S.C. 467.''

Response: This recommendation was not adopted. Gaming is allowed on the initial reservation under this exception. If other newly acquired land is declared a reservation, gaming can occur on it under a two part determination without precluding gaming on the initial reservation. To preclude gaming on the initial reservation would be contrary to the congressional intent in providing this exception.

''Restored Lands'' Exception

Section 292.7 What must be demonstrated to meet the ''restored lands'' exception?

A few comments noted that there are no opportunities for public comment on restored lands decisions.

Response: Unlike the exception in IGRA section 2719(b)(1)(A), the exceptions in section 2719(b)(1)(B) do not reference an opportunity for public comment. Because the section 2719(b)(1)(B) exceptions do not require public comment and since they present a fact-based inquiry, it is unnecessary to include a requirement for public comment in the regulations. Nonetheless, there are opportunities for pubic comment in other parts of the administrative process—for example, in the process to take the land in trust and during the NEPA review process. Although the regulations do not provide a formal opportunity for public comment under subpart B of these regulations, the public may submit written comments that are specific to a particular lands opinion. Submissions may be sent to the appropriate agency that is identified in § 292.3.

One comment suggested that the tests for significant historic connections and modern connections are deficient because they allow tribes without true historic ties and with inadequate modern ties to game on lands under the restored lands exception.

Response: The Department received comments suggesting the opposite of this argument as well; suggesting that the historical and modern tests were too restrictive. The final regulations consider both sides of this issue and modifications were made accordingly.

One comment suggested using the term ''recognized by the United States'' instead of the term ''federally recognized'' because of a concern of confusion arising from the defined term ''federally recognized'' in the proposed regulations.

Response: This recommendation was not adopted; however, the potential confusion was remedied through the omission of a defined term ''federally recognized'' in the final regulation in favor of a modification of the term ''Indian tribe or tribe.''

One comment suggested adding a paragraph to § 292.7 that the lands acquired in trust for the tribe meet the requirements of § 292.11.

Response: This recommendation was adopted for purposes of clarity.

Section 292.8 How does a tribe qualify as having been federally recognized?

One comment suggested that paragraph (a) include more details regarding the treaty negotiations with the tribe. For example, the comment suggested including the following requirements: Detailing who negotiated with a tribe; that the negotiations be authorized by the Department; that the facts and subject matter of the negotiations be memorialized; that the tribe be organized at the time of the negotiation; and that a definition of ''negotiates'' be included to mean a goal-oriented government-to-government discussion.

Response: These recommendations were not adopted. Paragraph (a) will be applied on a case by case basis.

One comment suggested that paragraph (b) should require that the Department make the opinion formally, in writing, and according to governing regulations.

Response: This recommendation was not adopted. While the opinions are always going to be in writing, in the past they were made with varying degrees of formality depending on the situation presented. Regulatory guidance making these requirements mandatory is not feasible and is unnecessary.

One comment suggested paragraph (b) should not use the word ''could'' because there is a difference between tribes that could and tribes that actually did organize under the Acts.

Response: This recommendation was not adopted because a Departmental opinion that a tribe could organize is evidence of Federal recognition, regardless of whether the tribe actually organized under the Acts.

One comment suggested that the word ''including'' in paragraph (c) be removed and that the paragraph be modified to require the legislation to specifically name the tribe in question and to describe the substance of the relationship.

Response: This recommendation was adopted in part. The word ''including'' was removed and replaced with the word ''naming.''

A few comments suggested paragraph (d) needs modification. One comment suggested differentiating between land acquired for organized and land acquired for landless Indians without ''ethno historic coherence.'' Another comment argued that the section is too permissive because it qualifies a tribe as having been recognized if the United States acquires land in trust for a tribe's benefit.

Response: These recommendations were not adopted. Paragraph (d), as written, provides sound guidance to the Department in issuing its opinion regarding whether a tribe was once federally recognized.

One comment suggested paragraph (e) should require certain standards regarding the tribe, the relationship with the Federal Government, and what constitutes evidence.

Response: These recommendations were not adopted because the regulation needs no further elaboration and is clear on its face.

One comment suggested striking the word ''federally'' from the introduction sentence and the word ''Federal Government'' from paragraph (e).

Response: These recommendations were not adopted because IGRA is a Federal statute concerning federally recognized tribes, 25 U.S.C. 2703(5).

One comment suggested that the section include a paragraph (f) that requires the tribe seeking a lands opinion to be the political and genealogical successor to the tribe identified through paragraphs (a) through (e).

Response: This recommendation was not adopted because it is unnecessary. These concerns are addressed and inherent in the restored lands analysis under §§ 292.9–12.

One comment suggested using Professor Cohen's test for Federal recognition, which it characterized as Congressional or Executive action and a continuing relationship with the group, and that restored lands opinion should be made by the BIA's Branch of Acknowledgment and Research (BAR), now the Office of Federal Acknowledgment (OFA).

Response: These recommendations were not adopted because OFA's expertise is in analyzing a petitioner under other criteria, such as community, political influence, and genealogy, not land matters. The section already requires Executive or Congressional action. The continuing relationship can be evaluated under (e), but is not required when any of factors (a) through (d) are demonstrated.

Section 292.9 How does a tribe show that it lost its government-to-government relationship?

A comment questioned how old a document must be to be considered ''historical'' and another comment wanted to include as acceptable evidence, documentation from sources other than the Federal Government, including oral histories, to show that the Federal Government either affirmatively terminated its relationship or that the relationship ceased to exist, such as through inaction.

Response: These recommendations were not adopted. Although ''historical'' is somewhat imprecise, it adds clarity to the type of documentation that is acceptable evidence under this section. Modern documents about events in the past are not acceptable evidence. Acceptable documentation is written documentation from the Federal Government specifically terminating the relationship, or indicating consistently that there is no longer a government-to-government relationship with the tribe or its members. Historical or modern accounts that conclude or assume that there is no government-to-government relationship, or that the relationship has lapsed through inaction of the tribe or the government, are secondary evidence and are not acceptable evidence within the meaning of this section. Similarly, historical or modern accounts that the Federal Government did not or does not acknowledge a specific responsibility with the group because there is no longer a trust asset to protect or disburse, or because the Federal Government did not or does not know who the group is, are not acceptable evidence, even if the account is from the Federal Government.

One comment stated that in paragraph (a), the Congressional action must be clear that the relationship was terminated and that the tribe be identified by name.

Response: This recommendation was not adopted because the commenter did not suggest how to clarify the paragraph. The paragraph, as written, is sufficient to address the commenter's concerns.

One comment suggested adding the phrase ''clearly and affirmatively acted to'' after ''Executive Branch,'' in paragraph (b), in order to preclude tribes from asserting that administrative errors constitute deliberate acts of termination.

Response: This recommendation was not adopted because the words ''show'' and ''no longer'' are adequate.

A few comments argued that the paragraph (b) should give no excessive deference to the Department of the Interior or the Department of Justice and that all branches of the Federal Government should be given equal weight. One comment suggested adding ''Federal Government'' at the end of the first sentence. In addition to adding ''Federal Government,'' another comment suggested striking everything but the first sentence.

Response: This recommendation was adopted in part and the paragraph was modified by using the words ''Federal Government.'' The second sentence was retained because it is necessary.

One comment stated that in paragraph (b) the rule should make clear that the

documentation include evidence that the tribal government existed at the time of the termination, that the acts constituting the termination were unambiguous, and that the subsequent acts by the Government were consistent with the tribe's termination.

Response: This recommendation was not adopted. Tribe is a defined term and the definition is adequate to address the commenter's concern. The language pertaining to government action requires that the action be unambiguous. When termination is unambiguous, then it is not necessary to review whether subsequent acts are consistent with the termination.

One comment suggested striking the language ''or its members'' in paragraph (b) because the comment stated that there cannot be a government-to-government relationship with members apart from a tribal government.

Response: This recommendation was not adopted. The language was kept in order to accommodate a wide variety of circumstances.

One comment suggested modifying the preamble of this section with the following: ''as having at some later time lost its government-to-government relationship with the United States.'' The comment stated that the change makes the preamble consistent with the language of § 292.7(b) and the introductions to §§ 292.8 and 292.10.

Response: This recommendation was adopted in general and the section was modified accordingly. The specific words ''with the U.S.'' were not added as they are understood in light of § 292.8.

One comment questioned whether California rancherias should be allowed to qualify as restored lands under IGRA.

Response: While the California tribes indeed share a unique path towards restoration, if the newly acquired lands otherwise meet the requirements of the statute and regulations, the exception pertains to them.

Section 292.10 How does a tribe qualify as having been restored to Federal recognition?

One comment suggested changing the term ''tribal government'' to ''tribe,'' in paragraph (a), in order to be consistent.

Response: This recommendation was adopted.

One comment stated that paragraph (a) should make clear that the statute must be unambiguous as to its intent and identify the tribe being restored.

Response: This recommendation was not adopted because the present language anticipates this clarity and specificity.

One comment stated that 25 U.S.C. 2719(b)(1)(B)(iii) unambiguously restricts application of the restored lands exception to ''an Indian tribe that is restored to Federal recognition.'' Thus, it argues, paragraph (a) is overly broad and should be modified because it allows recognition, acknowledgment or restoration through legislative enactment, including a tribe's initial recognition.

Response: This recommendation was not adopted because Congress has not been clear in using a single term in restoration bills. Additionally, the addition of ''(required for tribes terminated by Congressional action)'' in paragraph (a) addresses this issue. To the extent this comment concerned ''initial'' recognition by Congress where no prior relationship existed, legislation would not be encompassed by § 292.9.

Several comments suggested that this section needs to include administrative actions of restoration, recognition, and reaffirmation that are outside the Federal acknowledgment process. For example, one comment suggested modifying paragraph (b) to read; ''[r]ecognition through administrative action,'' and another suggested ''recognition through other official action of the Secretary or his/her designee.''

Response: This recommendation was not adopted. Neither the express language of IGRA nor its legislative history defines restored tribe for the purposes of section 2719(b)(1)(B)(iii). When Congress enacted IGRA in 1988, it authorized gaming by existing federally recognized tribes on newly acquired lands if those lands were within or contiguous to the boundaries of an existing reservation. If the tribe had no reservation, Congress authorized gaming on newly acquired lands within the boundaries of its former reservation. We can safely infer that Congress understood that a list of federally recognized tribes existed and authorized on-reservation, or on former reservation, gaming for those tribes. We must, therefore, provide meaning to Congress's creation of an exception for gaming on lands acquired into trust ''as part of the restoration of lands for an Indian tribe restored to Federal recognition.'' We believe Congress intended restored tribes to be those tribes restored to Federal recognition by Congress or through the part 83 regulations. We do not believe that Congress intended restored tribes to include tribes that arguably may have been administratively restored prior to the part 83 regulations.

In 1988, Congress clearly understood the part 83 process because it created an exception for tribes acknowledged through the part 83 process. The part 83 regulations were adopted in 1978. These regulations govern the determination of which groups of Indian descendants were entitled to be acknowledged as continuing to exist as Indian tribes. The regulations were adopted because prior to their adoption the Department had made *ad hoc* determinations of tribal status and it needed to have a uniform process for making such determinations in the future. We believe that in 1988 Congress did not intend to include within the restored tribe exception these pre-1979 *ad hoc* determination. Moreover, Congress in enacting the Federally Recognized Indian Tribe List Act of 1994 identified only the part 83 procedures as the process for administrative recognition. *See* Notes following 25 U.S.C. 479a.

The only acceptable means under the regulations for qualifying as a restored tribe under IGRA are by Congressional enactment, recognition through the Federal acknowledgment process under 25 CFR 83.8, or Federal court determination in which the United States is a party and concerning actions by the U.S. purporting to terminate the relationship or a court-approved settlement agreement entered into by the United States concerning the effect of purported termination actions. While past reaffirmations were administered under this section, they were done to correct particular errors. Omitting any other avenues of administrative acknowledgment is consistent with the notes accompanying the List Act that reference only the part 83 regulatory process as the applicable administrative process.

One comment stated that paragraph (c) is contrary to the Federally Recognized Indian Tribe List Act of 1994, which it stated controls the analysis of this rule. The comment argues that a ''court-approved stipulated entry of judgment'' is not a ''decision'' on the merits as specified in the Act.

Response: According to Department's analysis, paragraph (c) is not inconsistent with the List Act. The litigation encompassed by § 292.10 concerns challenges to specific actions taken by the Federal Government terminating, or purporting to terminate a relationship, such as the Tillie Hardwick litigation in California. There is no reason under IGRA or the List Act to preclude a settlement concerning challenged termination actions from ''restoring'' a government-to-government relationship if the U.S. is a party and the court approves it.

One comment suggested adding the following language to paragraph (c):

''Was entered into by the United States which:'' and striking paragraph (1).

Response: This recommendation was adopted in part and the paragraph was modified accordingly.

One comment suggested separating (c) into two parts as follows: ''(c) Recognition through a judicial determination; or (d) Recognition through a court-approved stipulated entry of judgment or other settlement agreement.'' The comment stated that recognition through a judicial determination should be sufficient, whether or not the judicial determination satisfies the criteria set forth in paragraphs (1) and (2).

Response: This recommendation was not adopted. While the structure of the paragraph was changed, the criteria set forth in (1) and (2) are still necessary. At issue is the government-to-government relationship between the U.S. and the tribe, and the U.S. must be a party in order to be bound by the court's decision.

One comment suggested that a court-approved ''settlement agreement'' should be sufficient, whether or not it is styled a ''stipulated entry of judgment.''

Response: This recommendation was adopted.

One comment suggests striking the word ''Provides,'' in paragraph (2), and replacing it with ''Settles claims'' in order to remedy a potential scenario where the settlement agreement omits pertinent language but, nonetheless, settles the tribe's claim that it was never legally terminated.

Response: This recommendation was adopted, consistent with prior administrative practice concerning the Tillie Hardwick litigation.

One comment stated that since there are no judicial findings in a court-approved stipulated entry of judgment, such means provide an inadequate basis to restore a tribe.

Response: This concern was addressed through the revision to paragraph (c). The relevant operative language in the Federal court determination or court-approved settlement agreement must include language pertaining to termination rather than restoration.

One comment noted that parties do not enter into judicial determinations. Thus, it argued, paragraph (1) does not make sense as it pertains to paragraph (c).

Response: This concern was addressed and the paragraph was amended accordingly.

One comment suggested that the regulations should provide a mechanism to give notice of any action to affected local communities. Furthermore, the comment suggested that the rule should make clear that the party has standing to intervene if it can demonstrate that it is affected and that the tribe should not be able to raise sovereign immunity as a bar.

Response: These recommendations were not adopted because they are beyond the scope of the regulations and inconsistent with IGRA.

One comment suggested inserting language requiring the applicant group to clearly establish by documented evidence that its current members are directly descended from members of the terminated tribe.

Response: This recommendation was not adopted because requiring genealogies of tribal members is beyond the scope of the regulations, inconsistent with IGRA and not necessary in order to decide whether the applicant tribe is a restored tribe.

Section 292.11 What are ''restored lands?''

One comment suggested striking the word ''specific'' in paragraph (a). A few comments suggested striking any language in paragraph (a) and § 292.11 pertaining to a geographical area or parameters.

Response: These recommendations were not adopted. The regulations include a contingency for legislation that requires or authorizes the Secretary to take land into trust for the benefit of a tribe within a specific geographic area because in such scenarios, Congress has made a determination which lands are restored. Because the inclusion or exclusion of specific geographical areas in restoration legislation is beyond the control of the Department, the regulations must address both contingencies.

One comment suggested that language in paragraph (b) should provide expert administrative guidance to Congress when it drafts restoration legislation.

Response: This recommendation was not adopted because it is outside the scope of the regulations and inconsistent with IGRA.

One comment suggested that the criteria in paragraph (b) should apply to land acquired by a tribe that is recognized through 25 CFR 83.8 as well.

Response: This recommendation was adopted and the paragraph was modified accordingly. In order to adopt this and other recommendations, the section was re-organized.

One comment suggested that paragraph (b) and all related paragraphs in § 292.12 should be revised with the requirement that the tribe's modern and historical connection to the land must have been continuous since at least before October 17, 1988.

Response: This recommendation was not adopted because it is inconsistent with the purposes of this provision of IGRA and is thus beyond the scope of the regulations.

One comment suggested inserting the words ''recognized, acknowledged or'' into both paragraph (a) and (b) because the broader language is consistent with § 292.10(a). Also, the comment suggested adding the words ''for the benefit of the tribe'' in paragraph (a) and replacing the words ''the restoration'' with the word ''such'' in paragraph (b).

Response: These recommendations were adopted in part and the paragraphs were modified accordingly.

One comment suggested modifying paragraph (b) by replacing ''modern connection'' with ''contemporary ties.'' The comment also suggested striking the word ''significant'' and removing the temporal requirement.

Response: These recommendations were not adopted. However, the modern connections test as set forth in the proposed regulations was modified using some of the suggestions that were given in relation to the ''contemporary ties'' test. Striking the word ''significant'' and removing the temporal requirement would so broaden the benefit to restored tribes that it would be detrimental to other recognized tribes, contrary to Congressional intent.

One comment suggested striking the words ''the restoration'' from paragraph (b) and striking the language pertaining to the modern, historical and temporal requirements in § 292.12. Instead, the comment suggested replacing the reference to the requirements with: ''The land is located within an area where the tribe has connections to the lands that meet the requirements of § 292.12.''

Response: These recommendations were adopted in part. The phrase ''the restoration'' is necessary and therefore retained in the regulations. The recommendation pertaining to referencing § 292.12, instead of listing the requirements, was adopted.

One comment stated that there is a structural ambiguity in § 292.11 because the conjunctions are not clear and that the section needs clarified. For example, the paragraph could be read as requiring (a or b) and c, or it could be read as requiring a or (b and c).

Response: This recommendation was adopted and the section was modified in order to clarify that ''the tribe must show at least one of the following'' in order for the newly acquired lands to qualify as restored lands.

One comment suggested adding a number of paragraphs in order to address Oklahoma tribes in this section.

Response: This recommendation was not adopted because it in unnecessary to single them out. Limitations on the Oklahoma tribes are specifically addressed in other parts of section 2719 and the regulations.

One comment stated that the rule should conform more closely to applicable law and suggested adding a paragraph (d) to require that the land be the first trust acquisition following restoration.

Response: This recommendation to add a paragraph (d) was not adopted; however, temporal limitations are addressed in § 292.12 of the regulations.

Section 292.12 How does a tribe establish its connection to the land?

This section was renamed, ''How does a tribe establish its connection to newly acquired lands for the purposes of the 'restored lands' exception?''

Paragraph (a):

Several comments concerned the ''headquarters test'' in paragraph (a). Comments ranged from support to requests to eliminate the test all together. For example, some comments requested that the rule be excluded because it is arbitrary and potentially subject to abuse or manipulation; some suggested removing the test without explanation—one comment suggests that the headquarters test was designed specifically to accommodate a particular tribe. Some comments suggested that if the headquarters test is included, there should be a temporal requirement that requires the headquarters to be located within 25 miles of the proposed lands since before the enactment of IGRA. Another comment suggested the temporal requirement be 30 years. One comment stated that 25 miles is too great a distance, while another comment suggested it should be extended to 50 miles.

Response: The recommendations to remove the headquarters test and to alter the 25-mile radius were not adopted because the headquarters test is a useful means of determining whether a tribe has a modern connection to the newly acquired land and the 25-mile radius is both useful and consistent. (The word radius was added to the regulation to provide clarity). Nonetheless, the concerns raised by these comments are legitimate because the version of the headquarters test in the proposed rule could be construed as being open to manipulation. Therefore, the qualifier was added in the final rule that the tribe's headquarters or other tribal governmental facilities be in existence at that location for at least two years at the time of the application for land-into-trust. The language of ''other tribal governmental facilities'' was added to address concerns that tribes often operate out of more than one headquarters or facility.

A few comments suggested adding a paragraph to the modern connection test that allows land that is located within the tribe's service area—as designated by legislation restoring the government-to-government relationship with the tribe, or by the BIA, Department of Health and Human Services or by the Department of Housing and Urban Development. Similarly, one comment suggested including the following language at the end of paragraph (a): ''or the land has been designated by the BIA as included within the [t]ribe's service population area.''

Response: These recommendations were not adopted because the service area is not necessarily defined by the DOI and would thus add complication to the analysis due to the added necessity of collaboration with other agencies. Furthermore, the tribe's service area is often based on factors not connected with the DOI's section 2719 analysis and is often ill-defined, overlapping and potentially inconsistent.

Several comments suggest removing the ''modern connections'' test because, for example, the test is not in the plain language of IGRA, and the test is contradicted by case law (e.g., *Grand Traverse Band of Ottawa and Chippewa Indians* v. *United States Attorney*, 198 F.Supp. 2d 920 (W.D. Mich. 2002), aff'd 369 F.3d 960 (6th Cir. 2004); *Confederated Tribes of the Coos, Lower Umpqua, and Suislaw Indians* v. *Babbitt*, 116 F.Supp. 2d 155 (D.C. Cir. 2000)) that focuses on whether the lands were historically occupied by the tribe.

Response: This recommendation was not adopted. Though the ''modern connections'' test is not in the plain language of IGRA, nor is the test for a historical connection. The cases cited by the commenter do not limit the Department from considering a modern connection and only discuss the historical connection in relation to the process by which the Department made its decision. Additionally, the cases cited by the commenter provide guidance for the interpretation of section 2719(b)(1)(B)(iii); lands that are taken into trust as part of the restoration of lands for an Indian tribe that is restored to Federal recognition. The Secretary has discretion to require a modern connection as part of the restoration of lands. The modern connection test remains in the final regulations because it offers a mechanism to balance legitimate local concerns with the goals of promoting tribal economic development and tribal self-sufficiency, both of which are reflected in IGRA.

Several comments addressed concerns about the ''modern connection test'' and suggested modifying it. For example, a few comments stated that the test for a modern connection to the land is too permissive and suggested that the casino site must be in the immediate vicinity of the tribe's current population or that the 50-mile majority requirement be narrowed. Several comments suggested that the modern connection test is too narrow and should be broadened to allow the Department to consider a greater degree of facts and circumstances or to expand or eliminate the 50-mile majority requirement. A few comments noted that a hard-line 50-mile majority requirement presents practical difficulties when it comes to implementation.

Response: The recommendations to narrow the modern connection test were not adopted. Given the potential difficulty and confusion in administering the 50-mile majority requirement, the recommendations to eliminate the requirement were adopted in favor of a test that allows for the consideration of a number of different factors. Additionally, in balancing these concerns, the Department added the following language in paragraph (a): ''The land is located within the State or States where the Indian tribe is presently located, as evidenced by the tribe's governmental presence and tribal population, and the tribe can demonstrate one or more of the following modern connections to the land.''

One comment suggested requiring both a majority population test and a headquarters test.

Response: This recommendation was not adopted. As noted, the 50-mile majority requirement was eliminated. Nonetheless, the purpose of the exception is to assist restored tribes in economic development. As long as the tribe has a modern connection to the land, the surrounding community has notice of the tribal presence.

One comment suggested adding a requirement for a culturally significant modern connection.

Response: This recommendation was not adopted because it is not clear what the commenter intended by ''culturally significant.'' Assuming the commenter suggested a more narrow interpretation of modern connections, the recommendation is not adopted because, while the modern connections

requirement was not eliminated entirely, the paragraph was modified in response to a number of comments that suggested that the requirement encompass a wider range of criteria. As discussed above, the 50-mile majority requirement was eliminated and the paragraph was amended to reference a significant number of tribal members or other factors that demonstrate the tribe's current connection to the land. The inclusion of a modern connections requirement provides an element of notice to the surrounding community yet the elimination of the 50-mile majority requirement recognizes that the standard is too difficult to apply in today's mobile work related environment.

One comment suggested striking (a) and replacing it with the following: ''Contemporary ties to the area in which the land is located.''

Response: This recommendation was not adopted; however, the modern connections test as set forth in the proposed regulations was modified using some of the suggestions that were given in relation to the ''contemporary ties'' test.

Paragraph (b):

One comment requested a definition of ''tribe'' that states that an unconnected group of Indians, with no common ethno historic affiliation, does not constitute a tribe for the purpose of paragraph (b).

Response: This recommendation was not adopted. Tribe is defined in the definition section and applies throughout the regulations.

One comment stated that the phrase ''significant historical connection'' in (b) is interpreted too broadly, and that it should only be found when a tribe has had exclusive use and occupancy of an area. Additionally, the comment suggested that an Indian Claims Commission determination on restored lands should be binding.

Response: This recommendation was not adopted. In response to numerous comments, the term ''significant historic connection'' is now defined in the definition section of these regulations. While not limited to the tribe's exclusive use and occupancy area, the definition specifies certain criteria that a tribe must show in order to meet the definition, e.g., ''the land is located within the boundaries of the tribe's last reservation under a ratified or unratified treaty, or a tribe can demonstrate by historical documentation the existence of the tribe's villages, burial grounds, occupancy or subsistence use in the vicinity of the land.''

One comment suggested that a tribe should not be able to establish a historical connection if they are a disparate group of traveling Indians traveling through territory at some point in their distant history.

Response: We received comments pertaining to the issue raised by this comment that argue both in favor of and against a tribe's ability to establish a connection to the land when their past contacts were transitory or brief in nature. The definition of ''significant historical connection'' establishes criteria which require something more than evidence that a tribe merely passed through a particular area.

One comment suggested (b)(2) should reflect advisories in case law that support the general idea that there are limits to what can be included as restored lands. Another comment suggested that the term ''significant'' in paragraph (b) is too vague.

Response: These recommendations were addressed through the addition of a definition for ''significant historical connection.''

A few comments suggested modifying (b)(2) by striking the word ''documented'' and one comment suggested adding ''whether evidenced by documentation or oral history.''

Response: This recommendation was not adopted because the paragraph was restructured. The definition of ''significant historical connection'' calls for ''historical documentation.'' Because a significant historical connection would be documented there is no need to include oral history as acceptable evidence. Such oral history is unnecessary when documentation is available; it would be insufficient alone.

One comment suggested adding the words ''or by other means'' in paragraph (b)(1) because there are other valid means by which a reservation may have been established other than by treaty for purposes of § 292.12(b).

Response: This recommendation was not adopted because it is unnecessary. The reference to reservation under a ratified or unratified treaty is only one manner in which a significant historical connection can be demonstrated according to the definition. There is no need to broaden this portion of the definition because the evidence of the tribe's villages, burial grounds, occupancy or subsistence use in the vicinity of the land will identify the historical connections without raising the ambiguity that ''other means'' may create.

One comment suggested modifying the language in the introduction to § 292.12 to read ''§ 292.11(b).''

Response: This recommendation was rendered unnecessary by the rewriting of § 292.11.

One comment suggested changing the word ''court'' to ''courts'' in paragraph (b)(2).

Response: This recommendation was not adopted because the paragraph was restructured and the reference to specific evidence deleted as unnecessarily restrictive.

One comment stated that the word ''significant'' in paragraph (b) is insufficient because it is ambiguous and provides little guidance as to temporal requirements. Some comments suggested deleting the word ''significant'' in paragraph (b) because it seems to create a higher standard for historical ties in comparison to modern ties. A few comments also suggested deleting the language pertaining to giving Federal Government documents significant weight. One comment suggested modifying the language to read, ''the land is located in an area to which the tribe has significant documented historical connections; or the tribe can establish any other evidence that demonstrates the existence of a significant historical connection to the land or area in which the land is located.''

Response: These recommendations were adopted in part and addressed by the changes to the definition of significant historical connection. The suggestion to delete ''significant'' was not adopted because the word reinforces the notion that the connection must be something more than ''any'' connection. The definition does not include a temporal requirement because such inquiry is highly dependant of the facts and circumstances of each tribe's historical connection to the land. The suggestion regarding the weight given to Federal Government documents was adopted as unnecessarily restrictive.

One comment suggested adding aboriginal language in paragraph (b).

Response: This recommendation was not adopted because it is unclear what the comment was meant to accomplish.

Paragraph (c):

One comment requested that the rules put all restored tribes on an even playing field by incorporating the, so called, *Grand Traverse* standard into the rule.

Response: This recommendation was adopted in so far as we followed the Grand Traverse standard that if the tribe is acknowledged under 25 CFR 83.8, and already has an initial reservation proclaimed after October 17, 1988, the tribe may game on newly acquired lands under the restored lands exception provided that it is not gaming on any other land.

One comment suggested that the rule further define ''temporal connection''

because the degree of temporal connection to the land varies among tribes, especially since their post-termination relations with State and local governments likewise varies, depending on the level of hostilities.

Response: This recommendation was not adopted. The paragraph, as written, takes into account a wide range of variables.

One comment suggested change the temporal limit from 25 to 20 years.

Response: This recommendation was not adopted. The Department received numerous comments arguing for both less than and more than 25 years. The 25 year number is both a practical and reasonable number based on the Department's experience under section 2719.

One comment stated that (c) is inadequate because (c)(1) allows anywhere from a 6 minute to a 100 year span and (c)(2) gives a 25 year period. One comment suggested changing the conjunction between paragraph (1) and (2) under (c) from an ''or'' to an ''and'' because the commenter suggested that this would make the section consistent with court decisions.

Response: These recommendations were not adopted. Paragraph (c)(1) considers that there are often a number of impediments involved in a tribe's efforts to acquire restored lands after the event officially restoring the tribe. Also, placing a time cap on the ability of a tribe to acquire land for gaming, when it is their first attempt to acquire a site for gaming, is contrary to Federal Indian policy as stated in IGRA. However, a cap of 25 years, as discussed in (c)(2), addresses the concerns about a tribe's open ended ability to acquire lands for gaming. If a tribe already has newly acquired lands, then a time cap and its limiting effect to acquire a site for gaming does not undermine IGRA's stated policy goals.

One comment suggested modifying paragraph (c)(1) by striking ''tribe has'' and adding ''United States * * * in trust status for the tribe.''

Response: This recommendation was addressed by the addition of the definition for ''newly acquired lands.''

One comment suggested striking (c)(1)&(2). One comment suggested striking (c)(2) and replacing it with the following: ''if a tribe has acquired no other land for gaming purposes since its restoration without regard to how much time has passed since the tribe's restoration.''

Response: These recommendations were not adopted because the temporal limitation effectuates IGRA's balancing of the gaming interests of newly acknowledged and/or restored tribes with the interests of nearby tribes and the surrounding community.

One comment suggested modifying paragraph (c)(1) to read, ''The land is the first land that the tribe has acquired pursuant to the Department of the Interior's regulations or procedures for gaming acquisitions since the tribe was restored to Federal recognition and the tribe is not gaming on any other trust lands; or.'' The comment stated that the phrase ''trust land'' should be added because § 292.12(c)(1) should only apply to land which has been acquired in trust; not to land which a tribe has acquired in fee. The phrase ''pursuant to the Department's * * *'' should be added because a tribe should not lose its chance to satisfy the criteria in § 292.12(c)(1) if it acquires land in trust for housing which is not intended for gaming and had not been acquired pursuant to the procedures for gaming acquisitions. The phrase ''and the tribe * * *'' is added to ensure that this paragraph in not used by a tribe which is already gaming.

Response: The recommendation regarding the phrase ''trust land'' was adopted in part through use of the term ''newly acquired lands,'' clarifying the type of land contemplated under (c). The recommendation to exclude trust land used for housing was unnecessary because paragraph (c)(2) allows a tribe that already has newly acquired lands, to acquire a site for gaming as long as the tribe submits an application within 25 years of its restoration. The recommendation to qualify (c)(1) with the phrase ''the tribe is not gaming on any other trust lands'' was adopted in part and added to (c)(2). The definition of newly acquired lands includes tribal land acquired in trust but does not include tribal fee land.

General Comments on § 292.12:

One comment suggested that the rule specify what role the NIGC plays in the restored lands opinion. One comment stated that there is nothing in the rule that discusses the process the BIA will use to make restored lands opinions.

Response: These comments are addressed with the addition of § 292.3 discussing the application process.

One comment suggested adding a geographical nexus requirement to § 292.12 in addition to the historical and temporal requirements.

Response: This recommendation was not adopted as the regulation's requirement of a modern, historical and temporal connection adequately implements the policy goals of IGRA.

One comment suggested that the regulations should require a tribe to acquire their former reservation land if it is available. One comment suggested that tribes should not be permitted to acquire restored lands if they were already compensated for such lands by some other means.

Response: These recommendations were not adopted because they do not have a basis in IGRA.

One comment suggested making the language in §§ 292.11 & 292.12 consistent with § 292.6.

Response: This recommendation was adopted. The Department made efforts to make these sections consistent where uniformity is necessary.

Subpart C—Secretarial Determinations and Governor's Concurrence

Section 292.13 When can a tribe conduct gaming activities on lands that do not qualify under one of the exceptions?

This section was renamed ''When can a tribe conduct gaming activities on newly acquired lands that do not qualify under one of the exceptions in subpart B of this part?''

Several comments suggested restricting the scope of consultation required under paragraph (b) by deleting ''local officials, including officials of nearby tribes'' thereby preventing excessive complication of the application process and promoting tribal self-determination.

Response: This recommendation was not adopted because the statute requires consultation with nearby tribes and local officials, 25 U.S.C. 2718(b)(1)(A).

One comment recommended that no land be taken into trust without the consent of the State and the affected county.

Response: This recommendation was not adopted because the comment raises issues pertaining to 25 CFR part 151—Land Acquisitions. Nonetheless, section 2719 of IRGA only requires the Governor's concurrence. Since this section of IGRA requires consultation with the Governor, local officials and nearby tribes, but only specifies the concurrence of the Governor, Congress has implicitly rejected the need for concurrence by other officials.

One comment suggested that citizen input and State legislative participation should be included in the Secretary's determination that the casino will not be detrimental to the community. One comment, on behalf of a concerned citizen, opposed the Secretary's authority to permit gambling in communities without her input.

Response: These recommendations were not adopted because the regulations already require consultation with appropriate State and local officials, consistent with the statutory

language. Further, there are various opportunities for local input in the process, depending on which exception is at issue.

One comment suggested that the regulations impose additional restrictions on gaming on lands acquired after October 17, 1988.

Response: The regulations were designed to conform to and interpret section 2719 of IGRA; every effort was made to stay consistent in that regard. Additional restrictions are inconsistent with 25 U.S.C. 2719.

One comment suggested that paragraph (b) use the phrase ''nearby Indian tribes'' and paragraph (d) read ''The Governor of the [S]tate in which the gaming establishment is to be located concurs in the Secretary's Determination'' in order to conform to IGRA.

Response: This recommendation was adopted and language was modified accordingly.

One comment stated that the two-part Secretarial Determination exception cannot be interpreted as requiring a tribe to have an ancestral tie to the lands they seek to acquire.

Response: The two-part Secretarial Determination does not require a tribe to have an ancestral tie to the lands they seek to acquire.

Section 292.14 Where must a tribe file an application for a Secretarial Determination?

The Department did not receive any comments regarding this section.

Section 292.15 May a tribe apply for a Secretarial Determination for lands not yet held in trust?

One comment stated that requiring a tribe to file its application for a two-part Secretarial Determination at the same time as its land-into-trust application precludes the tribe from using the land they have placed into trust for economic development. Accordingly, the comment suggested modifying § 292.15 in light of this concern.

Response: This recommendation was not adopted. The requirements in § 292.15 address land that is not yet held in trust. The section does not address a tribe's existing trust land.

Application Contents

Section 292.16 What must an application for a Secretarial Determination contain?

Several comments suggested that a tribe be required to submit only the information required under § 292.16, paragraphs (a) through (d) at the time it submits its land-into-trust application. The information required by § 292.16 paragraphs (e) and (f) could be submitted as the information becomes available.

Response: This recommendation was not adopted because the application for a Secretarial Determination must include all of the information in § 292.16 for the application to be complete.

One comment suggested that an additional requirement in paragraph (d) be added to require the tribe to submit ''evidence of an aboriginal or significant historical connection to the land, including cultural ties based upon actual inhabitance.'' This would, according to the commenter, bring the regulation into conformance with section 2719.

Response: This recommendation was not adopted because it is beyond the scope of the regulations and inconsistent with IGRA.

One comment observed that, throughout the regulations, ''application'' is used to refer both to the tribe's initial written request and to the subsequent application package developed by the BIA Regional Office for submission to the Secretary, creating confusion.

Response: In consideration of the comment, changes were made throughout the regulations accordingly.

Several comments suggested striking paragraphs (d) and (k).

Response: These recommendations were not adopted because paragraphs (d) and (k) inform the decision making process.

One comment suggested striking paragraphs (j) and (k) because these documents are not site specific and are either already on file with the BIA or do not apply.

Response: These recommendations were not adopted because paragraphs (j) and (k) inform the analysis. The word ''Any'' was deleted from the beginning of former paragraph (k) and the words ''if any'' were added to modified paragraph (l) for clarification.

Several comments noted that, while the Regional Director is required by § 292.20(a)(2) to provide officials with information regarding the proposed scope of the gaming, §§ 292.16–292.18 do not require the applicant tribe to submit this information.

Response: In response to these comments, language was added in (j) regarding the proposed scope of gaming and the size of the proposed gaming establishment.

Section 292.17 How must an application describe the benefits of a proposed gaming establishment to the tribe and its members?

Several comments suggested changing ''benefits'' in the title of § 292.17 to ''impacts.''

Response: This recommendation was adopted in part. The words ''and impacts'' were added to the title of § 292.17. The section was renamed ''How must an application describe the benefits and impacts of a proposed gaming establishment to the tribe and its members?''

Several comments suggested that paragraph (f) require a more specific identification of adverse impacts.

Response: This recommendation was not adopted because an adverse impacts analysis is fact specific and will vary depending on the given facts and circumstances.

One comment suggested that § 292.17 require consideration of land use, development alternatives to gaming, whether the proposed project is consistent with the tribe's economic needs (if any), and how fulfillment of such needs will be balanced against off-reservation environmental impacts.

Response: This recommendation was not adopted because development alternatives and environmental impact are addressed in the National Environmental Policy Act (NEPA) process.

One comment noted that paragraph (i) is a new requirement not previously contained in the discussion draft circulated prior to the publication of the proposed regulation.

Response: The concern raised by the commenter does not violate any standards or procedures.

Several comments suggested that paragraph (h) be amended to read ''* * * or holds other contractual rights to cause the land to be transferred to the United States, or to the [t]ribe.''

Response: This recommendation was not adopted because it is unnecessary. The first clause of paragraph (h) covers the commenter's concern.

One comment suggested that ''if any'' be stricken from paragraph (i) to require the applicant tribe to establish that it ''aboriginally'' used and occupied the land where it wishes to build a gaming establishment.

Response: This recommendation was not adopted because historical connections are not mandatory under IGRA for purposes of this subpart of the regulations.

Several comments suggested striking, in their entirety, paragraphs (a), (e), (g), and (j), and striking ''from the proposed

uses of the increased tribal income'' from paragraph (d).

Response: These recommendations were not adopted because all of the paragraphs are necessary in order to determine what is in the tribe's best interest.

One comment suggested striking ''and the tribe'' from paragraph (a), as it would be ''voluminous and time consuming.''

Response: This recommendation was not adopted because the words ''and the tribe'' must be included in the paragraph in order to conduct a thorough analysis under the two-part determination.

Several comments suggested replacing ''facility'' in paragraph (j), subparagraph (3) with ''establishment.''

Response: This recommendation was adopted, and the word ''facility'' was replaced with the word ''establishment.''

One comment suggested adding ''Any information provided within the application that is of a commercial or financial nature shall be protected from release to the public pursuant to the exemptions of the Freedom of Information Act [(''FOIA'')], 5 U.S.C. 522(b)(4).''

Response: This recommendation was not adopted because the FOIA provisions that protect commercial and financial information and the corresponding procedures stand on their own and need not be specifically referenced in these regulations.

One comment suggested requiring the information provided under § 292.17 be shared with State and local governments, who should be accorded the opportunity to respond to the information supplied by the tribe.

Response: This recommendation was not adopted because the Secretary can evaluate the financial information without having comments or analysis by the State or local governments. Nevertheless, the Department will provide financial information to the Governor under § 292.22 if there is a favorable Secretarial Determination.

Section 292.18 What information must an application contain on detrimental impacts to the surrounding community?

Several comments argued that tribal gaming by an out-of-State tribe is *per se* detrimental to the community.

Response: This recommendation was not adopted. While the regulations allow for a finding that gaming by an out-of-State tribe is detrimental to the community, such a finding will be made on a case-by-case basis.

Several comments suggested that ''detrimental to the surrounding community'' in paragraph (c) should be defined to consider the adverse impacts on self-sufficiency and economic development of other tribes in the State.

Response: This recommendation was not adopted because the definition of ''surrounding community'' already includes Indian tribes. Extending consideration to other tribes in the State goes beyond the Department's interpretation of the statute.

One comment raised the concern that § 292.18 did not limit the Secretary's discretion to consider ''detrimental information'' regarding non-Indian gaming interests.

Response: The Secretary can consider detrimental information regarding non-Indian gaming interests; it is considered within paragraph (c). While such interests can be considered, they are limited to surrounding community consistent with section 2719.

One comment suggested it was premature to require an environmental assessment (EA) or environmental impact statement (EIS) before the Secretary makes his decision.

Response: An EA or EIS are products of the NEPA process. The Secretary must have the results of the NEPA analysis in order to consider whether or not there is detriment to the surrounding community.

Several comments proposed the following subsection: ''An analysis by a qualified traffic engineer of the traffic impacts on the surrounding community and the mitigation measures necessary to alleviate the traffic impacts which would be caused by the proposed gaming establishment.''

Response: This recommendation was not adopted because it is unnecessary; it is implicit in (a) and (b).

One comment recommended that the regulation specify that ''surrounding community'' includes communities across State lines.

Response: This recommendation was not adopted because it is not necessary. The definition of surrounding community is defined by mileage, and is not limited by State boundaries.

Several comments suggested that paragraph (e) implied that the treatment program rather than compulsive gambling is a detrimental impact, and that there are no detrimental impacts to the surrounding community from compulsive gamblers who are not enrolled in treatment programs. It was suggested that paragraph (e) be changed to read, ''Costs of compulsive gambling attributable to the proposed gaming establishment, including the cost of treatment programs and the primary and secondary social costs attributable to compulsive gamblers enrolled and not enrolled in treatment programs.''

Response: This recommendation was adopted in part, and (e) was revised in order to clarify that the potential detrimental impact is any anticipated costs of treatment programs.

One comment suggested striking ''if any'' from paragraph (d).

Response: This recommendation was not adopted because the words ''if any'' do not appear in paragraph (d) of this section.

Several comments suggested amending paragraph (c) to read, ''Impacts on the economic development, income, and employment of the surrounding community, including any significant impacts on the income and employment generated by Indian gaming of nearby Indian tribes.''

Response: This recommendation was not adopted because tribes are already included in ''surrounding community.''

Several comments suggested adding further specificity to the information that is required in the application and set forth in paragraphs (a) through (f) of § 292.18.

Response: These recommendations were not adopted because the regulations, as written, provide sufficient specificity.

Several comments suggested striking paragraphs (d) and (e).

Response: The recommendation was not adopted because paragraphs (d) and (e) are required, according to the Department's definition and understanding of detriment.

Several comments suggested amending paragraph (a) to add a proviso ''if required pursuant to NEPA'' following the reference to an EA or an EIS.

Response: This recommendation was adopted and paragraph (a) was modified accordingly.

One comment suggested striking from paragraph (a) '' e.g. an Environmental Assessment * * * Statement (EIS).''

Response: This recommendation was not adopted because the examples provide useful guidance.

One comment suggested striking paragraph (f) to give tribes discretion to include, rather than the Secretary discretion to mandate, any additional information.

Response: This recommendation was not adopted because a well informed Secretary will promote sound decision making.

One comment suggested amending paragraph (a) to read, ''Information regarding environmental impacts and plans for mitigating detrimental impacts on the surrounding community * * *'' to conform to statutory language.

Response: This recommendation was not adopted because the NEPA uses ''adverse.''

One comment noted that ''social structure'' in paragraph (b) is vague and undefined.

Response: This recommendation was not adopted because the term ''social structure'' is necessary in order to interpret the statute.

Consultation

Section 292.19 How will the Regional Director conduct the consultation process?

Several comments suggested that 60 days was not a sufficient time for State and local officials to collect the necessary information to prepare a consultation letter.

Response: The State and local officials are not being asked to prepare a consultation letter, they respond to the Regional Director's letter. The relevant information is available at the time when the regulations require a consultation letter and therefore 60 days is adequate time for State and local officials to comment.

Several comments recommended that the Regional Director be required to notify appropriate officials if the tribe addresses or resolves any issue pursuant to paragraph (c)(2), and that such officials should be accorded a reasonable time to respond.

Response: This recommendation was not adopted because such a procedure would inject unnecessary delay into the process.

One comment requested that the Department exempt from the requirements of § 292.19 pending applications that have already completed the required consultations with the surrounding community under the current checklist procedures.

Response: This recommendation was not adopted. We are not including a general exemption in the regulations, but the Department will make a case-by-case determination whether pending applications have completed the necessary consultation.

One comment suggested the 25-mile radius for tribes to be included in the consultation process be expanded to 100 miles.

Response: This recommendation was not adopted as the focus on section 2719 is the surrounding community.

One comment suggested including the applicant tribe in the § 292.19 consultation process.

Response: This comment was not adopted because the tribe is already included in the process in paragraph (c) where the tribe can respond to issues raised in the responses.

Several comments suggested that, ''Citizens within a 50-mile radius (Public notices posted)'' be added to the requirements of paragraph (a) so as to solicit comments from the community. One comment suggested rewriting paragraph (b), in its entirety, with a focus on notice requirements.

Response: These recommendations were not adopted. The Department consults with appropriate State and local officials and nearby tribes. Therefore, the Department is not amending the regulations to solicit citizen comments directly. It is most appropriate that citizen comments funnel through appropriate State, local and tribal officials. Also, public comments are provided for in the NEPA process.

One comment suggested that 30 days was a sufficient comment period.

Response: This recommendation was not adopted because the 60-day comment period provides a balance between those wanting a longer period and those wanting a shorter time for comment.

One comment suggested changing ''nearby tribes'' in paragraph (a)(2) to the previously-defined ''nearby Indian tribes.''

Response: This recommendation was adopted and the paragraph was modified accordingly.

Several comments suggested that the BIA be required to meet with local officials throughout the acquisition process and that the comment period was not a legitimate consultation process.

Response: This recommendation was not adopted because the Secretarial Determination in section 2719 is not a negotiation process. Creating additional opportunities for back-and-forth is unnecessary, causes delay and is inconsistent with IGRA.

One comment suggested that the term ''consultation comments'' in paragraph (c)(1) was unclear and should be defined to include any comments received from residents and businesses.

Response: This recommendation was adopted and corresponding edits were made in order to clarify the paragraph.

Several comments suggested that officials of whom consultation is requested have access to information provided by the applicant pursuant to § 292.17.

Response: Consistent with the protection Congress affords financial, commercial or proprietary information under the FOIA, this recommendation was not adopted.

Several comments suggested requiring the information provided under § 292.18 be shared with State and local governments, who should be accorded the opportunity to respond to the information supplied by the tribe.

Response: This recommendation was not adopted because the requested process would add unnecessary delay at this stage of the process.

Section 292.20 What information must the consultation letter include?

One comment considered it ''absurd'' to require local communities and nearby tribes, rather than the applicant tribe, to provide funding to mitigate problems that might emerge from the proposed casino and to propose programs to address compulsive gambling (paragraph (b)).

Response: This comment misconstrues paragraph (b)(5). In order to clarify the paragraph, it was modified to make clear that the consultation letter is only requesting information regarding the anticipated costs, if any, of treatment programs. The paragraph does not consider the issue of who will bear such costs.

One comment suggested that paragraph (b)(4) be changed to, ''Reasonable estimates of costs of impacts * * *'' to eliminate the implication that all costs will be reimbursed by the applicant tribe.

Response: This recommendation was adopted in part. The word ''anticipated'' was inserted wherever necessary.

Several comments suggested that paragraph (b)(4) be changed to, ''Costs of impacts to the surrounding community, including nearby Indian tribes* * *'' and that the tribes be consulted in this determination.

Response: This recommendation was not adopted because ''nearby Indian tribes'' are included in the definition of surrounding community.

One comment suggested amending paragraph (b)(6) to read, ''Any other information that may assist the Secretary in determining whether gaming is or is not detrimental to the surrounding community'' to avoid sounding conclusory.

Response: This recommendation was adopted.

One comment suggested adding, ''such as the size of the proposed gaming establishment'' to paragraph (a)(3).

Response: This recommendation was not adopted because the proposed language is already included in the paragraph.

One comment suggested striking paragraph (b)(4) and (5).

Response: This recommendation was not adopted because the paragraphs are necessary to the evaluation.

One comment suggested that paragraph (b) should not apply to entities that do not intend to file a protest against the proposed establishment.

Response: This recommendation was not adopted because it is not necessary. The paragraph does not compel recipients to comment.

One comment suggested that the consultation letter and the published notice should specify the studies (including one on crime and one on impacts on existing gaming) and provide the Web site where these studies can be viewed.

Response: This recommendation was not adopted because it is unnecessary. The information is routinely available should an individual decide that they want such data.

Evaluation and Concurrence

Section 292.21 How will the Secretary evaluate a proposed gaming establishment?

Several comments suggested that the regulations should provide that lands ''far from the tribe's existing reservation will be disfavored for taking into trust for the purposes of gaming.''

Response: This recommendation was not adopted because it refers to an issue that is considered when the Secretary takes lands into trust under 25 CFR part 151.

Several comments suggested that the Secretary, when making his determination pursuant to paragraph (b), must not consider the financial effects of competition on other Indian or non-Indian gaming establishments, in accordance with the Congressional intent of IGRA.

Response: This recommendation was not adopted because the Secretary does not necessarily include in the analysis the financial effects of competition on other gaming establishments; however, the Secretary does examine detrimental effect on the surrounding community and nearby tribes, including detrimental financial effects.

Several comments suggested that all appropriate State, local, and nearby tribal officials should also be notified of a disapproval pursuant to paragraph (c).

Response: Because of restructuring, this comment addresses § 292.21(b). This recommendation was not adopted because it is unnecessary. Interested parties can make individual inquiries if there is a need.

One comment suggested that community disapproval of a casino should require the Secretary to disapprove an application.

Response: This recommendation was not adopted because it is not consistent with IGRA.

One comment suggested rewriting § 292.21 to read:

(b) The Secretary will consider all the information submitted or developed under § 292.18 and all the documentation received under § 292.19 in evaluating the proposed gaming establishment's detrimental impacts on the host-community and surrounding counties. (c) If the Secretary disapproves of the gaming proposal, the Secretary will inform the tribe and set forth the reasons for the disapproval. (d) If the Secretary approves of the gaming proposal, the Secretary will proceed under § 292.22.

Response: This recommendation was not adopted because the changes are unnecessary. The paragraph, as amended, is sufficient to address the commenter's concerns.

One comment suggested adding a new paragraph:

The Secretary will make a presumption that the proposed project will have a detrimental effect on the surrounding community if the proposal negatively impacts the stewardship, economic development, or cultural preservation plans of a federally recognized tribe that does have a strong ancestral or cultural nexus to the lands in question. That presumption may be overcome only by compelling evidence.

Response: This recommendation was not adopted because it is beyond the scope of the regulations and inconsistent with IGRA.

One comment recommended that the regulation establish specific standards by which the Secretary must abide in making his two-part determination.

Response: This recommendation was not adopted because the regulations provide the necessary procedures and standards for the Secretary to make a decision.

One comment suggested that any findings must be supported by substantial evidence in the record and that the findings include the evidence that is contained in the record.

Response: This recommendation was not adopted because it is unnecessary. Including a standard of proof adds a layer of potential ambiguity to the analysis.

Section 292.22 How does the Secretary request the Governor's concurrence?

Several comments suggested that the Governor's retention of a silent veto power over the proposal (paragraph (d)) is inconsistent with the Congressional intent of IGRA, and that the State must therefore be required to respond to the tribe's proposal.

Response: This recommendation was not adopted because the Governor's silent veto is consistent with IGRA.

Several comments suggested that a lack of response from the Governor should be interpreted as a concurrence.

Response: This recommendation was not adopted because there is no statutory basis on which to create a regulation that says a Governor's silence means concurrence.

One comment recommended that the Governor and the State legislature must concur in the decision.

Response: This recommendation was not adopted because IGRA specifically identifies the Governor and not the State; this provision is distinguished from other sections of IGRA that specifically mention the State.

One comment suggested that, if the Governor does not respond to a request for concurrence within the established period, the tribe should be permitted to reinstate the findings of fact within a reasonable period of time or, in the alternative, the tribe can provide information to supplement the material provided under §§ 292.16–292.18.

Response: This recommendation was not adopted. As a courtesy, however, the Department will notify the tribe when the time period has passed without a response from the Governor.

One comment disapproved of the Governor's power to approve or veto the proposal.

Response: The power is specifically detailed in IGRA.

One comment suggested replacing, ''makes a favorable Secretarial Determination'' in paragraph (a) with, ''approves the tribal gaming proposal.''

Response: This recommendation was not adopted because it is an unnecessary change.

One comment suggested striking paragraph (b), subparagraph (2), because the regulations do not require that the Governor be given notice of the intent to place a gaming facility on land already held in trust.

Response: This recommendation was not adopted because it is premised on a misreading of the statute and it is no longer applicable because the section was reorganized.

One comment suggested amending paragraph (b), subparagraph (1), to read, ''The land is not eligible for gaming pursuant to 25 U.S.C. 2719(b)(1)(A)'' so as to not preclude gaming pursuant to the exceptions set forth in 25 U.S.C. 2719(b)(1)(B).

Response: This recommendation was adopted in part. An additional section, now § 292.23, was added to the regulations in order to clarify what happens if the Governor does not affirmatively concur with the Secretarial Determination.

Several comments suggested that the 18-month period is too long.

Response: This recommendation was not adopted because the one-year time period with a possibility of a six-month extension is reasonable.

Section 292.23 Can the public review the application for a Secretarial Determination?

This section was renamed ''What happens if the Governor does not affirmatively concur with the Secretarial Determination?'' and reorganized.

One comment suggested clarifying former § 292.23 by indicating whether a formal FOIA request must be filed to review the application or if the application is immediately available, subject to the limitations on disclosure in the FOIA, the Privacy Act, and the Trade Secrets Act, upon request.

Response: This recommendation was not adopted because it is implicit that the application is available for review.

One comment suggested replacing, ''the tribe's application * * * over the land'' with the following:

The local BIA agency or Regional Office will provide a minimum of two copies of the tribe's application and all supporting documents for public review to: (1) Governor of the [S]tate's office; (2) Public County Office within the proposed host-community; and (3) the tribe's application and all material will also be available at the local BIA agency or Regional Office having administrative jurisdiction over the land.

Response: This recommendation was not adopted because the modification is unnecessary.

Several comments suggested that § 292.23 explicitly provide that the BIA will consult with the applicant tribe regarding what information should be protected from disclosure.

Response: This recommendation was not adopted; however, it will be suggested that the tribe submit a suggested redacted version of its documentation along with the full application, in order to speed the Department's identification and review of the material the tribe considers protected from disclosure.

One comment stated that § 292.23's public review provisions are, ''inadequate in the digital age.''

Response: This recommendation was not adopted because the provisions set forth in this section are adequate to provide public review.

Section 292.24 Do information collections in this part have Office of Management and Budget approval?

This section was renamed—''Can the public review the Secretarial Determination?'' and reorganized.

One comment suggested that former § 292.24 is in violation of the Paperwork Reduction Act (PRA), which requires the agency to include in its burden estimate all collections of information that will be solicited (even if voluntary) by ''ignoring'' the financial burden imposed on State and local governments and private entities.

Response: This recommendation was not adopted because this section is compliant with the PRA. The information collection requirements, along with a corresponding comment period, were published in the **Federal Register** on January 19, 2007. The requirements were approved by the OMB on February 27, 2007 and expire on February 28, 2010.

General Comments on the Section 2719 Regulations

Several comments suggested adding a so-called, ''grandfather clause'' in the regulations. For example, one comment suggested adding the following language: ''This regulation shall apply prospectively and existing Indian gaming on Indian lands recognized as eligible for gaming by the Secretary, the National Indian Gaming Commission, Congress or a Federal court shall not be disturbed.'' Some comments suggested waiving the regulations for complete applications that have been actively reviewed. Other comments suggested the regulations only apply to applications received after a certain date. Finally, several comments suggested that the regulations should apply to all pending applications with an opportunity to amend.

Response: This recommendation was adopted in part. A new § 292.26 was added in order to address these issues. During the course of implementing IGRA section 20, the Department and the NIGC have issued a number of legal opinions to address the ambiguities left by Congress and provide legal advice for agency decisionmakers, or in some cases, for the interested parties facing an unresolved legal issue. These legal opinions typically have been issued by the Department's Office of the Solicitor or the NIGC's Office of General Counsel. In some cases, the Department or the NIGC subsequently relied on the legal opinion to take some final agency action. In those cases, section 292.26(a) makes clear that these regulations will have no retroactive effect to alter any final agency decision made prior to the effective date of these regulations. In other cases, however, the Department or the NIGC may have issued a legal opinion without any subsequent final agency action. It is expected that in those cases, the tribe and perhaps other parties may have relied on the legal opinion to make investments into the subject property or taken some other actions that were based on their understanding that the land was eligible for gaming. Therefore, section 292.26(b) states that these regulations also shall not apply to applicable agency actions taken after the effective date of these regulations when the Department or the NIGC has issued a written opinion regarding the applicability of 25 U.S.C. 2719 before the effective date of these regulations. In this way, the Federal Government may be able to follow through with its prior legal opinions and take final agency actions consistent with those opinions, even if these regulations now have created a conflict. However, these regulations will not affect the Department's or the NIGC's ability to qualify, modify or withdraw its prior legal opinions. In addition, these regulations do not alter the fact that the legal opinions are advisory in nature and thus do not legally bind the persons vested with the authority to make final agency decisions.

One comment suggested including the Checklist for Gaming Acquisitions Gaming-Related Acquisitions and IGRA Section 2719 Determinations, in the regulations.

Response: This recommendation was not adopted. To the extent that the Checklist is inconsistent with the regulations, the regulations control. Matters in the Checklist that are not covered by the regulations, and are not otherwise inconsistent with the regulations, remain in effect.

One comment suggested that the regulations include a provision that says an application is still eligible for consideration even if a tribe is unable to include all the itemized information in the application.

Response: In order to promote informed decisionmaking, this recommendation was not adopted.

One comment suggested that the regulations clearly define the role of NIGC.

Response: Other than the changes to § 292.3, this recommendation was not adopted. The roles and responsibilities of the NIGC cannot be addressed by the Department of the Interior regulations and instead must be defined by that agency's own regulations.

One comment suggested adding an evidentiary standard to subpart B stating that the burden rests on the applicant tribe to demonstrate that a section 2719 exception applies.

Response: This recommendation was not adopted. It is understood that the burden is on the applicant tribe to establish its eligibility for an exception.

These regulations establish the standards that the applicant must meet.

One comment suggested that subpart B be revised to provide clarity and consistency by specifying which agency or official will issue opinions covered by § 292.4.

Response: This recommendation was adopted in the revised § 292.3.

One comment suggested that the regulations indicate what constitutes final agency action and that the regulations specify what constitutes a record and what is the appeals process, if any.

Response: This recommendation was not adopted. The standard provisions of the Administrative Procedure Act apply.

Several comments suggested that the regulations be rejected in their entirety because they promote ''casino shopping.''

Response: This recommendation was not adopted. The standards included in these regulations will limit the concerns addressed by the commenter consistent with the existing provisions of IGRA.

One comment suggested that if the local community does not want a casino, that should be the end of the inquiry.

Response: This recommendation was not adopted because IGRA requires only a Governor's concurrence, not a local community concurrence.

Several comments suggested that there be a role for public comment and participation in the initial reservation and restored lands to restored tribes processes.

Response: Unlike the exception in IGRA section 2719(b)(1)(A), the exceptions in section 2719(b)(1)(B) do not reference an opportunity for public comment. Because section 2719(b)(1)(B) presents a fact-based inquiry, it is unnecessary to include a requirement for public comment in the regulations. Nonetheless, there are opportunities for public comment in other parts of the administrative process—for example, in the process to take the land in trust and during the NEPA review process. Although the regulations do not provide a formal opportunity for public comment under subpart B of these regulations, the public may submit written comments that are specific to a particular lands opinion. Submissions may be sent to the appropriate agency that is identified in § 292.3.

One comment suggested including a ''fair-play'' clause to ensure that speculators do not use tribes and that there are no misrepresentations in the process.

Response: This recommendation was not adopted because it is beyond the scope of the regulations and inconsistent with IGRA.

One comment suggested that cities be given advance notice of gaming related trust land requests and that there be a good faith requirement that the parties negotiate the issues before the application is accepted.

Response: This recommendation was not adopted because it is beyond the scope of the regulations and inconsistent with IGRA.

One comment suggested that the Department should consult with any other tribe that can show historical ties to a particular site.

Response: This recommendation was not adopted. The Department will consult with a nearby Indian tribe at which time it can explain its significant historical connection to the land, and show any detrimental impact on that tribe's traditional cultural connection to the land.

One comment suggested that tribes be required to submit development agreements.

Response: This recommendation was not adopted because it is beyond the scope of the regulations and inconsistent with IGRA.

One comment suggested that the regulations comply with the mandates of *Adams* v. *U.S.*, 319 U.S. 3212 (1943) and *U.S.* v. *Fox*, 94 U.S. 315 (1876) regarding State cession of jurisdiction. The comment argues that State legislatures must give permission to cede jurisdiction to the Federal Government.

Response: This recommendation was not adopted because the comment raises issues pertaining to 25 CFR part 151—Land Acquisitions, not IGRA.

Several comments suggested that the regulations define ''gaming'' and the scope of gaming, i.e., the range of proposals to which the regulations would apply.

Response: This recommendation was not adopted as outside the scope of these regulations.

Several comments suggested adding a definition for ''detrimental to the surrounding community'' and including the standards by which the Department will make its decision regarding detrimental to the surrounding community.

Response: This recommendation was not adopted because the Department will evaluate detriment on a case-by-case basis based on the information developed in the application and consultation process.

One comment suggested that the Department of the Interior is without authority to issue these regulations since IGRA grants NIGC rule making authority and that only the NIGC has authority to make decisions regarding what constitutes Indian lands under IGRA.

Response: The NIGC's rule making authority is not to the exclusion of the Department of the Interior. Section 2719 specifically references the Secretary of the Interior.

Procedural Requirements

Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget (OMB) has determined that this rule is significant. OMB's guidance on Executive Order 12866 requires that a cost-benefit analysis be done for significant rules and that it contain three elements. These elements are a statement of record, an examination of alternative approaches, and an analysis of costs and benefits.

The anticipated expenses or costs to the public or to the tribes who submit applications for gaming on land acquired after October 17, 1988 will be more than $100 million, therefore the rule is an economically significant regulatory action.

The intent of Executive Order 12866 is to provide decision makers with appropriate information to determine that a regulatory action imposing costs and yielding benefits, or otherwise having the effects sought by authorizing legislation, is both needed and is economically justified.

The Indian Gaming Regulatory Act of 1988 (IGRA) generally prohibits gaming on land acquired in trust after October 17, 1988, but provides several exceptions. Executive Order 12866 applies only to gaming on land under the general exception, which requires a two-part determination by the Secretary that gaming on the land would be in the best interest of the tribe and its members, and not detrimental to the surrounding community.

No cost-benefit analysis is necessary for gaming on newly acquired trust land under the exceptions for lands located within or contiguous to the boundaries of the reservation (former reservation in Oklahoma, or last recognized reservation for tribes outside Oklahoma that have no reservation) of the Indian tribe on October 17, 1988; or lands that are taken into trust as part of a settlement of a land claim, the initial reservation of an Indian tribe acknowledged by the Secretary under the Federal acknowledgment process, or the restoration of lands for an Indian tribe that is restored to Federal recognition. Tribes eligible under these exceptions are permitted to game on

lands acquired in trust after October 17, 1988. For these exceptions the rule establishes regulations for the Secretary in establishing eligibility. Establishing eligibility is a factual analysis and decision that incurs no cost or benefits.

This rule establishes regulations that will impose costs on the tribe, the Bureau of Indian Affairs, State and local governments, and the public in the expectation that gaming revenues will increase for the benefit of the tribe, employees, and the surrounding community.

Tribes wishing to game on land acquired in trust after October 17, 1988 that are not excepted will need to make an application to the Secretary for a two-part determination. The Secretary of the Interior and Federal employees to whom the Secretary's authorities under IGRA are or will be delegated will incur costs for preparing and reviewing the application.

These regulations establish requirements for the submission, review and approval of a land acquisition application and a two-part determination in a timely manner. The anticipated expenses or costs to the public or to the tribes who submit applications will be substantial. Tribes will be required to gather and submit information to the Secretary that substantiates both parts of the two-part determination. The cost of application will vary widely for gaming projects of different size and complexity from two man-years to five man-years, or more for each application.

IGRA requires the Secretary to consult with the Indian tribe and appropriate State, and local officials, including officials of other nearby Indian tribes in making a two-part determination. Responding to the consultation will impose costs on State, local, and other tribal governments. In aggregate the cost is estimated at one to two man-years for each application.

Compliance with the National Environmental Policy Act (''NEPA'') will be required. While NEPA documents are Federal documents to be used by decision makers in taking major Federal actions, the cost associated with preparing the studies will be primarily a cost of the tribe. Depending on the NEPA document required, preparation is expected to cost between 4 and 20 man-years, or more, and the BIA will expend from one to three man-years reviewing and supplementing the studies for each application.

NEPA requires the consideration of input from all parties on the expected impact on the human environment of the proposed major Federal action. The cost to the public and interested parties will vary widely. For controversial actions interested parties may prepare parallel studies that are nearly equal in scope to the NEPA document, so the average estimated cost may be one-half the cost of NEPA compliance, therefore from 2 man-years to 10 man-years for each application.

A determination that results in a gaming facility on after-acquired land will result in costs to the surrounding community for roads, police and fire services, reduction of property tax rolls, government services, education, housing, and problem gambling. The NEPA document will address the mitigation of significant impacts. The cost of impacts that are not significant will be borne by the surrounding community at an unknown level.

On September 21, 2007, the Assistant Secretary—Indian Affairs issued a *Checklist for Gaming Acquisitions, Gaming-related Acquisitions, and IGRA Section 20 Determinations*. The Checklist provides a systematic format for Regional Directors to evaluate specified factors for a two-part determination.

The benefits of gaming on newly acquired land will be for the tribe, employees, State and local government, nearby businesses, and local economic conditions. Jobs created by a gaming establishment generally vary from 500 to 5,000. According to economic studies, the new employee payroll spent locally creates secondary jobs at nearby businesses from 75 to 750. Housing demand by new employees increases local property tax collections by amounts that vary widely depending on the existing stock of dwellings and the tax rate. Income tax collections on the new jobs increase depending on State income tax rates. Studies have shown that unemployment and welfare rolls decrease in the counties surrounding new gaming facilities, with the benefit variable depending on existing unemployment and welfare rates. The net gaming revenue that is available to the tribe will vary depending on the location and size of the new gaming facility, and is expected to be from $5,000,000 to $200,000,000.

Currently, there are approximately 225 Indian tribes engaged in class II (bingo) and class III (casino) gaming. Although IGRA permits a tribe to acquire off-reservation land for gaming, it does not require tribes to do so. The cost of an application is completely optional and avoidable for a tribe. Each applicant tribe may evaluate the high cost of applying to game on off-reservation after-acquired trust land against the expected net gaming revenue to determine whether to incur the cost of complying with this rule.

The alternative considered was continuing to review applications using the *Checklist*. The costs and benefits using the Checklist are essentially the same as under the rule. The alternative was rejected in favor of establishing mandatory factors to be used in making a two-part determination.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Indian tribes are not considered to be small entities for the purposes of this Act.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

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 or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(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.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal government or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required because only Indian tribes may conduct gaming activities on land acquired after October 17, 1988, only if the land meets the exceptions in section 2719 of IGRA.

Takings Implication Assessment (Executive Order 12630)

In accordance with Executive Order 12630, the Department has determined that this rule does not have significant takings implications. The rule does not pertain to the ''taking'' of private property interests, nor does it impact private property. A takings implication assessment is not required.

Federalism (Executive Order 13132)

In accordance with Executive Order 13132, the Department has determined that this rule does not have significant Federalism implications because it does not substantially and directly affect the relationship between the Federal and State governments and does not impose costs on States or localities. A Federalism Assessment is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Does not unduly burden the judicial system;

(b) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(c) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards. The rule does not preempt any statute.

National Environmental Policy Act

The Department has determined that this rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required under the National Environmental Policy Act of 1969.

Paperwork Reduction Act

The information collection has been reviewed and cleared by the Office of Information and Regulatory Affairs, Office of Management and Budget under the Paperwork Reduction Act of 1995, as amended. The collection has been assigned the tracking number of OMB Control Number 1076–0158. The collection of information is unique for each tribe even though each submission addresses the requirements found in § 292.16.

All information is collected in the tribe's application. Respondents submit information in order to obtain a benefit. Each response is estimated to take 1,000 hours to review instructions, search existing data sources, gather and maintain necessary data, and prepare in format for submission. We anticipate that two responses will be submitted annually for an annual burden of 2,000 hours.

Consultation With Indian Tribes (Executive Order 13175)

Under the criteria in Executive Order 13175, we have conducted consultation meetings with tribal leaders regarding the proposed regulations in the following locations: Uncasville, Connecticut on March 30, 2006; Albuquerque, New Mexico on April 5, 2006; Sacramento, California on April 18, 2006 and Minneapolis, Minnesota on April 20, 2006. A notice of the consultation meetings was published in the **Federal Register** on April 11, 2006 (71 FR 18350). In addition, a draft regulation was sent to all tribal leaders in the lower 48 States on March 15, 2006, seeking comments on the draft regulation. Numerous comments were received by the Department. The Department revised the draft regulation in response to written comments and oral comments received at the consultation meetings. No action is taken under this rule unless a tribe submits an application to acquire land under section 2719 of IGRA.

Effects on the Nation's Energy Supply (Executive Order 13211)

This rule does not have a significant effect on the nation's energy supply, distribution, or use as defined by Executive Order 13211.

Information Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Information Quality Act (Pub. L. 106–554).

List of Subjects in 25 CFR Part 292

Indians—business and finance, Indians—gaming.

■ For reasons stated in the preamble, the Bureau of Indian Affairs amends subchapter N, chapter I of title 25 of the Code of Federal Regulations to add part 292 to read as follows:

PART 292—GAMING ON TRUST LANDS ACQUIRED AFTER OCTOBER 17, 1988

Subpart A—General Provisions

Sec.

Subpart B—Exceptions to Prohibition on Gaming on Newly Acquired Lands

''Settlement of a Land Claim'' Exception

''Initial Reservation'' Exception

''Restored Lands'' Exception

Subpart C—Secretarial Determination and Governor's Concurrence

Application Contents

Consultation

Evaluation and Concurrence

Information Collection

Subpart D—Effect of Regulations

Authority: 5 U.S.C. 301, 25 U.S.C. 2, 9, 2719, 43 U.S.C. 1457.

Subpart A—General Provisions

§ 292.1 What is the purpose of this part?

The Indian Gaming Regulatory Act of 1988 (IGRA) contains several exceptions under which class II or class III gaming may occur on lands acquired by the United States in trust for an Indian tribe after October 17, 1988, if other applicable requirements of IGRA are met. This part contains procedures that the Department of the Interior will use to determine whether these exceptions apply.

§ 292.2 How are key terms defined in this part?

For purposes of this part, all terms have the same meaning as set forth in the definitional section of IGRA, 25 U.S.C. 2703. In addition, the following terms have the meanings given in this section.

Appropriate State and local officials means the Governor of the State and local government officials within a 25-mile radius of the proposed gaming establishment.

BIA means Bureau of Indian Affairs.

Contiguous means two parcels of land having a common boundary notwithstanding the existence of non-navigable waters or a public road or right-of-way and includes parcels that touch at a point.

Former reservation means lands in Oklahoma that are within the exterior boundaries of the last reservation that was established by treaty, Executive Order, or Secretarial Order for an Oklahoma tribe.

IGRA means the Indian Gaming Regulatory Act of 1988, as amended and codified at 25 U.S.C. 2701–2721.

Indian tribe or tribe means any Indian tribe, band, nation, or other organized group or community of Indians that is recognized by the Secretary as having a government-to-government relationship with the United States and is eligible for the special programs and services provided by the United States to Indians because of their status as Indians, as evidenced by inclusion of the tribe on the list of recognized tribes published by the Secretary under 25 U.S.C. 479a–1.

Land claim means any claim by a tribe concerning the impairment of title or other real property interest or loss of possession that:

(1) Arises under the United States Constitution, Federal common law, Federal statute or treaty;

(2) Is in conflict with the right, or title or other real property interest claimed by an individual or entity (private, public, or governmental); and

(3) Either accrued on or before October 17, 1988, or involves lands held in trust or restricted fee for the tribe prior to October 17, 1988.

Legislative termination means Federal legislation that specifically terminates or prohibits the government-to-government relationship with an Indian tribe or that otherwise specifically denies the tribe, or its members, access to or eligibility for government services.

Nearby Indian tribe means an Indian tribe with tribal Indian lands located within a 25-mile radius of the location of the proposed gaming establishment, or, if the tribe has no trust lands, within a 25-mile radius of its government headquarters.

Newly acquired lands means land that has been taken, or will be taken, in trust for the benefit of an Indian tribe by the United States after October 17, 1988.

Office of Indian Gaming means the office within the Office of the Assistant Secretary-Indian Affairs, within the Department of the Interior.

Regional Director means the official in charge of the BIA Regional Office responsible for BIA activities within the geographical area where the proposed gaming establishment is to be located.

Reservation means:

(1) Land set aside by the United States by final ratified treaty, agreement, Executive Order, Proclamation, Secretarial Order or Federal statute for the tribe, notwithstanding the issuance of any patent;

(2) Land of Indian colonies and rancherias (including rancherias restored by judicial action) set aside by the United States for the permanent settlement of the Indians as its homeland;

(3) Land acquired by the United States to reorganize adult Indians pursuant to statute; or

(4) Land acquired by a tribe through a grant from a sovereign, including pueblo lands, which is subject to a Federal restriction against alienation.

Secretarial Determination means a two-part determination that a gaming establishment on newly acquired lands:

(1) Would be in the best interest of the Indian tribe and its members; and

(2) Would not be detrimental to the surrounding community.

Secretary means the Secretary of the Interior or authorized representative.

Significant historical connection means the land is located within the boundaries of the tribe's last reservation under a ratified or unratified treaty, or a tribe can demonstrate by historical documentation the existence of the tribe's villages, burial grounds, occupancy or subsistence use in the vicinity of the land.

Surrounding community means local governments and nearby Indian tribes located within a 25-mile radius of the site of the proposed gaming establishment. A local government or nearby Indian tribe located beyond the 25-mile radius may petition for consultation if it can establish that its governmental functions, infrastructure or services will be directly, immediately and significantly impacted by the proposed gaming establishment.

Subpart B—Exceptions to Prohibitions on Gaming on Newly Acquired Lands

§ 292.3 How does a tribe seek an opinion on whether its newly acquired lands meet, or will meet, one of the exceptions in this subpart?

(a) If the newly acquired lands are already in trust and the request does not concern whether a specific area of land is a ''reservation,'' the tribe may submit a request for an opinion to either the National Indian Gaming Commission or the Office of Indian Gaming.

(b) If the tribe seeks to game on newly acquired lands that require a land-into-trust application or the request concerns whether a specific area of land is a ''reservation,'' the tribe must submit a request for an opinion to the Office of Indian Gaming.

§ 292.4 What criteria must newly acquired lands meet under the exceptions regarding tribes with and without a reservation?

For gaming to be allowed on newly acquired lands under the exceptions in 25 U.S.C. 2719(a) of IGRA, the land must meet the location requirements in either paragraph (a) or paragraph (b) of this section.

(a) If the tribe had a reservation on October 17, 1988, the lands must be located within or contiguous to the boundaries of the reservation.

(b) If the tribe had no reservation on October 17, 1988, the lands must be either:

(1) Located in Oklahoma and within the boundaries of the tribe's former reservation or contiguous to other land held in trust or restricted status for the tribe in Oklahoma; or

(2) Located in a State other than Oklahoma and within the tribe's last recognized reservation within the State or States within which the tribe is presently located, as evidenced by the tribe's governmental presence and tribal population.

''Settlement of a Land Claim'' Exception

§ 292.5 When can gaming occur on newly acquired lands under a settlement of a land claim?

This section contains criteria for meeting the requirements of 25 U.S.C. 2719(b)(1)(B)(i), known as the ''settlement of a land claim'' exception.

Gaming may occur on newly acquired lands if the land at issue is either:

(a) Acquired under a settlement of a land claim that resolves or extinguishes with finality the tribe's land claim in whole or in part, thereby resulting in the alienation or loss of possession of some or all of the lands claimed by the tribe, in legislation enacted by Congress; or

(b) Acquired under a settlement of a land claim that:

(1) Is executed by the parties, which includes the United States, returns to the tribe all or part of the land claimed by the tribe, and resolves or extinguishes with finality the claims regarding the returned land; or

(2) Is not executed by the United States, but is entered as a final order by a court of competent jurisdiction or is an enforceable agreement that in either case predates October 17, 1988 and resolves or extinguishes with finality the land claim at issue.

''Initial Reservation'' Exception

§ 292.6 What must be demonstrated to meet the ''initial reservation'' exception?

This section contains criteria for meeting the requirements of 25 U.S.C. 2719(b)(1)(B)(ii), known as the ''initial reservation'' exception. Gaming may occur on newly acquired lands under this exception only when all of the following conditions in this section are met:

(a) The tribe has been acknowledged (federally recognized) through the administrative process under part 83 of this chapter.

(b) The tribe has no gaming facility on newly acquired lands under the restored land exception of these regulations.

(c) The land has been proclaimed to be a reservation under 25 U.S.C. 467 and is the first proclaimed reservation of the tribe following acknowledgment.

(d) If a tribe does not have a proclaimed reservation on the effective date of these regulations, to be proclaimed an initial reservation under this exception, the tribe must demonstrate the land is located within the State or States where the Indian tribe is now located, as evidenced by the tribe's governmental presence and tribal population, and within an area where the tribe has significant historical connections and one or more of the following modern connections to the land:

(1) The land is near where a significant number of tribal members reside; or

(2) The land is within a 25-mile radius of the tribe's headquarters or other tribal governmental facilities that have existed at that location for at least 2 years at the time of the application for land-into-trust; or

(3) The tribe can demonstrate other factors that establish the tribe's current connection to the land.

''Restored Lands'' Exception

§ 292.7 What must be demonstrated to meet the ''restored lands'' exception?

This section contains criteria for meeting the requirements of 25 U.S.C. 2719(b)(1)(B)(iii), known as the ''restored lands'' exception. Gaming may occur on newly acquired lands under this exception only when all of the following conditions in this section are met:

(a) The tribe at one time was federally recognized, as evidenced by its meeting the criteria in § 292.8;

(b) The tribe at some later time lost its government-to-government relationship by one of the means specified in § 292.9;

(c) At a time after the tribe lost its government-to-government relationship, the tribe was restored to Federal recognition by one of the means specified in § 292.10; and

(d) The newly acquired lands meet the criteria of ''restored lands'' in § 292.11.

§ 292.8 How does a tribe qualify as having been federally recognized?

For a tribe to qualify as having been at one time federally recognized for purposes of § 292.7, one of the following must be true:

(a) The United States at one time entered into treaty negotiations with the tribe;

(b) The Department determined that the tribe could organize under the Indian Reorganization Act or the Oklahoma Indian Welfare Act;

(c) Congress enacted legislation specific to, or naming, the tribe indicating that a government-to-government relationship existed;

(d) The United States at one time acquired land for the tribe's benefit; or

(e) Some other evidence demonstrates the existence of a government-to-government relationship between the tribe and the United States.

§ 292.9 How does a tribe show that it lost its government-to-government relationship?

For a tribe to qualify as having lost its government-to-government relationship for purposes of § 292.7, it must show that its government-to-government relationship was terminated by one of the following means:

(a) Legislative termination;

(b) Consistent historical written documentation from the Federal Government effectively stating that it no longer recognized a government-to-government relationship with the tribe or its members or taking action to end the government-to-government relationship; or

(c) Congressional restoration legislation that recognizes the existence of the previous government-to-government relationship.

§ 292.10 How does a tribe qualify as having been restored to Federal recognition?

For a tribe to qualify as having been restored to Federal recognition for purposes of § 292.7, the tribe must show at least one of the following:

(a) Congressional enactment of legislation recognizing, acknowledging, affirming, reaffirming, or restoring the government-to-government relationship between the United States and the tribe (required for tribes terminated by Congressional action);

(b) Recognition through the administrative Federal Acknowledgment Process under § 83.8 of this chapter; or

(c) A Federal court determination in which the United States is a party or court-approved settlement agreement entered into by the United States.

§ 292.11 What are ''restored lands''?

For newly acquired lands to qualify as ''restored lands'' for purposes of § 292.7, the tribe acquiring the lands must meet the requirements of paragraph (a), (b), or (c) of this section.

(a) If the tribe was restored by a Congressional enactment of legislation recognizing, acknowledging, affirming, reaffirming, or restoring the government-to-government relationship between the United States and the tribe, the tribe must show that either:

(1) The legislation requires or authorizes the Secretary to take land into trust for the benefit of the tribe within a specific geographic area and the lands are within the specific geographic area; or

(2) If the legislation does not provide a specific geographic area for the restoration of lands, the tribe must meet the requirements of § 292.12.

(b) If the tribe is acknowledged under § 83.8 of this chapter, it must show that it:

(1) Meets the requirements of § 292.12; and

(2) Does not already have an initial reservation proclaimed after October 17, 1988.

(c) If the tribe was restored by a Federal court determination in which the United States is a party or by a court-approved settlement agreement entered into by the United States, it must meet the requirements of § 292.12.

§ 292.12 How does a tribe establish connections to newly acquired lands for the purposes of the ''restored lands'' exception?

To establish a connection to the newly acquired lands for purposes of § 292.11, the tribe must meet the criteria in this section.

(a) The newly acquired lands must be located within the State or States where the tribe is now located, as evidenced by the tribe's governmental presence and tribal population, and the tribe must demonstrate one or more of the following modern connections to the land:

(1) The land is within reasonable commuting distance of the tribe's existing reservation;

(2) If the tribe has no reservation, the land is near where a significant number of tribal members reside;

(3) The land is within a 25-mile radius of the tribe's headquarters or other tribal governmental facilities that have existed at that location for at least 2 years at the time of the application for land-into-trust; or

(4) Other factors demonstrate the tribe's current connection to the land.

(b) The tribe must demonstrate a significant historical connection to the land.

(c) The tribe must demonstrate a temporal connection between the date of the acquisition of the land and the date of the tribe's restoration. To demonstrate this connection, the tribe must be able to show that either:

(1) The land is included in the tribe's first request for newly acquired lands since the tribe was restored to Federal recognition; or

(2) The tribe submitted an application to take the land into trust within 25 years after the tribe was restored to Federal recognition and the tribe is not gaming on other lands.

Subpart C—Secretarial Determination and Governor's Concurrence

§ 292.13 When can a tribe conduct gaming activities on newly acquired lands that do not qualify under one of the exceptions in subpart B of this part?

A tribe may conduct gaming on newly acquired lands that do not meet the criteria in subpart B of this part only after all of the following occur:

(a) The tribe asks the Secretary in writing to make a Secretarial Determination that a gaming establishment on land subject to this part is in the best interest of the tribe and its members and not detrimental to the surrounding community;

(b) The Secretary consults with the tribe and appropriate State and local officials, including officials of other nearby Indian tribes;

(c) The Secretary makes a determination that a gaming establishment on newly acquired lands would be in the best interest of the tribe and its members and would not be detrimental to the surrounding community; and

(d) The Governor of the State in which the gaming establishment is located concurs in the Secretary's Determination (25 U.S.C. 2719(b)(1)(A)).

§ 292.14 Where must a tribe file an application for a Secretarial Determination?

A tribe must file its application for a Secretarial Determination with the Regional Director of the BIA Regional Office having responsibility over the land where the gaming establishment is to be located.

§ 292.15 May a tribe apply for a Secretarial Determination for lands not yet held in trust?

Yes. A tribe can apply for a Secretarial Determination under § 292.13 for land not yet held in trust at the same time that it applies under part 151 of this chapter to have the land taken into trust.

Application Contents

§ 292.16 What must an application for a Secretarial Determination contain?

A tribe's application requesting a Secretarial Determination under § 292.13 must include the following information:

(a) The full name, address, and telephone number of the tribe submitting the application;

(b) A description of the location of the land, including a legal description supported by a survey or other document;

(c) Proof of identity of present ownership and title status of the land;

(d) Distance of the land from the tribe's reservation or trust lands, if any, and tribal government headquarters;

(e) Information required by § 292.17 to assist the Secretary in determining whether the proposed gaming establishment will be in the best interest of the tribe and its members;

(f) Information required by § 292.18 to assist the Secretary in determining whether the proposed gaming establishment will not be detrimental to the surrounding community;

(g) The authorizing resolution from the tribe submitting the application;

(h) The tribe's gaming ordinance or resolution approved by the National Indian Gaming Commission in accordance with 25 U.S.C. 2710, if any;

(i) The tribe's organic documents, if any;

(j) The tribe's class III gaming compact with the State where the gaming establishment is to be located, if one has been negotiated;

(k) If the tribe has not negotiated a class III gaming compact with the State where the gaming establishment is to be located, the tribe's proposed scope of gaming, including the size of the proposed gaming establishment; and

(l) A copy of the existing or proposed management contract required to be approved by the National Indian Gaming Commission under 25 U.S.C. 2711 and part 533 of this title, if any.

§ 292.17 How must an application describe the benefits and impacts of the proposed gaming establishment to the tribe and its members?

To satisfy the requirements of § 292.16(e), an application must contain:

(a) Projections of class II and class III gaming income statements, balance sheets, fixed assets accounting, and cash flow statements for the gaming entity and the tribe;

(b) Projected tribal employment, job training, and career development;

(c) Projected benefits to the tribe and its members from tourism;

(d) Projected benefits to the tribe and its members from the proposed uses of the increased tribal income;

(e) Projected benefits to the relationship between the tribe and non-Indian communities;

(f) Possible adverse impacts on the tribe and its members and plans for addressing those impacts;

(g) Distance of the land from the location where the tribe maintains core governmental functions;

(h) Evidence that the tribe owns the land in fee or holds an option to acquire the land at the sole discretion of the tribe, or holds other contractual rights to cause the lands to be transferred from a third party to the tribe or directly to the United States;

(i) Evidence of significant historical connections, if any, to the land; and

(j) Any other information that may provide a basis for a Secretarial Determination that the gaming establishment would be in the best interest of the tribe and its members, including copies of any:

(1) Consulting agreements relating to the proposed gaming establishment;

(2) Financial and loan agreements relating to the proposed gaming establishment; and

(3) Other agreements relative to the purchase, acquisition, construction, or financing of the proposed gaming establishment, or the acquisition of the land where the gaming establishment will be located.

§ 292.18 What information must an application contain on detrimental impacts to the surrounding community?

To satisfy the requirements of § 292.16(f), an application must contain the following information on detrimental impacts of the proposed gaming establishment:

(a) Information regarding environmental impacts and plans for mitigating adverse impacts, including an Environmental Assessment (EA), an Environmental Impact Statement (EIS), or other information required by the National Environmental Policy Act (NEPA);

(b) Anticipated impacts on the social structure, infrastructure, services, housing, community character, and land use patterns of the surrounding community;

(c) Anticipated impacts on the economic development, income, and employment of the surrounding community;

(d) Anticipated costs of impacts to the surrounding community and identification of sources of revenue to mitigate them;

(e) Anticipated cost, if any, to the surrounding community of treatment programs for compulsive gambling attributable to the proposed gaming establishment;

(f) If a nearby Indian tribe has a significant historical connection to the land, then the impact on that tribe's traditional cultural connection to the land; and

(g) Any other information that may provide a basis for a Secretarial Determination whether the proposed gaming establishment would or would not be detrimental to the surrounding community, including memoranda of understanding and inter-governmental agreements with affected local governments.

Consultation

§ 292.19 How will the Regional Director conduct the consultation process?

(a) The Regional Director will send a letter that meets the requirements in § 292.20 and that solicits comments within a 60-day period from:

(1) Appropriate State and local officials; and

(2) Officials of nearby Indian tribes.

(b) Upon written request, the Regional Director may extend the 60-day comment period for an additional 30 days.

(c) After the close of the consultation period, the Regional Director must:

(1) Provide a copy of all comments received during the consultation process to the applicant tribe; and

(2) Allow the tribe to address or resolve any issues raised in the comments.

(d) The applicant tribe must submit written responses, if any, to the Regional Director within 60 days of receipt of the consultation comments.

(e) On written request from the applicant tribe, the Regional Director may extend the 60-day comment period in paragraph (d) of this section for an additional 30 days.

§ 292.20 What information must the consultation letter include?

(a) The consultation letter required by § 292.19(a) must:

(1) Describe or show the location of the proposed gaming establishment;

(2) Provide information on the proposed scope of gaming; and

(3) Include other information that may be relevant to a specific proposal, such as the size of the proposed gaming establishment, if known.

(b) The consultation letter must include a request to the recipients to submit comments, if any, on the following areas within 60 days of receiving the letter:

(1) Information regarding environmental impacts on the surrounding community and plans for mitigating adverse impacts;

(2) Anticipated impacts on the social structure, infrastructure, services, housing, community character, and land use patterns of the surrounding community;

(3) Anticipated impact on the economic development, income, and employment of the surrounding community;

(4) Anticipated costs of impacts to the surrounding community and identification of sources of revenue to mitigate them;

(5) Anticipated costs, if any, to the surrounding community of treatment programs for compulsive gambling attributable to the proposed gaming establishment; and

(6) Any other information that may assist the Secretary in determining whether the proposed gaming establishment would or would not be detrimental to the surrounding community.

Evaluation and Concurrence

§ 292.21 How will the Secretary evaluate a proposed gaming establishment?

(a) The Secretary will consider all the information submitted under §§ 292.16–292.19 in evaluating whether the proposed gaming establishment is in the best interest of the tribe and its members and whether it would or would not be detrimental to the surrounding community.

(b) If the Secretary makes an unfavorable Secretarial Determination, the Secretary will inform the tribe that its application has been disapproved, and set forth the reasons for the disapproval.

(c) If the Secretary makes a favorable Secretarial Determination, the Secretary will proceed under § 292.22.

§ 292.22 How does the Secretary request the Governor's concurrence?

If the Secretary makes a favorable Secretarial Determination, the Secretary will send to the Governor of the State:

(a) A written notification of the Secretarial Determination and Findings of Fact supporting the determination;

(b) A copy of the entire application record; and

(c) A request for the Governor's concurrence in the Secretarial Determination.

§ 292.23 What happens if the Governor does not affirmatively concur with the Secretarial Determination?

(a) If the Governor provides a written non-concurrence with the Secretarial Determination:

(1) The applicant tribe may use the newly acquired lands only for non-gaming purposes; and

(2) If a notice of intent to take the land into trust has been issued, then the Secretary will withdraw that notice pending a revised application for a non-gaming purpose.

(b) If the Governor does not affirmatively concur in the Secretarial Determination within one year of the date of the request, the Secretary may, at the request of the applicant tribe or the Governor, grant an extension of up to 180 days.

(c) If no extension is granted or if the Governor does not respond during the extension period, the Secretarial Determination will no longer be valid.

§ 292.24 Can the public review the Secretarial Determination?

Subject to restrictions on disclosure required by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), and the Trade Secrets Act (18 U.S.C. 1905), the Secretarial Determination and the supporting documents will be available for review at the local BIA agency or Regional Office having administrative jurisdiction over the land.

Information Collection

§ 292.25 Do information collections in this part have Office of Management and Budget approval?

The information collection requirements in §§ 292.16, 292.17, and 292.18 have been approved by the Office of Management and Budget (OMB). The information collection control number is 1076–0158. A Federal agency may not collect or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control.

Subpart D—Effect of Regulations

§ 292.26 What effect do these regulations have on pending applications, final agency decisions, and opinions already issued?

These regulations apply to all requests pursuant to 25 U.S.C. 2719, except:

(a) These regulations do not alter final agency decisions made pursuant to 25 U.S.C. 2719 before the date of enactment of these regulations.

(b) These regulations apply to final agency action taken after the effective date of these regulations except that these regulations shall not apply to applicable agency actions when, before the effective date of these regulations, the Department or the National Indian Gaming Commission (NIGC) issued a written opinion regarding the applicability of 25 U.S.C. 2719 for land to be used for a particular gaming establishment, provided that the Department or the NIGC retains full discretion to qualify, withdraw or modify such opinions.

Dated: May 12, 2008.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

[FR Doc. E8–11086 Filed 5–19–08; 8:45 am]

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Federal Register

Tuesday,
May 20, 2008

Part VI

The President

Federal Register
Vol. 73, No. 98
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Presidential Documents

Title 3—

The President

Proclamation 8256 of May 15, 2008

National Safe Boating Week, 2008

By the President of the United States of America

A Proclamation

Our Nation's beautiful waterways provide opportunities for recreational activities for millions of Americans. During National Safe Boating Week, we raise awareness of the importance of practicing and promoting safe boating.

Recreational boating is one of America's most popular pastimes, and it is important for every boater to take proper safety precautions. The United States Coast Guard encourages citizens to take preventive measures such as wearing a life jacket, never boating under the influence of drugs or alcohol, and taking a boating safety course. Too often, accidents occur on boats where the operator had not received boating safety instruction. Receiving a vessel safety check once a year will also help ensure a safe boating experience. To learn important information about boating, visit uscgboating.org. During National Safe Boating Week and throughout the year, I urge all Americans to put safety first when enjoying our country's magnificent waters.

In recognition of the importance of safe boating practices, the Congress, by joint resolution approved June 4, 1958 (36 U.S.C. 131), as amended, has authorized and requested the President to proclaim annually the 7-day period prior to Memorial Day weekend as ''National Safe Boating Week.''

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, do hereby proclaim May 17 through May 23, 2008, as National Safe Boating Week. I encourage the Governors of the 50 States and the Commonwealth of Puerto Rico, and officials of other areas subject to the jurisdiction of the United States, to join in observing this week. I also urge all Americans to learn more about safe boating practices and always act responsibly while on the water.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand eight, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 08–1283
Filed 5–19–08; 8:58 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 8257 of May 15, 2008

World Trade Week, 2008

By the President of the United States of America

A Proclamation

Free and fair trade helps secure a future of freedom and promise. During World Trade Week, we recognize the positive effects of opening markets around the world. Open markets play an integral role in America's economic progress, creating better-paying jobs, expanding consumer choices, and providing increased opportunities for American workers and employers. Free and fair trade also increases economic growth among our trading partners.

My Administration is committed to expanding economic freedom worldwide. We will continue to seek an ambitious outcome in the Doha Round that will reduce and eliminate tariffs and other barriers on goods and open new markets for services trade. The Doha Round provides a once-in-a-generation opportunity to advance open markets, strengthen economic growth, and help millions rise out of poverty.

We also encourage the Congress to approve our pending trade agreements with Colombia, Panama, and South Korea. Our free trade agreement with Colombia is important, because it will support one of our closest allies in the Western Hemisphere currently under assault from a terrorist network. Congressional approval of this agreement would make clear America's unshakeable commitment to advancing the benefits of free markets and the interests of free people.

Today, nearly 250,000 U.S. firms export U.S. products. Ninety-seven percent of those exporters are small- or medium-sized businesses. The number of U.S. small business exporters has more than doubled since 1992. Those businesses have surpassed a quarter of a trillion dollars in annual export sales.

Free and fair trade helps reinforce our Nation's commitments to democracy, transparency, and the rule of law. This week and throughout the year, we recognize the importance of trade in promoting prosperity and freedom in the United States and around the world.

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 May 18 through May 24, 2008, as World Trade Week. I encourage all Americans to observe this week with events, trade shows, and educational programs that celebrate the benefits of trade to our Nation and the global economy.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand eight, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 08–1284
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Florida and South Carolina; Open for comments until further notice; published 2-11-08 [FR 08-00596]

Navajo Nation; Underground Injection Control (UIC) Program:

Proposed Primacy Approval and Minor Revisions; comments due by 5-27-08; published 4-24-08 [FR E8-08961]

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Myclobutanil; comments due by 5-27-08; published 3-26-08 [FR E8-06205]

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Privacy Act of 1974; Publication of Notice of Proposed New Systems of Records and Amendment of Systems to Add New System Managers; comments due by 5-30-08; published 3-31-08 [FR E8-06619]

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Agency Information Collection Activities; Proposals, Submissions, and Approvals; comments due by 5-27-08; published 3-27-08 [FR E8-06030]

FEDERAL TRADE COMMISSION

Business Opportunity Rule; comments due by 5-27-08;

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 ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/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. 6051/P.L. 110–231

To amend Public Law 110-196 to provide for a temporary

extension of programs authorized by the Farm Security and Rural Investment Act of 2002 beyond May 16, 2008. (May 18, 2008; 122 Stat. 878)

Last List May 15, 2008

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