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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0171; FRL–8512–1]

RIN 2060–AM14

National Emission Standards for Hospital Ethylene Oxide Sterilizers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is issuing national emissions standards for new and existing hospital sterilizers that emit hazardous air pollutants and are area sources within the meaning of Clean Air Act section 112(a)(2). The final rule is based on EPA's determination as to what constitutes the generally available control technology or management practices for the hospital sterilizer area source category.

This action is being finalized as part of EPA's obligation to regulate area sources listed for regulation pursuant to Clean Air Act section 112(c)(3).

DATES: The final rule is effective on December 28, 2007.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2005–0171. All documents in the docket are listed in the Federal Docket Management System index at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744. For the Air and Radiation Docket and Information Center, the telephone number is (202) 566–1742, the fax number is (202) 566–9744, the Web site is *http://www.epa.gov/oar/docket.html,* and the e-mail address is *a-and-r-Docket@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. David Markwordt, Office of Air Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541–0837; fax number: (919) 541–0246; e-mail address: *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION: *Outline.* The information presented in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

The regulated categories and entities potentially affected by these final standards include:

Category	NAICS[1] code	Example of potentially regulated entities
General Medical and Surgical Hospitals	622110	Hospital sterilizers.
Specialty (Except Psychiatric and Substance Abuse) Hospitals	622310	Hospital sterilizers.

[1] North American Industrial Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria in 40 CFR 63.10382 of subpart WWWWW (National Emissions Standards for Hospital Ethylene Oxide Sterilizers). If you have any questions regarding the applicability of this action to a particular entity, consult either the air permit authority for the entity or your EPA regional representative as listed in 40 CFR 63.13 of subpart A (General Provisions).

B. Where can I get a copy of this document?

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

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available only by filing a petition for review in the United States

Court of Appeals for the District of Columbia Circuit by February 26, 2008. Under section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. This section also provides a mechanism for EPA to convene a proceeding for reconsideration, ''[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.'' Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Moreover, under section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by EPA to enforce these requirements.

II. Background Information for Final Area Source Standard

Sections 112(c)(3) and 112(k)(3)(B) of the CAA instruct EPA to identify not less than 30 hazardous air pollutants (HAP) which, as a result of emissions from area sources,[1] present the greatest threat to public health in the largest number of urban areas, and to list sufficient area source categories to ensure that sources representing 90 percent of the 30 listed HAP (the ''urban HAP'') are subject to regulation. Consistent with these provisions, in 1999, in the Integrated Urban Air Toxics Strategy (64 FR 38706, 64 FR 38715–716, July 19, 1999), EPA identified the 30 urban HAP and listed the source categories that account for 90 percent of the urban HAP emissions.[2]

Under CAA section 112(d)(5), the Administrator may, in lieu of standards requiring maximum achievable control technology (MACT) under section 112(d)(2), elect to promulgate standards or requirements for area sources ''which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants.'' As explained in the proposed national emission standards for hazardous air pollutants (NESHAP), we are setting standards for the Hospital Sterilizers Area Source category pursuant to section 112(d)(5) of the CAA. See 71 FR 64907, November 6, 2006.

III. Summary of the Final Rule and Significant Changes Since Proposal

This section summarizes the final rule and identifies and discusses the significant changes since proposal. For changes that were made as a result of public comments, we have provided detailed explanations of the changes and the rationale in the responses to comments in section V of this preamble.

A. What is the affected source and the compliance date?

This final rule applies to any existing or new hospital ethylene oxide sterilization facility that is an area source of HAP. The owner or operator of an existing area source must comply with this area source NESHAP by December 29, 2008. The owner or operator of a new area source must comply with this area source NESHAP by December 28, 2007 or upon initial startup, whichever is later.

B. What is required by the management practice?

In our November 6, 2006 proposal, we proposed two alternative emission standards for this area source category. As Alternative 1, we proposed to require that the affected source, as defined above, sterilize full loads of medical items having common aeration times except during emergency circumstances that dictate the use of less than full loads to protect human health. As Alternative 2, we proposed a finding that there are no generally available control technologies or management practices (GACT) within the meaning of CAA section 112(d)(5) for the Hospital Sterilizers Area Source category. As explained in more detail in section V of this preamble, based on the comments and information we received during the public comment period, we conclude that the management practice described in Alternative 1 reflects GACT for this area source category, and we, therefore, adopt Alternative 1 as the standard for area source hospital ethylene oxide sterilization facilities.

Specifically, the final rule requires that a hospital ethylene oxide sterilization facility sterilize full loads of items having a common aeration time except where medical necessity dictates the use of less than a full load to protect human health. As explained in more detail in section V.A.3 of this preamble, the determination that a medical necessity exists must be made by a hospital central services staff,[3] a hospital administrator, or a physician on duty. This management practice applies to all affected sources. As explained in more detail in section V.A.2 of this preamble, sources may demonstrate compliance with this requirement by operating their sterilizers with an air pollution control device and providing the certification required in this final rule.

C. What are the testing and initial compliance requirements?

There are no performance test requirements for the management practice standard. Affected sources are required to submit an Initial Notification of Compliance Status that notifies EPA that they operate a sterilizer covered by the rule and certify that they are operating their sterilizers in accordance with the requirement of the rule.

In the preamble to the proposed rule, we acknowledged that some hospitals operate their sterilizers with add-on controls and that such controls achieve reductions in ethylene oxide emissions that are at least equivalent to the ethylene oxide reductions resulting from the management practice. Therefore, the final rule includes the use of a control device as an alternative compliance option for the management practice requirement. Specifically, a source may demonstrate compliance by certifying that it is operating its sterilizer(s) with an air pollution control device. The source must certify that it is running the sterilizer(s) in accordance with any applicable State and/or local regulations, or, if there are no such regulations, with manufacturers' specifications.

D. What are the notification, recordkeeping, and reporting requirements?

As mentioned above, affected sources must submit an Initial Notification of Compliance Status that includes the

[1] An area source is a stationary source of HAP emissions that is not a major source. A major source is a stationary source that emits or has the potential to emit 10 tons per year (tpy) or more of any HAP or 25 tpy or more of any combination of HAP.

[2] Since its publication in the Integrated Urban Air Toxics Strategy in 1999, the area source category list has undergone several amendments.

[3] Hospital central services staffs are healthcare professionals, including managers and technicians, who are either directly involved in or responsible for sterile processing at a hospital.

required compliance certification described above. The final rule does not require ongoing reporting.

Except for hospital ethylene oxide sterilization facilities that demonstrate compliance by using add-on controls, affected sources must maintain on site records of the date and time of each sterilization operation. If less than a full load is sterilized due to medical necessity, the operator must record this as well. These sterilization records must be kept in a form suitable and readily available for expeditious review. They must be kept for 5 years and at least the most recent 2 years on site.

IV. Exemption of Certain Area Source Categories From Title V Permitting Requirements

Section 502(a) of the CAA provides that the Administrator may exempt an area source category from title V if he determines that compliance with title V requirements is ''impracticable, infeasible, or unnecessarily burdensome'' on an area source category. See CAA section 502(a). In December 2005, in a national rulemaking, EPA interpreted the term ''unnecessarily burdensome'' in CAA section 502 and developed a four-factor balancing test for determining whether title V is unnecessarily burdensome for a particular area source category, such that an exemption from title V is appropriate. See 70 FR 75320, December 19, 2005 (Exemption Rule).

The four factors that EPA identified in the Exemption Rule for determining whether title V is ''unnecessarily burdensome'' on a particular area source category include: (1) whether title V would result in significant improvements to the compliance requirements, including monitoring, recordkeeping, and reporting, that are proposed for an area source category (70 FR 75323); (2) whether title V permitting would impose significant burdens on the area source category and whether the burdens would be aggravated by any difficulty the sources may have in obtaining assistance from permitting agencies (70 FR 75324); (3) whether the costs of title V permitting for the area source category would be justified, taking into consideration any potential gains in compliance likely to occur for such sources (70 FR 75325); and (4) whether there are implementation and enforcement programs in place that are sufficient to assure compliance with the NESHAP for the area source category, without relying on title V permits (70 FR 75326).

In discussing the above factors in the Exemption Rule, we explained that we considered on ''a case-by-case basis the extent to which one or more of the four factors supported title V exemptions for a given source category, and then we assessed whether considered together those factors demonstrated that compliance with title V requirements would be 'unnecessarily burdensome' on the category, consistent with section 502(a) of the Act.'' See 70 FR 75323. Thus, in the Exemption Rule, we explained that not all of the four factors must weigh in favor of exemption for EPA to determine that title V is unnecessarily burdensome for a particular area source category. Instead, the factors are to be considered in combination, and EPA determines whether the factors, taken together, support an exemption from title V for a particular source category.

In the Exemption Rule, in addition to determining whether compliance with title V requirements would be unnecessarily burdensome on the hospital sterilizer area source category, we considered, consistent with the guidance provided by the legislative history of CAA section 502(a), whether exempting the Hospital Sterilizer Area Source category would adversely affect public health, welfare, or the environment. See 70 FR 15254–15255, March 25, 2005.

In the proposed rule, we evaluated the four factors described above in relation to the Hospital Sterilizer Area Source category and explained our proposed conclusion that the factors collectively demonstrated that compliance with title V requirements would be unnecessarily burdensome for the source category. Among other things, we explained in the preamble to the proposed rule, that title V permitting would not result in significant improvements to the compliance requirements for the Hospital Sterilizer Area Source category. In the proposal, we further explained that title V permitting may impose a significant burden on facilities within this source category, some of which are small businesses. We explained that, for many facilities, the cost of obtaining a title V permit may far exceed the cost of complying with the final rule without significant gains in compliance. Based on the above analysis, we proposed that title V permitting would be ''unnecessarily burdensome'' for hospital sterilizer area sources. We also proposed that the exemptions from title V would not adversely affect public health, welfare, and the environment.

In response to the proposed rule, we received two comments concerning the proposed title V exemption. However, as discussed in more detail in section V.A.7 of this preamble, neither comment addressed the above-mentioned factors that we considered in proposing the title V exemption. Accordingly, our assessment of these factors remains unchanged in light of these comments. We, therefore, finalize the proposed exemption for the Hospital Sterilizer Area Source category in this rule. Hospital sterilizer area sources are not required to obtain title V permits solely for purposes of being the subject of this final NESHAP; however, if they are otherwise required to obtain title V permits, such requirements are not affected by this exemption.

V. Summary of Comments and Responses

The hospital sterilizer area source rule was proposed on November 6, 2006 (71 FR 64907). The 60-day comment period ended on January 5, 2007, and we received a total of 10 comment letters on the proposed NESHAP. Comments were received from one industry trade association, a representative of one affected facility, representatives from two affected Federal agencies, one sterilant manufacturer, three State and local air pollution control agencies, one State agency association, and one private citizen. This final rule reflects our consideration of all of the comments received on the proposed action. This section summarizes the significant comments received on the proposed NESHAP and our response thereto. A summary of all of the minor comments and EPA's response thereto are presented here in this preamble and in the Response to Comments Document (RTC Document), which is available in Docket No. EPA–HQ–OAR–2005–0171.

A. Proposed Alternative 1: Management Practice

1. Management Practice Approach

Comment: Two commenters supported promulgation of the management practice approach, i.e., Regulatory Alternative 1. One of the commenters noted that EPA recognizes that, by minimizing ethylene oxide use with the management practice, hospital ethylene oxide sterilization facilities also minimize ethylene oxide emissions. Both commenters expressed that the proposed management practice alternative ensures that hospitals sterilize the most number of medical devices per pounds of ethylene oxide emitted, and it is consistent with hospital practices.

Two commenters stated that the management practice is common sense. One commenter argued that EPA's proposed GACT were neither acceptable nor consistent with legal requirements. Another commenter stated that EPA's

alternatives do not reflect what many sterilizers have achieved (using control technology) and are capable of achieving cost effectively.

Response: As previously mentioned, we are setting standards for hospital sterilizer area sources based on GACT (i.e., generally available control technologies or management practices) pursuant to section 112(d)(5) of the CAA. As several commenters noted, the management practice for running sterilizers with full loads will ensure that hospitals sterilize the most number of medical devices per pounds of ethylene oxide emitted. We believe that the comments indicating that the management practice is common sense, consistent with current operating practices at many hospitals, and cost-effective, all support our determination that this management practice represents a generally available management practice that is used to control ethylene oxide emissions from area source hospital sterilizers. We, therefore, disagree with the comment that the management practice requirement in this final rule is not consistent with legal requirements. In addition, for a detailed discussion on EPA's consideration of the existing control technologies, please see section V.C of this preamble.

2. Exemption of Certain Sources From the Rule

Comment: One commenter recommended that EPA exclude controlled sources (i.e., sources with add-on control) and sources that use an ethylene oxide concentration of less than 10 percent from all requirements associated with Alternative 1 should EPA adopt that alternative. The commenter expressed that Alternative 1 imposes no additional substantive requirements on controlled sterilizers and would only add administrative burdens with no additional environmental benefits. The commenter also asserted that sources that use an ethylene oxide concentration of less than 10 percent can be excluded with no detrimental effect.

Response: EPA disagrees that this rule contains no substantive requirements on controlled sterilizers. As we clarify in the final rule and in section III.B of this preamble, all area source hospital sterilizers, including sources with add-on controls, are subject to the requirements in this final rule. However, the final rule provides certain compliance options. Specifically, the final rule provides sources with add-on controls the option of demonstrating compliance with the management practice requirement by certifying that they will continue to operate their sterilizers with such control.

EPA also rejects the recommendation of excluding from this rule sources that use an ethylene oxide concentration of less than 10 percent. We recognize that there are hospital sterilization facilities that use sterilant gas blends with low ethylene oxide concentrations. However, we have no information suggesting that facilities using low ethylene oxide sterilant gas blends emit negligible amounts of ethylene oxide. On the contrary, it is our understanding that there is little difference in the amount of ethylene oxide usage (and, therefore, ethylene oxide emissions) between operating a sterilization cycle with pure ethylene oxide as opposed to using sterilant gas blend with less than 10 percent ethylene oxide. When we listed the Hospital Sterilizer Area Source category, we included hospital ethylene oxide sterilization facilities using sterilant gas blends and the commenter did not provide any information that suggests these facilities should not be part of the source category. Further, we have analyzed the costs and impacts associated with the management practice that we are finalizing and we believe the costs are reasonable. See section V.C.1 of this preamble. For the reasons stated above, we reject the commenter's recommendation to exclude from this regulation sources using sterilant gas blends with less than 10 percent ethylene oxide concentration.

3. Exception to the Management Practice Requirement

Comment: One commenter stated that EPA would need to establish, based on comments received and then propose again for comment, examples of definitions of circumstances that would be acceptable for an exemption to the full load requirement. Another commenter observed that hospitals try to minimize their use of ethylene oxide and avoid exceptions to full load runs. Although the commenter stated that generating and managing an inclusive list of all the exceptions to running a full load may be difficult, it provided examples for such exceptions. Specifically, the commenter stated that, on some days, a hospital may receive back from surgery just a few devices that must be ethylene oxide-sterilized and returned as soon as possible to surgery for cases scheduled for the next morning. The commenter stated that, in these instances, the hospital can be forced to run a sterilizer with less than a full load. The commenter also stressed that hospital surgical needs can be unpredictable.

The commenter stated that hospitals have reduced their use of ethylene oxide to sterilize medical devices (and its ethylene oxide emissions) by switching to single-use devices or alternative sterilizing and disinfection technologies, or by consolidating ethylene oxide sterilization. The commenter noted that, ironically, a hospital may increase the frequency with which it needs to run a partially loaded ethylene oxide sterilizer as a result. The commenter, however, emphasized that even with occasional running of less than full loads, there has been a continuing decline in hospital ethylene oxide use and emissions.

Another commenter similarly noted that hospitals currently strive to run full loads unless it is medically necessary to run less than a full load. According to the commenter, often the medical devices processed by the hospital ethylene oxide sterilizer are expensive and hospitals can only afford to retain a minimal number of such devices. The commenter further noted that some of the devices are older devices and cannot be replaced. The commenter stated that these devices are typically utilized in surgical areas and, at times, these devices may need to be used on consecutive days. The commenter stated that the ethylene oxide sterilizer load is processed at the end of the day so the devices will be ready for surgery the following day. According to the commenter, by waiting to run a sterilization cycle until the end of the day, the sterilizer load has a chance to fill up. The commenter noted, however, that if a medical device is needed the following day, the load will be processed even though the load is not full. The commenter stated that the determination to process a load is based on the needs of the patient.

Response: According to the comments, hospitals deviate from the full-load management practice only when patient safety may be at risk. EPA agrees that medical necessity warrants operating a partially loaded ethylene oxide sterilizer. To accommodate patient needs, we have incorporated in the final rule an exception based on medical necessity.

EPA also agrees with the comment that developing a comprehensive list of medically necessary circumstances warranting sterilization of a partial load is difficult. EPA is concerned that such a list may inadvertently exclude some justified circumstances. Further, as reflected in our final rule, we believe that the decision to run a partially loaded sterilizer due to medical necessity should be made by authorized hospital personnel who have knowledge

of patients' medical needs instead of by EPA. However, to assure that hospitals run sterilizers in full loads except during medically necessary circumstances, the final rule requires that facilities document and maintain records of every sterilization cycle, including each partially loaded sterilization, and confirm that it was medically necessary.

Comment: One commenter noted that many university hospitals develop new and unique surgical procedures and devices that may need to be sterilized in partial loads to comply with the more stringent requirements for sterilizing a new instrument.

Response: We believe that it is medically necessary to allow hospitals to sterilize medical devices that are under research and development without a full load. The novelty or uniqueness of the design in some instances require different sterilizing parameters than those used for regular medical devices. In addition, unlike medical devices that are regularly used for patient care, new and experimental medical devices that are under research and development do not have established or known sterilization cycles. Therefore, they may compromise the effectiveness of sterilizing other devices in the same loads. However, hospitals generally do not possess enough medical devices that are under research and development to fully load a sterilizer. To avoid compromising the sterilization process of medical devices regularly used for patient care, we believe that it is medically necessary to allow hospitals to sterilize medical devices that are under research and development in separate and partial loads. Hospitals may invoke the medical necessity exception in the final rule when sterilizing devices that are under research and development.

4. National or Urban

Comment: Three commenters recommended that EPA apply this rule nationwide. Two of the commenters noted that hospital parking areas are typically close to the hospital and that visitors and employees are, therefore, exposed to emissions from hospital ethylene oxide sterilizers regardless of the hospital's location (i.e., urban or rural). One commenter stated that the impacts of ethylene oxide emissions are localized and would be similar for most urban and rural areas. According to the commenter, hospitals are typically located in residential areas, whether or not they are in urban areas, and that populations residing nearby would likely be exposed to the ethylene oxide emissions from a hospital ethylene oxide sterilization facility. Another commenter further stated that hospitals clearly serve more sensitive populations who could be more susceptible to impacts from exposure to ethylene oxide. The commenter similarly noted that the impacts of ethylene oxide emissions are very local and would be roughly the same for both urban and rural areas, except perhaps for hospitals located in areas with a high population density.

Two commenters noted that the cost (of controlling a sterilizer) to a facility is the same for a rural hospital and an urban hospital. The commenters stated that, because the cost and impact are the same, there does not appear to be any rationale for treating rural hospitals differently from urban hospitals.

Response: We agree that a nationwide approach is appropriate given the facts and circumstances of this particular area source category. A rule of nationwide applicability is particularly appropriate here because requiring controls nationwide provides for equitable emission reductions. Control costs are not expected to differ in rural versus urban settings, therefore, the control's cost-effectiveness is the same, and economic impacts are equally distributed. Furthermore, because hospitals are generally located in densely populated areas, we expect negligible difference in the scope of this rule's coverage between a national and an urban (i.e., Urban-1 and Urban-2 areas) rule.[4] We have received no comments recommending that we limit this rule's applicability only to hospitals in Urban-1 and Urban-2 areas.

5. Compliance Date

Comment: One commenter stated that EPA's proposal that a source comply with the management practices within 1 year after the effective date of the final rule may not be a sufficient period of time. The commenter stated that two scenarios could result for medical facilities under the management practice alternative. According to the commenter, one scenario could be that medical facilities may need to purchase smaller ethylene oxide sterilizers to turn around medical instrumentation and equipment without having to purchase more of these medical items, and this could involve construction projects/costs to make ready additional space to accommodate the new sterilizers. The commenter stated that the other scenario could be that medical facilities may need to purchase additional medical instrumentation and equipment to allow for sufficient availability while waiting for enough items to accumulate to run a full load in an ethylene oxide sterilizer. The commenter suggested that EPA consider the costs of additional ethylene oxide sterilizer equipment and related construction, as well as the additional medical instrumentation and equipment costs in any proposed rule by EPA.

Response: EPA does not believe that the management practice requirement in Alternative 1 will result in either of the scenarios described above. The management practice requires sterilizing full loads except during medically necessary circumstances, i.e., necessary to protect human health. As discussed above, this exception to running sterilizers in full loads is based on patient needs. Under the final rule, whether a medically necessary circumstance exists must be determined by an authorized hospital personnel. The final rule, however, requires only that the hospital personnel consider whether sterilizing a partial load is necessary to protect human health; the personnel are not required to consider whether there are viable alternatives to running a partial load, such as purchasing additional sterilizer equipment or medical devices, before invoking the exception to the management practice requirement. Therefore, we do not expect any need for construction and/or capital expenditures associated with such new purchases, as the commenter suggested. We have received no other comments suggesting that hospitals may have difficulty achieving compliance with the management practice alternative within 1 year, as we proposed. We, therefore, retain the 1-year compliance deadline in the final rule.

6. Recordkeeping

Comment: In the proposed rule, EPA solicited comments on whether to require recordkeeping under Alternative 1. We received six comments on recordkeeping. One commenter asked that EPA specify what recordkeeping would entail if less than full loads were run and what EPA would propose to be done with these records. Another commenter stated that, regardless of the size of the load, all items sterilized are recorded following the Association for the Advancement of Medical Instrumentation standard, Ethylene

[4] In the *Integrated Urban Strategy,* EPA defined ''urban areas'' to include Urban-1 and Urban-2 areas. (64 FR 38724). The Urban-1 and Urban-2 definitions are based on the United States Census Bureau's most current decennial census data. Urban-1 areas are counties with metropolitan statistical areas with a population greater than 250,000. Urban-2 counties are all other counties where more than 50 percent of the population is designated urban by the United States Census Bureau.

Oxide Sterilization in Health Care Facilities: Safety and Effectiveness, ANSI/AAMI ST 41:1999. According to the commenter, the sterilizer records under this standard include the following: Load or lot number; item description and quantity; the department; the name of the sterilizer operator; aeration time and temperature; results of the biological monitoring (which is processed with each load to ensure that sterilization has occurred); chemical indicator results; and reports of nonresponsive chemical indicators.

Two commenters stated that hospitals keep a record of each load they run for traceability. Two commenters stated that hospitals could probably add a few more items of information to their records to comply with EPA's requirements. These commenters recommended that EPA's recordkeeping requirements be consistent with hospitals' current practice in maintaining records of sterilized loads.

Two commenters indicated that some State programs require keeping sterilization records, and one commenter stated that some States have required such recordkeeping for many years. The commenters indicated that some hospitals keep such records through computerized recordkeeping systems while others use handwritten records. The commenters believed that these requirements are not likely to be overly burdensome or costly to the facilities.

Response: In light of the comments indicating that hospitals are already keeping records of each sterilization cycle and that such recordkeeping provisions are not overly costly or burdensome, we are requiring affected facilities to keep sterilization records in the final rule. Specifically, the final rule requires that a facility record the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and, for each partial load, state that it was medically necessary. Based on information provided during the comment period, we believe that this recordkeeping requirement is consistent with hospitals' current practice. We also believe the time required to keep these records would be offset by the time saved by the reduced cycles run.

7. Title V Permitting

Comment: One commenter favored title V permitting. The commenter stated that, by requiring title V permits, title V funds could be used to assure compliance. The commenter noted that, according to an EPA Regional office, title V funds cannot be used for non-title V programs. The commenter stated that if, from a national perspective, EPA prefers to exempt area sources such as these from title V permitting, EPA should explain the level of effort they expect from State and local agencies, and develop a funding mechanism for that effort. The commenter further noted that, in this case, the commenter's State already has operating permits for affected facilities and that there would be little cost involved in updating these permits to reflect the Federal rule during the normal permit renewal process.

Response: As discussed in the preamble to the proposed rule, EPA considered four factors in determining whether title V is ''unnecessarily burdensome'' for a particular area source category. Based on its consideration of these factors, EPA concluded that the requirements of title V would be unnecessarily burdensome for area source hospital ethylene oxide sterilization facilities. Among other things, EPA concluded that title V permitting would not result in significant improvements to the compliance requirements for the hospital ethylene oxide sterilization area source category and that title V permitting would likely impose a significant burden on facilities within the source category, some of which are small businesses. The Agency also found that, for many facilities, the cost of obtaining a title V permit may far exceed the cost of complying with the final rule without significant gains in compliance. EPA further determined that the proposed exemptions from title V would not adversely affect public health, welfare, and the environment.

Although the commenter advocates title V permitting, the commenter failed to address EPA's application of the four factors described above, and its conclusion that the proposed exemptions would not adversely affect public health, welfare, and the environment. Indeed, none of the commenters disagreed with any of EPA's proposed findings described above and in the proposed rule that served as the basis for the proposed title V exemption.

Instead of challenging EPA's application of the four factors relevant to determining whether title V requirements would be unnecessarily burdensome on a particular area source category, the commenter focuses on the fact that, in its State, area source hospital sterilizers have State operating permits and that adding the requirements of this rule to those permits would involve little costs. The fact that title V permitting may not be burdensome or costly in one State does not reflect the burden or costs associated with title V permitting nationwide. Once again, the commenter has not identified any flaws in EPA's application of the four factor test described above, which involve an assessment of the costs of title V reporting for the entire source category. Therefore, for the reasons discussed above and in the proposed rule, we are exempting area source hospital ethylene oxide sterilization facilities from the requirements of title V in this final rule.

The commenter apparently favored title V permitting based on its belief that ''by requiring title V permits, EPA would allow title V funds to be used to assure compliance.'' The commenter requested that EPA explain the level of State and local efforts that may be involved in implementing and enforcing the requirements of the final rule and develop a funding mechanism for that effort. We expect such effort to be minimal. We believe that the management practice and the associated recordkeeping requirements in this final rule are straightforward and can, therefore, be easily implemented and enforced. Further, according to the comments received, the management practice requirement is consistent with hospital practices and hospitals are already keeping records of sterilization cycles. In light of the above, we do not anticipate that State and local agencies would need to spend a significant level of effort to implement and enforce this rule. EPA, however, remains committed to working with State and local agencies to implement this rule. State and local agencies that receive grants for continuing air programs under CAA section 105 should work with their project officers to determine what resources are necessary to implement and enforce this area source standard. EPA will continue to provide the resources appropriated for CAA section 105 grants consistent with the statute and the allotment formula developed pursuant to the statute.

Comment: One commenter agreed with EPA's proposal that title V permits are not necessary for area sources. The commenter noted that some hospitals, however, already have or are covered by title V permits, and that any rulemaking has the potential to impose additional permit modification costs. The commenter asserted that EPA should minimize title V permitting cost impacts by adding a provision in this rule stating that an existing title V permit does not have to be reopened or revised to address the requirements of this rule until the next time the permit is renewed, reopened, or revised for another reason. The commenter

alternatively proposed that EPA consider an exemption similar to that which was included in 40 CFR 63.7881(c)(3) of the recently finalized amendments to the Site Remediation NESHAP.

Response: The commenter requested that EPA prescribe in this rule the time for reopening and revising existing title V permits for area source hospital sterilizers. CAA section 502(a) authorizes EPA to exempt an area source category from title V permitting if the Administrator finds that compliance with title V is impracticable, infeasible, or unnecessarily burdensome on such category; however, to the extent that some sources within this area source category are already otherwise required to obtain title V permits, CAA section 502(a) does not authorize EPA to affect in any way these sources' existing obligations under title V, including when the permits must be renewed. As discussed above, pursuant to CAA section 502(a), EPA has determined that the requirements of title V would be unnecessarily burdensome for area source hospital ethylene oxide sterilization facilities. Accordingly, this final rule exempts area source sterilization facilities from the obligation to obtain title V permits for purposes of being subject to the requirements of this rule. The commenter, however, is requesting that EPA prescribe in this rule the time for reopening and revising existing title V permits for area source hospital sterilizers. The commenter's request is unrelated to and beyond the scope of EPA's authority to issue this area source rule pursuant to CAA sections 112(c)(3) and 112(d)(5). The request is also beyond the scope of EPA's authority under CAA section 502(a) to exempt area sources from title V permitting. We, therefore, reject the commenter's request to include its recommended language in this final rule.

B. Proposed Alternative 2: No Control

Comment: One commenter recommended that EPA select Regulatory Alternative 2 (the no additional control alternative). The commenter stated that hospitals have strong economic incentives to operate sterilizers with a full load because doing so reduces both material and labor costs. According to the commenter, because economics already drive hospital ethylene oxide sterilization facilities to implement the management practice, Alternative 1 is unlikely to result in significant emission reduction. The commenter states that it has encouraged its facilities to switch to alternative sterilization methods and, therefore, there are not many ethylene oxide sterilizers at its facility.

Response: As previously mentioned, we included two regulatory alternatives in the proposed rule. As Alternative 1, we proposed to require that hospitals sterilize full loads of medical items having common aeration times except during emergency circumstances that dictate the use of less than full loads to protect human health. However, at the time of the proposal, we had limited information to conclude that the proposed management practice in Alternative 1 reduced ethylene oxide emissions or was cost-effective. Therefore, we included an alternative proposal (Alternative 2) that there are no GACT within the meaning of CAA section 112(d)(5) for the Hospital Sterilizers Area Source category. We also solicited comments on the costs and emission reduction estimates for the management practice.

As explained in more detail in section V.A.1 of this preamble, we have since received comments indicating that the management practice minimizes ethylene oxide emissions by minimizing ethylene oxide use and that the practice is cost-effective. We, therefore, conclude that the management practice requirement we proposed as Alternative 1 reflects a generally available management practice within the meaning of CAA section 112(d)(5) for this area source category.

The commenter apparently agreed that the management practice is cost-effective. It stated that hospitals have economic incentives to run the sterilizers full because it reduces both labor and material costs. The commenter, nevertheless, recommended Alternative 2, claiming that Alternative 1 may not achieve significant reduction since it is already being implemented. However, the CAA does not require a GACT standard to achieve any specific level of emission reduction.

As explained above, we have determined that the management practice that we proposed as Alternative 1 represents GACT for this area source category. The commenter offered no information suggesting otherwise. Having determined that our proposed Alternative 1 represents GACT, we can no longer conclude that there are no GACT within the meaning of CAA section 112(d)(5). We, therefore, reject the commenter's recommendation that we adopt the no control option (Alternative 2) in this final rule.

C. Add-on Controls

1. Cost Considerations

Comment: Four commenters recommended that EPA require add-on controls for the area source hospital ethylene oxide sterilizers. Two commenters noted that, in the preamble to the proposed rule, EPA stated that the two predominant types of control devices (i.e., acid-water scrubbers and catalytic oxidation units) reduce emissions by approximately 99 percent. One of these two commenters also noted that, according to the National Toxicology Program, researchers have demonstrated that the application of these control technologies to hospital sterilizers effectively reduce ethylene oxide concentrations. This commenter, therefore, concluded that proven control technology is readily available to control ethylene oxide emissions from hospital sterilizers and that application of this technology is practicable, feasible, prudent, and not unnecessarily burdensome. Two commenters drew the same conclusion, noting that the control technologies have been required by some State programs for many years. One commenter similarly stated that if more than half of the sources already have add-on controls, it suggests that these controls are practical and feasible.

One commenter expressed that, with nearly half of the hospitals using add-on controls, it is hard to understand EPA's rationale in the proposed rule that add-on controls are too costly. One commenter suggested that, if cost is to be considered, EPA should consider a full array of alternatives, including the cost of alternatives to sterilization and alternative means of sterilization, and compare them to the cost of controlling ethylene oxide sterilization. The commenter stated that the proposed rule presumes ethylene oxide sterilization must be preserved. The commenter noted that in the Hospital, Medical, Infectious Waste Incinerator (HMIWI) standard, however, EPA recognized that there were alternatives to incineration of the wastes and, therefore, required emission controls that were not necessarily cost-effective. The commenter recommended that the same approach should be applied here.

One commenter stated that installing control would be an unnecessary cost to hospitals providing no benefits. The commenter observed that hospital ethylene oxide sterilization has declined due to Occupational Safety and Health Administration regulations, new sterilization methods, and new designs and materials used in medical devices. The commenter, however, emphasized that ethylene oxide sterilization is a

necessity in hospitals. The commenter explained that the medical devices processed by ethylene oxide are expensive and that hospitals can only afford minimal amounts on hand. The commenter further explained that some of the medical devices are old and cannot be replaced. The commenter noted that these devices are typically utilized in surgical areas. The commenter stated that EPA's rationale makes clear that existing ethylene oxide emission control technology will not provide the type of cost-benefit needed to justify new hospital investment in the control devices. The commenter noted that the cost of add-on control would include not just the cost of the device, but also the cost of installation, facility modification, annual testing of control devices, and utility and maintenance.

Response: CAA section 112(d)(5) provides that, with respect to area source categories listed pursuant to CAA section 112(c), the Administrator may, in lieu of MACT, promulgate standards or requirements which provide for the use of GACT. As explained in the preamble to the proposed rule, EPA is issuing the standards for the hospital sterilizers area source category under CAA section 112(d)(5).

In determining what constitutes GACT for a particular area source category, EPA evaluates the control technologies and management practices that reduce HAP emissions and are generally available for the area source category. The legislative history supporting CAA section 112(d)(5) provides that EPA may consider costs in determining what constitutes GACT for the area source category.[5]

In considering costs, the commenters who recommended add-on control focused mainly on the actual costs to hospitals and asserted that such control is likely not too costly if many hospitals are using it under existing State or local requirements. As we stated in the preamble to the proposed rule, EPA recognizes that over half of the hospitals use add-on controls. However, the actual cost to individual hospitals is but one cost factor that we considered in this rulemaking. We also noted that the total annualized cost for add-on controls, which we estimated to be $8.5 million, exceeds the total annualized cost for the management practice, which we estimated to range from $32,000 to $61,000, by more than 100 fold. In addition, we considered the cost-effectiveness of the add-on controls. See, e.g., *Husquavarna AB* v. *EPA*, 439 U.S. App. DC 118, 254 F.3d 195, 201 (DC Cir. 2001) (finding EPA's decision to consider costs on a per ton of emissions removed basis reasonable because CAA section 213 did not mandate a specific method of cost analysis). EPA's cost analysis for the add-on controls showed poor cost-effectiveness. Specifically, EPA's cost-effectiveness estimate for add-on controls was $200,000 per ton of ethylene oxide reduced. This cost-effectiveness excludes monitoring, recordkeeping, and reporting costs.

We also considered alternatives to ethylene oxide sterilization, as one commenter suggested. We learned from several commenters that, although ethylene oxide sterilization in hospitals has declined, it remains a necessity for certain medical devices that cannot be easily replaced or sterilized by other means. We agree with these commenters that, in light of the declined level of ethylene oxide sterilization and the lack of alternatives for sterilizing certain unique and expensive medical devices, the benefit of requiring add-on control is outweighed by the various costs associated with such control. Based on the foregoing, we determined that add-on controls do not represent GACT for this area source category.

One commenter argued that EPA required add-on control in the HMIWI standard that were not necessarily cost-effective and that EPA should take the same approach in this final rule.[6] The HMIWI standard, however, was promulgated pursuant to section 129 of the CAA, which requires that EPA establish standards that reflect the MACT. Consistent with the requirements of CAA section 129, EPA issued the original HMIWI standards based on MACT. CAA section 129(a)(2) does not allow EPA to consider costs in setting the floor for control. By contrast, EPA is issuing this final rule pursuant to CAA section 112(d)(5), which allows EPA to consider costs, including cost-effectiveness, in establishing GACT. Thus, the HMIWI rule is not relevant, because in that rule, EPA, by statute, could not consider costs.

2. Best Available Control Technology (BACT) or MACT

Comment: One commenter stated that, because ethylene oxide is a known human carcinogen, its emissions should be controlled using the BACT. The commenter stated alternatively that, due to the widespread use of control on hospital sterilizers, the MACT floor level of control would be add-on controls under CAA section 112(d)(2). The commenter stated that, based on the experience in its State, the MACT floor and associated recordkeeping are feasible and prudent and, therefore, none of EPA's proposals are in accordance with legal requirements. The commenter claimed that the proposed NESHAP must be revised to represent MACT floor of add-on emission control and recordkeeping as required by law.

Response: CAA section 112(c)(2) requires that EPA establish emission standards under CAA section 112(d) for the categories listed under CAA section 112(c), including area source categories listed pursuant to CAA section 112(c)(3). As mentioned above, EPA may issue standards for listed area source categories based on MACT (CAA section 112(d)(2)) or GACT (CAA section 112(d)(5)). CAA Section 112(d) does not contain a standard based on BACT. Therefore, EPA rejects the commenter's request to require the use of BACT because such standard is not authorized by the CAA.

The commenter also argued alternatively that neither of EPA's proposed alternatives was in accordance with legal requirements and that EPA must issue a MACT standard as required by law. The commenter, however, did not identify any legal requirement that allegedly is not satisfied by EPA's proposed alternatives or requires EPA to issue a MACT standard for the Hospital Sterilizer Area Source category. On the contrary, the commenter noted that ''EPA is 'exercising discretion' in promulgating standards or requirements under section 112(d)(5) of the CAA.'' Although the commenter acknowledged that EPA has discretion under CAA section 112(d)(5) to issue a GACT standard in lieu of a MACT standard for listed area source categories, it claimed that, based on its State's experience with regulating and controlling ethylene oxide emissions from hospital sterilizers, the MACT floor and associated recordkeeping are feasible and prudent. The commenter argued that, therefore, neither of EPA's proposals is acceptable in accordance with legal requirements and that EPA

[5] Additional information on the definition of ''generally available control technologies or management practices'' (GACT) is found in the Senate report on the 1990 amendments to the CAA (S. Rep. No. 101–228, 101st Cong. 1st session. 171–172). That report states that GACT is to encompass: * * * methods, practices and techniques which are commercially available and appropriate for application by the sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems.

[6] 40 CFR part 60, subpart Ce—Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators (constructed on or before June 20, 1996).

40 CFR part 60, subpart Ec—Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996.

must issue a MACT standard as required by law.

The commenter's argument seems to imply that EPA must first find that a MACT standard is infeasible, imprudent, or otherwise inappropriate before the Agency can legally issue a GACT standard for an area source category pursuant to section 112(d)(5) of the CAA. However, there is no such requirement under the CAA. In fact, the CAA does not contain any condition precedent for issuing a GACT standard under CAA section 112(d)(5). CAA section 112(d)(5), which is entitled ''Alternative standard for area sources,'' provides:

> With respect *only* to categories and subcategories of area sources listed pursuant to subsection (c) of this section, the Administrator *may, in lieu of* the authorities provided in paragraph (2) and subsection (f) of this section, elect to promulgate standards or requirements applicable to sources in such categories or subcategories which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants. (*Emphasis added*).

There are two critical aspects to CAA section 112(d)(5). First, CAA section 112(d)(5) applies only to those categories and subcategories of area sources listed pursuant to CAA section 112(c). The commenter does not dispute that EPA listed the Hospital Sterilizer Area Source category pursuant to CAA section 112(c)(3). Second, CAA section 112(d)(5) provides that, for area sources listed pursuant to CAA section 112(c), EPA ''*may, in lieu of*'' the authorities provided in CAA section 112(d)(2) and 112(f), elect to promulgate standards that provide for the use of generally available control technologies or management practices (GACT). Section 112(d)(2) provides that emission standards established under that provision ''require the maximum degree of reduction in emissions'' of HAP (also known as MACT).[7] Webster's dictionary defines the phrase ''in lieu of'' to mean ''in the place of'' or ''instead of.'' See Webster's II New Riverside University (1994). Thus, CAA section 112(d)(5) authorizes EPA to promulgate standards that provide for the use of GACT *instead of* issuing MACT standards. The statute does not set any condition precedent for issuing standards under CAA section 112(d)(5) other than that the area source category or subcategory at issue must be one that EPA listed pursuant to CAA section 112(c), which is the case here. Had Congress intended that EPA first conduct a MACT analysis for each area source category and only if cost or some other reason made applying the MACT standard inappropriate for the category would EPA be able to issue a standard under CAA section 112(d)(5), Congress would have stated so expressly in CAA section 112(d)(5). Congress did not require EPA to conduct any MACT analysis, floor analysis, or beyond-the-floor analysis before the Agency could issue a CAA section 112(d)(5) standard. Rather, Congress authorized EPA to issue GACT standards for area source categories listed under CAA section 112(c)(3), and that is precisely what EPA has done in this rulemaking.

Although EPA has no obligation to justify why it is issuing a GACT standard for an area source category as opposed to a MACT standard, we did so in the proposed rule. See 71 FR 64910, November 6, 2006. As explained in the proposed rule, we determined that the MACT floor level of control would be add-on controls if we were to develop this area source rule based on CAA section 112(d)(2). As explained in more detail in section V.C.1 of this preamble, we took costs into consideration and determined that the benefit of requiring add-on controls is outweighed by the costs associated with such control. We believe the consideration of costs is especially important for the well-controlled area sources at issue in this final action because, given current well-controlled levels, a MACT floor determination, where costs cannot be considered, could result in only marginal reductions in emission at very high costs.

3. Consideration of Health Impacts or Risks

Comment: According to one commenter, EPA's decision not to require add-on control appears to be based on cost-effectiveness without much regard for heath impact or risk. The commenter argued that an appropriate analysis would consider the health impacts where people are exposed. Four commenters identified health risks from ethylene oxide exposure as a basis for requiring add-on control. The commenters noted that ethylene oxide is a carcinogen and described in detail health effects from ethylene oxide exposure. In addition, one commenter stated that, since these sterilization units are located in hospitals which are densely populated with staff and patients, extra care should be taken to assure their health and safety. One commenter expressed concern that people living, working, and visiting the vicinity of the uncontrolled sources (i.e., those that do not have add-on controls) are not afforded the same level of protection as those near controlled sterilizers.

Two commenters stated that hospital ethylene oxide emissions are minimal and declining and that the potential risks of ethylene oxide emissions, based on the EPA analysis, are also minimal. Accordingly, both commenters stated that there is no benefit for installing ethylene oxide emission control equipment, and one commenter stated that any benefits would be insignificant and far outweighed by the real costs associated with the control.

Response: As previously explained, pursuant to sections 112(c)(3) and 112(k)(3)(B) of the CAA, EPA identified ethylene oxide as one of 30 HAP that present the greatest threat to public health in the largest number of urban areas and listed Hospital Sterilizers Area Source as a category needed to ensure that sources representing 90 percent of area source ethylene oxide emissions are subject to regulation.

In the 1990 CAA Amendments, Congress established a two-phase approach for setting HAP emission standards. *Sierra Club* v. *EPA*, 353 F.3d 976, 980 (D.C. Cir. 2004). The first phase is the initial standard setting phase, which is the phase at issue in this rulemaking.[8] In this phase, the standards are technology-based, and this is true regardless of whether we issue MACT standards under CAA section 112(d)(2) and (d)(3), or GACT standards under CAA section 112(d)(5).[9] See Senate Report at 148 (1989); *Sierra Club* v. *EPA*, 353 F.3d at 980.

In this final rule, EPA is establishing emissions standards for this area source category under CAA section 112(d)(5), which authorizes EPA to set emissions standards based on GACT for a listed area source category. The legislative history describes GACT as ''methods, practices, and techniques which are

[7] CAA section 112(d)(5) also references CAA section 112(f). See CAA section 112(f)(5) (entitled ''Area Sources'' and providing that EPA is not required to conduct a review or promulgate standards under CAA section 112(f) for any area source category or subcategory listed pursuant to CAA section 112(c)(3) and for which an emission standard is issued pursuant to CAA section 112(d)(5)).

[8] The second phase of standard setting involves a risk-based analysis. Specifically, CAA section 112(f)(2) requires EPA to determine—8 years after issuance of the initial MACT standard—whether residual risks remain that warrant more stringent standards than achieved through MACT. CAA Section 112(f)(5) provides that the Agency shall not be required to conduct a residual risk for area sources for which EPA has issued a GACT standard.

[9] CAA Section 112(d)(4) does provide, however, that with respect to pollutants for which the EPA Administrator has established a health threshold, EPA can consider such threshold in setting standards under CAA section 112(d). Ethylene oxide is a carcinogen and is, thus, not a pollutant for which the Administrator has established a health threshold, and, therefore, CAA section 112(d)(4) is not relevant to this category.

commercially available and appropriate for application by sources in the category considering economic impacts and the technical capabilities of the firms to operate and maintain the emissions control systems.'' S. Rep. No. 101–228, at 171 (1989) (Senate Report).

Consistent with the statute and the legislative history, in determining GACT, we evaluated the control technologies and management practices that reduce HAP emissions from the ethylene oxide Hospital Sterilizer Area Source category, and we assessed the costs of implementing such approaches. We did not consider health impacts or risks in establishing the emission standards for the Hospital Sterilizer Area Source category, as the commenters recommended, nor were we required by statute to do so. However, we note that health risk did play a role in this process in that the determination of which pollutants to regulate and from which categories was governed by the statutory requirement to regulate sources accounting for 90 percent or more of the 30 HAP that present the greatest health threat in urban areas.

4. Potential Backsliding

Comment: One commenter noted that many hospital ethylene oxide sterilizers are controlled (i.e., with add-on controls) as the result of State and local programs. The commenter stated that in the preamble to the proposed rule, EPA recognizes the contributions of the State and local programs and is apparently relying upon them to ensure adequate control of hospital sterilizers. The commenter stated that EPA's proposal to rely on these programs, in lieu of Federal requirements, is unwise and inappropriate. The commenter stated that the existence of State and local regulations does not relieve the agency of its duty to set emissions control requirements under CAA section 112. The commenter further noted that many State and local agencies are not able to be more stringent than Federal requirement and that it is conceivable that some agencies could be required to change their regulations to be consistent with those of the Federal government, resulting in relaxing of existing non-Federal rules. The commenter also claims that State and local regulations can change in the future for other reasons. The commenter stated that, in the absence of Federal requirements, there would be nothing to prevent backsliding by the sources if a State or local rule is realized or eliminated.

Another commenter stated that for sources in its State, EPA's issuance of this rule means that existing sources would continue to be subject to the State air toxics rule that requires 99 percent control, but new sources would only be subject to EPA's requirement. The commenter stated that this amounts to backsliding on emission control requirements and an increase in emissions.

Response: EPA has not shed its responsibility to set emission standards under CAA section 112 because of existing State and local regulations. On the contrary, EPA is issuing this final rule today to regulate ethylene oxide emissions from hospital sterilizers. As described above, pursuant to CAA section 112(d)(5), EPA has established in this final rule a management practice requirement that represents GACT for this area source category. EPA did not reject the add-on control option in this rulemaking because it was relying on existing State and local programs to require add-on controls, as one commenter contended. Rather, as previously explained in section V.C.1 of this preamble, EPA concludes that add-on controls do not represent GACT for this area source category.

Two commenters expressed concern that certain States may require that their existing regulations be relaxed as not to be more stringent than EPA's standards. However, CAA section 112(l) only prohibits States from setting standards that are less stringent than EPA's standards; the CAA does not affect State and local emission standards that are more stringent than the requirements of this final rule. The issue of potential backsliding that the commenters raised is based on State law, which EPA has no authority to change. We, however, encourage States to revisit their State laws to address this concern.

5. Emissions From Aeration

Comment: One commenter noted that some sterilizers only operate their catalytic control devices during the initial purge of ethylene oxide (following sterilization) and not during the entire aeration cycle. The commenter stated that the control device should be used for all discharges, not just the initial purge.

Response: The commenter appears to be arguing that a control device should be used to control both sterilization and aeration ethylene oxide emissions instead of just sterilization emissions. The final rule does not, however, require the use of a control device. EPA has determined that the management practice in the final rule represents GACT and requires that hospitals run sterilizers in full loads except during medically necessary circumstances. This requirement will reduce both sterilization and aeration ethylene oxide emissions by reducing the amount of ethylene oxide usage.

Although the final rule does not require the use of a control device, it allows the use of a control device as an alternative compliance option for the management practice requirement because the use of a control device achieves reduction in ethylene oxide emissions that are at least equivalent to the ethylene oxide reduction resulting from the management practice. This is true even if the control device is used to control ethylene oxide emissions from sterilization only. Therefore, controlling aeration emissions with a control device is not necessary under the alternative compliance option.

VI. Summary of Environmental, Energy, Cost, and Economic Impacts

We estimate that in 2002 there were, at most, 1,900 hospital area sources that conduct ethylene oxide sterilization, of which approximately 630 do not presently have add-on controls. The final management practice was estimated at proposal to reduce the 44 tpy emitted from ethylene oxide sterilizers by 2 to 9 tpy. We did not receive any comments that would allow us to improve this estimate. Several commenters, however, stated that they are already employing the management practice. With the management practice, we believe there is minimal effect on either air quality or non-air quality environmental impacts and there are negligible energy or economic impacts. Annualized costs to comply with the final standards are estimated to range from $32,000 to $61,000 per year.

VII. 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 may raise novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866, and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The information requirements in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* The information collection requirements are not enforceable until OMB approves them.

The recordkeeping and reporting requirements in the final rule are based

on the information collection requirements in the 40 CFR part 63 General Provisions (subpart A), some of which are incorporated into the final NESHAP. The ICR document includes the burden estimates for all applicable General Provisions. The recordkeeping and reporting requirements in the General Provisions are mandatory pursuant to section 114 of the CAA (42 U.S.C. 7414). All information submitted to EPA pursuant to the information collection requirements for which a claim of confidentiality is made is safeguarded according to CAA section 114(c) and the Agency's implementing regulations at 40 CFR part 2, subpart B.

The final NESHAP for area sources requires a one-time initial notification by hospital ethylene oxide sterilization facilities certifying that the facility is in compliance with rule requirements and requires recordkeeping for each sterilization cycle for sterilizers not equipped with an air pollution control device.

The annual burden for the information collection averaged over the first 3 years of this ICR is estimated to total 3,576 labor hours per year at a cost of $245,000 for the 1,900 existing hospital sterilizer area sources. Small annualized capital/startup costs and small operation and maintenance costs are associated with the requirements. No costs or burden hours are estimated for new area sources because no new sources are estimated during the next 3 years. 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. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For the purposes of assessing the impacts of the area source NESHAP on small entities, small entity is defined as: (1) A small business that is a hospital as defined by NAICS codes 622110 and 622310 whose parent company has less than $31.5 million in gross revenue (based on Small Business Administration (SBA) size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The final rule requires the use of a management practice to minimize the operation of the ethylene oxide sterilization unit and will, therefore, have minimal nationwide costs, i.e., range from $32,000 to $61,000 per year. We have determined that less than 3 percent of the hospitals are small businesses as defined by the SBA. We have also determined that none of these small businesses are significantly impacted by this proposal for none of them will incur annualized compliance costs of 0.1 percent of sales or greater.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. The final rule is designed to harmonize with existing State or local requirements.

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 to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation 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 final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, the final rule is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the final rule does not significantly or uniquely affect small governments. The final rule contains no requirements that apply to such governments, impose no obligations upon them, and will not result in expenditures by them of $100 million or more in any one year or any disproportionate impacts on them. Therefore, the final rule is not subject to section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) requires EPA to develop an accountable process to ensure ''meaningful and timely input by State

and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The final rule imposes requirements on owners and operators of specified area sources and not State and local governments. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. This final rule imposes requirements on owners and operators of specified area sources and not tribal governments. Thus, Executive Order 13175 does not apply to this final rule.

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

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined 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 those 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. This final rule is not subject to Executive Order 13045 because it is 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

This final rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, and Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, we have concluded that the final rule is not likely to have any adverse energy effects because energy requirements would likely be less than existing levels. No additional pollution controls or other equipment that would consume energy are required by this final rule.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Pub. L. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This final rule establishes national standards for the area source category.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the final rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final rule will be effective on December 28, 2007.

List of Subjects in 40 CFR Part 63

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

Dated: December 20, 2007.

Stephen L. Johnson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

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

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

■ 2. Part 63 is amended by adding subpart WWWWW to read as follows:

Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilizers

Sec.

Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilizers

Applicability and Compliance Dates

§ 63.10382 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate an ethylene oxide sterilization facility at a hospital that is an area source of hazardous air pollutant (HAP) emissions.

(b) The affected source subject to this subpart is each new or existing sterilization facility.

(1) An affected source is existing if you commenced construction or reconstruction of the affected source before November 6, 2006.

(2) An affected source is new if you commenced construction or reconstruction of the affected source on or after November 6, 2006.

§ 63.10384 What are my compliance dates?

(a) *Existing source.* If you have an existing affected source, you must comply with applicable requirements in this subpart no later than December 29, 2008.

(b) *New source.* If you start up a new affected source on or before December 28, 2007, you must comply with applicable requirements in this subpart by December 28, 2007.

(c) *New source.* If you start up a new affected source after December 28, 2007, you must comply with applicable requirements in this subpart upon startup of your affected source.

Standards

§ 63.10390 What management practice standard must I meet?

You must sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in § 63.10448.

Initial Compliance Requirements

§ 63.10400 How do I demonstrate initial compliance?

(a) Except as provided in paragraphs (b) and (c) of this section, you must demonstrate initial compliance with the management practice standard in § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are sterilizing full loads of items having a common aeration time except under medically necessary circumstances.

(b) If you operate your sterilization unit(s) with an air pollution control device pursuant to a State or local regulation, you may demonstrate initial compliance with § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are operating the sterilization unit in accordance with your State or local regulation and following control device manufacturer's recommended procedures.

(c) If you operate your sterilization unit(s) with an air pollution control device but are not subject to any State or local regulation, you may demonstrate initial compliance with § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device. You must certify that you are operating the control device during all sterilization processes and in accordance with manufacturer's recommended procedures.

§ 63.10402 By what date must I demonstrate initial compliance?

You must demonstrate initial compliance with § 63.10390 upon startup or no later than 180 calendar days after your compliance date, whichever is later.

Monitoring—Continuous Compliance Requirements

§ 63.10420 How do I demonstrate continuous compliance with the management practice requirements?

For each sterilization unit not equipped with an air pollution control device, you must demonstrate continuous compliance with the management practice standard in § 63.10390 by recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.

Notifications, Reports, and Records

§ 63.10430 What notifications must I submit and by when?

(a) You must submit an Initial Notification of Compliance Status that includes the information required in paragraphs (a)(1) through (5) of this section and the applicable certification in § 63.10400.

(1) The name and address of the owner or operator.

(2) The address (i.e., physical location) of the affected source.

(3) An identification of the standard and other applicable requirements in this subpart that serve as the basis of the notification and the source's compliance date.

(4) A brief description of the sterilization facility, including the number of ethylene oxide sterilizers, the size (volume) of each, the number of aeration units, if any, the amount of annual ethylene oxide usage at the facility, the control technique used for each sterilizer, and typical number of sterilization cycles per year.

(5) A statement that the affected source is an area source.

(b) You must submit the Initial Notification of Compliance Status to the appropriate authority(ies) specified in § 63.9(a)(4). In addition, you must submit a copy of the Initial Notification of Compliance Status to EPA's Office of Air Quality Planning and Standards. Send your notification via e-mail to *CCG-ONG@EPA.GOV* or via U.S. mail or other mail delivery service to U.S. EPA, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Attn: Hospital Sterilizers Project

Leader, Research Triangle Park, NC 27711.

(c) You must submit the Initial Notification of Compliance Status no later than 180 calendar days after your compliance date, consistent with § 63.10402.

§ 63.10432 What records must I keep?

You must keep the records specified in paragraphs (a) and (b) of this section.

(a) A copy of the Initial Notification of Compliance Status that you submitted to comply with this subpart.

(b) Records required by § 63.10420 for each sterilization unit not equipped with an air pollution control device.

§ 63.10434 In what form and for how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review.

(b) You must keep each record for 5 years following the date of each record.

(c) You must keep each record onsite for at least 2 years after the date of each record. You may keep the records offsite for the remaining 3 years.

Other Requirements and Information

§ 63.10440 What parts of the General Provisions apply to me?

Table 1 to this subpart shows which parts of the General Provisions in 40 CFR 63.1 through 63.16 apply to you.

§ 63.10442 Who implements and enforces this subpart?

(a) This subpart can be implemented and enforced by us, the U.S. EPA, or a delegated authority such as your State, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to your State, local, or tribal agency, then that agency has the authority to implement and enforce this subpart. You should contact your U.S. EPA Regional Office to find out if this subpart is delegated to your State, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a State, local, or tribal agency under 40 CFR part 63, subpart E, the authorities contained in paragraph (c) of this section are retained by the Administrator of the U.S. EPA and are not transferred to the State, local, or tribal agency.

(c) The authorities that will not be delegated to State, local, or tribal agencies include approval of alternatives to the applicability requirements under 40 CFR 63.10382, the compliance date requirements in 40 CFR 63.10384, and the management practice standards as defined in 40 CFR 63.10390.

§ 63.10446 Do title V permitting requirements apply to area sources subject to this subpart?

You are exempt from the obligation to obtain a permit under 40 CFR part 70 or 40 CFR part 71, provided you are not otherwise required by law to obtain a permit under 40 CFR 70.3(a) or 40 CFR 71.3(a). Notwithstanding the previous sentence, you must continue to comply with the provisions of this subpart.

§ 63.10448 What definitions apply to this subpart?

Terms used in this subpart are defined in the Clean Air Act (CAA), in 40 CFR 63.2, and in this section as follows:

Aeration process means any time when ethylene oxide is removed from the aeration unit through the aeration unit vent or from the combination sterilization unit through the sterilization unit vent, while aeration or off-gassing is occurring.

Aeration unit means any vessel that is used to facilitate off-gassing of ethylene oxide.

Air pollution control device means a catalytic oxidizer, acid-water scrubber, or any other air pollution control equipment that reduces the quantity of ethylene oxide in the effluent gas stream from sterilization and aeration processes.

Combination sterilization unit means any enclosed vessel in which both the sterilization process and the aeration process occur within the same vessel, *i.e.*, the vessel is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing and is followed by off-gassing of ethylene oxide.

Common aeration time means that items require the same length of time to off-gas ethylene oxide.

Full load means the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation in the sterilization unit.

Hospital means a facility that provides medical care and treatment for patients who are acutely ill or chronically ill on an inpatient basis under supervision of licensed physicians and under nursing care offered 24 hours per day. Hospitals include diagnostic and major surgery facilities but exclude doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis.

Hospital central services staff means a healthcare professional, including manager and technician, who is either directly involved in or responsible for sterile processing at a hospital.

Medically necessary means circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

State or local regulation means a regulation at the State or local level that requires a hospital to reduce the quantity of ethylene oxide emissions from ethylene oxide sterilization units.

Sterilization facility means the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing.

Sterilization process means any time when ethylene oxide is removed from the sterilization unit or combination sterilization unit through the sterilization unit vent.

Sterilization unit means any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing. As used in this subpart, the term includes combination sterilization units.

Table to Subpart WWWWW of Part 63

As required in § 63.10440, you must comply with the requirements of the General Provisions (40 CFR part 63, subpart A) shown in the following table:

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

Citation	Subject	Applies to subpart WWWWW	Explanation
§ 63.1(a)(1)–(4), (6), (10)–(12), (b)(1), (3)	Applicability	Yes.	
§ 63.1(a)(5), (7)–(9)	[Reserved].		
§ 63.1(b)(2)	[Reserved].		

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

Citation	Subject	Applies to subpart WWWWW	Explanation
§ 63.1(c)(1)–(2)	Applicability of this part after a relevant standard has been set.	Yes	§ 63.10446 of this subpart exempts affected sources from the obligation to obtain title V operating permits for purposes of being subject to this subpart.
§ 63.1(c)(3)–(4)	[Reserved].		
§ 63.1(c)(5)	Subject to notification requirements	No.	
§ 63.1(d)	[Reserved].		
§ 63.1(e)	Emission limitation by permit	Yes.	
§ 63.2	Definitions	Yes.	
§ 63.3	Units and abbreviations	Yes.	
§ 63.4	Prohibited activities	Yes.	
§ 63.5	Construction/reconstruction	No.	
§ 63.6(a), (b)(1)–(5), (7)	Compliance with standards and maintenance requirements.	Yes.	
§ 63.6(b)(6)	[Reserved].		
§ 63.6(c)(1)	Compliance dates for existing sources	Yes	Subpart WWWWW requires compliance 1 year after the effective date.
§ 63.6(c)(2), (5)	Compliance dates for CAA section 112(f) standards and for area sources that become major.	No.	
§ 63.6(c)(3)–(4)	[Reserved].		
§ 63.6(d)	[Reserved].		
§ 63.6(e)–(h)	Alternative nonopacity emission standard.	No.	
§ 63.6(i)–(j)	Compliance extension	Yes.	
§ 63.7	Performance testing requirements	No.	
§ 63.8	Monitoring requirements	No.	
§ 63.9(a)	Applicability and initial notifications addressees.	Yes.	
§ 63.9(b)	Initial notifications	No.	
§ 63.9(c)	Request for extension of compliance	Yes.	
§ 63.9(d)–(j)	Other notifications	No.	
§ 63.10(a)(1)–(2)	Recordkeeping and reporting requirements, applicability.	Yes.	
§ 63.10(a)(3)–(4)	General information	Yes.	
§ 63.10(a)(5)–(7)	Recordkeeping and reporting requirements, reporting schedules.	No.	
§ 63.10(b)(1)	Retention time	Yes.	
§ 63.10(b)(2)–(f)	Recordkeeping and reporting requirements.	No.	
§ 63.11	Control device requirements	No.	
§ 63.12	State authority and delegations	Yes.	
§§ 63.13–63.16	Addresses, Incorporations by Reference, availability of information, performance track provisions.	Yes.	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 65

[EPA–HQ–OAR–2007–0429; FRL–8511–7]

RIN 2060–A045

Revisions to Consolidated Federal Air Rule; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendments.

SUMMARY: The EPA issued a final rule on August 27, 2007 (effective date November 26, 2007) that revised the General Provisions for Consolidated Federal Air Rule to allow extensions to the deadline imposed for source owners and operators to conduct required performance tests in specified force majeure circumstances. The final rule inadvertently stated that we were revising paragraph (c) introductory text when we actually added introductory text to paragraph (c). The purpose of this action is to correct this error.

This action merely addresses a formatting issue. Thus, it is proper to issue this notice without notice and comment. Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the Agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making this action final without prior proposal and opportunity for comment because the change to the rule is a minor technical correction, is noncontroversial, and does not substantively change the agency actions taken in the final rule. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).