significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This proposed rule does not affect small businesses. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

List of Subjects in 38 CFR Part 19

Administrative practice and procedure, Claims, Veterans.

Dated: February 21, 2001.

Anthony J. Principi,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, we propose to amend 38 CFR part 19 as set forth below:

PART 19—BOARD OF VETERANS' APPEALS: APPEALS REGULATIONS

1. The authority citation for part 19 continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Section 19.2 is revised to read as follows:

§ 19.2 Composition of the Board; Titles.

(a) The Board consists of a Chairman, Vice Chairman, Deputy Vice Chairmen, Members and professional, administrative, clerical and stenographic personnel. Deputy Vice Chairmen are Members of the Board who are appointed to that office by the Secretary upon the recommendation of the Chairman.

(b) A Member of the Board (other than the Chairman) may also be known as a Veterans Law Judge. An individual designated as an acting Member pursuant to 38 U.S.C. 7101(c)(1) may also be known as an acting Veterans Law Judge.

(**Authority:** 38 U.S.C. 501(a), 512, 7101(a)).

[FR Doc. 01–5452 Filed 3–5–01; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6950–9]

RIN 2060–AC28

Ethylene Oxide Emissions Standards for Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed amendments.

SUMMARY: This proposal amends the emission standards for sterilization facilities by eliminating maximum achievable control technology (MACT) requirements for chamber exhaust vents. This action is being proposed to eliminate safety problems associated with the existing requirements. This proposal also amends testing and monitoring requirements for sterilization chamber, aeration, and chamber exhaust vents. Specific testing and monitoring requirements are being removed or simplified to correct technical problems associated with the existing requirements.

DATES: Submit comments on or before May 7, 2001.

Public hearing. If anyone contacts the EPA requesting to speak at a public hearing by March 26, 2001, a public hearing will be held on April 5, 2001.

ADDRESSES: *Comments.* Written comments should be submitted (in duplicate if possible) to: Air and Radiation Docket and Information Center (6102), Attention Docket Number A–88–03, U.S. EPA, 401 M Street, SW, Washington, DC 20460. The EPA requests a separate copy also be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

Docket. Docket No. A–88–03 contains supporting information used in developing the standards. The docket is located at the U.S. EPA, 401 M Street, SW., Washington, DC 20460, in room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

Public Hearing. If a public hearing is held, it will be held at 10 a.m. in the EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina, or at an alternate site nearby.

FOR FURTHER INFORMATION CONTACT: David Markwordt, Policy, Planning, and Standards Group, Emission Standards Division, (MD–13), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0837, electronic mail address *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION: *Comments.* Comments and data may be submitted by electronic mail (e-mail) to: a-and-r-docket@epa.gov. Electronic comments must be submitted as an ASCII file to avoid the use of special characters and encryption problems and will also be accepted on disks in WordPerfect® version 5.1, 6.1 or Corel 8 file format. All comments and data submitted in electronic form must note the Docket No. A–88–03. No confidential business information (CBI) should be submitted by e-mail. Electronic comments may be filed online at many Federal Depository Libraries.

Commenters wishing to submit proprietary information for consideration must clearly distinguish such information from other comments and clearly label it as CBI. Send submissions containing such proprietary information directly to the following address, and not to the public docket, to ensure that proprietary information is not inadvertently placed in the docket: Attention: David Markwordt, C/O OAQPS Document Control Officer, U.S. Environmental Protection Agency, 411 W. Chapel Hill Street, (Room 740B), Durham NC 27701. The EPA will disclose information identified as CBI only to the extent allowed by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies a submission when it is received by the EPA, the information may be made available to the public without further notice to the commenters.

Public Hearing. Persons interested in presenting oral testimony or inquiring as to whether a hearing is to be held should contact Dorothy Apple, Policy, Planning, and Standards Group, Emission Standards Division (MD–13), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–4487 at least 2 days in advance of the public hearing. Persons interested in attending the public hearing must also call Dorothy Apple to verify the time, date, and location of the hearing. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning these proposed emission standards amendments.

Docket. The docket is an organized and complete file of all the information we considered in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act (CAA)). The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–

7548. A reasonable fee may be charged for copying docket materials. *World Wide Web (WWW).* In addition to being available in the docket, an electronic copy of these proposed amendments will also be available on the Technology Transfer Network (TTN). Following signature, a copy of the rule will be posted on the policy and guidance page for newly proposed or promulgated rules *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call our HELP line at (919) 541–5384.

Regulated Entities. Categories and entities regulated by this action include:

Category	SIC[a]/NAICS[b]	Examples of regulated entities
Industry	3841, 3842	Medical suppliers.
	2834, 5122, 2831, 2833	Pharmaceuticals.
	2099, 5149, 2034, 2035, 2046	Spice Manufactures Contract.
	7399, 7218, 8091	Sterilizers.
Federal Government	Not Affected	
State/Local/Tribal Gov	Not affected	

[a] Standard Industrial Classification Code.
[b] North American Information Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by the NESHAP addressed in these proposed amendments. To determine whether your facility is regulated by this action, you should examine the applicability criteria in § 63.360 of the proposed rule. If you have questions regarding the applicability of the NESHAP addressed in this proposed rule to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

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

I. Chamber Exhaust Vents
A. Why are we reconsidering MACT for chamber exhaust vents?
B. What is MACT for chamber exhaust vents?
II. Monitoring
A. Why are we reconsidering the monitoring requirements?
B. How are we proposing to amend the monitoring requirements?
III. Testing
A. Why are we proposing to change the testing requirements?
B. How are we proposing to amend the testing requirements?
IV. Summary of Environmental, Energy, and Economic Impacts
V. Administrative Requirements
A. Executive Order 12866, Regulatory Planning and Review
B. Paperwork Reduction Act
C. Executive Order 13132, Federalism
D. Executive Order 13084, Consultation and Coordination with Indian Tribal Governments
E. Unfunded Mandates Reform Act of 1995
F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*
G. National Technology Transfer and Advancement Act of 1995
H. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

I. Chamber Exhaust Vents

A. Why Are We Reconsidering MACT for Chamber Exhaust Vents?

On December 6, 1994, we promulgated the ethylene oxide (EO) national emission standards for hazardous air pollutants (NESHAP) which regulate emissions of ethylene oxide from commercial sterilization and fumigation operations (59 FR 62585). In July 1997, we learned of explosions at ethylene oxide sterilization and fumigation facilities. We suspended the EO NESHAP for 1 year until December 6, 1998 to provide time to determine the appropriate action necessary to mitigate the cause of the explosions (62 FR 64736).

After becoming aware of the explosions, the industry worked through the Ethylene Oxide Sterilization Association (EOSA) to begin investigations. The EOSA established a Safety Committee in September 1997 which continues to meet bimonthly. Sterilization industry leaders, abatement device vendors, and Federal, State and local agencies have been participating in the Safety Committee meetings.

In a June 2, 1998 letter to EPA, the EOSA recommended, ''additional time to consider safe and economical control, installation, operation and maintenance alternatives applicable to aeration and chamber exhaust (backvent) emissions * * *.'' The Health Industries Manufacturers Association (HIMA) reviewed the recommendation. Together, the EOSA and HIMA memberships represent most of the ethylene oxide sterilization and fumigation industry. The EOSA concluded that ''The oxidizer systems had not been properly integrated with traditional ethylene oxide sterilization process operations, that is, installation, operation and maintenance issues had not been sufficiently addressed by sterilizer operators.'' The EOSA also concluded that ''improperly overfeeding the oxidizer system from the chamber backvent was the primary safety concern.''

The EPA conducted an independent investigation of the accidents and reviewed reports prepared by EPA Regional Offices and by EOSA member sterilization companies and, based on that investigation and review, concurred with the industry conclusion and recommendation. In 1998, we agreed with industry that, in the cases where explosions occurred, the catalytic oxidizer units were overfed with ethylene oxide in concentrations above the safe operations limit due to abnormal activation of the chamber exhaust (backvent). We concluded that the main sterilizer vent emissions routed through the vacuum pump played no role in the explosions. Therefore, the December 6, 1998 compliance date for the main sterilizer vent was allowed to take effect. However, we further suspended the EO NESHAP for both aeration room vents and chamber exhaust vents for 1 year (until December 6, 1999) to provide time to determine the appropriate action necessary to mitigate the cause of the explosions (63 FR 66990). Aeration room vents were included in the suspension because control systems typically integrate both vents to the same control device.

We also concluded that any emissions control technology necessary to comply with the EO NESHAP needs to be properly integrated into the sterilization system and operations; it must reflect the full range of normal and abnormal conditions that may occur. The December 1998 suspension was based on the assumption that sterilization chamber operators would be able to evaluate and integrate the emission control technology with sterilizer

operations to ensure prevention of future explosions by December 6, 1999. In June 1999, the EOSA and individual plant operators requested that EPA eliminate the control requirement for chamber exhaust vents. In response to the June 1999 request, we further suspended the control requirements for aeration and chamber exhaust vents on December 3, 1999 (64 FR 67789).

We suspended the control requirements for aeration room vents because they are typically combined with chamber exhaust vents and ducted to a single control device. The December 3, 1999 notice (64 FR 67789) explained that there is no safety issue associated with controlling only the aeration room vent; no revisions to control requirements were anticipated. The 1999 notice also suspended the compliance date for aeration room vents by 1 year to provide time to decouple them from any chamber exhaust vents. Aeration room vents were required to comply with the emission control requirements by December 6, 2000.

However, the compliance date for the chamber exhaust vent control requirements was suspended until December 6, 2001 in the 1999 notice (64 FR 67789). At the time we said, ''The suspension, in December 1998, for chamber exhaust vents was based on the assumption that sterilization chamber operators would be able to evaluate and integrate the emission control technology with sterilizer operations to ensure prevention of future explosions by December 6, 1999. To date, solutions to the safety problems have not been developed.'' We further stated that the Agency would reconsider its original MACT determination for chamber exhaust vents and propose a course of action in the near future.

In April 2000, a report jointly published by the National Institute for Occupational Safety and Health (NIOSH), EPA, and the EOSA concluded the following:

1. Fires and explosions result when sterilizer oxidizing emission control devices (OECD) are overfed with high concentrations of ethylene oxide;
2. Current procedures for aborting the ethylene oxide sterilizer cycle are deficient when OECD are used;
3. Current safety systems for ethylene oxide sterilization processes are deficient when OECD are used; and
4. When OECD are used as the only emission control device (that is, when acidified wet scrubbers are not used or are bypassed), the risk of fire and explosion is greatly increased.

The conclusions in this report are supportive of our conclusions in the December 3, 1999 notice.

We are still in the position today of being unable to make a finding that solutions to the safety problems have been developed. It is beyond the Agency's legal mandate and technical expertise to certify equipment for safe use. The CAA generally requires the Agency to assess existing emission control technology for application to non-controlled emission sources. The use of existing technology by some sources in the relevant category presumes the ability to operate that technology in a proven safe manner. At the time of rule promulgation (December 1994), state-of-the-art control technology for chamber exhaust emissions involved safety hazards not known at the time.

We are aware that some companies have removed their catalytic oxidizers and replaced them with alternative control devices. Some of these alternative control devices operate without a flame source and would presumably be safer than systems which rely on combustion. However, even non-combustion control devices must be designed to avert potential safety problems due to exothermic reaction resulting from the control of ethylene oxide. We are not aware of any authoritative institution which has evaluated these alternative systems for safe operation.

B. What Is MACT for Chamber Exhaust Vents?

In the preamble to the proposed NESHAP (59 FR 10598), we explained the basis of the MACT floor for chamber exhaust vents. The available data indicated that there were no chamber exhaust vents routed to a control device; we concluded that the MACT floor for chamber exhaust vents at new and existing major and area sources required no reduction in emissions from these vents. However, to ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continued to be routed to a control device rather than exhausted via an uncontrolled vent, the proposed NESHAP incorporated a concentration-based limit on emissions from chamber exhaust.

In public comments received on the proposed rule, an abatement device vendor provided sufficient data to establish a MACT floor consisting of control requirements for chamber exhaust vents at both existing and new major sources. The vendor data listed ethylene oxide sterilizer operations using catalytic oxidizers for control of chamber exhaust vents. No data indicating the use of technology other than catalytic oxidizers were supplied to us. As described in the preamble to the promulgated NESHAP (59 FR 62585), based on vendor data, we required control of chamber exhaust vent emissions at new and existing major sources. However, at the time, neither we nor the commercial sterilizer industry were aware of the potential safety issues associated with controlling chamber exhaust vents.

Experience over the last 5 years clearly demonstrates the over-simplification of controlling chamber exhaust by simply ducting the vent stream to a control device designed to control aeration room vent emissions. Based on what we have learned since the explosions, it is clear that no one was aware of the potential to overfeed the aeration control with ethylene oxide inadvertently routed from the chamber exhaust. Control systems designed for aeration room emissions had not been designed to handle potentially large quantities of ethylene oxide from chamber exhaust malfunctions. Obviously, appropriate safety design features are necessary to make this control approach acceptable as a viable means of emissions reductions. The same safety issue exists for control devices dedicated exclusively to chamber exhaust vent emissions.

The CAA requires that emission standards for HAP established under section 112(d) be based on ''* * * the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section * * * that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources in the category or subcategory to which such emission standards applies * * *.'' These emission standards are commonly referred to as MACT.

The requirement to consider ''any non-air quality health and environmental impacts and energy requirements'' would necessarily require control devices to be intrinsically safe. Had we known of the potential safety issue and known this control approach was blind to the safety issue, we would have refuted the commenters' assertion and made a finding of MACT floor as no control of chamber exhaust emissions. As stated above, it is beyond the Agency's legal mandate and technical expertise to certify equipment for safe use. Since no one has demonstrated to the Agency's satisfaction that the equipment is safe for this purpose, we are reconsidering

our original MACT determination for chamber exhaust vents.

Today, we are proposing that MACT for chamber exhaust vents at major sources should be no control. To ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continues to be routed to a control device rather than exhausted via an uncontrolled vent, we are proposing a concentration-based limit on emissions from major source chamber exhaust vents. This is the same requirement that was originally proposed for the major sources and currently applies to area sources.

II. Monitoring

A. Why Are We Reconsidering the Monitoring Requirements?

Commercial sterilization facilities subject to the rule were originally required to demonstrate compliance by June 8, 1998. Before that date, the Agency received requests to clarify specific testing and monitoring requirements. Companies conducting tests questioned how to determine the level of the monitored temperature which would be used to determine compliance on a continuous basis.

There are three emission vents associated with the sterilization process: the sterilization chamber vent, the aeration room vent, and the chamber exhaust vent. The sterilization process results in short-term episodic releases of various concentrations of ethylene oxide. The majority of facilities use either scrubbers or catalytic oxidizers or a combination of both to reduce emissions.

Catalytic oxidizers combust ethylene oxide, an exothermic reaction, which increases the catalyst bed temperature. The higher the concentration of ethylene oxide fed to the catalytic oxidizer, the higher the bed temperature. The bed temperature spikes during periods when higher concentrations of ethylene oxide are fed to the catalyst bed. Generally, a catalytic oxidizer bed is designed to be at or above a minimum temperature to be hot enough to combust ethylene oxide when it contacts the bed.

Sterilization chambers are filled with the product to be sterilized and then infused with ethylene oxide gas. The ethylene oxide is pumped from the chamber after completion of the sterilization cycle. After the chamber is evacuated, the chamber is flooded with air to facilitate off-gassing of ethylene oxide residing in the product. Then, the chamber pump is turned on and the chamber is evacuated again. This air wash/evacuation cycle is repeated multiple times. The amount of ethylene oxide decreases with each subsequent evacuation. For main sterilization vents controlled with a catalytic oxidizer, chamber evacuations cause temporary spikes in catalyst bed temperature.

The existing rule requires a 99 percent reduction in emissions for the main sterilizer vent, and either a 99 percent reduction in emissions or a 1 parts per million per volume (ppmv) maximum outlet concentration for aeration room vents. For the main sterilizer vent, the existing rule requires the operator to demonstrate compliance with the 99 percent reduction requirement only during the first evacuation.

The existing rule also requires facilities to meet appropriate operating limits to ensure continuous compliance with the emission reduction requirements. We did not establish the relationship between any of the operating limits and the emissions reductions associated with the technologies used in the industry.

Nearly all operators who had installed controls prior to promulgation of the final rule used either catalytic oxidizers or acid scrubbers to reduce emissions. Acid scrubbers are used primarily to control the main sterilizer vent. The existing rule requires monitoring of either the ethylene oxide glycol concentration of the scrubbing liquor or the level of liquor in the scrubber tank. Facilities could perform the initial compliance test when the ethylene glycol concentration or liquor level was at the highest level at which the emission reduction requirement could be met. Both the ethylene glycol concentration and liquor level increase with each sterilization batch that is run. Over a period of time, which could be weeks or months, the concentration of ethylene glycol gradually increases and will result in less emissions reductions; the liquor level is an indirect method of measuring ethylene glycol concentration. The rule states that to exceed these parameters would violate the emission reduction requirement. As stated previously, we have not established a precise relationship between ethylene glycol concentrations or levels and the 99 percent/1 ppmv emission reduction requirements. On the other hand, we have not received data showing problems using the ethylene glycol concentration or scrubber level, determined during the initial performance test, on a continuous basis to indicate good operation (as opposed to compliance with the specific 99 percent/1 ppmv emission reduction requirements).

Catalytic oxidizers are used primarily to control emissions from aeration room vents. To ensure continuous compliance with the emission reduction requirements for the main sterilizer, aeration, or chamber exhaust vent, the promulgated rule (59 FR 62585, December 6, 1994) requires the oxidizer to operate at a temperature, averaged over the sterilization cycle, above the baseline temperature established during the initial compliance test. This requirement is based on the premise that the temperature at which the equipment operated during the initial performance test directly correlates with the 99 percent emission reductions requirement under all operating conditions. The existing requirement also states that if the operating temperature falls below the baseline temperature, then the facility has violated the 99 percent emission reduction requirement. Again, we did not establish the relationship between temperature and emission reduction. Given the fluctuations in temperature of this batch process, it is unlikely that a single temperature could be selected to correlate with emissions reductions.

The basic difference between using operating limits determined during the initial performance test for scrubbers and catalytic oxidizers is that catalytic oxidizer operating limits are sensitive to changing operating conditions during each batch operation. Scrubber operating limits change gradually over many batch operations.

In the response to comments published with the promulgated rule, we added a specific additional test during the final evacuation in an attempt to establish an operating limit valid for the full range of operating conditions. We stated that, ''Demonstration of the baseline temperature during the last evacuation addresses concerns that a baseline temperature established during the first evacuation would not be sustainable for subsequent evacuations where the ethylene oxide concentration is lower.''

However, in practice we have found that this additional test did not solve the problem because operating temperatures during the last evacuation, although lower than temperatures during the first evacuation, are typically higher than temperatures during periods when ethylene oxide is not being fed to the control devices. Therefore, facilities cannot meet either temperature requirement on a continuous basis.

The catalytic oxidizer operates at a design temperature of approximately 280°F when little or no ethylene oxide is being fed to the oxidizer. During the short periods when ethylene oxide is introduced to the oxidizer (approximately 10 minutes), the

temperature spikes to about 400°F. Therefore, the average temperature over the sterilization cycle is between the design temperature (280°F) and the highest temperature (400°F). In fact, the only temperature that can actually be met consistently is the temperature when little or no ethylene oxide is being fed to the oxidizer (i.e., approximately 280°F).

The requirement to operate at the average temperature is inconsistent with normal operation of the equipment. Properly operated equipment will maintain the design temperature, approximately 280°F, to ensure proper combustion when ethylene oxide is introduced to the catalyst. Short term temperature spikes do not directly correlate to the 99 percent emission reduction requirement for the control system.

B. How Are We Proposing To Amend the Monitoring Requirements?

To correct the problems discussed in the previous section, we are proposing a new rule structure. There will be no change to the emission limits. We are proposing a different workable approach for ensuring continuous compliance. We will maintain the 99 percent emission reduction requirement and measure compliance only through performance testing during the first evacuation. An initial performance test is still required; facilities that have performed this test need not repeat the test. (Note that enforcement agencies can always request another test at a later date if they choose.)

We have decided the only practical way to ensure continuous compliance of catalytic control devices is to establish two requirements. One concerns catalyst replacement to ensure that the catalyst remains active. The other concerns maintaining a minimum temperature to ensure that ethylene oxide is combusted when it passes through the catalytic oxidizer.

First, to ensure that the catalyst remains active we are proposing a work practice standard. The work practice standard would require that facilities periodically replace the catalyst. Failure to perform the work practice would be a violation of the work practice standard.

Efficient emission destruction depends on the catalyst being active. Vendors advertise a 3 to 5 year catalyst life after which performance may decline. Therefore, to ensure proper combustion, we are proposing that facilities replace the catalyst every 2 years.

We are proposing an operating limit that requires facilities to maintain a minimum design temperature sufficiently high to ensure combustion when ethylene oxide contacts the catalyst. We are proposing that the combustion device be operated at or above the vendor-recommended minimum design temperature. Operating at or above the vendor minimum design temperature would ensure that combustion takes place but does not require direct correlation to the 99 percent requirement.

Because we are proposing a minimum temperature based on the vendor minimum design temperature, we can eliminate the existing requirement to test the last evacuation. We originally required a test on the last evacuation of the main sterilizer vent because we believed this would be a lower ''average'' temperature than that during the first evacuation. Since we are proposing a new approach, there is no longer a need for this test.

We are proposing the reporting of ''deviations.'' A deviation occurs when control equipment fails to achieve the 99 percent emission reduction during a performance test, when one doesn't perform a required work practice, or when the operating limits for maintaining a minimum temperature are not met.

Although we are not changing the monitoring requirements for scrubbers, we are proposing the removal of rule language which states that the failure to maintain an operating limit ''shall constitute a violation of the * * * standard.'' However, failure to meet either the minimum liquor level or ethylene glycol concentration requirement will constitute a deviation from the operating limit. We are replacing the current reporting requirements with the requirement to report all deviations.

The current rule has two alternative standards for aeration room vents; facilities can demonstrate initial compliance with either the 99 percent emission reduction or the 1 ppmv concentration limit. Facilities demonstrating compliance with the 99 percent emission reduction are required to use temperature as an operating limit. Facilities demonstrating compliance with the 1 ppmv concentration limit are required to use ethylene oxide concentration as an operating limit.

The 1 ppmv concentration limit was based on phone conversations with facilities operating catalytic oxidizers. These facilities stated that their test results showed no measurable ethylene oxide after controls; 1 ppmv was the lower detectable limit at the time. We allowed an alternative 99 percent emission reduction limit to provide a demonstrable emission limit for facilities which have high inlet concentrations; in this situation, it would not be possible to demonstrate compliance with the 1 ppmv limit even though the control unit was operating efficiently. We had very limited data to support these limits and no knowledge that the limits are achievable under all operating conditions.

Although ethylene oxide concentration measurements would indicate whether outlet concentrations are above or below 1 ppmv, it would not indicate proper operation under all operating conditions. For this reason, we are proposing, for facilities which demonstrate initial compliance with the 1 ppmv concentration limit, an operating limit that requires facilities to maintain the vendor minimum design temperature.

III. Testing

A. Why Are We Proposing To Change the Testing Requirements?

Prior to promulgation of the rule in 1994, many facilities used chlorofluorocarbons with ethylene oxide. The current rule requires the use of the EPA Method 18 because chlorofluorocarbons will distort test results. If a source is using an organic compound along with ethylene oxide in the sterilizer, the current Method 25A or Performance Specification (PS) 8 test method requirement would count the organic constituent as ethylene oxide. Since the industry has shifted almost exclusively to using only ethylene oxide, we are proposing a test method change to a less expensive test method.

B. How are we proposing to amend the testing requirements?

We are proposing the use of Method 25A and PS 8 as an option to avoid the higher cost of the current test method requirement. The affected sources would have the option of using a flame ionization analyzer (Method 25A or PS 8) or a gas chromatograph (Method 18 or PS 9) to measure ethylene oxide concentration.

IV. Summary of Environmental, Energy and Economic Impacts

There are negligible environmental, energy, and economic impacts associated with these amendments.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we must determine whether a proposed regulatory action is ''significant'' and,

therefore, subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a ''significant regulatory action'' because none of the listed criteria apply to this action. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Paperwork Reduction Act

The information collection requirements of the EO NESHAP were submitted to and approved by Management and OMB. A copy of this Information Collection Request (ICR) document (OMB control number 2060–0283) may be obtained from Ms. Sandy Farmer by mail at the U.S. Environmental Protection Agency, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, Washington, DC 20460, by email at *farmer.sandy@epa.gov*, or by calling (202) 260–2740. A copy may also be downloaded off the internet at *http://www.epa.gov/icr.*

Today's action has little or no impact on the information collection burden estimates made previously. Today's action eliminates requirements for chamber exhaust vents and clarifies testing and monitoring requirements for sterilization and aeration room vents. These changes revise existing requirements and do not impose new additional burdens; consequently, the ICR has not been revised.

C. Executive Order 13132, Federalism

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

These proposed amendments do not have federalism implications and 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. Today's action eliminates requirements for chamber exhaust vents and streamlines requirements for monitoring and testing which were promulgated in December 1994. There are minimal, if any, impacts associated with this action. Thus, Executive Order 13132 does not apply to these proposed amendments.

D. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

On January 1, 2001, Executive Order 13084 was superseded by Executive Order 13175. However, this proposed rule was developed during the period when Executive Order 13084 was still in force, and so tribal considerations were addressed under Executive Order 13084. Development of the final rule will address tribal considerations under Executive Order 13175.

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or we consult with those governments. If EPA complies by consulting, EPA is required by Executive Order 13084 to provide to the OMB in a separately identified section of the preamble to the rule, a description of the extent of EPAs prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's proposed amendments do not significantly or uniquely affect the communities of Indian tribal governments because the affected facilities are not located on tribal lands. Accordingly, the requirements of Executive Order 13084 do not apply to these proposed amendments.

E. Unfunded Mandates Reform Act of 1995

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 aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least-costly, most cost-effective, or least-burdensome alternative that achieves the objective 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 the 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.

Today's proposed amendments contain no Federal mandates for State, local, and tribal governments or the private sector. Instead, these proposed amendments either eliminate or

streamline requirements of the existing rule. Thus, today's proposed amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, we have determined that these proposed amendments contain no regulatory requirements that might significantly or uniquely affect small governments because they contain no requirements that apply to such governments or impose obligations upon them.

F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

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

For the purposes of assessing the impacts of today's proposed amendments on small entities, a small entity is defined as: (1) A small business whose parent company has fewer than 1000 employees; (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; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

We believe there will be little or no impact on any small entities because these proposed amendments do not impose additional requirements but instead either eliminate or streamline some existing requirements of the EO NESHAP. The Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities.

G. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, (Public Law No. 104–113) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in their regulatory and procurement activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

These proposed amendments do not establish or modify technical standards in the existing rule. The EPA believes that the use of voluntary consensus standards for these proposed amendments is not necessary. These proposed amendments do not require sources to take substantive steps that lend themselves to voluntary consensus standards.

H. 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 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 reasonable alternatives considered by the Agency.

These proposed amendments are not subject to Executive Order 13045 because they are not an economically significant regulatory action as defined by Executive Order 12866. In addition, the EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks. These proposed amendments are not subject to Executive Order 13045 because they are based on technology performance and not on health or safety risks.

List of Subjects in 40 CFR Part 63

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

Dated: February 28, 2001.

Christine Todd Whitman,

Administrator.

For reasons set out in the preamble, part 63 of title 40, chapter I 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 O—[Amended]

2. Table 1 of § 63.360 is amended by revising the entry for ''63.7(a)(2)'' to read as follows:

§ 63.360 Applicability.

(a) * * *

TABLE 1 OF SECTION 63.360–GENERAL PROVISIONS APPLICABILITY TO SUBPART O

Reference	Applies to sources using 10 tons in subpart O [a]	Applies to sources using 1 to 10 tons in subpart O [a]	Comment
* * *	*	*	*
63.7(a)(2)	(Yes)		
* * *	*	*	*

[a]–See definition.

* * * * *

3. Section 63.361 is amended by removing the definition for ''Parametric monitoring'' and revising the definition for ''Baseline temperature'' to read as follows:

§ 63.361 Definitions.

* * * * *

Baseline temperature means an average minimum temperature at the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber for a thermal oxidation control device.

* * * * *

4. Section 63.362 is amended by:

a. Revising Table 1 of paragraph (a);

b. Removing and reserving paragraph (e)(1);

c. Revising paragraph (e)(2).

The revisions read as follows:

§ 63.362 Standards.

(a) * * *

TABLE 1 OF SECTION 63.362—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

Existing and new sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size	<907 kg (<1 ton)	No control required; minimal recordkeeping requirements (see § 63.367(c))		
	≥907 kg and <9,070 kg (≥1 ton and <10 tons).	99% emission reduction (see § 63.362(c)).	No control	Maximum chamber concentration limit of 5,300 ppm prior to activation of the chamber exhaust[1] (see § 63.362(e)).
	≥9,070 kg (≥10 tons)	99% emission reduction (see § 63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d)).	Maximum chamber concentration limit of 5,300 ppm prior to activation of the chamber exhaust[1] (see § 63.362(e)).

[1] Affected sources may show compliance by manifolding emissions to a control device used to comply with § 63.362(c) or (d) by reducing emissions by at least 99%.

* * * * *

(e)(1) [Reserved]

(2) *Chamber exhaust vent at sources using 1 to 10 tons or sources using 10 tons.* Each owner or operator of a sterilization source using 1 to 10 tons or a sterilization source using 10 tons shall limit ethylene oxide emissions from the chamber exhaust vent to the atmosphere to a maximum concentration of 5,300 ppmv from each chamber exhaust vent. If the owner or operator chooses to limit emissions to 5,300 ppmv concentration through the use of a control device, the owner or operator may choose either to manifold ethylene oxide emissions from each chamber exhaust vent to a control device used to comply with paragraph (c) or (d) of this section or to reduce ethylene oxide emissions to the atmosphere (without manifolding) to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent.

5. Section 63.363 is revised (including the section heading) to read as follows:

§ 63.363 Compliance and performance provisions.

(a)(1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 of subpart A of this part according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

(b) The procedures in paragraphs (b)(1) through (3) Of this section shall be used to determine initial compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard;

(1) The owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b). The owner or operator shall also determine:

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating parameter either:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(3) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish a baseline temperature for an operating parameter using the procedures described in § 63.365(f) and shall, after the initial compliance test, comply with the following work practice by, every 2 years, replacing the catalyst bed with new catalyst material and conducting a performance test using the procedures described in § 63.365(b) or (d) as appropriate.

(c) The procedures in paragraphs (c)(1) through (c)(3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with § 63.362(d)) using the methods in § 63.365(c)(1); or

(3) Determine the efficiency of the control device used to comply with § 63.362(d) using the test methods and procedures in § 63.365(d)(1).

(d) The procedures in paragraphs § 63.363(d)(1) through (3) shall be used to determine initial compliance with the emission limits under § 63.362(e)(2), the chamber exhaust vent standard for sources using 1 to 10 tons or sources using 10 tons:

(1) For facilities manifolding emissions from the chamber exhaust vent to a control device controlling emissions from the sterilization chamber vent, the owner or operator shall comply with the applicable compliance provisions for the appropriate control technology (see paragraphs (b)(2) and (3) of this section).

(2) For facilities controlling only emissions from the chamber exhaust vent with a control device, the owner or operator shall determine the efficiency of control devices used to comply with § 63.362(e)(2) using the test methods and procedures in § 63.365(d)(2), as well as the following:

(i) For facilities with acid-water scrubbers, the owner or operator shall comply with paragraph (b)(2) of this section.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall comply with paragraph (b)(3) of this section.

(3) For facilities exhausting emissions to the atmosphere, the owner or operator shall determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust using the test methods and procedures in § 63.365(c)(2).

(e) For facilities complying with the emissions limits under section § 63.362 with a control technology other than

acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system including recommendations for the operating parameters to be monitored to indicate proper operation and maintenance of the air pollution control system. Based on this information, the Administrator will determine the operating parameter(s) to be established during the performance test. During the performance test required in paragraph (a) of this section using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating parameter(s) approved by the Administrator.

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under § 63.363, except during periods of startup and shutdowns, according to the methods specified in § 63.364.

6. Section 63.364 is amended by:

a. Revising paragraph (b) introductory text;

b. Adding a sentence to the end of paragraph (b)(2);

c. Revising paragraph (c) introductory text;

d. Removing and reserving paragraphs (c)(1), (2) and (3);

e. Adding a sentence to the end of paragraph (c)(4);

f. Revising paragraph (d);

g. Revising paragraph (e); and

h. Revising paragraph (f).

The additions and revisions read as follows:

§ 63.364 Monitoring requirements.

* * * * *

(b) For sterilization facilities complying with § 63.363 (b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

* * * * *

(2) * * * Monitoring is required during a week only if the scrubber unit has been operated.

(c) For sterilization facilities complying with § 63.363(b), (c), or (d) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature.

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) * * * As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) For sterilization facilities complying with § 63.363(b), (c), or (d) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(g).

(e) For sterilization facilities complying with § 63.363, (c)(2), or through the use of direct measurement of ethylene oxide concentration, the owner or operator shall follow paragraph (e)(1) of this section. For sterilization facilities complying with § 63.363(d)(3) through the use of direct measurement of ethylene oxide concentration, the owner or operator shall follow paragraph (e)(2) of this section.

(1) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in § 63.365(c)(1). The owner or operator shall compute and record a 3-hour average every third hour. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specifications (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

(2) Measure and record the ethylene oxide concentration in the sterilization chamber immediately before the chamber exhaust is activated according to the procedures specified in § 63.365(c)(2). The owner or operator shall install, calibrate, operate, and maintain a monitor consistent with the requirements of PS 8 or 9 to measure ethylene oxide concentration. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when the chamber exhaust is activated. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS 8.

(f) For sterilization facilities complying with § 63.363(d)(1) by manifolding emissions from the chamber exhaust vent to a control device controlling emissions from another vent type, the owner or operator shall monitor the control device to determine which emissions from the chamber exhaust vent are manifolded using the applicable monitoring requirements in paragraphs (a) through (e) of this section and record the monitoring data.

7. Section 63.365 is amended by:

a. Revising paragraph (b)(1) introductory text;

b. Revising paragraph (b)(1)(iv)(B);

c. Removing and reserving paragraph (b)(1)((iv)(C);

d. Removing and reserving paragraph (b)(2);

e. Revising paragraph (c);

f. Revising paragraph (d);

g. Revising paragraph (f);

h. Revising paragraph (h).

The revisions read as follows:

§ 63.365 Test methods and procedures.

* * * * *

(b) * * *

(1) *First evacuation of the sterilization chamber.* These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

* * * * *

(iv) * * *

(A) * * *

(B) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A respectively), shall be used to measure the concentration of ethylene oxide.

(*1*) Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(*2*) Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \frac{MW}{SV} \times \frac{1}{10^6}$$

Where:

Wo = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide in ppmv

V = volume of gas exiting the control device corrected to standard conditions, L (ft^3)

$1/10^6$ = correction factor $L_{EO}/10^6\ L_{TOTAL\ GAS}$ ($ft^3_{EO}/10^6\ ft^3_{TOTAL\ GAS}$)

(*3*) Calculate the efficiency by the equation in paragraph (*B*)(1)(v) of this section.

(C) [Reserved]

* * * * *

(2) [Reserved]

* * * * *

(c) *Concentration determination.* The following procedures shall be used to determine the ethylene oxide concentration as the monitored parameter for aeration room vents as established in § 63.364(e)(1) and to monitor the ethylene oxide concentration before activation of the chamber exhaust vents as established in § 63.364(e)(2).

(1) *Parameter Monitoring.* For determining the ethylene oxide concentration established in § 63.363(b)(2)(i), (c)(2), and (d)(2), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS 8.

(2) *Sterilization chamber prior to activation of the chamber exhaust.* For determining the ethylene oxide concentration established in § 63.363(d)(2) for the sterilization chamber before activation of the chamber exhaust, follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS 8.

(d) *Efficiency determination at the aeration room vent and at the chamber exhaust vent (not manifolded).* The following procedures shall be used to determine the efficiency of a control device used to comply with § 63.362(d) or (e), the aeration room vent standard or the chamber exhaust vent standards.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Test Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

Where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

* * * * *

(f) *Determination of baseline temperature for oxidation units.* The procedure in paragraph (f)(1) of this section shall be used to establish the baseline temperature required in § 63.363(b), (c), or (d) for catalytic oxidation units or thermal oxidation units.

(1) The owner or operator shall maintain the recommended minimum oxidation temperature provided by the oxidation unit manufacturer.

(2)–(3) [Reserved]

* * * * *

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the standards found at § 63.362(d) or (e) with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would indicate proper operation and maintenance of the device or procedure. The Administrator may request further information and will specify appropriate test methods and procedures.

8. Section 63.366 is amended by revising paragraph (a)(3) as follows:

* * * * *

§ 63.366 Reporting requirements.

(a) * * *

(3) Content and submittal dates for excess emissions and monitoring system performance reports. All excess emissions and monitoring system performance reports and all summary reports, if required per § 63.10(e)(3)(vii) and (viii) of subpart A of this part, shall be delivered or postmarked or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see § 63.10(e)(3)(i) through (iv) for applicability). Written reports of exceedances, excursions, or violations of process or control system parameters, or operating limits, shall include all information required in § 63.10(c)(5) through (13) of subpart A of this part, as applicable in Table 1 of § 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no exceedances, excursions, or violations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

* * * * *

9. Section 63.367 is revised to read as follows:

§ 63.367 Recordkeeping requirements.

(a) The owner or operator of a source subject to the emissions standards in § 63.362 shall comply with the recordkeeping requirements in § 63.10(b) and (c) of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to an emissions standard in § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to an emissions standard in § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to the emissions standard in § 63.362).

[FR Doc. 01–5414 Filed 3–5–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF ENERGY

48 CFR Parts 904, 952 and 970

RIN 1991–AB54

Acquisition Regulations; Conditional Payment of Fee, Profit, and Other Incentives

AGENCY: Department of Energy.

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On February 1, 2001, the Department of Energy (DOE) published a Notice of Proposed Rulemaking to consider amending its Acquisition Regulation to: implement, in part, the requirements of Section 3147 of the National Defense Authorization Act for Fiscal Year 2000 relating to the safeguarding of classified information; establish more objective standards and procedures for considering and applying reductions of fee or other amounts payable for contractor performance