Friday, 8:30 to 4:30, excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Nacosta C. Ward may be reached by phone at (404) 562–9140 and via electronic mail at *ward.nacosta@epa.gov.* Amanetta Wood may be reached by phone at (404) 562–9025 and via electronic mail at *wood.amanetta@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the Rules section of this **Federal Register.**

Dated: October 24, 2006.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. E6–18582 Filed 11–3–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0171; FRL–8239–8]

RIN 2060–AM14

National Emission Standards for Hospital Ethylene Oxide Sterilizers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing two primary regulatory alternatives 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 first alternative proposes a generally available management practice requirement for new and existing hospital sterilizers that are area sources. The second alternative proposes that there are no generally available control technologies or management practices within the meaning of Clean Air Act section 112(d)(5) for this source category. We are proposing these two different alternatives because we currently have imperfect information concerning the ability of the proposed management practice to reduce hazardous air pollutant emissions and the cost-effectiveness of such management practice.

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

DATES: *Comments.* Written comments must be received on or before January 5, 2007.

Public Hearing. If anyone contacts EPA by November 27, 2006 requesting to speak at a public hearing, a public hearing will be held on December 6, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2005–0171, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–1741.
- *Mail:* U.S. Postal Service, send comments to: Air and Radiation Docket (6102T), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies. We request that a separate copy also be sent to the contact person identified below (see **FOR FURTHER INFORMATION CONTACT**).

Hand Delivery: In person or by courier, deliver comments to: Air and Radiation Docket (6102T), Environmental Protection Agency, EPA West Building, 1301 Constitution Avenue, NW., Room B–102, Washington, DC 20014. Please include a total of two copies. Such deliveries are accepted only during the Docket's normal hours of operation and special arrangements should be made for deliveries of boxed information. We request that a separate copy also be sent to the contact person identified below (see **FOR FURTHER INFORMATION CONTACT**).

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2005–0171. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket, Docket ID No. EPA–HQ–OAR–2005–0171, EPA West Building, Room B–102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

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

Public Hearing: If a public hearing is held, it will be held at 10 a.m. at the EPA's Environmental Research Center Auditorium, Research Triangle Park, NC, or at an alternate site nearby.

FOR FURTHER INFORMATION CONTACT: For questions about the proposal, contact Mr. David Markwordt, EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Research Triangle Park, NC 27711;

telephone number (919) 541–0837; fax number (919) 541–0246; e-mail address: *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION: *Regulated Entities.* Categories and entities potentially regulated by the proposed action are hospitals which sterilize with ethylene oxide. The proposed action would affect the following categories of sources:

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 Code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the proposed rule. If you have any questions regarding the applicability of the proposed action to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Submitting CBI. Do not submit information which you claim to be CBI to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Public Hearing. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should contact Mr. David Markwordt, EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143–01), Research Triangle Park, NC 27711, telephone number (919) 541–0837, e-mail address: *markwordt.david@epa.gov*, at least 2 days in advance of the potential date of the public hearing. Persons interested in attending the public hearing must also call Mr. David Markwordt to verify the time, date, and location of the hearing. A public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposed action.

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

Organization of this Document. The information presented in this preamble is organized as follows:

I. Background

Section 112(k)(3)(B) of the Clean Air Act (CAA) requires us to identify not less than 30 hazardous air pollutants (HAP) which, as the result of emissions from area sources, present the greatest threat to public health in the largest number of urban areas, and section 112(c) requires us to list sufficient area source categories or subcategories to ensure that emissions representing 90 percent of the 30 listed HAP (area source HAP) are subject to regulation under section 112(d) of the CAA. The Urban Air Toxics Strategy (Strategy), issued on July 19, 1999 (64 FR 38706) included a list of 30 area source HAP and a list of area source categories emitting the listed HAP. CAA Section 112(d) includes authority to issue new and existing source maximum achievable control technology (MACT) standards, health threshold standards, and generally available control technology (GACT) or management practice standards for area sources. We are issuing today's proposal pursuant to CAA section 112(d)(5) to address our obligation under CAA section 112(c)(3) to subject to regulation the listed area source category of hospital sterilizers.

II. Summary of the Proposed Standards

The source category at issue in this proposal is hospital sterilizers that emit HAP and that are area sources. EPA is proposing two primary regulatory alternatives for this source category. The first alternative (Regulatory Alternative 1) proposes a management practice to reduce HAP emissions from hospital sterilizers that do not use control devices to reduce ethylene oxide emissions.

The second alternative (Regulatory Alternative 2) proposes that there are no generally available control technologies or management practices within the meaning of section 112(d)(5) for this particular source category. We are proposing these two alternatives because we currently have limited information concerning the ability of the proposed management practice to reduce HAP emissions and the cost-effectiveness of such management practice. As explained below, we believe this proposal meets the requirements of CAA sections 112(c)(3) and 112(d)(5).

A. What Source Category Would Be Affected by This Proposal?

The source category that is affected by this proposed action is the hospital sterilizer area source category. This source category includes area source facilities that perform the operations necessary to sterilize medical items with ethylene oxide at hospitals.

B. Proposed Regulatory Alternative 1

1. What Would Be the Affected Sources and Emission Points?

The affected source to which the proposed management practice applies is the group of ethylene oxide sterilizers at a hospital and that are located at hospitals that emit less than major source quantities of HAP. If EPA finalizes Regulatory Alternative 1, you would be subject to the requirements in

the proposed subpart if you own or operate one or more of the affected sources identified above. These requirements would apply nationwide. We are also considering applying proposed Regulatory Alternative 1 to urban areas only and are taking comment on this approach. In a separate action, we are proposing various definitions related to the urban only approach (*e.g.*, definitions for ''Metropolitan Statistical Area,'' ''Urban,'' ''Urban 1 areas,'' and ''Urban 2 areas''). These proposed definitions are included in the proposed National Emission Standards for Hazardous Air Pollutants for Source Categories: Gasoline Distribution Bulk Terminals, Bulk Plants, Pipeline Facilities, and Gasoline Dispensing Facilities; this proposal is in Docket EPA–HQ–OAR–2006–0406. If we decide to finalize the urban-only approach, we would include in this final rule definitions related to that approach.

The emission source subject to the management practice is the sterilization unit.

2. What Would Be the Emission Limits, Equipment Standards, and/or Management Practice Standards?

Under Regulatory Alternative 1, we are proposing two different alternatives with regard to uncontrolled hospital sterilizers. First, we propose to require that hospitals with uncontrolled sterilizers follow the management practice of sterilizing full loads of items having a common aeration time, except where emergency circumstances dictate the use of less than full loads to protect human health. As discussed below, we are soliciting comment on particular circumstances where an exemption to the full load requirement would be necessary for medical or other reasons. Alternatively, we propose that hospitals with uncontrolled sterilizers follow the management practice of sterilizing full loads of items having a common aeration to the extent practical. Unlike the first proposed approach, this alternative would eliminate the need for a specific list of exemptions.

As for hospitals with controlled sterilizers, we propose that these hospitals be required to certify that the control devices are operating and will continue to operate in accordance with applicable State and/or local laws or, if controls are voluntary, in accordance with manufacturers' specifications. If controls are subsequently removed, the management practice would take effect.

3. What Would Be the Testing and Initial Compliance Demonstration Requirements?

There are no performance test requirements for the proposed management practice standard.

4. What Would Be the Notification, Recordkeeping, and Reporting Requirements?

We are proposing an initial compliance notification/certification status that would require affected sources to notify EPA that they operate a sterilizer covered by the rule and certify that they will operate the sterilizer in accordance with the requirements of the rule. We are taking comment on the costs and benefits of this initial compliance notification/certification status and whether or not there should be annual compliance certifications.

For Regulatory Alternative 1, we are also proposing two options for recordkeeping. The first option does not require recordkeeping. The second option requires that affected sources maintain records on-site of the date and time of each sterilization operation. If less than a full load is sterilized at any time, the operator must, in addition to noting the date and time of the sterilization operation, identify the reason why a less-than-full load was sterilized.

We are soliciting comment on the particular circumstances where a hospital may need to run the sterilizer with less than a full load, and whether to require records of such loads and the reason they were run.

C. Proposed Regulatory Alternative 2

As explained further below, we alternatively propose today that there are no generally available control technologies or management practices within the meaning of section 112(d)(5) for this category of sources. We are proposing this alternative in addition to Regulatory Alternative 1 because of the possibility that the proposed management standard will not result in meaningful or cost-effective reductions in ethylene oxide. That is, given the incentives that operators have to minimize ethylene oxide emissions to reduce operating costs as well as their own exposures, it is uncertain whether the issuance of additional work practice standards would result in meaningful HAP emission reductions. Even if such reductions occurred, they could be expensive. For example, as noted above, we assume that work practice standards would reduce emissions by 2 to 9 tons per year (tpy), and that recordkeeping costs can be as high as $1.3 million per year, resulting in reductions that cost $150,000 to $650,000 per ton. Costs would be reduced significantly without recordkeeping requirements, but emission reductions would be expected to be lower in this instance. For these reasons, the Agency is alternatively proposing today to find that there are no GACT or management practices within the meaning of CAA section 112(d)(5) for this category of sources. We believe that this would be a reasonable approach given the high costs of controlling emissions of ethylene oxide from hospital sterilizers using the identified control technology and the uncertainties as to whether the proposed work practice standard will result in HAP emission reductions and whether such reductions are cost-effective. We request comment on this alternative.

III. Rationale for the Proposed Standards

Ethylene oxide is used in hospitals to sterilize medical items, particularly heat-sensitive items that cannot be steam sterilized. Ethylene oxide can be used directly in pure gaseous form or in gaseous mixtures. The ethylene oxide sterilization process includes preparation of the sterilization chamber (temperature, evacuation, humidification, and ethylene oxide gas concentration), the sterilization cycle when the medical item is exposed to ethylene oxide, evacuation and air washes, and the aeration (or off-gas) cycle. Emissions points from hospital ethylene oxide sterilization processes include: (1) Emissions from evacuating the chamber following sterilization, (2) emissions from the chamber during aeration, and (3) emissions that occur when the sterilizer door is opened. Most hospitals have eliminated another potential source of emissions, the once-through water-sealed vacuum pump used to evacuate the ethylene oxide from the chamber, in order to meet Occupational Safety and Health Administration (OSHA) guidelines for worker exposure. Hospitals now use recirculating vacuum-sealed pumps.

There were an estimated 5,800 hospitals nationwide in the United States in 2002. Based on a nationwide and State search for permits and inventory data, we specifically compared the number of hospitals identified and the number confirmed to conduct ethylene oxide sterilization, and extrapolated to nationwide numbers. The percentage of hospitals with ethylene oxide sterilization ranges from 28 to 33 percent. Based on this range, there are approximately 1,600 to

1,900 hospitals nationwide that conduct ethylene oxide sterilization.

The predominant type of air pollution control devices are the EtO-Abator™ and the Safe-Cell technology. Both technologies reduce emissions by approximately 99 percent. The EtO-Abator™ oxidizes the ethylene oxide with a catalyst to form carbon dioxide and water vapor. The latest version of the EtO-Abator™ (sold by 3M) is sold only for use with pure ethylene oxide systems; however, earlier versions were used with gas blends. The Safe-Cell technology, which can be used with either pure ethylene oxide or ethylene oxide gas blends, is a two-stage process. In the first stage, an acid hydrolysis scrubber removes ethylene oxide from the gas stream and converts it to ethylene glycol; in the second stage, the remaining ethylene oxide is captured and destroyed on a dry bed filter impregnated with a chemical reactant.

We estimated that ethylene oxide emissions were 1,060 megagrams per year (Mg/yr) (1,170 tpy) from hospital sterilization processes nationwide in 1990. As discussed below, there have been declines in ethylene oxide usage and emissions for sterilization processes. Nationwide ethylene oxide usage was estimated to be 192 Mg/yr (212 tpy) in 2000 and 122 Mg/yr (135 tpy) in 2005. We estimate that at least half of the ethylene oxide being used by hospitals with controlled sterilizers, which would emit negligible amounts of ethylene oxide, and the other half is used in uncontrolled sterilizers. This resulted in about 40 Mg/yr (44 tpy) of ethylene oxide emissions in 2005. We estimate approximately 0.05 cases of cancer per year resulting from the release of the 40 Mg/yr of ethylene oxide to the atmosphere. Ethylene oxide emissions for hospital sterilizers therefore have decreased over 90 percent from 1990 to 2005 (from 1,060 to 40 Mg/yr reduction).

The decline in ethylene oxide usage for hospital sterilization is due mainly to: (1) New regulations and excise taxes on chlorofluorocarbons, (2) development of new sterilization processes, such as liquid peracetic acid and hydrogen peroxide plasma processes, for certain medical items, (3) increased concern over the toxicity of ethylene oxide residuals, and (4) new restrictions on reprocessing single use devices (SUD). As a corollary to the decline in EO usage and emissions, the number of hospitals that conduct ethylene oxide sterilization has been declining. Regulation of ethylene oxide sterilization at hospitals has contributed to the decline in the number of hospitals that conduct sterilization processes. In California, there were approximately 600 hospitals that operated ethylene oxide sterilizers in 1991. Since implementation of the California Air Resources Board regulation for hospital sterilizers in 1991, at least 60 percent of these hospitals are no longer conducting sterilization operations.

In 2000, the Food and Drug Administration (FDA) regulated the reprocessing of SUD, and these regulations have made it more difficult for hospitals to continue the reprocessing. Many hospitals have reacted to the 2000 FDA regulations by discontinuing the reuse of SUD or by outsourcing the sterilization processing of SUD. With the trends mentioned, hospitals in urban areas have begun to consolidate ethylene oxide sterilization processes, and one hospital with a large sterilizer may conduct sterilization processes for its neighbor or affiliated hospitals or those in close proximity. As a result of the many SUD reuse issues, when hospitals are outsourcing and using reprocessed devices, ethylene oxide usage by contract sterilizers is increasing, and when hospitals are not reprocessing SUD, ethylene oxide usage by medical device manufacturers has increased as they manufacture more SUD. (Sterilization processes by commercial sterilizers, which include commercial contract sterilizers and medical device manufacturers, are subject to MACT controls under 40 CFR part 63, subpart O.)

Emissions from controlled hospital sterilizers are negligible, and we are not aware of any practical emission reduction strategies to further reduce emissions after control. The ethylene oxide emissions from hospitals average less than 300 pounds per year. The capital costs of add-on controls for these facilities range from $23,000 to $130,000 per hospital and the annualized costs of add-on controls range from $10,000 to $46,000 per year. These costs do not include any potential monitoring, recordkeeping, and reporting (MRR) costs that would be necessary to ensure continuous compliance if controls were required. Total nationwide annualized cost to control all uncontrolled facilities would be approximately $8.5 million. The cost to reduce a ton of ethylene oxide emissions is over $200,000 per year.

As a first step in our analysis, we considered the option of applying a MACT standard to hospital sterilizers under CAA section 112(d)(2). Hospitals that are currently controlling their ethylene oxide sterilizers generally are doing so to comply with existing State or local requirements. More than half of the hospital sterilizers have add-on controls. Due to this widespread use of controls on hospital sterilizers, 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). We propose to reject the application of MACT and the requirement to control all presently uncontrolled hospital sterilizers based on the small amount of ethylene oxide emissions from uncontrolled hospital sterilizers and the poor cost-effectiveness associated with requiring add-on controls on the currently uncontrolled sources. The average hospital emits less than 300 pounds per year of ethylene oxide. The cost-effectiveness of applying MACT is over $200,000 per ton of ethylene oxide reduced, excluding any potential MRR costs, which we think is excessive for control of these emissions.

Consequently, the Administrator is exercising his discretion to promulgate standards or requirements under CAA section 112(d)(5) which provide for the use of management practices to reduce emissions of HAP from uncontrolled sterilizers.

The FDA regulates the hospital sterilizer as a medical device; these requirements help ensure sterility of the sterilized product. The FDA requires the manufacturer follow the Association for the Advancement of Medical Instrumentation (AAMI) standards for sterilizers. The FDA does not directly regulate the hospital use of the sterilizer unit. However, the amount of ethylene oxide used per sterilizer cycle is factory set by the manufacturers to comply with the AAMI standards, *i.e.*, for a given sterilizer cycle, one uses the same amount of ethylene oxide whether the sterilizer is full or not. Because of this, hospital sterilizer operators have little discretion in the operation of the sterilizer other than to minimize the use of the sterilizer by only running full loads. Under Regulatory Alternative 1, we are therefore proposing the management practice that requires the sterilization of full loads to minimize the number of times the sterilizer is operated. As explained above, we are considering two different approaches for framing the standard under Regulatory Alternative 1.

This management practice is consistent with the American National Standards Institute, Inc. (ANSI) and the AAMI jointly developed American National Standard ANSI/AAMI ST41:1999. The ANSI/AAMI ST41:1999 standard is recognized by the FDA as a consensus standard. The ANSI/AAMI standard requires the operator sterilize full loads of items having a common aeration time, to the extent practical.

The rationale provided in the standard states the following:

As compared to sterilizing the same volume in partial loads, sterilizing full loads of items having a common aeration time is cost-effective and reduces the potential for occupational exposure and for environmental release of ethylene oxide. This practice also reduces the temptation for workers to attempt to retrieve items with short aeration times from cabinets in which other items might not be fully aerated and thus helps avoid unnecessary exposure to ethylene oxide.''

It is possible that not all hospitals sterilize every load consistent with this standard. We believe that the management practice should increase the awareness of pollution prevention and that it has the potential to reduce emissions from uncontrolled hospital sterilizers. For purposes of Regulatory Alternative 1, we assume that the cost of implementing the management practice is low. We believe the cost of performing the management practice may be off-set by the reduced purchasing costs of ethylene oxide and other operating costs resulting from fewer loads. We also believe the implementation of the management practice can be done relatively quickly due to the expected low effort to set up the recordkeeping necessary for the practice. For these reasons, we are proposing Regulatory Alternative 1, which would require compliance with the management practice requirements within 1 year after the effective date of the final rule.

Under Regulatory Alternative 1, we are proposing that the management practice apply to uncontrolled hospital sterilizers. Hospitals controlling their sterilizers with add-on emission control devices would be required to certify either compliance with all State or local requirements applicable to the controls or, if controls are voluntary, certify that they are operating the controls in accordance with the manufacturer's specifications. If controls are subsequently removed, the management practice would take effect. Facilities complying with the management practice will be required to maintain records on-site of the date and time of sterilization and whether a full load was sterilized, and the reason for not running a full load. We estimated the costs to keep records at $1.3 million per year for the uncontrolled facilities. We are assuming the controlled facilities will certify compliance with either State or local requirements, or they are operating the controls consistent with the manufacturer's specifications. The cost estimates noted above are only estimates, however. We are taking comment on the costs and benefits of this recordkeeping requirement and on whether this rule should apply nationally or only to hospitals in urban areas. We are considering applying today's proposal only to urban areas as defined in the proposed National Emission Standards for Hazardous Air Pollutants for Source Categories: Gasoline Distribution Bulk Terminals, Bulk Plants, Pipeline Facilities, and Gasoline Dispensing Facilities in Docket EPA–HQ–OAR–2006–0406.

Based on the information and assumptions noted above, we are proposing two options for Regulatory Alternative 1. First, we propose that full loads of items having a common aeration time be sterilized, except where emergency circumstances dictate the use of less than full loads to protect human health. With regard to this proposed option, we specifically solicit comment on whether there are other exemptions to the full load requirement that are appropriate. Alternatively, we propose that operators be required to sterilize full loads of items having a common aeration time to the extent practical. Under this alternative approach, there is no need for a specified list of exemptions for specific circumstances, as is the case with the first proposed approach. Rather, the operator must fully load the sterilizer to the extent practical.

Both options recognize that hospital sterilizers have strong economic incentives to operate sterilizers with a full load because doing so reduces the quantity of ethylene oxide needed to run their operation and, accordingly, reduces costs. This alternative approach is consistent with the ANSI/AAMI standard described above. Indeed, as noted by the AAMI and FDA, operation at full loads reduces operating costs by reducing the consumption of ethylene oxide, minimizing wear and tear on machines, and reducing associated labor costs. We solicit comment on these two alternative approaches.

Under Regulatory Alternative 2, we are proposing that there are no GACT or management practices within the meaning of section 112(d)(5) of the CAA for this source category. We are currently not aware of any control technology or management practice other than those discussed in this proposal that would reduce ethylene oxide emissions from hospital sterilizers. We have already identified that there is a high cost of controlling emissions of ethylene oxide from hospital sterilizers using the identified control technology, such that we currently do not believe that there is any GACT. We also have limited information to conclude either that the proposed management practice reduces emissions of ethylene oxide or that the proposed practice is cost-effective. We are therefore co-proposing Regulatory Alternative 2.

We are soliciting comment on whether, for this source category, it is reasonable to conclude that no such generally available means of reducing emissions is available. In this regard, we specifically solicit comment on whether there is any other control technology or management practice that is not described in this proposal, but that may provide a cost-effective means of reducing ethylene oxide emissions from hospital sterilizers. To the extent a commenter identifies such an alternative means of emission reduction, we request information relating to the nature of the emission reduction and the cost of obtaining such reduction.

Section 502(a) of the CAA provides that EPA may exempt one or more area sources from the requirements of title V if EPA finds that compliance with such requirements is ''impracticable, infeasible, or unnecessarily burdensome'' on such area sources. EPA must determine whether to exempt an area source from title V at the time we issue the relevant CAA section 112 standard (40 CFR 70.3(b)(2)). If we pursue Regulatory Alternative 1 in the final rule, we are proposing today to exempt hospital sterilizer area sources from the requirements of title V. Hospital sterilizer area sources would not be required to obtain title V permits solely as a function of being the subject of today's proposed national emission standards for hazardous air pollutants (NESHAP); however, if they were otherwise required to obtain title V permits, such requirement(s) would not be affected by today's proposed exemption.

Consistent with the statute, EPA has found that compliance with title V permitting is ''unnecessarily burdensome'' for hospital sterilizer area sources. EPA's inquiry into whether this criterion was satisfied was based primarily upon consideration of the following four factors: (1) Whether title V would result in significant improvements to the compliance requirements that we are proposing for this area source category; (2) whether title V permitting would impose a significant burden on hospital sterilizer area sources; (3) whether the costs of title V permitting for hospital sterilizer area sources would be justified, taking into consideration any potential gains in compliance likely to occur for such sources; and (4) whether there are

implementation and enforcement programs in place that are sufficient for assuring compliance with this NESHAP without relying on title V permits.

Additionally, EPA also considered whether exempting hospital sterilizer area sources would adversely affect public health, welfare, or the environment. We first determined the extent to which these factors were present for this area source category. We then determined whether those factors collectively demonstrated that compliance with title V requirements would be unnecessarily burdensome for hospital sterilizer area sources.

In our consideration of these factors, we believe the addition of title V permitting would not result in significant improvements to the compliance requirements that we are proposing for this area source category. Under Regulatory Alternative 1, we are unaware of any additional compliance procedures, in or outside the title V program, which would improve the assurance of significantly more gains in compliance and emission reductions. We have not identified any adverse effect on public health, welfare, or the environment by the proposed title V exemption.

We also believe that title V permitting may impose a significant burden on facilities within this source category, some of which are small businesses. For many facilities, the cost of obtaining a title V permit may far exceed the cost of complying with this proposed rule without significant gains in compliance. Based on the above analysis, we conclude that title V permitting would be ''unnecessarily burdensome'' for hospital sterilizer area sources. We are therefore proposing that this area source category be exempt from title V permitting requirements if we pursue Regulatory Alternative 1.

We have prepared regulatory text for proposed Regulatory Alternative 1. The proposed regulatory text implements the first option described above for Regulatory Alternative 1 and includes proposed recordkeeping requirements. We have included regulatory text for this proposed approach because it is the approach that would involve the most extensive regulatory text. If we finalize the second option described above for Regulatory Alternative 1 (*i.e.*, following the ANSI/AAMI standard), we will modify the regulatory text appropriately.

IV. Summary of Environmental, Energy, Cost, and Economic Impacts of the Proposed Standards

We estimate that in 2002 there were, at most, 1,900 hospital area sources, of which approximately 630 do not presently have add-on controls. The management practice that we are proposing today as Regulatory Alternative 1 is estimated to reduce the 40 Mg/yr emitted from uncontrolled sterilizers from 2 to 9 Mg/yr per year based on a range of assumptions for the extent to which hospital sterilizers are presently not being run with full loads. We estimate cancer incidence would be reduced from approximately 0.05 to 0.044 cases of cancer per year. We further believe that if we pursue Regulatory Alternative 1 in the final rule, there will be minimal effect on other air quality or non-air quality environmental impacts and will be negligible energy or economic impacts. Annualized costs to comply with the proposed standards are estimated to be less than $2 million per year. There will be no environmental, energy, cost, or economic impacts associated with Regulatory Alternative 2.

V. Solicitation of Public Comments

A. Introduction and General Solicitation

We request comments on all aspects of the proposed action. All significant comments received during the public comment period will be considered in the development and selection of the final rulemaking.

B. Specific Comment and Data Solicitations

1. Management practice costs and benefits—We are requesting comment on our estimate of the costs to comply with the management practice and the associated MRR requirements. As stated earlier, we are proposing one time initial compliance notification/certification. We are requesting comment on the costs and benefits of the proposed initial compliance notification/certification status and recordkeeping and on the costs and benefits of hospitals also annually certifying their compliance with the proposed rule. We are requesting comment on the two proposed options for recordkeeping. The first option does not require records to minimize the burden compared to the emission reduction benefit. The second option requires recordkeeping to ensure compliance. We solicit comments on approaches other than recordkeeping which may ensure compliance at a smaller cost. Finally, we are requesting comment on whether this rule should apply nationally or only to hospitals in urban areas.

2. Full loads—The ANSI/AAMI ST41:1999 standards rationale for load configuration states the following:

''Overloading impedes proper air removal, humidification of the load, and sterilant penetration and evacuation. Proper loading ensures that the sterilized items will not touch the operator's hands during transfer from the sterilizer to the aerator.''

We do not want the proposed requirements to impede the sterilization cycle or in any way compromise the process of sterilization. We are requesting comment on our definition of full load and for specific cases where it would not be practical or appropriate to require full loads. We are also soliciting comment on our alternative proposal of requiring hospitals with uncontrolled sterilizers to follow the management practice of sterilizing full loads of items having a common aeration, to the extent practical.

3. Emission estimate for the management practice—We currently have insufficient information concerning the ability of the proposed management practice to reduce HAP emissions. Our emissions reduction estimates attributed to the management practice are based on assumptions concerning the current practice at hospitals. The basis of our emissions estimate is the assumption that 10 to 50 percent of the sterilization is performed on half loads and that the amount of ethylene oxide used is fixed per cycle. The emission estimate also makes the assumption that all loads could be full. We are requesting comments on the extent to which hospitals presently sterilize less than full loads, to what extent these less than full loads could be eliminated, and any additional information that may assist in estimating emissions. We are requesting comment on whether this management practice is an effective means of reducing emissions from these sources and, if not, whether it would be appropriate to set no standard on the grounds that no technology or management practice are generally available to reduce emissions from these sources.

VI. 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 and 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 the proposed NESHAP for Hospital Ethylene Oxide Sterilization Area Sources have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2245.01.

The proposed information collection requirements are based on the information collection requirements in the part 63 General Provisions (40 CFR part 63, subpart A), some of which are incorporated into the proposed NESHAP. The ICR document includes the burden estimates for all applicable General Provisions. These recordkeeping and reporting requirements 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.

Proposed Regulatory Alternative 2 does not impose any new information collection burden. Proposed Regulatory Alternative 1 does propose information collection requirements. Specifically, the annual burden for the information collection averaged over the first 3 years of this ICR is estimated to total 23,694 labor hours per year at a cost of $1.6 million for the 1,900 existing hospital sterilizer area sources. No capital/startup costs or operation and maintenance costs are associated with the proposed requirements. No costs or burden hours are estimated for new area sources because no new sources are estimated during the 3-year period of the ICR. We have no indication there will be any new sources in the next 3 years.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, 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 part 63 are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this action, which includes this ICR, under Docket ID number EPA–HQ–OAR–2005–0171. Submit any comments related to the ICR for the proposed rules to EPA and OMB. See ''Addresses'' section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after November 6, 2006, a comment to OMB is best assured of having its full effect if OMB receives it by December 6, 2006. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

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

For the purposes of assessing the impacts of today's proposed area source NESHAP on small entities, a 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 today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Proposed Regulatory Alternative 1 proposes to require the use of a work practice to minimize the operation of the ethylene oxide sterilization unit and will, therefore, have minimal nationwide costs, *i.e.*, less than $2 million 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. There are no costs associated with proposed Regulatory Alternative 2.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most 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 proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. As discussed previously in this preamble, if we finalize Regulatory Alternative 1, the estimated expenditures for the private sector in any 1 year are less than $2 million. There are no costs associated with proposed Regulatory Alternative 2. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the proposed rule does not significantly or uniquely affect small governments. The proposed rule would not result in expenditures by them of $100 million or more in any 1 year or any disproportionate impacts on them. Therefore, the proposed rule is not subject to section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

The proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. To the extent the proposed rule proposes requirements, it does so only with respect to owners and operators of specified area sources and not State and local governments. Thus, Executive Order 13132 does not apply to the proposed rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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

Executive Order 13175 (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.'' ''Policies that have tribal implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

The proposed 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. To the extent the proposed rule proposes requirements, it does so only with respect to owners and operators of specified area sources and not Tribal governments. Thus, Executive Order 13175 does not apply to the proposed rule.

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

Executive Order 13045 (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 EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the EPA.

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. The proposed rule is not subject to the Executive Order. It is based on control technology and not on health or safety risks.

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

The proposed rule is not a ''significant energy action'' as defined in Executive Order 13211 (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 proposed 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 the proposed rules.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Public Law 104–113, 12(d), (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. The 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.

The proposed rule does not include technical standards.

List of Subjects in 40 CFR Part 63

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

Dated: October 31, 2006.

Stephen L. Johnson,

Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is proposed to be 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.*

Subpart A—[Amended]

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

Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilization

Applicability and Compliance Dates

Standards

Initial Compliance Requirements

Monitoring—Continuous Compliance Requirements

Notifications, Reports, and Records

Other Requirements and Information

Tables to Subpart WWWWW of Part 63

Subpart WWWWW—National Emission Standards for Hospital Ethylene Oxide Sterilization

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. Your hospital facility is an area source of HAP if it is a stationary source or group of stationary sources within a contiguous area under common control that emits or has the potential to emit any single HAP at a rate of less than 9.07 megagrams (10 tons) per year and any combination of HAP at a rate of less than 22.68 megagrams (25 tons) per year.

(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 [1 YEAR AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**].

(b) *New source.* If you have a new or reconstructed affected source for which the initial startup date is on or before [DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], you must comply with applicable requirements in this subpart by [DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**].

(c) *New source.* If you have a new or reconstructed affected source for which the initial startup date is after [DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], you must comply with applicable requirements in this subpart upon initial startup.

Standards

§ 63.10390 What management practice standards must I meet?

(a) You must sterilize full loads of items having a common aeration time, except under the following conditions: emergency circumstances dictate the use of less than full loads to protect human health.

(b) You are exempt from the management practice standards in paragraph (a) of this section if your sterilization unit is equipped with an add-on air pollution control device and you submit a certification in accordance with § 63.10400.

Initial Compliance Requirements

§ 63.10400 How do I demonstrate initial compliance?

(a) *Uncontrolled sources.* You must demonstrate initial compliance with the management practice standards in § 63.10390(a) by submitting an initial Notification of Compliance Status certifying that you are sterilizing with full loads of items having a common aeration time.

(b) *Controlled sources subject to State and local regulation.* You must demonstrate initial compliance with § 63.10390(b) 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) *Controlled sources not subject to State and local regulation.* You must demonstrate initial compliance with § 63.10390(b) 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 add-on air pollution control device, you must demonstrate continuous compliance with the management practice standards in § 63.10390(a) by checking and recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, which allowable reason.

Notifications, Reports, and Records

§ 63.10430 What notifications must I submit and when?

(a) You must submit the initial Notification of Compliance Status to the authority provided for in § 63.9(a)(4). In addition to submitting your initial Notification of Compliance Status to the State or Region Office, you must also 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.

(b) You must submit an initial Notification of Compliance Status for the initial compliance demonstration in § 63.10400(a), (b), or (c) before 5 p.m. on the 60th calendar day following the compliance demonstration, consistent with § 63.10402. Your Notification of Compliance Status must include the information required in paragraphs

(b)(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 relevant standard, or other requirement, that is the basis of the notification and the source's compliance date.

(4) A brief description of the nature, size, design, and method of operation of the source and an identification of the types of emission points within the affected source subject to the relevant standard and types of hazardous air pollutants emitted.

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

§ 63.10432 What records must I keep?

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

(a) *All sources.* A copy of the initial Notification of Compliance Status that you submitted to comply with this subpart.

(b) *Uncontolled sources.* Records of checks needed to document continuous compliance with the management practice standards required by § 63.10420.

§ 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, according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, report, or record.

(c) You must keep each record onsite for at least 2 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1). 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 from 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.

Controlled source means a sterilization facility using ethylene oxide in sterilization units with an add-on air pollution control device used to reduce the quantity of ethylene oxide emissions.

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, including diagnostic and major surgery facilities, 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. Doctor's offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals on an outpatient basis are excluded.

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.

Uncontrolled source means a sterilization facility using ethylene oxide in sterilization units with no add-on air pollution control device used to reduce the quantity of ethylene oxide emissions.

Tables 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), (a)(6), (a)(10)–(12), (b)(1).	Applicability	Yes	
§ 63.1(a)(5), (7)–(9)	[Reserved]		
§ 63.1(b)(2)	[Reserved]		
§ 63.1(c)(1)–(2)	Applicability of this part after a relevant standard has been set.	Yes	States have the option to exclude area sources affected by this rule—Area Source Permitting.
§ 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), b(7)	Compliance with standards and maintenance requirements.	Yes	
§ 63.6(b)(6)	[Reserved]		
§ 63.6(c)(1)	Compliance dates for existing sources	No	Subpart WWWWW requires compliance 1 year after the effective date.
§ 63.6(c)(2)–(c)(5)	Compliance dates for CAA section 112(f) standards and for area sources that become major.	No	
§ 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.	No	
§ 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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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 27

[WT Docket Nos. 06–169, 96–86; DA 06–2116]

Upper 700 MHz Guard Band Licenses; Development of Operational, Technical and Spectrum Requirements for Meeting Federal, State and Local Public Safety Communications Requirements Through the Year 2010

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.

SUMMARY: In this document, the Wireless Telecommunications Bureau (WTB) of the Federal Communications Commission (Commission) extends the reply comment deadline in response to the Notice of Proposed Rulemaking (NPRM) in WT Docket Nos. 06–169 and 96–86. The deadline to file reply comments is extended from November 6, 2006 to November 13, 2006. This action is taken to provide interested parties sufficient time within which to respond meaningfully to the relevant issues raised in the NPRM.

DATES: The agency must receive reply comments on or before November 13, 2006.

ADDRESSES: Interested parties may submit reply comments, identified by WT Docket Nos. 06–169 and 96–86, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Appropriate addresses for submitting reply comments may be found in the **SUPPLEMENTARY INFORMATION** section of this document.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov*