that, prior to release of bond liability, the permittee must demonstrate that development of the industrial, commercial, or residential land use has substantially commenced and is likely to be achieved.

[FR Doc. 94–29984 Filed 12–5–94; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH02

Omnibus Budget Reconciliation Act of 1993

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations to extend the date concerning limitation of pension benefits for veterans and surviving spouses receiving Medicaid-covered nursing home care. This amendment is necessary to conform the regulations to statutory provisions.

EFFECTIVE DATE: This amendment is effective August 10, 1993, the date Pub. L. 103–66 was signed into law.

FOR FURTHER INFORMATION CONTACT: Lorna Weston, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7210.

SUPPLEMENTARY INFORMATION: Section 8003 of Pub. L. 101–508 required VA to reduce the pension benefits of any veteran having neither spouse nor child who receives Medicaid-covered nursing home care to $90 per month. These statutory provisions expired September 30, 1992. Section 601 of Pub. L. 102–568 reestablished this requirement, effective until September 30, 1997, and required an identical reduction in death pension payments to surviving spouses having no children who receive Medicaid-covered nursing home care. Section 12005 of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66, further extends these statutory provisions with respect to both veterans and their surviving spouses until September 30, 1998. VA accordingly hereby amends 38 CFR 3.551(i) to reflect this statutory change.

VA is issuing a final rule to amend 38 CFR 3.551(i) to be consistent with the provisions of Pub. L. 103–66. Because this amendment merely corresponds to the provisions of section 12005 of Pub. L. 103–66, publication as a proposal for public notice and comment is unnecessary.

This regulatory amendment will not have a significant economic impact on a substantial number of small entities since it merely reflects a statutory amendment.

The Catalog of Federal Domestic Assistance program numbers are 64.104 and 64.105.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

Approved: November 23, 1994.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 3 is amended as set forth below:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A, continues to read as follows:

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

§ 3.551 [Amended]

2. In § 3.551(i), the date "September 30, 1997" is revised to read "September 30, 1998".

[FR Doc. 94–29870 Filed 12–5–94; 8:45 am]

BILLING CODE 8320–01–P

38 CFR Part 3

RIN 2900–AG74

Dependents' Educational Assistance; Certification

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning eligibility for Dependents' Educational Assistance (DEA) in cases where it has been established that a veteran has a permanent and total service-connected disability. This action conforms the regulations to a decision of the Court of Veterans Appeals which held that entitlement to DEA may be established in such cases where the disabilities are of paired organs or extremities that are treated as service-connected under 38 U.S.C. 1160. Section 1160 provides that the combination of service-connected disability of one organ or extremity and nonservice-connected disability of the respective paired organ or extremity is treated as if the combination of disabilities is the result of service-connected disability.

EFFECTIVE DATE: This amendment is effective December 6, 1994.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: The Survivors' and Dependents' Educational Assistance (DEA) Program, established under 38 U.S.C. Chapter 35, authorizes monetary educational benefits to a qualifying spouse or child, or surviving spouse or child, of a veteran whose death or permanent and total disability was due to military service.

38 CFR 3.807 provides that a spouse or child of a veteran has basic eligibility for Chapter 35 benefits if the veteran has a permanent total service-connected disability. The surviving spouse or child of a deceased veteran has basic eligibility for Chapter 35 benefits if a permanent total service-connected disability was in existence at the date of the veteran's death or the veteran died of a service-connected disability.

38 U.S.C. 1160 provides that where a veteran has suffered service-connected loss of use of an eye, kidney, ear, hand, foot, or lung and nonservice-connected loss of use of the paired eye, kidney, ear, hand, foot, or lung, the veteran shall be paid compensation as if the combination of disabilities were the result of service-connected disability. 38 CFR 3.383 is the corresponding regulation.

In Precedent Opinion 75–90 dated July 18, 1990, the VA General Counsel held that Chapter 35 eligibility is not established where a disability of paired organs treated as if service-connected under 38 U.S.C. 1160 for purposes of disability compensation is evaluated as permanently and totally disabling. The General Counsel reasoned that the threshold criterion for DEA eligibility is total service-connected disability and stated that this criterion is not satisfied where permanent and total disability is based on the "as if service-connected" status established under 38 U.S.C. 1160.

In a recent decision (*Kimberlin v. Brown*, No. 91–1972), however, the United States Court of Veterans Appeals held that Chapter 35 entitlement was established where the veteran was entitled to compensation for a total disability, permanent in nature, regardless of whether entitlement was

based on loss of use of paired organs treated as if service-connected under 38 U.S.C. 1160. The Court's opinion overrules General Counsel Precedent Opinion 75–90 insofar as it relates to Chapter 35 eligibility.

Currently the regulation does not specifically address whether Chapter 35 eligibility may be established based on a combination of disabilities treated as if service-connected under 38 CFR 3.383(a). We are amending 38 CFR 3.807 to reflect the Court's determination that such an evaluation may be the basis for Chapter 35 eligibility.

Administrative Procedure Act

This final rule constitutes an interpretative rule. Accordingly, pursuant to 5 U.S.C. 553, there is a basis for dispensing with prior notice and comment on this final rule and dispensing with a 30-day delay of its effective date.

Regulatory Flexibility Act

Because no notice of proposed rulemaking was required in connection with the adoption of this final rule, no regulatory flexibility analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

There are no affected Catalog of Federal Domestic Assistance program numbers.

List of Subjects in 38 CFR Part 3

Administrative practices and procedure, Claims, Individuals with disabilities, Health care, Pensions, Veterans.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR Part 3 is amended as set forth below:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

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

2. Section 3.807 is amended, by adding a sentence after the heading of paragraph (c), and by adding an authority citation at the end of the section, as follows:

§ 3.807 Dependents' educational assistance; certification.

* * * * *

(c) *Service connection.* For purpose of this section, the term "service-connected disability" encompasses combinations of disabilities of paired organs or extremities treated as if service-connected under the provisions of § 3.383(a) of this part. * * *

* * * * *

(Authority: 38 U.S.C. 1160, 3501)

[FR Doc. 94–29893 Filed 12–5–94; 8:45 am]

BILLING CODE 8320–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD–FRL–5115–8]

RIN 2060–AC28

National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: National emission standards for hazardous air pollutants (NESHAP) for ethylene oxide commercial sterilization and fumigation operations were proposed in the **Federal Register** on March 7, 1994. This **Federal Register** action announces the EPA's final decisions on the rule. This action promulgates NESHAP for ethylene oxide commercial sterilization and fumigation operations. These standards implement section 112 of the Clean Air Act (Act) and are based on the Administrator's determination that commercial sterilization and fumigation operations emit ethylene oxide, a pollutant identified in the Act list of 189 hazardous air pollutants (HAP). The intent of the standards is to protect public health by requiring existing and new major sources to control emissions to the level achievable by the maximum achievable control technology (MACT) and by requiring existing and new area sources to control emissions using generally available control technology (GACT). These standards are consistent with section 112(d) of the Act.

EFFECTIVE DATE: This regulation is effective December 6, 1994.The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 6, 1994. See **SUPPLEMENTARY INFORMATION** section concerning judicial review.

ADDRESSES: *Background Information Document.* The background information document (BID) for the promulgated standards may be obtained from the U.S. Department of Commerce, National Technical Information Service (NTIS), Springfield, Virginia 22161, telephone number (703) 487–4650. Please refer to "Ethylene Oxide Emissions from Commercial Sterilization/Fumigation Operations—Background Information for Final Standards," NTIS number EPA–453/R–94–084b. The BID contains: (1) A summary of all the public comments made on the proposed standards and the Administrator's response to the comments, and (2) a summary of the changes made to the standards since proposal.

Electronic versions of the promulgation BID as well as this final rule are available for download from the EPA's Technology Transfer Network (TTN), a network of electronic bulletin boards developed and operated by the Office of Air Quality Planning and Standards. The TTN provides information and technology exchange in various areas of air pollution control. The service is free, except for the cost of a phone call. Dial (919) 541–5742 for data transfer of up to a 14,400 bits per second (bps). If more information on TTN is needed, contact the systems operator at (919) 541–5384.

Docket. Docket No. A–88–03, containing supporting information used in developing the promulgated standards, is available for public inspection and copying from 8 a.m. to 4 p.m., Monday through Friday, at the EPA's Air and Radiation Docket and Information Center (formerly known as the Air Docket), Waterside Mall, room M–1500, Ground Floor, 401 M Street SW., Washington DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the standards or technical aspects, contact Mr. David Markwordt at (919) 541–0837, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For information concerning the health effects of EO, contact Dr. Nancy Pate at (919) 541–5347, Information Transfer and Program Integration Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: Under section 307(b)(1) of the Act, judicial review of NESHAP is available only by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings

brought by the EPA to enforce these requirements.

The information presented in this preamble is organized as follows:

I. The Standards

National emission standards for hazardous air pollutants established under section 112(d) of the Act reflect:

> * * * the maximum degree of reduction in emissions of the hazardous air pollutants subject to this section (including a prohibition on such emissions, where achievable) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any nonair 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 standard applies * * * (the Act section 112(d)(2))

The promulgated standards include multiple alternatives to allow owners or operators maximum compliance flexibility. A summary of today's final standards is listed in Table 1. Included in this table are applicability cutoffs based on annual EO use, general descriptions of the standards, and the estimated impacts associated with these standards for each vent type.

Section 114(a)(3) of the Act requires enhanced monitoring and compliance certifications of all major stationary sources. The annual compliance certifications certify whether compliance has been continuous or intermittent. Enhanced monitoring shall be capable of detecting deviations from each applicable emission limitation or standard with sufficient representativeness, accuracy, precision, reliability, frequency, and timeliness to determine if compliance is continuous during a reporting period. The monitoring in this regulation satisfies the requirements of enhanced monitoring.

Owners or operators of all commercial EO sterilization and fumigation operations with an initial startup date before December 8, 1997 that are subject to the emissions standards are required to install the control technology needed to comply with the standards within 3 years from December 6, 1994. Owners or operators of new commercial EO sterilization and fumigation operations with initial startup after December 8, 1997 would be required to comply with all requirements upon startup.

TABLE 1.—PROPOSED STANDARDS, NATIONAL COSTS, AND EMISSION REDUCTIONS FOR MAJOR AND AREA SOURCES

Vent type	Ethylene oxide use, kg/yr (ton/yr)	Standard	Emission reduction, Mg/yr (ton/yr)	Annual cost, $MM
Sterilizer vent	≥907 (≥1)	99 percent reduction	950 (1,050)	3.8
Chamber exhaust	≥9,070 (≥10)	Manifold to a control device controlling emissions from another vent type or 99 percent emission reduction.	34 (37)	0.2
	907–9,070 (1–10)	Maximum chamber concentration limit of 5,300 ppmv prior to activation of the chamber exhaust.	0	0.05
Aeration room	≥9,070 (≥10)	1 ppmv maximum concentration or 99 percent reduction.	48 (53)	2.6

II. Summary of Impacts

These standards will reduce nationwide emissions of hazardous air pollutants (HAP) from ethylene oxide commercial sterilization and fumigation operations by 1,030 Mg (1,140 tons), or 96 percent, in 1997 compared to the emissions that would result in the absence of the standards. No significant adverse secondary air impacts, water, solid waste or energy impacts are anticipated from the promulgation of these standards.

The implementation of this regulation is expected to result in nationwide annualized costs for existing commercial EO sterilization facilities of about $6.6 million beyond baseline based on an analysis of the application of controls to all existing facilities not currently controlled to the level of the standards. Capital costs incurred by a typical uncontrolled existing source such as a large commercial EO sterilization and fumigation operation using 68,000 kg/yr (75 ton/yr) of EO would be about $310,000 for controlling the sterilization chamber vent emissions, and about $290,000 for controlling the aeration room vent and chamber exhaust vent emissions. The annualized cost incurred by this typical source to operate the control devices would be about $100,000 to control the sterilization chamber vent emissions and about $80,000 to control the aeration room vent and chamber exhaust vent emissions.

The economic impact analysis done prior to proposal showed that the economic impacts from the proposed standard would not be significant. No changes have been made to the proposed rule that would increase the economic impacts to a significant level.

III. Significant Changes to the Proposed Standards

A. Public Participation

Prior to proposal of the standards, interested parties were advised by public notice in the **Federal Register** (56 FR 1186), of a meeting of the National Air Pollution Control Techniques Advisory Committee to discuss the ethylene oxide commercial sterilization and fumigation source category recommended for proposal. This meeting was held on January 29–31, 1991. The meeting was open to the public and each attendee was given an opportunity to comment on the standards recommended for proposal.

The standards were proposed and the preamble was published in the **Federal Register** on March 7, 1994 (59 FR 10591). The preamble to the proposed standards discussed the availability of the regulatory text and proposal BID, which described the regulatory alternatives considered and the impacts of those alternatives. Public comments were solicited at the time of proposal, and copies of the regulatory text and BID were distributed to interested parties. Electronic versions of the preamble, regulation, and BID were made available to interested parties via the TTN (see **ADDRESSES** section of this preamble).

To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was offered at proposal; however, one was not requested. The public comment period was from March 7 to May 6, 1994. Twenty comment letters were received (two letters were received from one commenter; nineteen commenters submitted comments). The comments have been carefully considered, and changes have been made to the proposed standards when determined by the Administrator to be appropriate.

B. Comments on the Proposed Standards

Comments on the proposed standards were received from nineteen commenters composed mainly of States, environmental groups, control device vendors, industry, and trade associations. A detailed discussion of these comments and responses can be found in the promulgation BID, which is referred to in the **ADDRESSES** section of this preamble. The summary of comments and responses in the BID serve as the basis for the revisions that have been made to the standards between proposal and promulgation. Most of the comment letters contained multiple comments. The comments have been divided into the following areas:

(1) Determination of MACT floor for major source chamber exhaust vents.

(2) Selection of MACT/GACT regulatory approach for area sources.

(3) Request for flexibility in meeting the aeration room vent standard.

(4) Stringency of MACT for sterilization chamber vents.

(5) Compliance schedule.

(6) Alternative monitoring and compliance demonstration requirements.

(7) Revisions to monitoring requirements for acid-water scrubbers, catalytic oxidizers, and aeration room vents.

(8) Addition of compliance provisions and monitoring requirements for thermal oxidizers.

(9) Revision of requirements to calibrate the temperature monitors used for catalytic oxidizers and thermal oxidizers.

(10) Applicability of the rule to research and laboratory facilities, hospital facilities, and sources emitting less than 907 kg/yr (1 ton/yr) of ethylene oxide.

(11) Incorporation of the final General Provisions to part 63 into these standards.

(12) Revisions to reporting requirements.

(13) Importance of residual risk to the selection of a regulatory approach.

(14) Revisions to definitions and wording of the regulation.

C. Significant Changes

Several changes have been made since the proposal of these standards. The majority of the changes have been made to clarify portions of the rule that were unclear to the commenters. Other changes include adding additional flexibility to sources by allowing alternative monitoring approaches to meet the standards. A summary of the major changes is presented below.

(1) A controlled MACT floor for chamber exhaust vents at operations using 9,070 kg/yr (10 tons/yr) or more of EO was determined based on data submitted by commenters (see Docket Entry IV–B–02). Existing and new sources using 9,070 kg/yr (10 tons/yr) or more of EO are now required to control the emissions from the chamber exhaust vent. Owners or operators of new and existing chamber exhaust vents at sources using 9,070 kg/yr (10 tons/yr) or more of EO must parametrically monitor the control device used in achieving the emissions reduction requirements of the standards.

As noted above, the Agency has required control of emissions from the chamber exhaust vent at major sources because data were received from commenters indicating that the emissions from this vent are routed to a control device used to control emissions from other vent types (i.e., manifolded to either the aeration room vent or sterilization chamber vent). The Agency also received data showing minimal nationwide annualized cost impacts of approximately $240,000 associated with manifolding these emissions (see Docket Entry IV–B–03). The Agency therefore believes that the requirements to control this vent at the MACT floor are not burdensome for major sources and do not represent a significant change in the Agency's regulatory approach.

(2) The format of the standard for aeration room vents at sources using 9,070 kg/yr (10 tons/yr) or more of EO was revised to provide owners or operators flexibility to either meet a maximum emission limit of 1 ppmv ethylene oxide or achieve a 99 percent reduction in ethylene oxide emissions, whichever is less stringent.

(3) The compliance date for all sources has been changed from 2 to 3 years. This extension has been provided to allow sources additional time to achieve compliance with these standards. New sources with startup after the 3 year compliance date will be required to comply upon startup of the source.

(4) Owners or operators of all chamber exhaust vents at sources using 907 kg/yr (1 ton/yr) or more but less than 9,070 kg/yr (10 tons/yr) of EO were provided additional flexibility to show compliance by either measuring the ethylene oxide concentration in the chamber prior to activation of the chamber exhaust vent (as proposed) or parametrically monitoring the performance of a control device used to reduce emissions from this vent.

(5) The monitoring requirements for aeration room vents at sources using 9,070 kg/yr (10 tons/yr) or more of EO were revised to provide sources additional flexibility to monitor either the ethylene oxide outlet concentration or parameters of control device performance. For sources choosing to measure the EO outlet concentration, measurements of ethylene oxide concentration that are below the detection limit of 0.5 ppmv for ethylene oxide are accepted as a demonstration of compliance with the aeration room vent standards.

(6) The Agency reduced the frequency of monitoring of the ethylene glycol concentration in the scrubber liquor for sources complying with emission reduction standards using an acid-water scrubber. Owners or operators are now only required to monitor the ethylene glycol concentration weekly. The Agency also provided sources using this control technology flexibility to alternatively monitor the level of the scrubber liquor in the liquor tank on a weekly basis.

(7) Several commenters suggested that maintenance of catalytic oxidizers within a temperature range was not appropriate. In the final rule, a baseline temperature is established as a minimum oxidation temperature.

(8) Based on information from commenters, compliance provisions and monitoring requirements have been included in the final rule for thermal oxidizers. These requirements include the establishment of a baseline temperature and continuous monitoring of this temperature.

(9) The frequency for calibrating the temperature monitor used for catalytic oxidizers and thermal oxidizers has been reduced from once per month to twice per year.

(10) Several commenters requested clarification of the general provisions to part 63 as they relate to this rule. A table identifying the relationship of the final General Provisions requirements has been added to the final regulation.

Language similar to that in the General Provisions has been added to subpart O in cases where a direct reference to the General Provisions was not appropriate.

(11) Based on comments received, an excess emissions report is required semi-annually, whether the source has experienced excess emissions or not; the Administrator may determine on a case basis that more frequent reporting is necessary.

(12) Revisions to definitions and phrasing have been made to clarify the regulation.

One topic for which comments were received that did not result in a change in the regulation concerned hospital sterilization. Several comments were received that recommended the inclusion of hospital ethylene oxide sterilization operations under the standards promulgated in today's action. While the EPA listed "commercial sterilization facilities" and "hospital sterilization facilities" as two separate categories on the proposed source category list, hospital sterilizers were removed from the final source category list and only commercial sterilization facilities were included on the list. Section 112(c) specifies that the source category list will periodically be revised, and hospitals (with EO emissions greater than 1 ton/yr) may be added to the source category list at a future date. Hospital sterilization sources (under 1 ton/yr ethylene oxide emissions) will likely be assessed as part of section 112(k) of the Act.

IV. Administrative Requirements

A. Docket

The Docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The Docket is a dynamic file, since material is added throughout the rulemaking development. 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 statement of basis and purpose of the proposed and promulgated standards and the EPA responses to significant comments, the contents of the Docket will serve as the record in case of judicial review (section 307(d)(7)(A)).

B. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number (2060–0283). An Information Collection Request (ICR) document has been prepared by the EPA (ICR No. 1666.02) to reflect the changed information requirements of the final rule.

This collection of information has an estimated burden per affected facility of about 510 hours for the first year. In subsequent years, the burden is approximately 60 hours per affected facility. These burden estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch; U.S. Environmental Protection Agency (Mail Code 2136); 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

C. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), the EPA is required to judge whether a regulation is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order to prepare a regulatory impact analysis (RIA). The 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 obligation 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 "significant" because none of the listed criteria apply to this action. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the EPA to consider potential impacts of proposed regulations on small business "entities." If a preliminary analysis indicates that a proposed regulation would have a significant economic impact on 20 percent or more of small entities, then a regulatory flexibility analysis must be prepared. The EPA's analysis of these impacts was provided in the preamble to the proposed rule (59 FR 10591).

Pursuant to the provisions of 5 U.S.C. 605(b), the EPA certifies that this rule will not have a significant economic impact on a substantial number of small business entities because: (1) In all industry categories except the contract sterilization industry, there is not a substantial number of small entities, and (2) contract sterilizers should experience an increase in demand for their services as other facilities switch from in-house to contract sterilization (see Docket Entry II–A–22). As a result, contract sterilizers will not be adversely impacted by this rule.

List of Subjects in 40 CFR Parts 9 and 63

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

Dated: November 22, 1994.

Carol M. Browner,

Administrator.

For reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 135–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding a new entry to the table under the indicated heading in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB Control No.
. . . . .	. .
National Emissions Standards for Hazardous Air Pollutants for Source Categories:	
. . . . .	. .
63.363–63.367	2060–0283
. . . . .	. .

PART 63—[AMENDED]

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

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

2. Section 63.14 is amended by adding paragraph (b)(4) to read as follows:

§ 63.14 Incorporation by reference.

* * * * *

(b) * * *

(4) ASTM D 3695–88, Standard Test Method for Volatile Alcohols in Water by Direct Aqueous-Injection Gas Chromatography, IBR approved for § 63.365(e)(1) of subpart O of this part.

* * * * *

3. By adding a new subpart O to read as follows:

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

Sec.

Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities

§ 63.360 Applicability.

(a) All sterilization sources using 1 ton (see definition) in sterilization or fumigation operations are subject to the emissions standards in § 63.362, except as specified in paragraphs (b) through (e) of this section. Owners or operators of sources using 1 ton (see definition) subject to the provisions of this subpart must comply with the requirements of subpart A, of this part according to the applicability of subpart A of this part to such sources in Table 1 of this section.

TABLE 1 OF SECTION 63.360. GENERAL PROVISIONS APPLICABILITY TO SUBPART Q

Reference	Applies to sources using 10 tons in subpart O [a]	Applies to sources using 1 to 10 tons in subpart O [a]	Comment
63.1(a)(1)		Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.1(a)(2)		Yes	
63.1(a)(3)		Yes	
63.1(a)(4)		Yes	Subpart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O.
63.1(a)(5)		No	Reserved.
63.1(a)(6)		Yes	
63.1(a)(7)		Yes	
63.1.1(a)(8)		Yes	
63.1(a)(9)		No	Reserved.
63.1(a)(10)		Yes	
63.1(a)(11)		Yes	§ 63.366(a) of subpart O also allows report submissions via fax and on electronic media.
63.1(a)(12)–(14)		Yes	
63.1(b)(1)–(2)		Yes	
63.1(b)(3)		No	§ 63.367 clarifies the applicability of recordkeeping requirements for sources that determine they are not subject to the emissions standards.
63.1(c)(1)		Yes	Supart O clarifies the applicability of each paragraph in subpart A to sources subject to subpart O in this table.
63.1(c)(2)		Yes	Subpart O also specifies which sources are required to obtain a Title V permit in § 63.360.
63.1(c)(3)		No	Reserved.
63.1(c)(4)		Yes	
63.1(c)(5)		No	§ 63.360 specifies applicability.
63.1(d)		No	Reserved.
63.1(e)		Yes	
63.2		Yes	Additional terms defined in § 63.361; when overlap between subparts A and O occurs, subpart O takes precedence.
63.3		Yes	Other units used in supart O are defined in the text of subpart O.
63.4(a)(1)-(3)		Yes	
63.4(a)(4)		No	Reserved.
63.4(a)(5)		Yes	
63.4(b)		Yes	

TABLE 1 OF SECTION 63.360. GENERAL PROVISIONS APPLICABILITY TO SUBPART Q—Continued

Reference	Applies to sources using 10 tons in subpart O[a]	Applies to sources using 1 to 10 tons in subpart O[a]	Comment
63.4(a)(5)	Yes		
63.4(b)	Yes		
63.4(c)	Yes		
63.5(a)	No		§63.366(b)(1) contains applicability requirements for constructed or reconstructed sources.
63.5(b)(1)	Yes	No	
63.5(b)(2)	No		Reserved.
63.5(b)(3)	No		See §63.366(b)(2).
63.5(b)(4)	Yes	No	
63.5(b)(5)	Yes	No	
63.5(b)(6)	Yes	No	
63.5(c)	No		Reserved.
63.5(d)(1)-(2)	No		See §63.366(b)(3).
63.5(d)(3)-(4)	Yes	No	
63.5(e)	Yes	No	
63.5(f)(1) and (2)	No		See §63.366(b)(4).
63.6(a)(1)	Yes		
63.6(a)(2)	No		§63.360 specifies applicability.
63.6(b) and (c)	No		§63.360(g) specifies compliance dates for sources.
63.6(d)	No		Reserved.
63.6(e)	No		Subpart O does not contain any operation and maintenance plan requirements.
63.6(f)(1)	No		§63.362(b) specifies when the standards apply.
63.6(f)(2)(i)	Yes		
63.6(f)(2)(ii)	No		§63.363 specifies parameters for determining compliance.
63.6(f)(2)(iii)-(iv)	Yes		
63.6(f)(2)(v)	No		
63.6(f)(3)	Yes		
63.6(g)	Yes		
63.6(h)	No		Subpart O does not contain any opacity or visible emission standards.
63.6(i)(1)-(14)	Yes		
63.6(i)(15)	No		Reserved
63.6(i)(16)	Yes		
63.6(j)	Yes		
63.7(a)(1)	Yes		
63.7(a)(2)	No		§63.365(a)(2) specifies performance test dates.
63.7(a)(3)	Yes		
63.7(b)	Yes		
63.7(c)	Yes	No.	
63.7(d)	Yes	No.	
63.7(e)	Yes		§63.365 also contains test methods specific to sources subject to the emissions standards.
63.7(f)	Yes		
63.7(g)(1)	Yes		
63.7(g)(2)	No		Reserved
63.7(g)(3)	Yes		
63.7(h)	Yes		
63.8(a)(1)	Yes		
63.8(a)(2)	Yes		
63.8(a)(3)	No		Reserved
63.8(a)(4)	Yes		
63.8(b)(1)	Yes		
63.8(b)(2)	Yes		
63.8(b)(3)	No		
63.8(c)(1) (i) and (ii)	No		A startup, shutdown, and malfunction plan is not required for these standards.
63.8(c)(1)(iii)	Yes		
63.8(c)(2)-(3)	Yes		
63.8(c)(4)–(5)	No		Frequency of monitoring measurements is provided in §63.364; opacity monitors are not required for these standards.
63.8(c)(6)	No		Performance specifications for gas chromatographs and temperature monitors are contained in §63.365.
63.8(c)(7)(i)(A)–(B)	No		Performance specifications for gas chromatographs and temperature monitors are contained in §63.365.
63.8(c)(7)(i)(C)	No		Opacity monitors are not required for these standards.
63.8(c)(7)(ii)	No		Performance specifications for gas chromatographs and temperature monitors are contained in §63.365.
63.8(c)(8)	No		

TABLE 1 OF SECTION 63.360. GENERAL PROVISIONS APPLICABILITY TO SUBPART Q—Continued

Reference	Applies to sources using 10 tons in subpart O[a]	Applies to sources using 1 to 10 tons in subpart O[a]	Comment
63.8(d)	Yes	No.	
63.8(e)(1)		Yes	
63.8(e)(2)		Yes	
63.8(e)(3)	Yes	No.	
63.8(e)(4)		Yes	
63.8(e)(5)(i)		Yes	
63.8(e)(5)(ii)		No	Opacity monitors are not required for these standards.
63.8(f)(1)–(5)		Yes	
63.8(f)(6)		No	
63.8(g)(1)		Yes	
63.8(g)(2)		No	
63.8(g)(3)–(5)		Yes	
63.9(a)		Yes	
63.9(b)(1)–(i)		Yes	
63.9(b)(1)(ii)–(iii)		No	§63.366(c)(1)(i) contains language for sources that increase usage such that the source becomes subject to the emissions standards.
63.9(b)(2)–(3)		Yes	§63.366(c)(3) contains additional information to be included in the initial report for existing and new sources.
63.9(b)(4)–(5)		No	§63.366(c)(1)(ii) and (iii) contains requirements for new or reconstructed sources subject to the emissions standards.
63.9(c)		Yes	
63.9(d)		No	
63.9(e)		Yes	
63.9(f)		No	Opacity monitors are not required for these standards.
63.9(g)(1)		Yes	
63.9(g)(2)–(3)		No	Opacity monitors and relative accuracy testing are not required for these standards.
63.9(h)(1)–(3)		Yes	
63.9(h)(4)		No	Reserved.
63.9(h)(5)		No	§63.366(c)(2) instructs sources to submit actual data.
63.9(h)(6)		Yes	
63.9(i)		Yes	
63.9(j)		Yes	
63.10(a)		Yes	
63.10(b)(1)		Yes	
63.10(b)(2)(i)		No	Not applicable due to batch nature of the industry.
63.10(b)(2)(ii)		Yes	
63.10(b)(2)(iii)		No	
63.10(b)(2)(iv)–(v)		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(b)(2)(vi)–(xii)		Yes	
63.10(b)(2)(xiii)		No	
63.10(b)(2)(xiv)		Yes	
63.10(b)(3)		No	§63.367 (b) and (c) contains applicability determination requirements.
63.10(c)(1)		Yes	
63.10(c)(2)–(4)		No	Reserved.
63.10(c)(5)		Yes	
63.10(c)(6)		No	
63.10(c)(7)		No	Not applicable due to batch nature of the industry.
63.10(c)(8)		Yes	
63.10(c)(9)		No	Reserved.
63.10(c)(10)–(13)		Yes	
63.10(c)(14)	Yes	No	
63.10(c)(15)		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(d)(1)		Yes	
63.10(d)(2)		Yes	
63.10(d)(3)		No	Subpart O does not contain opacity or visible emissions standards.
63.10(d)(4)		Yes	
63.10(d)(5)		No	A startup, shutdown, and malfunction plan is not required for these standards.
63.10(e)(1)		Yes	
63.10(e)(2)(i)		Yes	
63.10(e)(2)(ii)		No	Opacity monitors are not required for these standards.
63.10(e)(3)(i)–(iv)		Yes	

TABLE 1 OF SECTION 63.360. GENERAL PROVISIONS APPLICABILITY TO SUBPART Q

Reference	Applies to sources using 10 tons in subpart O[a]	Applies to sources using 1 to 10 tons in subpart O[a]	Comment
63.10(e)(3)(v)	No		§63.366(a)(3) specifies contents and submittal dates for excess emissions and monitoring system performance reports.
63.10(e)(3)(vi)–(viii)	Yes		
63.10(e)(4)	No		Opacity monitors are not required for these standards.
63.10(f)	Yes		
63.11	Yes		
63.12–63.15	Yes		

[a] See definition.

(b) Sterilization sources using less than 1 ton (see definition) are not subject to the emissions standards in §63.362. The recordkeeping requirements of §63.367(c) apply.

(c) This subpart does not apply to beehive fumigators.

(d) This subpart does not apply to research or laboratory facilities as defined in section 112(c)(7) of title III of the Clean Air Act Amendment of 1990.

(e) This subpart does not apply to ethylene oxide sterilization operations at stationary sources such as hospitals, doctors offices, clinics, or other facilities whose primary purpose is to provide medical services to humans or animals.

(f) The owner or operator of a source using 1 ton (see definition) is required to obtain a title V permit from the permitting authority in which the source is located.

(g) The owner or operator shall comply with the provisions of this subpart as follows:

(1) All sources subject to the emissions standards in §63.362 with an initial startup date before December 8, 1997, no later than 3 years after the effective date.

(2) All sources subject to the emissions standards in §63.362 with an initial startup date after December 8, 1997, immediately upon initial startup of the source.

(3) All sources using less than 10 tons that increase their ethylene oxide usage after December 8, 1997 such that any vent becomes subject to the emissions standards in §63.362, immediately upon becoming subject to the emissions standards.

§63.361 Definitions.

Terms and nomenclature used in this subpart are defined in the Clean Air Act (the Act) as amended in 1990, §§63.2 and 63.3 of subpart A of this part, or in this section. For the purposes of subpart O, if the same term is defined in subpart A and in this section, it shall have the meaning given in this section.

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Baseline temperature means any temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device established during the performance test when the respective unit achieves at least 99-percent control of ethylene oxide emissions.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in §63.362 is required to be in compliance with the standard.

Effective date means the date of promulgation in the **Federal Register** notice.

Initial startup date means the date when a source subject to the emissions standards in §63.362 first begins operation of a sterilization process.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Parametric monitoring means monitoring of a specific operating parameter of the control device that demonstrates that the control device is operating under conditions that meet the standard.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide

is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

§ 63.362 Standards.

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in § 63.360(g). The standards of this section are summarized in Table 1 of this section.

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 controls required; minimal recordkeeping requirements apply (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)(2)).
	≥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)).	Manifold to a control device used to comply with § 63.362 (c) or (d) or 99 percent emission reduction (see § 63.362(e)(1)).

[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 percent.

(b) *Applicability of emission limits.* The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) *Sterilization chamber vent at sources using 1 ton.* Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) *Aeration room vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

(e) (1) *Chamber exhaust vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall either reduce ethylene oxide emissions to the atmosphere by manifolding emissions from each chamber exhaust vent to a control device used to comply with paragraphs (c) or (d) of this section or shall reduce ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolding).

(2) *Chamber exhaust vent at sources using 1 to 10 tons.* Each owner or operator of a sterilization source using 1 to 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) of this section or to reduce ethylene oxide emissions by at least 99 percent (without manifolding).

§ 63.363 Compliance and performance testing.

(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 following procedures shall be used to determine compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard:

(1) During the performance test required in paragraph (a) of this section, 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)(1). The owner or operator shall also determine the following:

(i) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter during the test methods and procedures in § 63.365(b)(1) either:

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

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

(ii) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature during the performance test in § 63.365(b)(2) using the procedures described in § 63.365(f)(1).

(2) Following the date on which the initial performance test is completed, the owner or operator shall comply with one of the following provisions:

(i) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the sterilization chamber vent standard.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over three cycles, more than 5.6°C (10°F) below the baseline temperature shall constitute a violation of the sterilization chamber vent standard.

(c) The following procedures shall be used to determine compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) During the performance test required in paragraph (a) of this section, the owner or operator shall determine either:

(i) 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

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

(2) For facilities seeking to comply with paragraph (c)(1)(ii) of this section with catalytic oxidizers or thermal oxidizers, the owner or operator must also establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(2).

(3) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(i) For facilities continuously measuring the ethylene oxide concentration emitted from the aeration room (after any control device), operation of the facility with a 3-hour average ethylene oxide concentration in excess of the 1 ppmv ethylene oxide concentration limit shall constitute a violation of the aeration room vent standard.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over three hours, more than 5.6°C (10°F) below the baseline temperature shall constitute a violation of the aeration room vent standard.

(d) The following procedures shall be used to determine compliance with the emission limits under § 63.362(e)(1), the chamber exhaust vent standard for 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 and/or the aeration room vent, the owner or operator shall comply with the appropriate compliance provisions for that vent type and control device (see paragraphs (b) and (c) of this section).

(2) For facilities not manifolding emissions from the chamber exhaust vent (to a control device used to comply with § 63.362(c) or (d)), the owner or operator shall comply with the following:

(i) During the performance test required in paragraph (a) of this section, the owner or operator shall determine the efficiency of control devices used to comply with § 63.362(e)(1) using the test methods and procedures in § 63.365(d)(2) as well as the following:

(A) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter either:

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

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

(B) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(3).

(ii) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(A) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the chamber exhaust vent standard for sources using 10 tons.

(B) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over the cycle, more than 5.6°C (10°F) below the baseline temperature shall constitute a violation of the chamber exhaust vent standard for sources using 10 tons.

(e) The following procedures shall be used to determine compliance with the emission limits under § 63.362(e)(2), the chamber exhaust vent standard for sources using 1 to 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 appropriate compliance provisions for the appropriate control technology (see paragraph (b) of this section).

(2) For facilities not manifolding emissions from the chamber exhaust vent (to a control device used to comply with § 63.362(c)), during the performance test required in paragraph (a) of this section, the owner or operator shall either:

(i) 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); or

(ii) 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:

(A) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter either:

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

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

(B) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature using the procedures described in § 63.365(f)(3).

(3) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(i) For facilities determining the ethylene oxide concentration, operation of the facility with the ethylene oxide concentration in the sterilization chamber (immediately prior to activation of the chamber exhaust) in excess of the 5,300 ppmv ethylene oxide concentration standard shall constitute a violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(ii) Following the date on which the initial performance test is completed, the owner or operator of a facility shall comply with one of the following provisions:

(A) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(B) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over the cycle, more than 5.6°C (10°F) below the baseline temperature shall constitute a violation of the chamber exhaust vent standard for sources using 1 to 10 tons.

(f) For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers:

(1) The owner or operator of the facility shall provide to the Administrator information describing the design and operation of the air pollution control system including

recommendations for the operating parameters to be monitored to indicated proper operation and maintenance of the air pollution control system. Based on this information, the Administrator will determine the site-specific 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.

(2) Operation of the facility in a manner that exceeds a site-specific parameter established as a maximum requirement or falls below a site-specific parameter established as a minimum requirement (depending on the parameters monitored) shall constitute a violation of the applicable emissions standard under § 63.362.

§ 63.364 Monitoring requirements.

(a)(1) The owner or operator of a source subject to emissions standards in § 63.362 shall comply with the monitoring requirements in § 63.8 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this section.

(2) Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

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

(1) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in § 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.).

(c) For sterilization facilities complying with § 63.363(b), (c), (d), or (e) 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.

(1) For the sterilization chamber vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test in § 63.365(b)(2)) and a three-cycle block average every third cycle.

(2) For the aeration room vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature each hour and a 3-hour block average every third hour.

(3) For the chamber exhaust vent, a data acquisition system for the temperature monitor shall compute and record an average oxidation temperature over the length of the cycle (based on the length of the cycle used during the performance test in § 63.365(d)(2)).

(4) The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6°C (±10°F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

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

(1) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere from the aeration room vent 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 gas chromatograph consistent with the requirements of performance specification (PS) 9 in 40 CFR part 60, Appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 are required only on days when ethylene oxide emissions are vented to the control device from the aeration room vent.

(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 gas chromatograph consistent with the requirements of PS 9 to measure ethylene oxide concentration. The daily calibration requirements of section 7.2 of PS 9 are required only on days when the chamber exhaust is activated.

(f) For sterilization facilities complying with § 63.363(d)(1) or (e)(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 which emissions from the chamber exhaust vent are manifolded using the appropriate monitoring requirements in paragraphs (a) through (e) of this section and record the monitoring data.

§ 63.365 Test methods and procedures.

(a) *Performance testing.* The owner or operator of a source subject to the emissions standards in § 63.362 shall comply with the performance testing requirements in § 63.7 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this section.

(b) *Efficiency at the sterilization chamber vent.* The following procedures shall be used to determine the efficiency of all types of control devices used to comply with § 63.362(c), sterilization chamber vent standard.

(1) *First evacuation of the sterilization chamber.* This procedure shall be performed on an empty sterilizer for the duration of the first evacuation under normal operating conditions (i.e., sterilization cycle pressure and temperature) and charging a typical amount of ethylene oxide to the sterilization chamber.

(i) The amount of ethylene oxide loaded into the sterilizer (W_c) shall be determined by either:

(A) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.

(B) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

$$W_c = F_v \times t \times \%EO_v \times \left(\frac{MW}{SV}\right)$$

where:

W_c=weight of ethylene oxide charged, g (lb)

F_v=volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)

t=time, min

$\%EO_V$=volume fraction ethylene oxide

SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 °C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 °F and 1 atm).

MW=molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or

(C) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$W_c = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

P=chamber pressure, kPa (psia)

V=chamber volume, liters (L) (ft^3)

R=gas constant, 8.313 L•kPa/g-mole• (10.73 psia•ft^3/mole°R)

T=temperature, K (°R)

Note: If the ethylene oxide concentration is in weight percent, use the following equation to calculate mole fraction:

$$\%EO_v = \frac{W_{EO}}{W_{EO} + \left(W_x \times \frac{MW}{MW_x}\right)}$$

where:

W_{EO}=weight percent of ethylene oxide

W_x=weight percent of compound in the balance of the mixture

MW_x=molecular weight of compound in the balance gas mixture

(ii) The residual mass of ethylene oxide in the sterilizer shall be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

$$W_r = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

W_r=weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)

(iii) Calculate the total mass of ethylene oxide at the inlet to the control device (W_i) by subtracting the residual mass (W_r) calculated in paragraph (b)(1)(ii) of this section from the charged weight (W_c) calculated in paragraph (b)(1)(i) of this section.

(iv) The mass of ethylene oxide emitted from the control device outlet (W_o) shall be calculated by continuously monitoring the flow rate and concentration using the following procedure.

(A) Measure the flow rate through the control device exhaust continuously during the first evacuation using the procedure found in 40 CFR part 60, appendix A, Test Methods 2, 2A, 2C, or 2D, as appropriate. (Method 2D (using orifice plates or Rootstype meters) is recommended for measuring flow rates from sterilizer control devices.) Record the flow rate at 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero. Time zero is defined as the moment when the pressure in the sterilizer is released. Correct the flow to standard conditions (20°C and 101.325 kPa (68°F and 1 atm)) and determine the flow rate for the run as outlined in the test methods listed in paragraph (b) of this section.

(B) The Tedlar bag sampling procedure in section 7.1 of Test Method 18, 40 CFR part 60, appendix A (hereafter referred to as Method 18) shall be used to collect samples of exhaust gas throughout the test cycle. Follow the procedures in paragraph (b)(1)(iv)(B)(*1*) or (*2*) of this section.

(*1*) Continuously sample a slipstream of the control device outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(*i*) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(*ii*) Prepare a graph of volumetric flow rate versus time corresponding to the period each bag was sampled. Integrate the area under the curve to determine the volume.

(*iii*) Calculate the mass of ethylene oxide for each bag by using the following equation:

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

where:

W_b=Mass of ethylene oxide for each bag, g (lb)

C=concentration of ethylene oxide in ppmv

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

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

Sum the mass corresponding to each bag (W_b) used during the evacuation to calculate the total mass (W_o).

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

(*2*) Collect a Tedlar bag (or equivalent collection device) sample at 1-minute intervals throughout the test cycle. (The first bag must be in place and sampling at t=15 seconds. A fresh bag shall be in place and sampling exhaust gas at each 1-minute mark after time zero.) Collect enough sample gas in each bag to complete the analysis. Each bag sample shall be labeled with the sampling time and run number.

(*i*) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection. (Syringe samples should be analyzed within 4 hours.)

(*ii*) Plot a concentration versus time curve using the average concentration, in ppmv, determined in each bag sample. Prepare another graph of volumetric flow rate versus time. Calculate the mass flow at each 1-minute interval point by selecting the concentration (C) and volumetric flow rate corrected to standard conditions (F_v) at each 1-min point.

(*iii*) Use the following equation to determine the mass flow rate of ethylene oxide exiting the control device:

$$W_t = C \times F_v \times \frac{MW}{SV} \times \frac{1}{10^6}$$

where:

W_t = mass flow rate of ethylene oxide

(*iv*) Plot a curve of mass flow rate versus time and integrate for total mass of ethylene oxide for the control device outlet (W_o).

(*v*) Calculate efficiency by the equations in paragraphs (b)(1) (v) and (vi) of this section.

(C) As an alternative to paragraph (b)(1)(ii) of this section, the direct interface sampling and analysis procedure described in Method 18, section 7.2, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a gas chromatograph with flame ionization detector (GC/FID) or photoionization detector (GC/PID). This procedure may be used only if a vent sample may be sampled and analyzed by the GC/FID or GC/PID at least once per minute.

(*1*) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(*2*) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*) (*ii*) through (v) of this section.

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

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

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(vi) Repeat the procedures in paragraphs (b)(1) (i) through (v) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) *Last evacuation of the sterilization chamber.* One of the following procedures (paragraph (b)(2) (i) or (ii) of this section) shall be performed during the last evacuation of the sterilization chamber:

(i) The direct interface sampling and analysis procedure described in Method 18, section 7.2, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; this procedure may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once per minute for the duration of the last cycle.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

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

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

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(D) Repeat the procedures in paragraphs (b)(2)(i) (A) through (C) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18, may be used to collect samples of inlet and exhaust gas for the duration of the last cycle.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

(D) Determine control device efficiency (% Eff) using the equation in paragraph (b)(2)(i)(C) of this section.

(E) Repeat the procedures in paragraphs (b)(2)(ii)(A) through (D) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(iii) In the event that the outlet concentration from the control device is below the detection limit for ethylene oxide for determining the efficiency in paragraph (b)(2)(i)(C) or (ii)(D) of this section, the owner or operator shall assume the control device is meeting the standard in § 63.362(e)(1) or (2) if the inlet ethylene oxide concentration is at or below approximately 50 ppmv.

(c) *Concentration determination.* The following procedures shall be used to determine the ethylene oxide concentration as the monitored parameter established in § 63.363(c) and (e) for aeration room emissions and chamber exhaust vents, respectively, and to continuously monitor the ethylene oxide concentration for aeration room vents as established in § 63.364(e)(1) and to monitor the ethylene oxide concentration before activation of the chamber exhaust for chamber exhaust vents as established in § 63.364(e)(2).

(1) *Aeration room vent.* For determining the ethylene oxide concentration for aeration room emissions, the procedures outlined in section 7.2 of Method 18 shall be used. Repeat these procedures three times. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device. Compliance testing of gas chromatographs shall be performed using PS 9 in 40 CFR part 60.

(2) *Sterilization chamber prior to activation of the chamber exhaust.* For determining the ethylene oxide concentration in the sterilization chamber before activation of the chamber exhaust, the procedures outlined in sections 7.2 or 7.3 of Method 18 shall be used. The ethylene oxide concentration from one test run shall determine the outlet ethylene oxide concentration from the chamber exhaust vent. Compliance testing of gas chromatographs shall be performed using PS 9 in 40 CFR part 60.

(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 (without manifolding the chamber exhaust vent emissions to another vent type):

(1) *Aeration room vent.* For determining the efficiency of aeration room vent control devices, either of the following test methods (paragraph (d)(1)(i) or (ii) of this section) may be used:

(i) the direct interface sampling and analysis procedure described in Method 18, section 7.2, may be used to continuously monitor ethylene oxide

concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; this procedure may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once every 5 minutes throughout a 1-hour test run.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

C) 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

(D) Repeat the procedures in paragraphs (d)(1)(i)(A) through (C) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18 may be used to collect samples of inlet and exhaust gas throughout a 1-hour test run.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

(D) Determine control device efficiency (% Eff) using the equation in paragraph (d)(1)(i)(C) of this section.

(E) Repeat the procedures in paragraphs (d)(1)(ii)(A) through (D) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) *Chamber exhaust vent (not manifolded).* For determining the efficiency of non-manifolded chamber exhaust vent control devices, either of the following test methods (paragraph (d)(2)(i) or (ii) of this section) may be used:

(i) The direct interface sampling and analysis procedures described in Method 18, section 7.2 or 7.3, may be used to continuously monitor ethylene oxide concentration at the inlet and outlet of the control device using a GC/FID or GC/PID; these procedures may be used only if a vent may be sampled and analyzed by the GC/FID or GC/PID once per minute for the duration of each cycle when the chamber exhaust vent is operated.

(A) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the sample.

(B) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

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

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

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(D) Repeat the procedures in paragraphs (d)(2)(i)(A) through (C) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(ii) The Tedlar bag sampling procedure in section 7.1 of Method 18 may be used to collect samples of inlet and exhaust gas for the duration of each cycle when the chamber exhaust vent is operated.

(A) Continuously sample a slipstream of the control device inlet and outlet into a Tedlar bag by having a Tedlar bag attached to the slipstream for the entire duration of the run for an integrated bag sample. Whenever a Tedlar bag is full, a new bag must be reattached immediately. Note the time the bag is changed so the sample time and corresponding flow rates can be determined for each bag.

(B) Follow the procedures in section 6 of Method 18 and choose the appropriate column, analytical apparatus, and calibration gases for the analysis of the bag samples collected. The bag samples shall be analyzed within 8 hours of collection.

(C) Follow the procedures in paragraphs (b)(1)(iv)(B)(*2*)(*ii*) through (*iv*) of this section.

(D) Determine control device efficiency (% Eff) using the equation in paragraph (d)(2)(i)(C) of this section.

(E) Repeat the procedures in paragraphs (d)(2)(ii)(A) through (D) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(iii) In the event that the outlet concentration from the control device is below the detection limit for ethylene oxide for determining the efficiency in paragraph (d)(2)(i)(C) or (ii)(D) of this section, the owner or operator shall assume the control device is meeting the standard in § 63.362(e)(1) or (2) if the inlet ethylene oxide concentration is at or below approximately 50 ppmv.

(e) *Determination of baseline parameters for acid-water scrubbers.* The procedures in this paragraph shall be used to determine the monitored parameters established in § 63.363(b), (d), or (e) for acid-water scrubbers and to monitor the parameters as established in § 63.364(b).

(1) *Ethylene glycol concentration.* For determining the ethylene glycol concentration, the facility owner or operator shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; the sampling and analysis procedures in ASTM D 3695–88, Standard Test Method for Volatile Alcohols in Water By Direct Aqueous-Injection Gas Chromatography, (incorporated by reference—see § 63.14) shall be used to determine the ethylene glycol concentration.

(2) *Scrubber liquor tank level.* For determining the scrubber liquor tank level, the sterilization facility owner or operator shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

(f) *Determination of baseline temperature for oxidation units.* The procedures in this paregraph shall be used to demonstrate the baseline temperature required in § 63.363(b), (c), (d), or (e) for catalytic oxidation units or thermal oxidation units and to continuously monitor the oxidation temperature as established in § 63.364(c).

(1) *Sterilization chamber vent.* The sterilization facility owner or operator shall establish the baseline temperature for the sterilization chamber vent as the temperature for the catalytic oxidation unit or the oxidation temperature at the

exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in paragraph (b)(2) of this section.

(2) *Aeration room vent.* The sterilization facility owner or operator shall establish the baseline temperature for the aeration room vent as the temperature for the catalytic oxidation unit or the oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in paragraph (d)(1) of this section.

(3) *Chamber exhaust vent.* The sterilization facility owner or operator shall establish the baseline temperature for the chamber exhaust vent as the temperature for the catalytic oxidation unit or the oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in paragraph (d)(2) of this section.

(g) An owner or operator of a sterilization facility seeking to demonstrate compliance with the standards found at § 63.362(c), (d), or (e) with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit shall provide to the Administrator the information requested under § 63.363(f). The owner or operator shall submit: a description of the device; test results collected in accordance with § 63.363(f) verifying the performance of the device for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored; and the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan submitted identifying the compliance monitoring is subject to the Administrator's approval. The owner or operator of the sterilization facility shall install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted by the owner or operator. The owner or operator shall include in the information submitted to the Administrator proposed performance specifications and quality assurance procedures for their monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

(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 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.

§ 63.366 Reporting requirements.

(a) The owner or operator of a source subject to the emissions standards in § 63.362 shall fulfill all reporting requirements in §§ 63.10(a), (d), (e), and (f) of subpart A, according to the applicability in Table 1 of § 63.360. These reports will be made to the Administrator at the appropriate address identified in § 63.13 of subpart A of this part.

(1) Reports required by subpart A and this section may be sent by U.S. mail, fax, or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Administrator on or before the specified date.

(2) If acceptable to both the Administrator and the owner or operator of a source, reports may be submitted on electronic media.

(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 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 excess emissions or exceedances of process or control system parameters 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 excess emissions or exceedances have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(b) *Construction and Reconstruction.* The owner or operator of each source using 10 tons shall fulfill all requirements for construction or reconstruction of a source in § 63.5 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this paragraph.

(1) *Applicability.* (i) This paragraph and § 63.5 of subpart A of this part implement the preconstruction review requirements of section 112(i)(1) for sources subject to these emissions standards. In addition, this paragraph and § 63.5 of subpart A of this part include other requirements for constructed and reconstructed sources that are or become subject to these emissions standards.

(ii) After the effective date, the requirements in this section and in § 63.5 of subpart A of this part apply to owners or operators who construct a new source or reconstruct a source subject to these emissions standards after December 6, 1994. New or reconstructed sources subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b) (2) and (3) of this section and § 63.5(d) (3) and (4) and (e) of subpart A of this part.

(2) After the effective date, whether or not an approved permit program is effective in the State in which a source is (or would be) located, no person may construct a new source or reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and § 63.5(d) (3) and (4) and (e) of subpart A of this part.

(3) *Application for approval of construction or reconstruction.* The provisions of paragraph (b)(3) of this section and § 63.5(d) (3) and (4) of subpart A of this part implement section 112(i)(1) of the Act.

(i) *General application requirements.*

(A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new source subject to these emissions standards, the reconstruction of a source subject to these emissions standards, or the reconstruction of a source such that the source becomes a source subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup

date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (c)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(*1*) The applicant's name and address.

(*2*) A notification of intention to construct a new source subject to these emissions standards or make any physical or operational change to a source subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2 of subpart A of this part.

(*3*) The address (i.e., physical location) or proposed address of the source.

(*4*) An identification of the relevant standard that is the basis of the application.

(*5*) The expected commencement date of the construction or reconstruction.

(*6*) The expected completion date of the construction or reconstruction.

(*7*) The anticipated date of (initial) startup of the source.

(*8*) The type and quantity of hazardous air pollutants emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the source reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(*9*) Other information as specified in paragraph (b)(3)(ii) of this section and § 63.5(d)(3) of subpart A of this part.

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(*8*) and (ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) *Application for approval of construction.* Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior State preconstruction review.*

(i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and § 63.5(d)(3) and (4) of subpart A of this part if the owner or operator of a new or reconstructed source who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in § 63.5(e)(1) of subpart A of this part.

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5 of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) *Notification requirements.* The owner or operator of each source subject to the emissions standards in § 63.362 shall fulfill all notification requirements in § 63.9 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this paragraph.

(1) Initial Notifications

(i)(A) If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month period after December 6, 1996, such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of § 63.9 of subpart A of this part.

(B) Sources subject to these emissions standards may use the application for approval of construction or reconstruction under paragraph (b)(3)(ii) of this section and § 63.5(d) (3) of subpart A of this part, respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed source subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (b)(3) of this section and § 63.5(d) (3) and (4) of subpart A of this part shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (b)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (b)(3) of this section and § 63.5(d)(3) and (4) of subpart A of this part. For sources subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9 of subpart A of this part.

(2) If an owner or operator of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (b)(3)(ii) of this section and § 63.5(d)(3) of subpart A of this part, respectively, in place of the actual emissions data or control efficiencies required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) The owner or operator of any • existing sterilization facility subject to this subpart shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3) of subpart A of this part. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

§ 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.

(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). These records shall be kept onsite at the source for a period of 5 years.

(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 standards in § 63.362). These records shall be kept onsite at the source for a period of 5 years.

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GENERAL SERVICES ADMINISTRATION

41 CFR Part 101-9

[FPMR Amendment A-53]

RIN 3090-AF14

Federal Mail Management

AGENCY: Federal Supply Service, GSA.

ACTION: Final rule.

SUMMARY: This regulation establishes Federal mail management policy within the Federal Property Management Regulations. The regulation is necessary to improve the management of Federal incoming, internal, and outgoing mail, and to reduce mail costs through a comprehensive mail management program. This mail management program requires that agencies keep mail processing steps to a minimum; apply sound workflow principles; use automation and modern equipment, supplies, and training to the maximum extent cost-effective; and streamline operations to increase efficiency. Each Federal agency is expected to establish an appropriate program for the management of mail at each agency facility as well as on an agencywide basis.

EFFECTIVE DATE: December 6,1994.

FOR FURTHER INFORMATION CONTACT: Bill Percival, Mail Management Branch (703-305-7577).

SUPPLEMENTARY INFORMATION: The General Services Administration (GSA) has determined that this rule is not a significant rule for the purposes of Executive Order 12866.

Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment. Therefore the Regulatory Flexibility Act does not apply.

List of Subjects in 41 CFR Part 101-9

Government property management, Mail management.

For the reasons set forth in the preamble, 41 CFR Chapter 101 is amended as follows:

Part 101-9 is added to Subchapter A, General, to read as follows:

PART 101-9—FEDERAL MAIL MANAGEMENT