action, with the same title, that is located in the "Rules and Regulations" section of this Federal Register publication.

Dated: December 18, 2006.

#### Donald S. Welsh,

Regional Administrator, Region III. [FR Doc. E6-22415 Filed 12-29-06; 8:45 am] BILLING CODE 6560-50-P

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### 40 CFR Part 63

[EPA-HQ-OAR-2004-0094; FRL-8263-3] RIN 2060-AM75

#### National Emission Standards for **Hazardous Air Pollutants: General Provisions**

**AGENCY:** Environmental Protection

**ACTION:** Proposed rule.

Agency (EPA).

**SUMMARY:** The EPA is proposing amendments to the General Provisions to the national emission standards for hazardous air pollutants (NESHAP). The proposed amendments would replace the policy described in the May 16, 1995 EPA memorandum entitled, "Potential to Emit for MACT Standards—Guidance on Timing Issues," from John Seitz, Director, Office of Air Quality Planning and Standards (OAQPS), to EPA Regional Air Division Directors. The proposed amendments provide that a major source may become an area source at any time by limiting its potential to emit hazardous air pollutants (HAP) to below the major source thresholds of 10 tons per year (tpy) of any single HAP or 25 tpy of any combination of HAP. Thus, under the proposed amendments, a major source can become an area source at any time, including after the first substantive compliance date of an applicable MACT standard so long as it limits its potential to emit to below the major source thresholds. We are also proposing to revise tables in numerous MACT standards that specify the applicability of General Provisions requirements to account for the regulatory provisions we are proposing to add through this notice.

DATES: Comments. Written comments must be received on or before March 5,

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by January 23, 2007, a public hearing will be held on February 2, 2007. Persons interested in attending

the public hearing should contact Ms. Lala Alston at (919) 541-5545 to verify that a hearing will be held.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2004-0094, by one of the following methods:

- www.regulations.gov. Follow the on-line instructions for submitting comments.
- Email: a-and-r-docket@epa.gov, Attention Docket ID No. EPA-HQ-OAR-2004-0094.
- Facsimile: (202) 566-1741, Attention Docket ID No. EPA-HQ-OAR-2004-0094.
- Mail: U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Ave., NW., Room: 3334, Mail Code: 6102T, Washington, DC 20460, Attention E-Docket ID No. EPA-HQ-OAR-2004-
- Hand Delivery: Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Ave., NW., Room: 3334, Mail Code: 6102T, Washington, DC, 20460, Attention Docket ID No. EPA-HQ-OAR-2004-0094. 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-2004-0094. 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 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. Send or deliver information identified as CBI only to the following address: Mr. Roberto Morales, OAQPS Document Control Officer, U.S. EPA (C404–02), Attention Docket ID No. EPA-HQ-OAR-2004-0094, Research Triangle Park, NC 27711. Clearly mark the part or all of the information that you claim to be CBI. 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 vou 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.

Docket: All documents in the docket are listed in the index. Although listed in the www.regulations.gov index, some information is not publicly available, (i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material will be publicly available only in hard copy. Publicly available docket materials are available either electronically at www.regulations.gov or in hard copy at the Air and Radiation Docket, 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 is (202) 566-1742.

Note: The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to make hand deliveries or visit the Public Reading Room to view documents. Consult EPA's Federal Register notice at 71 FR 38147 (July 5, 2006) or the EPA Web site at http://www.epa.gov/epahome/dockets.htm for current information on docket operations, locations and telephone numbers. The Docket Center's mailing address for U.S. mail and the procedure for submitting comments to www.regulations.gov are not affected by the flooding and will remain the same.

Public Hearing. If a public hearing is held, it will be held at the EPA facility complex in Research Triangle Park, NC or an alternate site nearby.

FOR FURTHER INFORMATION CONTACT: Rick Colver, Program Design Group (D205-02), Sector Policies and Programs Division, Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, NC 27711, telephone number (919) 541-5262, electronic mail (e-mail) address, colyer.rick@epa.gov.

#### SUPPLEMENTARY INFORMATION:

Regulated Entities. Categories and entities potentially regulated by this action include all major sources regulated under section 112 of the CAA.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of today's proposal will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of this action will be posted on the TTN's policy and guidance page for newly proposed rules at <a href="http://www.epa.gov/ttn/oarpg">http://www.epa.gov/ttn/oarpg</a>. The TTN provides information and technology exchange in various areas of air pollution control.

#### Outline

The information presented in this preamble is organized as follows:

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  - B. Paperwork Reduction Act
  - C. Regulatory Flexibility Act
  - D. Unfunded Mandates Reform Act
  - E. Executive Order 13132: Federalism
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  - G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act

#### I. Summary of Proposed Action

Today's proposed amendments would replace an existing EPA policy established in a May 16, 1995, EPA memorandum entitled "Potential to Emit for MACT Standards-Guidance on Timing Issues." See "Potential to Emit for MACT Standards-Guidance on Timing Issues," from John Seitz, Director, Office of Air Quality Planning and Standards, to EPA Regional Air Division Directors. The 1995 policy provides that a major source may become an area source by limiting its potential to emit (PTE) HAP emissions to below major source levels (10 tpy or more of any individual HAP or 25 tpy or more of any combination of HAP), no later than the source's first substantive compliance date under an applicable

NESHAP (also known as a MACT standard). Thus, under the 1995 policy, a source that limits its PTE and thereby attains area source designation by the first compliance date of the MACT is not subject to major source requirements. By contrast, a source that does not have a PTE limit in place by the first substantive compliance date would be subject to major source MACT, regardless of its subsequent HAP emissions. The 1995 policy is generally referred to as EPA's "once in, always in" (OIAI) policy for MACT standards.

The regulatory amendments proposed today, if finalized, would replace the 1995 OIAI policy and allow a major source of HAP emissions to become an area source at any time by limiting its PTE for HAP to below the major source thresholds.

#### II. Background

Section 112 of the CAA distinguishes between "major" and "area" sources of HAP. A major source of HAP is defined as "\* \* any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any hazardous air pollutant or 25 tpy or more of any combination of hazardous air pollutants." (section 112(a)(1)). An area source is defined as any stationary source of HAP that is not a major source. (section 112(a)(2)). "Hazardous air pollutant" is defined as "\* \* \* any air pollutant listed pursuant to subsection (b)" of section 112. (section 112(a)(6)).

"Potential to emit" is currently defined in the NESHAP General Provisions as "\* \* \* the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the stationary source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable." (40 CFR 63.2).1

The CAA treats the regulation of major sources and area sources differently. Generally, major source categories are listed under section 112(c)(1), while area source categories are listed under section 112(c)(3) following a finding that either the source category presents a threat of adverse human health or environmental effects that warrants regulation under section 112, or the category falls within the purview of CAA section 112(k)(3)(B). See CAA section 112(c)(1)and (3). Standards for major sources are based on the performance of the maximum achievable control technology (MACT) currently employed by the best controlled sources in the industry. Standards for area sources may be based on MACT, but alternatively may be based on generally available control technology (GACT) or generally available management practices that reduce HAP emissions. See CAA section 112(d)(2) and (5).

Major sources can achieve significant HAP emission reductions and emit at levels below the major source thresholds through a variety of mechanisms. In order to be recognized as an area source and thereby avoid the application of major source MACT requirements, however, a major source must limit its potential to emit HAP to ensure that its emissions remain below major source thresholds. See CAA section 112(a)(1) (defining major source HAP thresholds); 40 CFR 63.2 (same).

A significant question that arose early in the development of the MACT program was when major sources may limit their PTE to below the major source thresholds in order to avoid having to comply with major source MACT standards. The EPA issued

component in the potential to emit definition in the PSD and NSR (40 CFR parts 51 and 52) regulations. In Clean Air Implementation Project v. EPA, No. 96–1224 1996 WL 393118 (D.C. Cir. June 28, 1996) (CAIP), the court vacated and remanded the federal enforceability requirement in the title V (40 CFR part 70) regulations. The CMA and the CAIP orders were similar in that they contained no independent legal analysis, but rather relied on the National Mining decision.

Before any of the above cases were decided, EPA implemented a "transitional" policy to allow sources to rely on state-only enforceable PTE limits. "Options for Limiting the Potential to Emit (PTE) of a Stationary Source Under Section 112 and Title V of the Clean Air Act (Act)" (Jan. 25, 1995), available at http://www.epa.gov/Region7/programs/artd/air/title5/t5memos/ptememo.pdf. After the court decisions, EPA extended the transition policy several times. See "Third Extension of January 25, 1995 Potential to Emit Transition Policy (December 20, 1999), available at http:// www.epa.gov/Region7/programs/artd/air/title5/ t5memos/4thext.pdf. Under the Third Extension, sources can rely on state-only enforceable PTE limits until we finalize our response to the remands. EPA intends to issue a proposed PTE rule in the near future.

¹As explained further below, in National Mining Association v. EPA, 59 F. 3d 1351(D.C. Cir. 1995) (NMA), the D.C Circuit remanded the definition of "potential to emit" found in 40 CFR 63.2 to the extent it required that physical or operational limits be "federally enforceable." The court did not vacate the rule during the remand. Two additional cases were decided after National Mining. In Chemical Manufacturers Ass'n v. EPA, (CMA) No. 89–1514, 1995 WL 650098 (D.C. Cir. Sept. 15, 1995), the court, in light of National Mining, vacated and remanded to EPA the federal enforceability

guidance on this and related issues on May 16, 1995, in a memorandum from John Seitz, Director of the Office of Air Quality Planning and Standards, to the EPA regional air division directors. The May 1995 memorandum addressed three issues:

- "By what date must a facility limit its potential to emit if it wishes to avoid major source requirements of a MACT standard?"
- "Is a facility that is required to comply with a MACT standard permanently subject to that standard?"
- · "In the case of facilities with two or more sources in different source categories: If such a facility is a major source for purposes of one MACT standard, is the facility necessarily a major source for purposes of subsequently promulgated MACT standards?"

In the May 1995 memorandum, EPA took the policy position that the latest date by which a source could obtain area source status by limiting its HAP PTE would be the first substantive compliance date of an applicable MACT standard. For existing sources, this would be no later than 3 years after the effective date of the regulation (which for MACT standards is the date of publication in the Federal Register), but could be sooner; for example, some standards for leaking equipment require compliance no later than 6 months after the effective date of the regulation.

Furthermore, in the May 16, 1995, memorandum, EPA stated that once a source was required to comply with a MACT standard, i.e., once the first substantive compliance date had passed without the source limiting its PTE, it must always comply, even though compliance with the standard may reduce HAP emissions from the source to below major source thresholds.

Finally, the May 16, 1995 memorandum provided that a source that is major for one MACT standard would not be considered major for a subsequent MACT standard if the potential to emit HAP emissions were reduced to below major source levels by complying with the first MACT standard.

The 1995 memorandum, on which we did not seek notice and comment, set forth transitional policy guidance and was intended to remain in effect only until such time as the Agency proposed and promulgated amendments to the Part 63 General Provisions. We are today proposing to amend the General Provisions and replace the 1995 policy memorandum.

#### III. Rationale for the Proposed Amendments

A. Why Is EPA Proposing These Amendments?

EPA issued the May 1995 memorandum in an effort to provide answers to pressing questions raised shortly after the inception of the air toxics program. Since issuance of the memorandum, EPA has received questions concerning the OIAI policy and recommendations to revise the policy.

In August 2000, EPA met with representatives of the State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) to explore ways to revise the OIAI policy to promote pollution prevention (P2). The STAPPA/ALAPCO stated its belief that the OIAI policy provides no incentive for sources, after the first substantive compliance date of a MACT standard, to implement P2 measures in order to reduce their emissions to below major source thresholds because there are no benefits to be gained, e.g., no reduced monitoring, recordkeeping, and reporting, and no opportunity to get out of major source requirements. In light of these concerns, the STAPPA/ALAPCO recommended that the Agency revise the OIAI policy to encourage P2. To accommodate some of these P2 concerns, in May 2003 we proposed to amend the part 63 General Provisions (68 FR 26249; May 15, 2003) in the following ways. First, the proposed amendments encourage P2 by allowing an affected source that completely eliminates all HAP emissions after the first compliance date of the MACT standard to submit a request to the Administrator that it no longer be subject to the MACT standard. If the request is approved, the affected source would no longer be subject to the MACT standard provided the source does not resume emitting HAP from the regulated source(s) of emissions. Second, the proposed amendments encourage P2 by allowing an affected source that uses P2 to reduce HAP emissions to the level required by the MACT standard, or below, to request "P2 alternative compliance requirements," which could include alternative monitoring, recordkeeping and reporting. If the request is approved, the alternative compliance requirements would replace the compliance requirements in the MACT standard.

It is important to understand the differences in applicability between the P2 amendments, and OIAI and today's proposal revising that policy. The

proposed P2 amendments are targeted at the "affected source" as that term is defined in 40 CFR 63.2. "Affected source" describes the collection of regulated emission points defined as the entity subject to a specific MACT standard. See 40 CFR 63.2. For example, an affected source could be a single production unit or the combination of all production units within a single contiguous area and under common control, or a single emission point or a collection of many related emission points within a single contiguous area and under common control. Each MACT standard defines the "affected source" for regulation.

By contrast, the 1995 OIAI policy and today's proposed amendments that seek to replace that policy focus on "major sources," as defined in 40 CFR 63.2. As explained above, major sources are defined by the total amount of HAP emitted from a stationary source or group of stationary sources located within a contiguous area and under common control. See 40 CFR 63.2. A major source can include several different affected sources subject to

multiple MACT standards.

The relationship between the proposed P2 amendments and today's proposal is best illustrated by the following example. Consider a major source that emits 50 tpy total HAP which is comprised of 5 affected sources subject to various MACT. If the Agency finalizes the P2 amendments and one of the affected sources that emitted 15 tpy of HAP eliminated all its HAP emissions, the affected source, if its request is approved by the permitting authority, would no longer be subject to MACT. However, the other four affected sources within the major source would still be subject to their respective MACT because the sources' combined emissions would be 35 tpy, which exceeds the major source threshold. We are considering the comments received on the proposed P2 amendments and have not yet taken any final action with regard to that proposal.

In addition to the feedback from STAPPA concerning the OIAI policy, EPA has heard from others who have taken the position that the OIAI policy serves as a disincentive for sources to reduce emissions of HAP beyond the levels actually required by an applicable standard. For example, one source whose emissions after applying MACT were still above major source thresholds has significant emissions of one HAP for which the MACT standard does not require reductions. The source has indicated it is willing to substantially reduce that HAP to achieve area source status, but would not do so as long as

the OIAI policy applied and the source could not be redesignated as an area source. Another source, which has maintained actual HAP emissions well below major source levels, discovered its PTE limit (designating it as an area source) was based on an erroneous emission factor. Even though actual emissions have always been below major source levels, its PTE, when recalculated using the correct emission factors, exceeded the major source threshold. In this example, the source did not realize its problem until after the first substantive compliance date, which meant that, under the OIAI policy, the source was subject to the MACT standard.

Moreover, the OIAI policy, as written, does not encourage sources to explore the use of different control techniques, P2, or new and emerging technologies that would result in lower emissions. Thus, under OIAI, the same source could be subject to substantially different requirements based solely on the date by which the source reduced its potential to emit HAP to below the major source thresholds. For example, under OIAI, a major source that is subject to a MACT standard may become an area source prior to the first substantive compliance date of that standard, without reaching MACT levels of emissions reductions. As a result, prior to the first substantive compliance date of a MACT standard, a source emitting 30 tpy of a combination of HAP could reduce emissions by 10 tpy, take a HAP PTE limitation at 20 tpy, emit less than 10 tpy of any one HAP, and become an area source. Such a source would no longer meet the applicability criteria of a potentially applicable major source MACT standard and would, therefore, not be required to comply with that standard. By contrast, if the same source reduced its emissions of HAP to 20 tpy (and didn't emit 10 tpy or more of any single HAP) by complying with an applicable major source MACT standard after the first substantive compliance date of the standard, it would have to continue to comply with the requirements of the major source MACT standard because the first substantive compliance date had passed. The only difference in these two situations is the date on which the source reduced its emissions. As explained below, there is nothing in the CAA that compels the conclusion that a source cannot attain area source status after the first substantive compliance date of a MACT standard.

B. What Is the Authority for This Action?

As noted above, Congress expressly defined the terms "major source" and "area source" in section 112(a). A "major source" is a source that "emits or has the potential to emit considering controls, in the aggregate," 10 tons per year or more of any HAP or 25 tons per vear or more of any combination of HAP, and an "area source" is any stationary source that is not a "major source." CAA section 112(a)(1) and (a)(2).2 Notably absent from these definitions is any reference to the compliance date of a MACT standard. Rather, Congress defined major source by reference to the amount of HAP the source "emits or has the potential to emit considering controls," and required EPA to determine whether that amount exceeds certain specified levels. 42 U.S.C. 112(a)(1) (emphasis added). Congress placed no temporal limitations on the determination of whether a source emits or has the potential to emit HAP in sufficient quantity to qualify as a major source.

In March 1994, EPA issued final regulations interpreting the term "major source." See 59 FR 12408 (March 16, 1994) (the General Provisions governing the section 112 program).3 The regulatory definition of "major source" is virtually identical to the statutory definition. Specifically, EPA defined "major source" as "any stationary source or group of stationary sources \* \* \* that emits or has the potential to emit considering controls" at or above major source thresholds. 40 CFR 63.2. EPA, in turn, defined the phrase "potential to emit" that appears in the definition of "major source," as the "maximum capacity of a stationary

source to emit a pollutant under its physical and operational design." *Id.* To give effect to the phrase "considering controls" in the statutory definition of "major source," (CAA section 112(a)(1)), EPA further defined the term "potential to emit" in its regulations as follows:

Any physical or operational limitation on the capacity of the stationary source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable.

40 CFR 63.2.

The Court of Appeals for the District of Columbia Circuit reviewed EPA's definition of "potential to emit" and, in July 1995, remanded the definition to EPA to the extent the definition required that physical or operational limitations be "federally enforceable." National Mining Ass'n v. EPA, 59 F.3d 1351 (D.C. Cir. 1995).4 In remanding the rule, the D.C. Circuit held that "EPA has not explained \* \* \* how its refusal to consider limitations other than those that are 'federally enforceable' serves the statute's directive to 'consider[] controls' when it results in a refusal to credit controls imposed by a state or locality even if they are unquestionably effective." Id. at 1363. The court also noted that "[i]t is not apparent why a state's or locality's controls, when demonstrably effective, should not be credited in determining whether a source subject to those controls should be classified as a major or area source.' Id.; see also id. at 1365 ("By no means does that suggest that Congress necessarily intended for state emissions controls to be disregarded in determining whether a source is classified as a 'major' or 'area' source.").

As noted above, EPA is in the process of developing a proposed PTE rule that responds to the Court's remand in *NMA* and, among other things, proposes amendments to the definition of PTE in 40 CFR part 63. EPA anticipates issuing the proposed rule in the near future. See n.1.

Today's proposed rule is wholly consistent with the plain language of section 112(a)(1). Specifically, under today's proposed regulations, any source with a PTE limit that limits HAP emissions to less than the major source thresholds is, by definition, not a "major source" because its "potential to emit considering controls" is less than the identified major source thresholds. 42 U.S.C. 7412(a)(1) (emphasis added). By

<sup>&</sup>lt;sup>2</sup> In addition to "major sources" and "area sources," Congress identified a third type of source under section 112: electric utility steam generating units ("Utility Units"). See section 112(a)(8). Congress created a special statutory provision for Utility Units in section 112(n)(1)(A). Discussion of that provision is not relevant to this proposal. Today's proposal focuses solely on "major sources" and "area sources." See CAA 112(a)(1), 112(a)(2).

<sup>&</sup>lt;sup>3</sup> The General Provisions in 40 CFR Part 63 eliminate the repetition of general information and requirements in individual NESHAP subparts by consolidating all generally applicable information in one location. The General Provisions include sections on applicability, definitions, compliance dates, and monitoring, recordkeeping and reporting requirements, among others. In addition, the General Provisions include administrative sections concerning actions that the EPA Administrator must take, such as making determinations of applicability, reviewing applications for approval of new construction, responding to requests for extensions or waivers of applicable requirements, and generally enforcing NESHAP. The General Provisions apply to every facility that is subject to a NESHAP subpart, except where specifically overridden by that subpart.

<sup>&</sup>lt;sup>4</sup> In that same opinion, the Court otherwise upheld EPA's definition of "major source."

contrast, under the 1995 policy memorandum, a source is treated as a major source in perpetuity even if sometime after the first compliance date of a MACT standard the source no longer meets the statutory definition of "major source" (i.e., the source has a "potential to emit considering controls" less than the major source thresholds). EPA believes that the approach proposed today gives full effect to the statutory definitions and to the distinctions that Congress created between "major" and "area" sources. Id. at 1353-54 (discussing differences in requirements affecting major and area sources and recognizing that Congress did not contemplate that all area sources be subject to regulation); see also 42 U.S.C. 7412(c)(3), 7412(k)(3)(B).

Moreover, nothing in the structure of the Act counsels against today's proposed approach. Congress defined major and area sources differently and established different requirements for such sources. See NMA, 59 F3d 1353-54. The 1995 policy memorandum creates a dividing line between major and area sources that does not exist on the face of the statute by including a temporal limitation on when a source can become an area source by limiting its PTE.

Furthermore, as noted in the May 1995 OIAI memorandum itself, EPA intended that the memorandum be a transitional policy which would remain in effect only until EPA undertook notice and comment rulemaking, which it is now doing. Nothing precludes the Agency from revising a prior agency position where, as here, we have a principled basis for doing so. As the Supreme Court recently observed:

"An initial agency interpretation is not instantly carved in stone. On the contrary, the agency \* \* \* must consider varying interpretations and the wisdom of its policy on a continuing basis, Chevron, supra at 863-64, for example, in response to changed factual circumstances, or a change in administrations.

National Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005) (citations omitted); see also American Trucking Ass'n v. Atchison, Topeka & Santa Fe Ry., 387 U.S. 397, 416 (1967); Mobil Oil Corp. v. EPA, 871 F.2d 149, 152 (D.C. Cir. 1989) ("an agency's reinterpretation of statutory language is nevertheless entitled to deference, so long as the agency acknowledges and explains the departure from its prior views"). We solicit comment on all aspects of today's proposal, including EPA's position that today's proposed approach gives proper effect to the statutory definitions in

section 112(a) and is consistent with the language and structure of the Act.

C. What Are the Implications of This Proposed Action?

In the 1995 memorandum, EPA stated, as a matter of policy, that without the OIAI policy, facilities could backslide from MACT levels of control and increase their emissions to a level slightly below the major source thresholds. The 1995 memorandum further asserts that if this occurred, the "maximum achievable emissions reductions that Congress mandated for major sources would not be achieved.' We agree that Congress mandated that sources that meet the definition of "major source" in section 112(a) be required to comply with MACT, but a source that takes a PTE limit that limits its PTE to below the major source HAP thresholds does not, as explained above, meet the statutory definition of "major source," and therefore should not be subject to the requirements applicable to a major source.

EPA recognizes that some sources in complying with an applicable MACT standard will reduce HAP emissions below the major source thresholds because that is the level of emissions necessary to maintain compliance with the MACT standard. If this rule is finalized, we believe it is unlikely that such sources would, in becoming area sources, increase their current emissions to a level just below the major source thresholds. While this may occur in some instances, it is more likely that sources will adopt PTE limitations at or near their current levels of emissions, which is the level needed to meet the MACT standard(s).<sup>5</sup> This conclusion is based on a number of factors.

First, many sources attaining area source status do so because of the control devices that they installed to meet the MACT standards. Such control systems are designed to operate a certain way and cannot be operated at a level which achieves only a partial emission reduction, i.e., the devices either operate effectively or they do not. Thus, we expect that sources that have attained area source status by virtue of a particular control technology will maintain their current level of emissions.

Second, several additional programs have been implemented under the CAA since the issuance of the 1995 OIAI memorandum. Specifically, in many cases, sources will maintain the level of emission reduction associated with the MACT standard because that level is needed to comply with other requirements of the Act, such as RACT controls on emissions of volatile organic compounds, which are also HAP. Sources may also need to maintain their current level of control for other reasons, including, for example, for emissions netting and emissions trading purposes.

Third, if this rule is finalized, those sources that seek to maintain area source status will likely take PTE limits at or near their current MACT emission levels to ensure that their emissions remain below the major source thresholds. Sources have no incentive to establish their PTE limit too close to the major source thresholds because repeated or frequent exceedances above the PTE could provide the permitting authority reason to revoke the PTE and bring an enforcement action. 42 U.S.C. 7413(g); see NMA, 59 F.3d at 1363 n.20 (noting that a source that claims to have lowered its emissions to below major source thresholds, but has actual emissions that exceed such thresholds, can be subject to sanctions under CAA section 113).

Fourth, permitting authorities will likely encourage emission reduction maintenance and impose more stringent PTE terms and conditions on the source the closer the source's PTE is to the major source thresholds. Such terms and conditions may include shorter compliance periods and perhaps more robust monitoring, recordkeeping, and reporting to ensure that the source does not exceed its PTE.

Finally, many sources that take a PTE limitation to become an area source will ultimately be subject to area source standards issued pursuant to section 112. To date, EPA has issued emission standards for approximately 20 area source categories. Over the next three years, EPA is required to develop area source standards for approximately 50 additional categories. While the level at which those standards will be set is not known at this time, the standards will reflect at least generally available control technology and some may be set at MACT-based levels, which would mean that many sources could be required to maintain their current emission levels. See, e.g., 42 U.S.C. 7412(d)(2), (d)(5), 7412(k)(3)(B).

For all of these reasons, we believe it is unlikely that a source that currently emits at a level below the major source

<sup>&</sup>lt;sup>5</sup> We recognize that there may be instances where a source will emit at a level that is below the level required by the MACT. EPA cannot mandate that sources emit at such a level. Accordingly, in discussing potential emission increases as the result of today's proposal, we properly limit our discussion to those sources that emit below the major source thresholds because they must do so to meet the MACT standard, not those sources that, for other reasons, emit at a level below the level required by the MACT standard.

thresholds as the result of compliance with a MACT standard would increase its emissions in response to this rule. However, even if such increases occur, the increases will likely be offset by emission reductions at other sources that should occur as the result of this proposal. Specifically, this proposal provides an incentive for those sources that are currently emitting above major source thresholds and complying with MACT, to reduce their HAP emissions to below the major source thresholds.

We solicit comment on the issues discussed above. Please include with your comments any relevant factual information and describe the scenarios under which sources, in response to this proposal, would likely increase emissions from the level required by MACT to just below the major source thresholds.

### D. What Regulatory Changes Are We Proposing?

For the reasons discussed above, we believe that the 1995 OIAI policy should be replaced and today are proposing to allow a major source to become an area source at any time by taking a PTE limit on its HAP emissions. Specifically, we are proposing to amend section 63.1 by adding a new paragraph (c)(6). That paragraph would specify that a major source may become an "area source" at any time by restricting its "potential to emit" (PTE) hazardous air pollutants, as that term is defined in 40 CFR Part 63, Subpart A, to below major source thresholds. 67 If a source takes a PTE limit, it will no longer be subject to major source requirements that apply to HAP emissions, subject to certain restrictions described below. The major source requirements to which the source would no longer be subject, include, but are not limited to, compliance assurance monitoring and title V requirements

(assuming the source is not otherwise subject to title V permitting). As an area source complying with its PTE limit, the source would nonetheless be subject to any applicable area source requirements issued pursuant to section 112, and title V if EPA has not exempted the area source category from such requirements.

There are two provisions of the current regulations that are relevant for background purposes: Sections 63.6(b)(7) and 63.6(c)(5). Section 63.6(b)(7) provides that when an area source becomes a major source "by the addition of equipment or operations that meet the definition of new affected source in the relevant standard, the portion of the existing facility that is a new affected source must comply with all requirements of that standard applicable to new sources," and the source must comply with the relevant standard upon startup. 40 CFR 63.6(b)(7) (Emphasis added). Section 63.6(c)(5), in turn, states: "Except as provided in section 63.6(b)(7)," an area source that becomes a major source is treated as an existing major source and must comply with applicable MACT standards by the date specified in the standard for area sources that become major sources.8 For those major source MACT standards that do not specify such a date, the affected source has a period of time to comply that is equivalent to the compliance period specified in the standard for existing affected sources (which is up to three vears). 40 CFR 63.6(c)(5). Section 63.6(c)(5) was designed to address existing area sources that have not previously been subject to a MACT standard, but that later increase their emissions and become a major source. Section 63.6(c)(5) only applies, however, where the change that resulted in the increased emissions does not meet the definition of a new affected

source under the relevant major source MACT standard.

As noted above, EPA today proposes to amend section 63.1 to add a new paragraph (c)(6) that would authorize a major source to become an area source at any time by obtaining a PTE limit limiting its HAP emissions to below major source thresholds. EPA proposes, however, the following restrictions.

The first restriction relates to a regulatory provision that we are adding to address the situation where sources switch between major and area source status more than once. Specifically, there may be situations where sources that are major sources as of the first substantive compliance date of the MACT standard later take PTE limitations to attain area source status. and then subsequently seek to switch back to major source status. In these situations, EPA proposes that 40 CFR 63.6(c)(5) not apply, and that, except as noted below, the source must meet the major source MACT standard immediately upon that standard again becoming applicable to the source. See proposed regulations at 40 CFR 63.1(c)(6)(i).9 In this scenario, existing affected sources at the major source were previously subject to the MACT standard. The affected sources therefore should be able to comply with the standard immediately upon the standard again becoming applicable to them. Id.

To date, we have identified one set of circumstances where additional time would be necessary for the source to comply with the major source MACT. Specifically, there are situations where major source MACT rules may be amended and either become more stringent or apply to additional emission points or additional HAP. For example, under section 112(d)(6) MACT standards must be reviewed every 8 years and revised if necessary. If revisions issued pursuant to section 112(d)(6) increase the stringency of the standards or revise the standards such that they apply to additional emission points or HAP, it would be necessary to allow existing sources sufficient time to come into compliance with the new requirements. The revision of a MACT standard pursuant to section 112(d)(6) is only one example of a situation where a MACT rule may be revised. MACT rules are also amended for other reasons, including as the result of settlements resolving pending litigation over a standard. Any type of rule amendment situation where the

<sup>&</sup>lt;sup>6</sup>We recognize that there may be sources that were major sources as of the first substantive compliance date of a MACT standard that, by complying with non-section 112 CAA requirements, became area sources for HAP emissions. In this instance, EPA proposes that the source obtain a PTE limit for its HAP emissions to ensure that those emissions remain below major source thresholds.

<sup>&</sup>lt;sup>7</sup> Some individual MACT standards in Part 63 provide sources the opportunity to become area sources not by limiting total mass emissions directly, but by limiting material use or by taking other measures, which in turn, correlate to emissions below major source levels (e.g., see subpart KK, Printing and Publishing and subpart JJ, Wood Furniture Manufacturing Operations (limiting HAP usage to below major source thresholds). We recommend that sources refer to the applicable NESHAP for guidance in determining whether the source meets the major source thresholds. See 40 CFR 63.2 (defining "potential to emit"by reference to physical or operational limitations, including, for example, "restrictions on hours of operation, or on the type or amount or material combusted, stored, or processed").

<sup>&</sup>lt;sup>8</sup> EPA explained the purpose of section 63.6(b)(7) in the preamble to the General Provisions as follows:

Section 63.6(b)(7) states that an unaffected new area source that increases its emissions of (or its potential to emit) HAP such that it becomes a major source, must comply with the relevant emission standard immediately upon becoming a major source. [Under section 63.6(b)(7), a]n unaffected existing area source that increases its emissions (or its potential to emit) such that it becomes a major source, must comply by the date specified for such a source in the standard. If such a date is not specified, the source would have an equivalent period of time to comply as the period specified in the standard for other existing sources. However, if the existing area source becomes a major source by the addition of a new affected source, or by reconstructing, the portion of the source that is new or reconstructed is required to comply with the standard's requirements for new sources.

<sup>59</sup> FR 12408, 12413 (Mar. 16, 1994).

<sup>&</sup>lt;sup>9</sup> The new proposed 40 CFR 63.1(c)(6)(i), like section 63.6(c)(5), is subject to the provisions of 40 CFR 63.6(b)(7).

amendments substantively modify the MACT could necessitate additional time for compliance. We are thus proposing that sources that switch status from major source to area source and then revert back to major source status, be allowed additional time for compliance if the major source standard has changed such that the source must undergo a physical change, install additional controls and/or implement new control measures. We propose that such sources have the same period of time to comply with the revised MACT standard as is allowed for existing sources subject to the revised standard. We solicit comment on this proposed compliance time-frame and whether the proposed regulatory text adequately captures the intended exception.

We are proposing the immediate compliance rule, with the above-noted exception, because we believe that in most cases, sources achieve and maintain area source status by operating the controls they used to meet the MACT standard. Therefore, a source that reverts to major source status should be in a position to comply immediately with the MACT standard. Sources may, in addition to, or in lieu of, operating controls, reduce their production level or hours of operation, but regardless of the means employed to attain area source status, we believe that the sources will likely not be removing the controls used to meet the MACT standard. We recognize that some MACT standards allow alternative compliance options, such as the use of low HAP materials, but these options should continue to be available for the affected source. Moreover, the addition of equipment or process units to an existing affected source should not change the source's ability to meet the MACT standard upon startup of the new equipment or unit because the equipment or process units should be accompanied by either a tie-in to existing controls or installation of new controls. See also 40 CFR 63.6(b)(7) (applying to new affected sources). We solicit comment on whether our assumptions, as stated in this paragraph, are correct.

More specifically, we solicit comment on the appropriateness of the proposed immediate compliance rule and whether such rule should be finalized. If it should be maintained, we solicit comment on whether there are other situations, in addition to the one noted above, that would necessitate an extension of the time period for compliance with the MACT standards. We further solicit comment on whether we should instead allow all sources that revert back to major source status a

specific period of time in which to comply with the MACT standard, which would be consistent with the approach provided for in 40 CFR 63.6(c)(5). If we pursue this approach in the final rule, we request comment on whether we should provide the same time periods as are already provided for in 40 CFR 63.6(c)(5), or whether a different time period is appropriate and why. To the extent a commenter proposes a compliance time-frame, we request that the commenter explain the basis for providing that time-frame. Thus, depending on the comments received and the factual circumstances identified, we will consider (1) not finalizing the immediate compliance, with exceptions, approach, and instead providing all sources that revert back to major source status a defined period of time to comply consistent with the provisions of 40 CFR 63.6(c)(5); and (2)retaining the proposed immediate compliance rule, and adopting additional exceptions to that rule, if we receive persuasive and concrete scenarios that we believe would warrant allowing additional time to comply with a previously applicable MACT standard. 10 If we pursue the former approach, we would likely amend 40 CFR 63.6(c)(5). If we pursue the latter approach and retain the immediate compliance rule, but create exceptions in addition to the one noted above, there are two ways to implement the exceptions: Through a case-by-case compliance extension request process or by identifying in the final rule specific exceptions to the immediate compliance rule and providing a time period for compliance for each identified exception. Under the case-by-case approach, the permitting authority could grant limited additional time for compliance upon a specific showing of need. A case-by-case compliance extension request process would call for the owners or operators of sources to submit to the relevant permitting authority a request that (i) identifies the specific additional time needed for compliance, and (ii) explains, in detail, why the source needs additional time to come into compliance with the MACT standard. The permitting authority would review the request and could either approve it in whole, or in part

(i.e., by specifying a different compliance timeframe or allowing different timeframes for different parts of the affected sources), or deny the request.

We envision that a request for a compliance extension, if such an option is provided in the final rule, would ordinarily be made in the context of the title V permit application or an application to modify an existing title V permit. Any compliance extension, if granted, would be memorialized in the title V permit. Another option sources may consider is seeking approval to include in their title V permit alternative operating scenarios that address the source's different projected operating scenarios. By incorporating alternative operating scenarios into the permit, the source could avoid having to reopen and revise the permit if it chooses to switch source status and again become a major source.

If we retain the proposed immediate compliance rule with exceptions, we will also consider the option of including in the final rule defined compliance extension time-frames for defined factual scenarios, as we have done for the exception described above. Under this approach, if a source satisfies the criteria identified in the final rule, it would automatically be afforded the defined extension of time to comply with the MACT standard upon the source again becoming subject to MACT. This extension approach would be useful if there are specific factual scenarios that affect a broad number of sources, because defining the compliance extension time-frame in the final rule eliminates the burden on permitting authorities associated with the case-by-case approach.

In submitting your comments on the above-noted issues and proposed section 63.6(c)(6), please identify, with specificity, the factual circumstances that would warrant a compliance extension, explain why the source would need the extension under the circumstances identified, and why the source could not comply with the standard immediately upon returning to major source status given the identified circumstances. We specifically solicit comment on our discussion above as to the mechanics of obtaining a compliance extension if a case-by-case approach is finalized, including, for example, the type of information requested from the source seeking the proposed compliance extension, the permit vehicle used to obtain the extension, and any limitations on

<sup>&</sup>lt;sup>10</sup> The new proposed regulatory provision at 40 CFR 63.1(c)(6)(i) is subject to the provisions of 40 CFR 63.6(b)(7). Thus, if a source adds a piece of equipment which results in emissions at levels in excess of the major source thresholds, and that equipment meets the definition of a new affected source under the relevant MACT standard, the source is subject to the provisions of 40 CFR 63.6(b)(7) and must meet the requirements for new sources in the relevant major source MACT standard including compliance at startup.

providing extensions. <sup>11</sup> We further solicit comment on the approach of providing a compliance extension in the final rule for certain defined factual scenarios. With regard to this approach, we solicit comment on the nature of the scenario that would warrant such an extension and the amount of additional time that would be needed to comply with the MACT standard and why such a period of time is needed to comply.

The second restriction to the new proposed regulatory provision at 40 CFR 63.1(c)(6) concerns those major sources that take PTE limits to become area sources and thereby become subject to area source standards in 40 CFR part 63. We propose that a major source with affected sources subject to a major source MACT standard that switches to area source status where the EPA has established area source standards for the same affected source would have to comply immediately with those area source standards if the first substantive compliance date has passed or would have to comply by the first substantive compliance date if it has not passed. Because the area source standard is not likely to be more stringent than the major source MACT standard that the source was already meeting, the source likely will not need additional compliance time after the source status change. However, if different emission points are controlled or different controls are necessary to comply with the area source standard or other physical changes are needed to comply with the standard, additional time, not to exceed 3 years, may be granted by the permitting authority if adequate support for the additional time is provided by the source.12

Accordingly, EPA is proposing to add 40 CFR 63.1(c)(6)(ii), which provides that a major source that subsequently becomes an area source by limiting its PTE must meet all applicable area source requirements in Part 63

immediately upon the effective date of the permit containing the PTE limits, provided the first compliance date for the area source standard has passed. We further propose that if a source (or a portion thereof) must undergo a physical change or install additional control equipment to meet the applicable area source standard, the source may submit to the relevant permitting authority a request that (i) identifies the specific additional time needed for compliance (i.e., such request cannot exceed three years) with the area source standard, and (ii) explains, in detail, why the additional time is necessary to comply with the standard. The proposed new regulatory provision—40 CFR 63.1(c)(6)(ii)—is delegable. See generally 42 U.S.C. 7412(l); 40 CFR Subpart E. A permitting authority may approve, in whole or in part, or deny the request.

The proposed new regulatory provision, 40 CFR 63.1(c)(6)(ii), is analogous to 40 CFR 63.6(c)(5), which is briefly described above. We promulgated 40 CFR 63.6(c)(5) as part of the General Provisions, because we recognized a gap in the statute. Specifically, the statute is silent as to how to address sources that are existing area sources at the time the MACT standard is promulgated and that, at some later date, become major sources subject to the MACT standard. Section 63.6(c)(5) fills this particular gap. Similarly, the statute does not address the scenario where a major source becomes an area source and the compliance date for the area source standard has already passed and modifications to the source are needed to achieve compliance with the standard. EPA today proposes 40 CFR 63.1(c)(6)(ii) to address this situation. Section 112(i)(3) does not directly address either of these identified scenarios. Rather, it directly addresses those sources that are existing affected sources as of the date the emission standard is promulgated. See CAA section 112(i)(3) ("After the effective date of any emission standard \* \* \* promulgated under this section and applicable to a source, no person may operate such source in violation of such standard \* \* \* except in the case of an existing source," EPA shall provide a compliance date that provides for compliance as expeditiously as practicable, but no later than 3 years 'after the effective date of the standard.") (emphasis added). Moreover, the new proposed regulatory provision, 40 CFR 63.1(c)(6)(ii), is consistent with CAA section 112(i)(3), because it requires sources to comply

immediately with the area source standard upon the effective date of the permit containing the PTE limit (which is the permit that provides area source status), and authorizes additional time only if the Permitting Authority determines that such time is appropriate based on the facts and circumstances. In any event, any extension of time provided pursuant to proposed 40 CFR 63.1(c)(6)(ii) cannot exceed three years.

Under today's proposed regulations, sources that reduce their emission levels and obtain a PTE HAP limit below major source thresholds must meet that limit and all associated conditions, as specified in the relevant permit, on the effective date of the permit. Prior to the effective date of the permit, the source must continue to comply with the relevant major source MACT standard(s) and other conditions in its title V permit. Of course, permitting authorities may deny a request to adopt area source status where the source has changed its status more than once, if, in the opinion of the permitting authority, these actions are an indication that the restrictions on PTE are, in practice, ineffective.

To the extent an area source standard applies, the compliance date for that standard has passed, and the source needs a compliance extension, the source must apply for and obtain that compliance extension before becoming subject to the area source standard; otherwise, the source will be in violation of the area source standard. We solicit comment on the proposed case-by-case compliance extension date approach, including, for example, the type of information that should be requested from the source seeking the proposed compliance extension, the permit vehicle used to obtain the extension, and whether the limitations proposed above (i.e., the affected source must undergo a physical change or install additional control equipment in order to meet the area source standard) are appropriate. See proposed regulations at 40 CFR 63.1(c)(6)(ii). We also solicit comment generally on the mechanics of obtaining the compliance extension and the appropriate vehicle for requesting the compliance extension. If the area source category is not exempted from the requirements of title V, the request for a compliance extension can be made in the context of the title V permit process. If, however, the area source category at issue is exempt from title V, the source could submit its compliance date extension request to the permitting authority issuing its PTE HAP limitation, provided that the permitting authority is the same State authority that has been

<sup>&</sup>lt;sup>11</sup> Some major sources that switch to area source status may, as an area source, no longer be subject to title V requirements and therefore apply to their permitting authority to terminate their title V permits and obtain a PTE limit through another permit vehicle. Presumably, such sources would have their title V permit terminated at the same time the non-title V permit limiting their PTE becomes effective. If, however, the area source reverts back to major source status, the source will once again have to obtain a title V permit. The source would also have to terminate the non-title V permit containing its PTE limit to allow it to emit at major source levels. Once the HAP PTE limitation no longer applies to the source, the source must comply with applicable major source MACT standards or have taken appropriate steps to apply for a compliance extension.

<sup>&</sup>lt;sup>12</sup> The existing regulations do not address the issue of compliance time-frames for sources that switch from major source status to area source status. See CAA section 112(i)(3), 40 CFR 63.6(c)(5).

delegated authority to implement the Section 112 program. We further solicit comment on whether the proposed compliance date extension provision in 40 CFR 63.1(c)(6)(ii) should be extended to major sources that become area sources only a few months prior to the compliance date of an applicable area source standard, to the extent the source needs additional time to comply.

We solicit comment on all aspects of the proposed new regulatory provisions at 40 CFR 63.1(c)(6)(i) and (ii). For either of the two situations described above (*i.e.*, where a source switches from major, to area, and back to major source status, and where a source switches from major to area source status), a source must notify the Administrator under § 63.9(b) of any standards to which it becomes subject.

The final restriction relevant to the regulations we are proposing to add to 40 CFR 63.1 relates to an enforcement issue. See proposed regulations at 40 CFR 63.1(c)(6)(iii). Specifically, we do not intend to allow major sources that are subject to enforcement investigations or enforcement actions to avoid the results of such investigations or the consequences of such actions by becoming area sources. Although sources that are the subject of an investigation or enforcement action may still seek area source status for purposes of future applicability, they are not absolved of any previous or pending violations of the CAA that occurred while they were a "major source," and the source must bear the consequences of any enforcement action or remedy imposed upon it, which could include fines or imposition of additional emission reduction requirements. Accordingly a source cannot use its new area source status as a defense to MACT violations that occurred while the source was a major source. Similarly, becoming a major source does not absolve a source subject to an enforcement action or investigation for area source violations or infractions from the consequences of any actions occurring when the source was an area source

Finally, we are proposing to amend each of the General Provisions applicability tables contained within most subparts of part 63 to add a reference to new paragraph 63.1(c)(6). In addition, in reviewing several of the MACT standards, we identified one general category of regulatory provisions that may need revision and we solicit comment on whether any revisions are in fact necessary. This category of provisions addresses the date by which a major source can become an area source. The provisions that we have

identified to date, however, all include the specific compliance date of the standard, which in all instances has passed. See e.g., 40 CFR 63.787(b)(iv) ("Existing major sources that intend to become area sources by the December 18, 1997 compliance date may choose to \* \* \* "). Thus, although these regulatory provisions reflect the 1995 OIAI policy that this proposed rule seeks to replace, the provisions themselves have no current effect because the compliance date specified in the regulations has passed. In light of this, we are not proposing regulatory changes to these provisions, but we solicit comment on whether such changes are necessary. We further solicit comment on whether there are any other regulatory provisions in any of the individual subparts that would warrant modification or clarification consistent with today's proposal.

### IV. Impacts of the Proposed Amendments

The environmental, economic, and energy impacts of the proposed amendments cannot be quantified without knowing which sources will avail themselves of the regulatory provisions proposed in this rule and what methods of HAP emission reductions will be used. It is unknown how many sources would choose to take permit conditions that would limit their PTE to below major source levels. Within this group it also is not known how many sources may increase their emissions from the major source MACT level (assuming the level is below the major source thresholds). Similarly we cannot identify or quantify the universe of sources that would decrease their HAP emissions to below the level required by the NESHAP to achieve area source status. We believe that many, if not most, sources that could reduce HAP emissions to area source levels prior to the first substantive compliance date of a MACT standard have already done so. We solicit comment on potential impacts, specifically the number of potential and likely sources that may avail themselves of the approach provided for in today's proposal and additional emission reductions that may be achieved or increases that may occur; please provide any analysis in your comment. There is no requirement that sources avail themselves of the approach proposed today, and each source should assess its own situation to determine whether the additional costs associated with achieving additional emission reductions is beneficial to the source, in exchange for becoming an area source and realizing the associated benefits.

#### V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" because it raises novel legal or policy issues arising out of legal mandates.

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.

#### B. Paperwork Reduction Act

The proposed amendments would impose no information collection requirements. Sources opting to become area sources may experience some reduction in reporting and recordkeeping requirements, as they would no longer be subject to major source MACT requirements. Any changes in reporting or recordkeeping would be done through the permitting mechanisms of the responsible permitting authority. It is not possible to identify how many sources would choose to employ these provisions, nor is it possible to determine what, if any changes, to reporting and recordkeeping would be made. Permitting authorities may, in fact, choose to establish the NESHAP provisions themselves as the PTE limits and change little or nothing.

Furthermore, approval of an ICR is not required in connection with these proposed amendments. This is because the General Provisions do not themselves require any reporting and recordkeeping activities, and no ICR was submitted in connection with their original promulgation or their subsequent amendment. Any recordkeeping and reporting requirements are imposed only through the incorporation of specific elements of the General Provisions in the individual MACT standards which are promulgated for particular source categories which have their own ICRs.

The Office of Management and Budget has previously approved the information collection requirements contained in the existing regulations of 40 CFR part 63 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501, et seq. A copy of the OMB approved Information Collection Request (ICR) for any of the existing regulations may be obtained from Susan Auby, Collection Strategies Division; U.S. EPA (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460, or by calling (202) 566–1672.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

#### C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any proposed 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 not-for-profit enterprises, and small governmental jurisdictions.

For purposes of assessing the impacts of the proposed amendments on small entities, small entity is defined as: (1) A small business as defined in each applicable subpart; (2) a government 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 that is not dominant in its field.

After considering the economic impacts of the proposed amendments on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives which minimize any

significant economic impact on a substantial number of small entities (5 U.S.C. 603–604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

Small entities that are subject to MACT standards would not be required to take any action under this proposal; any action a source takes to become reclassified as an area source would be voluntary. In addition, we expect that any sources using these provisions will experience cost savings that will outweigh any additional cost of achieving area source status.

The only mandatory cost that would be incurred by air pollution control agencies would be the cost of reviewing sources' permit applications for area source status and issuing permits. No small governmental jurisdictions operate their own air pollution control agencies, so none would be required to incur costs under the proposal. In addition, any costs associated with application reviews and permit issuance are expected to be offset by reduced agency oversight obligations for sources that no longer must meet major source MACT requirements.

Based on the considerations above, we have concluded that the proposed amendments will relieve regulatory burden for all affected small entities. Nevertheless, we continue to be interested in the potential impacts of the proposed amendments 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. 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 by State, local, and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most costeffective, 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.

EPA has determined that the proposed amendments do 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 1 year. Sources subject to MACT standards would not be required to take any action under this proposal, including sources owned or operated by State, local, or tribal governments; the provisions in these proposed amendments are strictly voluntary. In addition, the proposed amendments are expected to result in reduced burden on any source that achieves area source status in accord with them. Under the proposed amendments, a State, local, or tribal air pollution control agency to which we have delegated section 112 authority would be required to review permit applications and make modifications to the permit as necessary. However, most applications would not be lengthy or complicated, and costs would not approach the \$100 million annual threshold. In addition, any costs associated with these reviews are expected to be offset by reduced agency oversight obligations for sources that no longer must meet major source requirements. Thus, the proposed amendments are not subject to the requirements of sections 202 and 205 of UMRA. EPA has determined that the proposed amendments contain no regulatory requirements that might significantly or uniquely affect small governments because they contain no requirements that apply to such governments or impose obligations upon them. Thus, the proposed

amendments are 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."

These proposed amendments do not have federalism implications. They 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. Although the proposed amendments would require State air pollution control agencies to review and modify permits as appropriate, the burden on States will not be substantial. In addition, we expect that the overall effect of the proposed amendments will be to reduce the burden on State agencies as their oversight obligations become less demanding for sources no longer subject to major source MACT requirements. Thus, Executive Order 13132 does not apply to these proposed amendments.

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 these proposed amendments 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 6, 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." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes."

These proposed amendments do not have tribal implications, as specified in Executive Order 13175. They will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Any tribal government that owns or operates a source subject to MACT standards would not be required to take any action under this proposal; the provisions in the proposed amendments would be strictly voluntary. In addition, achieving area source status would result in reduced burden on any source that no longer must meet major source requirements. Under the proposed amendments, a tribal government with an air pollution control agency to which we have delegated section 112 authority would be required to review permit applications and to modify permits as necessary. However, such reviews are not expected to be lengthy or complicated, so the effects will not be substantial. In addition, any costs associated with these reviews are expected to be offset by reduced agency oversight obligations for sources no longer required to meet major source requirements. Thus, Executive Order 13175 does not apply to these proposed amendments.

However, in the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Indian tribes, EPA specifically solicits comment on the proposed amendments from tribal officials.

#### G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to regulatory actions that are based on health or safety risks, such that the analysis required under

section 5-501 of the Executive Order has the potential to influence the regulation. These proposed amendments are not subject to Executive Order 13045 because they are not "economically significant" and because all MACT standards governed by the General Provisions are based on technology performance and not on health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

The proposed amendments are not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because they are not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we believe that the proposed amendments are not likely to have any adverse energy impacts.

#### I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104-113,12(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, 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.

These proposed amendments do not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards. EPA welcomes comments on this aspect of the proposed amendments, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the proposed amendments.

#### List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 21, 2006.

#### Stephen L. Johnson,

Administrator.

For the reasons cited in the preamble, title 40, chapter 1 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 63—[AMENDED]

1. The authority citation of part 63 continues to read as follows:

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

#### Subpart A—[Amended]

2. Section 63.1 is amended by adding a new paragraph (c)(6) to read as follows:

#### §63.1 Applicability.

\* \* \*

(c) \* \* \*

- (6) A major source may become an area source at any time by obtaining a permit limiting its potential to emit (PTE) hazardous air pollutants, as defined in this subpart, to below the major source thresholds established in 40 CFR 63.2, subject to the restrictions in paragraphs (c)(6)(i) through (iii) of this section. Until the permit containing the PTE limit becomes effective, the source remains subject to major source requirements. After the permit containing the PTE limit becomes effective, the source is subject to any applicable requirements for area sources.
- (i)(A) The owner or operator of a major source subject to standards under this part that subsequently becomes an area source by limiting its PTE to below major source thresholds, and then later again becomes a major source by increasing its emissions to the major source thresholds or above, must comply immediately with the major source requirements of this part upon becoming a major source, notwithstanding § 63.6(c)(5), except as noted in paragraph (i)(B) below. Such

major sources must comply with the notification requirements of § 63.9(b).

- (B) If, as described in paragraph (i)(A), a source again becomes subject to the standard for major sources, that standard has been revised since the source was last subject to the standard and, in order to comply, the source must undergo a physical change, install additional controls and/or implement new control measures, the source will have up to the same amount of time to comply as the amount of time allowed for existing sources subject to the revised standard.
- (ii) A major source that becomes an area source by limiting its PTE must meet all applicable area source requirements promulgated under this part immediately upon the effective date of the permit containing the PTE limits, provided the first substantive compliance date for the area source standard has passed, except that the permitting authority may grant additional time, up to 3 years, if the source must undergo physical changes or install additional control equipment in order for the source (or portion thereof) to comply with the applicable area source standard and the permitting authority determines that such additional time is warranted based on the record. A source seeking additional compliance time must submit a request to the permitting authority that identifies the amount of additional time requested for compliance and provides a detailed justification supporting the requested. Area sources not previously subject to area source standards must comply with the notification requirements of § 63.9(b).
- (iii) Becoming an area source does not absolve a source subject to an enforcement action or investigation for

major source violations or infractions from the consequences of any actions occurring when the source was major. Becoming a major source does not absolve a source subject to an enforcement action or investigation for area source violations or infractions from the consequences of any actions occurring when the source was an area source.

\* \* \* \* \*

3. Section 63.6 is amended by revising the second sentence in paragraph (c)(5) to read as follows:

### § 63.6 Compliance with standards and maintenance requirements.

\* \* \* \* \*

(c) \* \* \*

- (5) \* \* \* Except as provided in § 63.1(c)(6)(i) such sources must comply by the date specified in the standards for existing area sources that become major sources. \* \* \*
- 4. Section 63.9 is amended by adding a sentence to the end of paragraph (b)(1)(ii) to read as follows:

#### § 63.9 Notification requirements.

\* \* \* \* \* (b) \* \* \*

(1)(i) \* \* \*

(ii) \* \* \* Area sources previously subject to major source requirements that again become major sources are also subject to the notification requirements of this paragraph.

### Subpart F—[Amended]

5. Table 3 to subpart F of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 3 TO SUBPART F OF PART 63—GENERAL PROVISIONS APPLICABILITY TO SUBPARTS F, G, AND HA TO SUBPART F

| Reference  |   | Арр  | Applies to subparts F, G, and H |   | Comment |   |
|------------|---|------|---------------------------------|---|---------|---|
| *          | * | *    | *                               | * | *       | * |
| 63.1(c)(6) |   | Yes. |                                 |   |         |   |
| *          | * | *    | *                               | * | *       | * |

<sup>&</sup>lt;sup>a</sup> Wherever subpart A specifies "postmark" dates, submittals may be sent by methods other than the U.S. Mail (*e.g.*, by fax or courier). Submittals shall be sent by the specified dates, but a postmark is not necessarily required.

#### Subpart N—[Amended]

6. Table 1 to subpart N of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| TABLE 1 TO SUBPART N OF PART | 63—GENERAL PROVISIONS | APPLICABILITY TO SUBPART N |
|------------------------------|-----------------------|----------------------------|
|                              |                       |                            |

| General P       | General Provisions Reference |           | Applies to subpart N |   | Comment |   |
|-----------------|------------------------------|-----------|----------------------|---|---------|---|
| *<br>63.1(c)(6) | *                            | *<br>Yes. | *                    | * | *       | * |
| *               | *                            | *         | *                    | * | *       | * |

#### Subpart O—[Amended]

#### §63.360 Applicability.

7. Table 1 to  $\S$  63.360 is amended by adding an entry for  $\S$  63.1(c)(6) to read as follows:

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

#### TABLE 1 OF SECTION 63.360.—GENERAL PROVISIONS APPLICABILITY TO SUBPART O

| Reference |   | lies to sources using in subpart Oa | g 10 tons Applies to | o sources using 1 to 10 ns in subpart O a | ( | Comment |
|-----------|---|-------------------------------------|----------------------|---|---|---------|
| *         | * | *                                   | *<br>Voc             | *   | * | *       |
| *         | * | *                                   | Yes.                 | *   | * | *       |

<sup>&</sup>lt;sup>a</sup> See definition.

#### Subpart R—[Amended]

8. Table 1 to subpart R of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART R OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART R

| Reference  |   | Applies to | Applies to subpart R |   | Comment |   |  |
|------------|---|------------|----------------------|---|---------|---|--|
| *          | * | *          | *                    | * | *       | * |  |
| 63.1(c)(6) |   | Yes.       |                      |   |         |   |  |
| *          | * | *          | *                    | * | *       | * |  |

#### Subpart S—[Amended]

9. Table 1 to subpart S of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 1 TO SUBPART S OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART SA

| Reference  |   | Applies to subpart S |   | Comm | nent |   |
|------------|---|----------------------|---|------|------|---|
| *          | * | *                    | * | *    | *    | * |
| 63.1(c)(6) |   | Yes.                 |   |      |      |   |
| *          | * | *                    | * | *    | *    | * |

<sup>&</sup>lt;sup>a</sup> Wherever subpart A specifies "postmark" dates, submittals may be sent by methods other than the U.S. Mail (*e.g.*, by fax or courier). Submittals shall be sent by the specified dates, but a postmark is not required.

#### Subpart T—[Amended]

10. Appendix B to subpart T of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

Appendix B to Subpart T of Part 63— General Provisions Applicability to Subpart T

|             | Deference |     | Applies to su | ıbpart T |   | 0        |  |
|-------------|-----------|-----|---------------|----------|---|----------|--|
|             | Reference | В   | BCC           |          |   | Comments |  |
| *           | *         | *   | *             | *        | * | *        |  |
| 3.1(c)(6) . |           | Yes | Ү             | es.      |   |          |  |
| *           | *         | *   | *             | *        | * | *        |  |

#### Subpart U—[Amended]

11. Table 1 to subpart U of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

Table 1 to subpart U of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART U OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART U AFFECTED SOURCES

| Reference    |   | Applies to s | Applies to subpart U |   | Explanation |   |  |
|--------------|---|--------------|----------------------|---|-------------|---|--|
| *            | * | *            | *                    | * | *           | * |  |
| 63.1(c)(6) . |   | Yes.         |                      |   |             |   |  |
|              | * | *            | *                    | * | *           | * |  |
|              |   |              |                      |   |             |   |  |

#### Subpart W—[Amended]

12. Table 1 to subpart W of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART W OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART W

|            |     |     | Applies to subpa | art W                        |   |         |
|------------|-----|-----|------------------|------------------------------|---|---------|
| Reference  |     | BLR | WSR              | WSR al<br>and BL<br>standard | ternative standard,<br>R equipment leak<br>d (40 CFR part 63,<br>subpart H) | Comment |
| ,          | *   | *   | *                | *                            | *   | *       |
| 63.1(c)(6) | Yes |     | Yes              | Yes.                         |   |         |
|            | *   | *   | *                | *                            | *   | *       |

#### Subpart Y—[Amended]

§ 63.560 Applicability and designation of affected sources.

13. Table 1 of § 63.560 is amended by adding an entry for § 63.1(c)(6) to read as follows:

\* \* \* \*

#### TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y

| Reference | Applies to affected sources in subpart Y | Comment |
|-----------|--|---------|

|            | TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y—Continued |      |                     |           |         |   |  |  |  |
|------------|--|------|---------------------|-----------|---------|---|--|--|--|
| F          | Reference Applies  |      | affected sources in | subpart Y | Comment |   |  |  |  |
| *          | *  | *    | *                   | *         | *       | * |  |  |  |
| 63.1(c)(6) |  | Yes. |                     |           |         |   |  |  |  |
|            |  |      |                     |           |         |   |  |  |  |

#### Subpart AA—[Amended]

14. Appendix A to subpart AA of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| 40 CFR cita     | R citation Requirement |   | Арр       | Applies to subpart AA |   | omment |
|-----------------|------------------------|---|-----------|-----------------------|---|--------|
| *<br>63.1(c)(6) | *                      | * | *<br>Yes. | *                     | * | *      |
| *               | *                      | * | *         | *                     | * | *      |

#### Subpart BB—[Amended]

15. Appendix A to subpart BB of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

Appendix A to Subpart BB of Part 63— Applicability of General Provisions (40 CFR Part 63, Subpart A) to Subpart BB

| 40 CFR citation Requirement |   | Requirement | nt Applies to subpart BB |   | Co | Comment |  |
|-----------------------------|---|-------------|--------------------------|---|----|---------|--|
| *<br>63.1(c)(6)             | * | *           | *<br>Yes.                | * | *  | *       |  |
| *                           | * | *           | * res.                   | * | *  | *       |  |

#### Subpart CC—[Amended]

Appendix to Subpart CC of Part 63— Tables

16. Table 6 to Appendix of subpart CC of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

\* \* \* \* \*

#### TABLE 6.—GENERAL PROVISIONS APPLICABILITY TO SUBPART CCA

| Reference  |   |      | Applies to subpart CC |   | Comment |   |
|------------|---|------|-----------------------|---|---------|---|
| *          | * | *    | *                     | * | *       | * |
| 63.1(c)(6) |   | Yes. |                       |   |         |   |
| *          | * | *    | *                     | * | *       | * |

<sup>&</sup>lt;sup>a</sup> Wherever subpart A specifies "postmark" dates, submittals may be sent by methods other than the U.S. Mail (*e.g.*, by fax or courier). Submittals shall be sent by the specified dates, but a postmark is not required.

#### Subpart DD—[Amended]

17. Table 2 to subpart DD of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

# TABLE 2 TO SUBPART DD OF PART 63.—APPLICABILITY OF PARAGRAPHS IN SUBPART A OF THIS PART 63—GENERAL PROVISIONS TO SUBPART DD

| Subpart A reference Applies to subpart DD Explanation |
|---|
|---|

# TABLE 2 TO SUBPART DD OF PART 63.—APPLICABILITY OF PARAGRAPHS IN SUBPART A OF THIS PART 63—GENERAL PROVISIONS TO SUBPART DD—Continued

| Subpart A reference |   | Applies to subpart DD |   | Explanation |   |   |
|---------------------|---|-----------------------|---|-------------|---|---|
| *                   | * | *                     | * | *           | * | * |
| 63.1(c)(6)          |   | Yes.                  |   |             |   |   |
| *                   | * | *                     | * | *           | * | * |

#### Subpart EE—[Amended]

18. Table 1 to subpart EE of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART EE OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART EE

| F               | Reference |          | Applies to subpart EE |   | Comment |   |
|-----------------|-----------|----------|-----------------------|---|---------|---|
| *<br>63 1(c)(6) | *         | *<br>Ves | *                     | * | *       | * |
| *               | *         | *        | *                     | * | *       | * |

#### Subpart GG—[Amended]

19. Table 1 to subpart GG of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART GG OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GG

| Reference       |   | Applies to | Applies to affected sources in subpart GG |   | Comment |   |
|-----------------|---|------------|---|---|---------|---|
| *<br>63.1(c)(6) | * | *<br>Yes.  | *   | * | *       | * |
| *               | * | *          | *   | * | *       | * |

#### Subpart HH—[Amended]

Appendix to Subpart HH of Part 63-Tables

20. Table 2 of Appendix to subpart HH of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 2 TO SUBPART HH OF PART 63.—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART HH

| General provisions reference |   | Applies to subpart HH |   | Explanation |   |   |
|------------------------------|---|-----------------------|---|-------------|---|---|
| *<br>§ 63.1(c)(6)            | * | *<br>Yes.             | * | *           | * | * |
| *                            | * | res.<br>*             | * | *           | * | * |

#### Subpart JJ—[Amended]

21. Table 1 to subpart JJ of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| LABLE 1 TO SUBPART JJ OF PART 63 —GENERAL PROVISIONS APPLICABILITY TO SUBPAR | OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART J. | SUBPART J.J OF PART | TABLE 1 TO SUBPAR |
|--|--|---------------------|-------------------|
|--|--|---------------------|-------------------|

| Reference       |   |          | Applies to subpart JJ |   | Comment |   |
|-----------------|---|----------|-----------------------|---|---------|---|
| *<br>63.1(c)(6) | * | *<br>Yes | *                     | * | *       | * |
| *               | * | *        | *                     | * | *       | * |

#### Subpart KK—[Amended]

22. Table 1 to subpart KK of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 1 TO SUBPART KK OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART KK

| General provisions reference |   | Applicable to subpart KK |   | Comment |   |   |
|------------------------------|---|--------------------------|---|---------|---|---|
| *<br>8 63 1(c)(6)            | * | *<br>Yes                 | * | *       | * | * |
| *                            | * | *                        | * | *       | * | * |

#### Subpart MM—[Amended]

23. Table 1 to subpart MM of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART MM OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART MM

| Reference Summary of require |   | Summary of requirements   | , Д      | applies to subpart MM | Ex | Explanation |  |
|------------------------------|---|---------------------------|----------|-----------------------|----|-------------|--|
| *<br>63.1(c)(6)              | * | * Becoming an area source | *<br>Ves | *                     | *  | *           |  |
| *                            | * | *                         | *        | *                     | *  | *           |  |

#### Subpart DDD—[Amended]

24. Table 1 to subpart DDD of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 1 TO SUBPART DDD OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART DDD OF PART 63

| General provisions citation |   | Requirement | Appli | es to subpart DDD? | Ex | planation |
|-----------------------------|---|-------------|-------|--------------------|----|-----------|
| *                           | * | *           | *     | *                  | *  | *         |
| 63.1(C)(6)                  |   |             | Yes.  |                    |    |           |
| *                           | * | *           | *     | *                  | *  | *         |

#### Subpart GGG—[Amended]

25. Table 1 to subpart GGG of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART GGG OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART GGG

| General provisions reference       |   | Summary of requirements | Арр  | lies to subpart GGG | Comments |   |
|------------------------------------|---|-------------------------|------|---------------------|----------|---|
| *                                  | * | *                       | *    | *                   | *        | * |
| 63.1(c)(6) Becoming an area source |   |                         | Yes. |                     |          |   |
| *                                  | * | *                       | *    | *                   | *        | * |

#### Subpart HHH—[Amended]

26. Table 2 to subpart HHH of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

Appendix: Table 2 to Subpart HHH of Part 63—Applicability of 40 CFR Part 63 General Provisions to Subpart HHH

| General Pro      | General Provisions Reference |           | Applies to subpart HHH |   | Explanation |   |
|------------------|------------------------------|-----------|------------------------|---|-------------|---|
| *<br>§63.1(c)(6) | *                            | *<br>Yes. | *                      | * | *           | * |
| *                | *                            | *         | *                      | * | *           | * |

#### Subpart JJJ—[Amended]

27. Table 1 to subpart JJJ of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

## TABLE 1 TO SUBPART JJJ OF PART 63—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART JJJ AFFECTED SOURCES

| Reference         |   |           | Applies to subpart JJJ |   | Explanation |   |
|-------------------|---|-----------|------------------------|---|-------------|---|
| *<br>\$63.1(a)(6) | * | *<br>Voc  | *                      | * | *           | * |
| * *               | * | res.<br>* | *                      | * | *           | * |

#### Subpart LLL—[Amended]

28. Table 1 to subpart LLL of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART LLL OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS

| Citation Requirement |   | Арр | Applies to subpart LLL |   | planation |   |
|----------------------|---|-----|------------------------|---|-----------|---|
| *<br>63.1(c)(6)      | * | *   | <br>Yes.               | * | *         | * |
| *                    | * | *   | *                      | * | *         | * |

#### Subpart MMM—[Amended]

29. Table 1 to subpart MMM of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 1 TO SUBPART MMM OF PART 63.—GENERAL PROVISIONS APPLICABILITY TO SUBPART MMM

| Reference to subpart A | Applies to subpart MMM | Explanation |
|------------------------|------------------------|-------------|
|------------------------|------------------------|-------------|

| TABLE 1 TO SUBPART MMM OF PART 63      | -GENERAL PROVISION    | NS APPLICABILITY TO SUBP | ART MMM—Continued         |
|--|-----------------------|--------------------------|---------------------------|
| TABLE I TO GODFART IVIIVITO I TART 05. | - GLINLIAL I NOVISIOI | NO AFFLICABILITI TO GODE | Ant Iviiviivi—Ootiliitucu |

| Referer      | Reference to subpart A |      | Applies to subpart MMM |   | Explanation |   |
|--------------|------------------------|------|------------------------|---|-------------|---|
| *            | *                      | *    | *                      | * | *           | * |
| § 63.1(c)(6) |                        | Yes. |                        |   |             |   |
| *            | *                      | *    | *                      | * | *           | * |

#### Subpart NNN—[Amended]

30. Table 1 to subpart NNN of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

# TABLE 1 TO SUBPART NNN OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART NNN

| General provisions citation |   | Requirement | Requirement Applies to subpart N |   | NN Explanation |   |
|-----------------------------|---|-------------|----------------------------------|---|----------------|---|
| *<br>63.1(c)(6)             | * | *           | *<br>Yes.                        | * | *              | * |
| *                           | * | *           | *                                | * | *              | * |

#### Subpart OOO—[Amended]

31. Table 1 to subpart OOO of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

# TABLE 1 TO SUBPART OOO OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART OOO AFFECTED SOURCES

| R               | Reference |          | Applies to subpart OOO |   | Explanation |   |
|-----------------|-----------|----------|------------------------|---|-------------|---|
| *<br>63 1(c)(6) | *         | *<br>Yes | *                      | * | *           | * |
| *               | *         | *        | *                      | * | *           | * |

#### Subpart PPP—[Amended]

32. Table 1 to subpart PPP of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

## TABLE 1 TO SUBPART PPP OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART PPP AFFECTED SOURCES

| Reference  |   | Applies to subpart PPP |   | Explanation |   |   |
|------------|---|------------------------|---|-------------|---|---|
| *          | * | *<br>V                 | * | *           | * | * |
| 63.1(c)(6) | * | Yes.                   | * | *           | * | * |

#### Subpart RRR—[Amended]

33. Appendix A to subpart RRR of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| APPENDIX A TO SUBPART RRR OF PART 63. | GENERAL PROVISIONS APPLICABILITY TO SUBPART RRR |
|---------------------------------------|---|
|                                       |   |

| Citation         |   | Requirement |           | pplies to RRR | Со | Comment |  |
|------------------|---|-------------|-----------|---------------|----|---------|--|
| *<br>863.1(c)(6) | * | *           | *<br>Yes. | *             | *  | *       |  |
| *                | * | *           | *         | *             | *  | *       |  |

#### Subpart VVV—[Amended]

34. Table 1 to subpart VVV of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 1 TO SUBPART VVV OF PART 63.—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART VVV

| General p         | General provisions reference |          | pplicable to subpart \ | <b>/</b> VV | Explanation |   |
|-------------------|------------------------------|----------|------------------------|-------------|-------------|---|
| *<br>\$63.1(c)(6) | *                            | *<br>Yes | *                      | *           | *           | * |
| *                 | *                            | *        | *                      | *           | *           | * |

#### Subpart HHHH—[Amended]

35. Table 2 to subpart HHHH of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 2 TO SUBPART HHHH OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS (40 CFR PART 63, SUBPART A) TO SUBPART HHHH

| Citation         |   | Requirement | A         | Applies to HHHH |   | lanation |
|------------------|---|-------------|-----------|-----------------|---|----------|
| *<br>863.1(c)(6) | * | *           | *<br>Yes. | *               | * | *        |
| *                | * | *           | *         | *               | * | *        |

#### Subpart IIII—[Amended]

36. Table 2 to subpart IIII of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 2 TO SUBPART IIII OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART IIII OF PART 63

| Citation          |   | Subject                   | Арр      | Applicable to subpart IIII |   | planation |
|-------------------|---|---------------------------|----------|----------------------------|---|-----------|
| *<br>& 63.1(c)(6) | * | * Becoming an area source | *<br>Vac | *                          | * | *         |
| *                 | * | *                         | *        | *                          | * | *         |

#### Subpart JJJJ—[Amended]

37. Table 2 to subpart JJJJ of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 2 TO SUBPART JJJJ OF PART 63.—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART JJJJ

| General pro       | General provisions reference |           | pplicable to subpart J | ble to subpart JJJJ Explanation |   |   |
|-------------------|------------------------------|-----------|------------------------|---------------------------------|---|---|
| *<br>§ 63.1(c)(6) | *                            | *<br>Yes. | *                      | *                               | * | * |
| *                 | *                            | res.      | *                      | *                               | * | * |

#### Subpart KKKK—[Amended]

38. Table 5 to subpart KKKK of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 5 TO SUBPART KKKK OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART KKKK

| Citation         |   | Subject                      | Subject Applicable to subpart KKKK |   | Explanation |   |
|------------------|---|------------------------------|------------------------------------|---|-------------|---|
| *<br>863.1(c)(6) | * | *<br>Becoming an area source | *<br>Vac                           | * | *           | * |
| *                | * | *                            | *                                  | * | *           | * |

#### Subpart MMMM—[Amended]

39. Table 2 to subpart MMMM of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 2 TO SUBPART MMMM OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART MMMM OF PART 63

| Citation         |   | Subject                   | Арр      | Applicable to subpart III |   | planation |
|------------------|---|---------------------------|----------|---------------------------|---|-----------|
| *<br>863.1(c)(6) | * | * Becoming an area source | *<br>Yes | *                         | * | *         |
| *                | * | *                         | *        | *                         | * | *         |

#### Subpart NNNN—[Amended]

40. Table 2 to subpart NNNN of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 2 TO SUBPART NNNN OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNN

| Citation          |   | Subject                   | Appli    | Applicable to subpart NNNN |   | xplanation |
|-------------------|---|---------------------------|----------|----------------------------|---|------------|
| *<br>& 63.1(c)(6) | * | * Becoming an area source | *<br>Vac | *                          | * | *          |
| *                 | * | *                         | *        | *                          | * | *          |

#### Subpart OOOO—[Amended]

41. Table 3 to subpart OOOO of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| TABLE 3 TO SUBPART OOOO | D 00                     | O D                     | 0 0000            |
|-------------------------|--------------------------|-------------------------|-------------------|
| LARIES TO SURPART CICIO | OF PART 63 -APPLICABILIT | A UE GENIEBAL BBUMBIUMS | TO SURPART CHOICE |
|                         |                          |                         |                   |

| Citation         |            | Subject | Applica  | ble to subpart OOOO | E | xplanation |
|------------------|------------|---------|----------|---------------------|---|------------|
| *<br>863.1(c)(6) | *<br>Becoi | *       | *<br>Vac | *                   | * | *          |
| *                | *          | *       | *        | *                   | * | *          |

#### Subpart PPPP—[Amended]

42. Table 2 to subpart PPPP of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 2 TO SUBPART PPPP OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART PPPP OF PART 63

| Citation           |       | Subject | Applic          | Applicable to subpart PPPP |   | Explanation |  |
|--------------------|-------|---------|-----------------|----------------------------|---|-------------|--|
| *<br>\$ 62 1(a)(6) | *     | *       | * Voc           | *                          | * | *           |  |
| *                  | Becor | *       | * ··········· * | *                          | * | *           |  |

#### Subpart QQQQ—[Amended]

43. Table 4 to subpart QQQQ of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 4 TO SUBPART QQQQ OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART QQQQ OF PART 63

| Citation          |   | Subject                   | Appli    | Applicable to subpart QQQQ |   | kplanation |
|-------------------|---|---------------------------|----------|----------------------------|---|------------|
| *<br>8 63 1(c)(6) | * | * Becoming an area source | *<br>Yes | *                          | * | *          |
| *                 | * | *                         | *        | *                          | * | *          |

#### Subpart RRRR—[Amended]

44. Table 2 to subpart RRRR of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 2 TO SUBPART RRRR OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART RRRR

| Citation         | Citation Subject |                           | Ą                | oplicable to subpart | Ex | planation |
|------------------|------------------|---------------------------|------------------|----------------------|----|-----------|
| *<br>863.1(c)(6) | *                | * Becoming an area source | *<br><b>Y</b> es | *                    | *  | *         |
| *                | *                | *                         | *                | *                    | *  | *         |

#### Subpart SSSS—[Amended]

45. Table 2 to subpart SSSS of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

| TABLE 2 TO SUBPART SSSS | OF DART CO. APPLICABILI | TV OF CENERAL PROVIDION | TO CURRANT CCCC   |
|-------------------------|-------------------------|-------------------------|-------------------|
| IADLE Z IU SUDPARI SSSS | OF FART US.—APPLICABILI | IT OF GENERAL PROVISION | S IU SUBPARI SSSS |

| General provisions reference |   |          | plicable to subpart S | SSS | Explanation |   |
|------------------------------|---|----------|-----------------------|-----|-------------|---|
| *<br>\$ 63.1(c)(6)           | * | *<br>Yes | *                     | *   | *           | * |
| *                            | * | *        | *                     | *   | *           | * |

#### Subpart VVVV—[Amended]

46. Table 8 to subpart VVVV of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 8 TO SUBPART VVVV OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO (40 CFR PART 63, SUBPART A)

TO SUBPART VVVV

| Citation           | Citation Requirement |   | Appli     | Applies to subpart VVVV |   | xplanation |
|--------------------|----------------------|---|-----------|-------------------------|---|------------|
| *<br>\$ 62 1(a)(6) | *                    | * | *<br>Yes. | *                       | * | *          |
| * *                | *                    | * | res.      | *                       | * | *          |

#### Subpart WWWW—[Amended]

47. Table 15 to subpart WWWW of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

# TABLE 15 TO SUBPART WWWW OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS (SUBPART A) TO SUBPART WWWW OF PART 63

| The general provisions reference |   | That addresses          | And appli | es to subpart WWWW of part 63 | Su<br>follov<br>info | Subject to the following additional information |  |
|----------------------------------|---|-------------------------|-----------|-------------------------------|----------------------|---|--|
| *                                | * | *                       | *         | *                             | *                    | *   |  |
| § 63.1(c)(6)                     |   | Becoming an area source | Yes.      |                               |                      |   |  |
| *                                | * | *                       | *         | *                             | *                    | *   |  |

#### Subpart AAAAA—[Amended]

48. Table 8 to subpart AAAAA of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

TABLE 8 TO SUBPART AAAAA OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA

| Citation     | Citation Summary of requirement |                     | Am I subj | Am I subject to this requirement? |   | Explanation |  |
|--------------|---------------------------------|---------------------|-----------|-----------------------------------|---|-------------|--|
| *            | *                               | *                   | *         | *                                 | * | *           |  |
| § 63.1(c)(6) | Beco                            | ming an area source | Yes.      |                                   |   |             |  |
| *            | *                               | *                   | *         | *                                 | * | *           |  |

#### Subpart PPPPP—[Amended]

49. Table 7 to subpart PPPPP of part 63 is amended by adding an entry for § 63.1(c)(6) to read as follows:

#### TABLE 7 TO SUBPART PPPPP OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART PPPPP

| Citation           | Citation Subject |                 |             | Brief description |          | Applies to subpart PPPPP |  |
|--------------------|------------------|-----------------|-------------|-------------------|----------|--------------------------|--|
| *<br>\$ 62 1(a)(6) | *                | * Applicability | *<br>Rocomi | *                 | *<br>Voc | *                        |  |
| *                  | *                | *               | *           | *                 | *        | *                        |  |

[FR Doc. E6–22283 Filed 12–29–06; 8:45 am] BILLING CODE 6560–50-P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 72

RIN 0920-AA03

### Interstate Shipment of Etiologic Agents

**AGENCY:** Centers for Disease Control and Prevention (CDC), HHS.

**ACTION:** Notice for proposed rulemaking.

**SUMMARY:** HHS proposes to remove Part 72 of Title 42, Code of Federal Regulations, which governs the interstate shipment of etiologic agents, because the U.S. Department of Transportation (DOT) already has in effect a more comprehensive set of regulations applicable to the transport in commerce of infectious substances. DOT harmonizes its transport requirements with international standards adopted by the United Nations (UN) Committee of Experts on the Transport of Dangerous Goods for the classification, packaging, and transport of infectious substances. Rescinding the rule will eliminate duplication of the more current DOT regulations that cover intrastate and international, as well as interstate, transport. HHS replaced those sections of Part 72 that deal with select biological agents and toxins with a new set of regulations found in Part 73 of Title 42. HHS anticipates that removal of Part 72 will alleviate confusion and reduce the regulatory burden with no adverse impact on public health and

**DATES:** Written comments must be received on or before March 5, 2007. Written comments on the proposed information collection requirements should also be submitted on or before March 5, 2007. Comments received after March 5, 2007 will be considered to the extent practicable.

**ADDRESSES:** You may submit written comments to the following address: U.S. Department of Health and Human

Services, Centers for Disease Control and Prevention, National Center for Infectious Diseases/OD, ATTN: Interstate Shipment of Etiologic Agents Comments, 1600 Clifton Road, NE (C12), Atlanta, GA 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE, Atlanta, GA. Please call Ruenell Massey at 404-639 -945 to schedule your visit. Comments also may be viewed at http:// www.cdc.gov/ncidod/agentshipment/ index.htm. You may submit written comments by fax to 404-639-3039, Attention: Dr. Janet Nicholson, or electronically via the Internet at http:// www.regulations.gov. To download an electronic version of the rule, you may access http://www.regulations.gov. You must include the agency name (Centers for Disease Control and Prevention) and Regulatory Information Number (RIN) on all submissions for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Dr. Janet K. Nicholson, National Center for Infectious Diseases/OD, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Rd., NE (MS—C12), Atlanta GA 30333; telephone: 404–639–3945; e-mail jkn1@cdc.gov.

**SUPPLEMENTARY INFORMATION:** Part 72 of Title 42 of the Code of Federal Regulations provides minimal requirements for packaging and shipping materials, including diagnostic specimens and biological products, reasonably believed to contain an etiologic agent. It provides more detailed requirements, including labeling, for materials containing certain etiologic agents, with a list of the biological agents and toxins provided. For agents on the list, the rule requires reporting to HHS/CDC damaged packages and packages not received. The rule also requires sending certain agents on the list by registered mail or an equivalent system.

The rule, as currently promulgated, is out-of-date, and duplicates more current regulations of DOT. Further, the regulation is inconsistent with the procedures of other transport governing bodies, such as the International Civil

Aviation Organization (ICAO) and the International Air Transport Association (IATA), for air, and the U.S. Postal Service for ground.

Section 72.6, a major portion of 42 CFR 72 that dealt with select agents, was superseded by the issuance of an Interim Final Rule for 42 CFR 73 on December 13, 2002 (67 FR 76886). Part 73 implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The continued existence of the remaining provisions of the out-of-date HHS/CDC regulation is confusing to the packaging and transport communities. The provisions serve no useful purpose that merits their retention. HHS/CDC will remain available for consultation on and response to public-health issues and emergencies, in accordance with its normal duties in the interest of public health and safety.

# Transition From HHS to DOT Regulations

DOT has the primary statutory authority to regulate the safe and secure transportation of all hazardous materials, including infectious materials, shipped in intrastate, interstate, and foreign commerce. The etiologic agents covered by 42 CFR 72 are considered to be hazardous materials, and, in practice, the DOT regulations, 49 CFR 171-178, have superseded since DOT began including more specific regulations on infectious substances. The earlier versions of the DOT regulations on etiologic agents were based on and virtually identical to the HHS regulations. These regulations have been modified over time, as necessary, to continue to provide protection for persons who handle shipments with as few impediments as possible to quick shipment. In 1990, DOT authorized the term "infectious substance" as synonymous with ''etiologic agent.'' In 1991, DOT expanded the definition of "etiologic agent" to include agents listed in 42 CFR 72, plus others that cause or could cause severe, disabling or fatal human disease, thereby including agents such as human immunodeficiency virus that were not on the HHS list. DOT also issued expanded packaging