State of California
California Environmental Protection Agency
AIR RESOURCES BOARD

STAFF REPORT

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENTS TO THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

Prepared by:
Ronald Walter

Stationary Source Division

Reviewed by:

Peter D. Venturini, Chief, Stationary Source Division
Robert D. Fletcher, Chief, Emissions Assessment Branch
Clifford A. Popejoy, Manager, Process Evaluation Section

April 1998

State of California
California Environmental Protection Agency
AIR RESOURCES BOARD

INITIAL STATEMENT OF REASONS FOR PROPOSED RULEMAKING

Public Hearing to Consider

PROPOSED AMENDMENTS TO THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

To be considered by the Air Resources Board on May 21, 1998 at

Air Resources Board
Board Hearing Room, Lower Level
2020 L Street
Sacramento, California

Air Resources Board
P. O. Box 2815
Sacramento, California

Acknowledgments

ARB staff wishes to acknowledge the contributions of many individuals and organizations in developing these proposed amendments.

George Ames	South Coast Air Quality Management District
Clint Cooney	San Diego County Air Pollution Control District
Archie Delacruz	San Diego County Air Pollution Control District
Angela Durr	San Diego County Air Pollution Control District
Catherine Fortney	Bay Area Air Quality Management District
Bill Galorward	Allergan Medical Optics
John Higuchi	South Coast Air Quality Management District
Henry Jordan	Air Resources Board, Compliance Division
Larry Joslyn	Joslyn Valve System
Karen Kelley	Sacramento Metropolitan Air Quality Management District
Daniel Kremer	Kremer Environmental
Mike Lewis	University of California, Davis Medical Center
Steven Marinoff	South Coast Air Quality Management District
Val Mitchum	Kaiser Hospital
Kevin Mongar	Air Resources Board, Monitoring and Laboratory Division
Ian Morrison	San Diego County Air Pollution Control District
Jeff Naus	CHIPs Environmental
Rick Rioux	Griffith Micro Science
Joseph Salcedo	Griffith Micro Science
John Schindler	San Diego County Air Pollution Control District
Bill Shovelton	Kaiser South Sacramento
Tommy Skipper	Kaiser Hospital
Frank St. Clair	Mojave Desert Air Quality Management District
Kathy Steilen	Griffith Micro Science
Joe Tramma	South Coast Air Quality Management District
Pam Tsai	U.S. EPA, Region IX
Mae Wang	U.S. EPA, Region IX

Mr. Kevin Mongar and Ms. Cindy Castronovo of the Air Resources Board Monitoring and Laboratory Division provided invaluable assistance in evaluating EtO emissions, and were responsible for developing the proposed revisions to the ARB 431 test method.

TABLE OF CONTENTS

Contents **Page**

TABLE OF CONTENTS (cont.)

Contents **Page**

APPENDICES

A. Introduction

In November 1987, the Air Resources Board (Board) identified ethylene oxide (EtO) as a toxic air contaminant. Ethylene oxide is used as a biocide to sterilize medical products and fumigate foodstuffs and other materials. Ethylene oxide has been classified as a probable human carcinogen by the California Department of Health Services (now the Office of Environmental Health Hazard Assessment), and by the International Agency for Research on Cancer. Inhalation of ethylene oxide may lead to an increased risk of contracting leukemia and stomach cancer. As part of the ethylene oxide identification regulation, the Board determined that ethylene oxide is a toxic air contaminant for which there is not sufficient evidence to identify a threshold exposure level. A threshold exposure level is that level below which no significant adverse carcinogenic health effects are anticipated to occur.

After ethylene oxide was identified as a toxic air contaminant, the ARB staff developed an Airborne Toxic Control Measure (ATCM) for EtO sterilizers and aerators. While developing the ATCM, the staff consulted with potentially affected facilities, the air pollution control districts and air quality management districts (districts), sterilizer and control equipment manufacturers, and other interested parties. The Board approved the staff proposal in May 1990, and it became effective as State law in May 1991. The districts adopted the ATCM or equivalent district rules, and facility operators took action to comply with the recordkeeping and emission control requirements of those rules.

In 1994, the United States Environmental Protection Agency (U.S. EPA) promulgated a National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations (NESHAP). The NESHAP affects large commercial sterilizers, fumigators, and aerators throughout the United States. Six facilities in California (operated by five companies) are subject to the NESHAP. The emission control requirements of the NESHAP are less stringent than those of the ATCM, but the NESHAP contains more detailed and prescriptive monitoring, recordkeeping, and reporting requirements than the ATCM.

The ARB staff is proposing to amend the ATCM for four reasons. First, we are proposing to streamline the compliance testing requirements and source testing method; the principle change is the inclusion of an alternative to calculate rather than directly measure the EtO passing into the control device. Second, we are proposing to include limits for EtO in water to simplify the emission limit performance standards for certain types of control devices. Third, we are making other modifications to clarify or improve the effectiveness of the ATCM; for instance, we are proposing a change to the definition of "leak-free" to include EtO supply piping as well as exhaust vents. These modifications also include minor non-substantive changes to definitions. Fourth and last, we are proposing to simplify and incorporate into the ATCM the requirements of the NESHAP. This involves the restructuring of the ATCM into sections for non-commercial/small commercial facilities and large commercial facilities based on the amount of EtO used, and inclusion of additional monitoring, recordkeeping, and reporting requirements as needed to establish equivalency with the NESHAP. These changes will make it easier for the affected facilities to comply with the requirements, while retaining the same degree of EtO emission reductions and resulting public health protection as the existing ATCM.

B. Background

1. What are ethylene oxide sterilizers and aerators?

An ethylene oxide sterilizer is a chamber in which EtO is used as a biocide to kill microorganisms or other organisms on materials, including medical products, foodstuffs, and other items. Following sterilization, a process called aeration is carried out, during which the EtO is removed from the treated materials until the EtO level in the materials is low enough that they are deemed safe to use. In most cases, aeration is done in the same chamber in which sterilization was done; in other cases, the materials are transferred to a separate device or space for aeration. The device or space in which materials previously sterilized with EtO are placed to allow the residual EtO to dissipate is called an aerator.

2. What are the potential health effects associated with ethylene oxide exposure?

Ethylene oxide has been classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC) and the California Department of Health Services (DHS), now the Office of Environmental Health Hazard Assessment (OEHHA). Inhalation of EtO may lead to an increased risk of contacting leukemia and stomach cancer. DHS, the Scientific Review Panel, and the ARB determined that EtO has no identifiable threshold exposure level. A threshold exposure level is that level below which carcinogenic effects are not anticipated to occur.

3. Why are we proposing to changes some of the compliance testing requirements of the ATCM?

The ATCM includes specific requirements for compliance determination testing. For instance, the ATCM requires that the efficiency of the control device be measured while a typical load of material is being sterilized, and that the EtO be measured at the inlet and the outlet of the control device. The ATCM includes a provision that an alternative approach can be used, but it must be formally approved by the Executive Officer of the ARB. We found during the implementation of the ATCM that a particular alternative to the testing requirements was commonly requested to simplify the testing and improve worker safety. These changes allow testing of the control device with no load in the chamber, and they will allow the tester to calculate (rather than directly measure) the EtO at the inlet of the control device. By incorporating these changes into the ATCM and test method, we are eliminating the need for case-by-case approval of this alternative method.

We are proposing to include an alternative emission limit for combined sterilizer and aerator EtO control efficiency. The combined efficiency performance standard is equivalent to the existing separate standards. The separate standards will be retained for those instances where it is more appropriate to measure the control device efficiencies separately.

Based on our experience in reviewing the requests from the districts and facility operators to use alternative methods, we are also proposing to change the ATCM to authorize the districts to approve alternative methods for non-commercial facilities. This will streamline testing in those instances where it's necessary or advantageous to use an alternative compliance testing approach. The proposed change in the ATCM requires the districts to consult with ARB concerning the technical aspects of alternative methods.

4. Why are we proposing to include a limit for EtO in liquid discharges and add a test method for EtO in water to ARB Method 431?

We are proposing to add a limit on EtO in liquid discharged from sterilizers and aerators to simplify the compliance demonstration for a new type of technology.

When we developed the existing ATCM, we evaluated control methods available to reduce EtO emissions. Based on the demonstrated performance of control equipment, we defined the "lowest achievable emission rates" achievable through the application of the best available control technology (BACT), in consideration of risk and cost, as dictated by Health and Safety Code section 39666(b). The technologies identified as able to achieve BACT emission levels were based on the destruction of the EtO using incineration, catalytic combustion, or acid scrubbing. The emission limit performance standards in the ATCM were designed in consideration of the operation and performance of these control devices.

During the implementation of the ATCM, a new technology--one which reclaims the EtO for re-use--began to be used to comply with the ATCM. The reclamation systems are fundamentally different in their operation and emission characteristics than the destruction systems. We found that such systems typically recovered 50 percent to 90 percent of the EtO used. The remaining 10 to 50 percent was released to the environment through EtO-laden water discharge and ultimately was emitted to the atmosphere as the EtO disassociated from the water. The manufacturers of reclamation equipment developed modifications to their systems that could reduce the amount of EtO released in water. Reclamation systems at facilities were modified to meet the requirements of the ATCM by achieving emissions equal to the lowest achievable emission rate possible with BACT.

The emission limit performance standards in the ATCM were not designed to apply to these systems, so application of the ATCM directly was not possible. To ensure that public health was protected, the ARB staff worked with the reclamation system manufacturers, the facility operators, consultants, and the districts to evaluate these systems and develop permitting criteria guidance for use by the districts. The permitting criteria developed are equivalent to the BACT-based requirements of the ATCM. Reclamation systems are successfully operating in California in compliance with these criteria.

We are proposing to incorporate into the ATCM requirements to address the EtO discharged from reclamation systems. These proposed requirements are concentration limits for

EtO in water discharged from EtO control systems. The proposed limits are equivalent to the direct air emissions limits developed for destruction-based systems, and will clarify and simplify compliance demonstration for reclamation systems.

We are also proposing to modify test Method 431 to add a procedure to measure EtO in water to the method so that the requirements limiting discharge of EtO can be implemented and enforced.

5. Why are we proposing to incorporate the NESHAP requirements into the ATCM?

We are proposing to incorporate the NESHAP requirements (with some simplification) into the ATCM so that the operators of facilities that are subject to the NESHAP can comply with one regulation and one set of requirements.

The U.S. EPA promulgated a NESHAP for commercial sterilizers and fumigators on December 6, 1994. It affects commercial facilities using more than 2,000 pounds per year of EtO to sterilize medical products or fumigate foodstuffs or other materials. Commercial facilities include medical product manufacturers which sterilize material they produce, contract sterilizers which treat products manufactured by others, and spice fumigators. There are six facilities (operated by five companies) in California which are subject to the NESHAP.

Our intent in incorporating the NESHAP requirements into the ATCM is to reduce the regulatory burden to the facility operators and to the districts, who are the implementing agencies for the NESHAP. The proposed amendments to the ATCM for commercial facilities will add additional recordkeeping, reporting, and monitoring requirements to satisfy the NESHAP, but there will be no change in the ATCM's stringency or requirements for emission control for facilities in the state.

The proposed amendments include a change in the control requirement for the large commercial aeration-only category. This is for consistency with the NESHAP. There are no known facilities of this type operating in California.

6. What are the differences between the ATCM and the NESHAP?

The NESHAP differs from the ATCM in three aspects--applicability, control requirement stringency, and administrative requirements. The NESHAP applies to six facilities in California that use more than 2,000 pounds per year of ethylene oxide to sterilize medical products or supplies, or to fumigate spices and other foodstuffs. This is a small subset of the sources affected by the ATCM, which covers approximately 400 facilities including commercial facilities, hospitals, medical clinics, and some other operations (such as museums) that use EtO sterilizers. The NESHAP's emission control requirements are less stringent than the applicable requirements of the ATCM. The NESHAP contains more detailed and prescriptive monitoring, recordkeeping, and reporting requirements than the ATCM. A summary comparison the ATCM and the NESHAP is included in Appendix B.

7. What is the status of the NESHAP?

The NESHAP was promulgated on December 6, 1994. The U.S. EPA delayed the NESHAP compliance date of December 6, 1997, to December 6, 1998. The U.S. EPA took this action because of concerns over the possible role of emission control equipment in fires and explosions at commercial facilities. Two commercial sterilizer facilities and one EtO packaging facility, all outside of California, were operating control equipment in advance of the NESHAP compliance date, and experienced fires and explosions. Although no formal findings are available on the incidents, the information available to us indicates that the fires or explosions were either triggered by causes other than the control equipment, or were caused by a combination of human error and inadequate safety design of the sterilizer and control equipment. One fire and explosion has occurred in California at a commercial sterilizer facility. We understand that this incident was due to human error and inadequate safety design of the sterilizer-control device system. That facility is operating under a variance while it modifies its equipment to prevent any recurrence.

8. Will the amended ATCM automatically replace the NESHAP?

No, the amended ATCM will not automatically replace the NESHAP. When the federal Clean Air Act was amended in 1990, a provision was included that allows states to receive delegation for their own toxic rules or programs as equivalent to the corresponding NESHAP. We must formally seek approval from the U. S. EPA for the amended ATCM to replace the NESHAP. We have worked closely with U.S. EPA staff in developing the proposed amendments to identify and address equivalency issues. We intend to submit an application to the U.S. EPA for equivalency of the ATCM if the Board approves the proposed amendments. If the U.S. EPA approves the amended ATCM as equivalent to the NESHAP, the ATCM would then replace the NESHAP.

9. How did the staff develop the amendments to the ATCM?

The ARB staff developed the proposed amendments to the ATCM through extensive consultation with facilities affected by the ATCM, the districts, the U.S. EPA, consultants, and manufacturers and vendors of sterilization and emissions control equipment. During the development of the proposed amendments, we mailed approximately 800 notices concerning the development of the proposed amendments to facility operators, held three public consultation meetings to discuss the proposal, conducted numerous telephone conferences and calls with affected parties, visited 30 facilities, conducted engineering evaluations of approximately 20 facilities, tested emissions from 10 facilities and evaluated test data and reports from approximately 20 additional facilities. The emission testing done by the ARB staff consisted of comprehensive measurement of EtO emissions and discharge from control systems. ARB staff also worked with testing consultants and the Environmental Health Laboratory Branch of the Department of Toxics Substances Control to evaluate and develop the water testing method.

10. What is our recommendation?

We recommend that the Board approve the proposed amendments to the Ethylene Oxide ATCM for Sterilizers and Aerators to incorporate changes to streamline the compliance testing requirements and source testing method; to include limits for EtO in water to simplify the emission limit performance standards for certain types of control devices; to make other modifications to clarify or improve the effectiveness of the ATCM (for instance, a change to the definition of "leak-free" to include EtO supply piping as well as exhaust vents); to make minor non-substantive changes to definitions; and, to simplify and incorporate into the ATCM the requirements of the NESHAP. This involves the restructuring of the ATCM into two sections, one for non-commercial/small commercial facilities and a new one (as a new regulation, section 93108.5) for large commercial facilities (based on the amount of EtO used), and inclusion of additional monitoring, recordkeeping, and reporting requirements to the regulation for large commercial facilities as needed to establish equivalency with the NESHAP. These changes will make it easier for the affected facilities to comply with the requirements, while retaining the same degree of EtO emission reductions and resulting public health protection as the existing ATCM.

C. Rationale and Basis for Amendments to the ATCM

This section describes the rationale and basis for the proposed amendments. The discussion generally follows the order in which the modifications or additions appear in the proposed amended ATCM.

The ATCM was separated into two parts, one of which is a new regulation for large commercial facilities. Part 1 (section 93108) addresses standards and requirements for non-commercial sterilizers and aerators and commercial sterilizers and aerators using less than 2,000 pounds of EtO per consecutive 12 month period. Part 2 (section 93108.5) addresses commercial sterilizers and aerators using 2,000 or more pounds of EtO per consecutive 12-month period. The division between commercial facilities is based on EtO use in a consecutive a 12-month period, because this is the applicability criterion used in the NESHAP, and U.S. EPA staff required it for equivalency. The EtO use categories which dictate control requirements for the non-commercial and small commercial facilities continue to be based on EtO use per calendar year, as in the existing ATCM.

This change is proposed to make it easier to implement the ATCM. The commercial facilities using 2,000 pounds or more of EtO per continuous 12 month period are subject to the NESHAP-equivalent requirements, which comprise considerable additional monitoring, recordkeeping, and reporting requirements. Separating the elements of the regulation that pertain to large commercial facilities makes the ATCM more "user-friendly" to the majority of facilities which have to meet the simpler requirements. Separating the requirements for the two categories of facilities also will facilitate our application to the U.S. EPA for equivalency of the ATCM with the NESHAP and ensure that the requirements for the smaller facilities will not become federally enforceable.

1. Part 1 (a) Definitions

We are proposing to make the following changes to the definitions. Note that sections have been renumbered to reflect additions and deletions. The numbers shown below reflect the new section numbers; the old numbers are deleted.

(a)(7) "Commercial sterilizer." A definition for commercial sterilizer is added. This is necessary because of the proposed different requirements for commercial and non-commercial sterilize.

(a)(9) "Date of Compliance." This is proposed to be deleted because facilities in California are required to already be in compliance by the existing ATCM. Therefore, no future compliance dates are needed.

(a)(12) "Facility." This is modified to clarify that the term "parcel" means "parcel of land".

(a)(16) "Non-commercial sterilizer." A definition of non-commercial sterilizer is added. This is necessary because the proposed ATCM requirements are different for large commercial and for small commercial and non-commercial sterilizers.

(a)(19) "Sterilizer cycle." This was modified to reflect the operation of reclamation systems, which use steam washes rather than air washes after the initial evacuation of EtO after the sterilization is complete.

(a)(22) "Sterilizer exhaust vacuum pump." This was clarified to use terms defined in the ATCM ("start of the sterilizer cycle," sterilizer cycle being defined, to replace "introduction of ethylene oxide").

2. Part 1 (b) Applicability

This section is changed to exclude commercial sterilizer and aerators using 2,000 pounds or more of EtO per consecutive 12-month period after December 6, 1996. Under the proposed amendments, such facilities will be subject to the requirements in Part 2, section 93108.5.

3. Part 1 (e) Requirements

The reference to the "applicable date" (for compliance) is deleted. See change to definition (a)(9), above.

(e)(1) The requirement that there be no discharge of sterilizer exhaust vacuum pump working fluid to wastewater streams is deleted. It is no longer needed because of the proposed new requirement (e)(3), which is a limit on EtO in any liquid discharge associated with the sterilizer cycle. The limit on EtO in the liquid discharge is sufficiently low that no sterilizer exhaust vacuum pump working fluid can be discharged to wastewater. As a consequence, recirculating pumps will continue to be used.

(e)(1) The requirement that the sterilizer and control equipment be leak-free is modified to include the EtO gas supply to the sterilizer. This is a potential source of EtO emissions which generally is kept leak-free for protection of worker health and safety. We became aware during implementation of the regulation that leaks in supply piping are more frequent than we expected. This requirement will encourage facility operators to keep supply piping leak-free, and will help protect air pollution inspectors from EtO exposure.

(e)(3) New requirements limiting EtO in liquid discharges from the sterilizer cycle (30 ug/ml) and the aerator cycle (10 ug/ml) are added. These requirements will address the release of EtO from reclamation control systems. In normal operation, reclamation systems have no direct air emission of EtO, but do emit EtO via wastewater streams. Based on the operating characteristics and measured emissions/discharges of EtO from these systems, we have concluded that 30 micrograms per milliliter (μg/ml) of EtO in the sterilizer discharge and 10 μg/ml of EtO in the aerator discharge represent the lowest achievable emission rate, and are equivalent to the BACT emission limits set for destruction-based technologies. These limits will result in emissions equal to or less than those from a system meeting the existing percent efficiency standard. It will be simpler and less costly for operators of reclamation systems to demonstrate compliance with the concentration-based performance standards.

Table I

The "Date of Compliance" column is deleted. See rationale in definition (a)(9), above.

A new control efficiency is added for combined sterilizer and aerator emissions. We are proposing to add an alternative performance standard emission limit of 99.7 percent combined sterilizer and aerator control efficiency for the 600 to 5,000 pound per year control category. The proposed combined sterilizer and aerator control efficiency emission standard is derived from the mass-weighted average of the separate emission stream efficiency requirements. Its inclusion in the ATCM will provide flexibility in the compliance testing of catalytic oxidizer control systems in particular. The South Coast Air Quality Management District rule for sterilizers and aerators includes such an option.

4. Part 1 - (f) Compliance

The reference to the compliance date in column (d) of Table I is deleted. See rationale in definition (a)(9), above.

5. Part 1 - (g) Alternative Compliance Date

This section is deleted. It allowed, for a limited time which has already passed, operation of a facility at a less stringent level of control than had been determined to be technically feasible and cost-effective. It was intended to address the needs of a facility which was considering discontinuing EtO sterilizer operations. It is no longer needed, because the alternative compliance dates are already passed, and the underlying rationale and basis for the alternative compliance dates no longer exists.

6. Part 1 - (h) Source Testing

This section is modified to provide authority to the district to approve alternative source testing methods in consultation with the Executive Officer of the ARB. Previously the ATCM vested that authority in the Executive Officer of the ARB. During implementation of the regulation, we found that the districts and source testing consultants used good technical judgement in developing and proposing alternative source testing methods. We believe that allowing the district the authority to approve alterative source testing methods will streamline source testing, and with it the compliance process, and that districts will act in good faith in consulting with the ARB to ensure that any alternative testing method is technically sound.

(h)(1) The requirement that the test on a control device for a sterilizer exhaust stream shall be run with a typical load in the chamber is deleted. We found during implementation of the ATCM that an alternative approach which provided equivalent information could be used to test the performance of the control device. This change will allow source testing to be done more quickly and so at lower cost, because the entire multi-hour sterilizing cycle need not be run for the test. The requirement that all EtO emission point shall be sampled during the entire testing period is added. This requirement is added to address the operational and emission characteristics of reclamation technology-based control devices which were not in use in California at the time the ATCM was developed. These reclamation systems in normal operation have more than one point of release of EtO. The requirement is needed to ensure that EtO emissions and discharges are measured, to prevent excess emissions and consequent increase in risk of harm to public health.

(h)(2) The requirement that the test on a control device for an aerator exhaust stream shall be run with a typical load in the chamber is deleted. The proposed amendments to ARB Method 431, the emissions testing method used to determine compliance with the ATCM, stipulate on page 6, "Option 2", that aeration tests shall be run with a load in the chamber. Consequently, this requirement is not necessary in the ATCM.

7. Part 2

The creation of a separate part, section 93108.5, for commercial sterilizers using 2,000 pounds or more of EtO per consecutive 12 month period after December 6, 1996, is added to satisfy the NESHAP requirements. The additional NESHAP requirements for monitoring, recordkeeping, and reporting do not provide any quantifiable emissions reductions benefits. We believe that the existing ATCM requirements and the district permitting systems, procedures, conditions, and enforcement mechanisms provide for sufficient monitoring, recordkeeping, and reporting to provide for effective implementation of the ATCM. However, based on negotiations with staff of the U.S. EPA, the additional requirements are necessary to gain equivalency of the ATCM with the NESHAP.

8. Part 2 - (a) Definitions

Several definitions are added to be consistent with the NESHAP. The additional definitions are: (1) "Administrator", (6) "baseline temperature," (7) "control system," (9) "commercial sterilizer,"(10) "date of compliance," (17) "manifolding emissions," (18) "maximum ethylene glycol concentration," (19) " maximum liquor tank level," (20) "modification," (21) "oxidation temperature," and (22) "parametric monitoring." One term is modified to be consistent with the NESHAP definition; it is (5) " Back-draft valve/chamber exhaust vent."

9. Part 2 - (b) Applicability

The applicability is changed to include only commercial sterilizers and aerators using 2,000 pounds or more of ethylene oxide per 12 month consecutive period. This is the subset of facilities to which the NESHAP applies.

The applicability is made effective on the date that the NESHAP becomes effective. This is so that the NESHAP-driven requirements of the amended ATCM take effect coincident with the NESHAP. The existing requirements (as modified by the amendments) are to continue in effect until then. This ensures continued application of the ATCM requirements until the NESHAP becomes effective.

10. Part 2 - (c) Initial Notification

This is a new section which requires the facility operator to provide certain information on the operation of the sterilizer and aerator to the district and the U.S. EPA Administrator. This information (such as location and description of sterilizer, and usage of EtO) is required by the NESHAP.

11. Part 2 - (d) Requirements

(d)(1) This is a new section specific to large commercial sterilizers and aerators. It includes emission control performance standards equivalent to those in the existing ATCM, which are significantly more stringent in most cases than the NESHAP requirements. For instance, the existing ATCM and the proposed amended ATCM require 99.9 percent control of EtO emissions from sterilizers at any facility using more than 600 pounds of EtO per year. The NESHAP requires 99 percent control of EtO only at commercial facilities using 2,000 ponds of EtO per 12 months. The ATCM requires 95 percent control of aerator emissions by facilities using above 600 and less than 5,000 pounds of EtO per year, and 99 percent control of aerator emissions by facilities using 5,000 pounds or more of EtO per year. The NESHAP requires 99 percent control of aerator emissions only at facilities using more than 20,000 pounds of EtO per 12 months. The NESHAP does require 99 percent control of emissions at aeration-only facilities, whereas the existing ATCM requires 95 percent control. Although there are no known aeration-only facilities in the state, we are incorporating the 99 percent requirement for aeration-only facilities to be consistent with our commitment to achieve any public health benefit of the federal regulations.

(d)(3) This is a new section which requires facilities to obtain a Title V permit from the U.S. EPA Administrator. It is included here for consistency with the NESHAP.

12. Part 2 - (e) Compliance Procedures

This section is new and contains compliance testing notification, compliance testing, and reporting requirements as required by the NESHAP.

13. Part 2 - (f) Monitoring Requirements

This is a new section which prescribes monitoring requirements for control system parameters as required by the NESHAP. It references Appendix 1 "Requirements for Continuous Monitoring System," which is the NESHAP requirement for the continuous monitoring systems.

14. Part 2 - (g) Recordkeeping

This new section requires that certain records be maintained by the facility operator, and includes provisions for waiver of the recordkeeping requirements. These requirements are required by the NESHAP.

15. Part 2 - (h) Reporting

This section is new and dictates that a facility operator report certain compliance information to the U.S. EPA Administrator semi-annually.

16. Part 2 - (i) Construction or Modification

This section is new and requires that written approval of the U.S. EPA Administrator be obtained before any person constructs or modifies a large source subject to the requirements. It also describes the information that must be provided in certain cases in seeking that approval.

17. Compliance Test Method

We are proposing changes to ARB Method 431 that affect the method used to determine the mass of EtO used to calculate the control efficiency. Second, we are also proposing to add a test method to determine the maximum EtO in water.

The addition of a method to calculate the mass of EtO going to the control device addresses safety concerns over sampling very high concentrations of EtO, and circumstances where it is not technically feasible to directly measure the EtO. This approach has been successfully used to demonstrate compliance with the ATCM, but case-by-case approval is currently required by the ATCM. Testing consultants, the districts, and ARB have amassed sufficient experience in implementing the ATCM to conclude that an inlet calculation approach is technically sound.

We are also adding a test method for determining EtO concentration in water so that a concentration-based standard can be used as an alternative for reclamation systems to a mass-balance, overall efficiency approach. The current test method does not include such a protocol because the existing ATCM does not include a limit for EtO in water. The control technologies deemed to be BACT at the time the ATCM was developed did not discharge EtO in water except as vacuum pump working fluid. The ATCM addresses that EtO discharge in water by prohibiting the discharge of vacuum pump working fluid. EtO in water discharged from the control equipment represents an indirect but potentially significant source of EtO emission to the atmosphere, because the EtO will disassociate from the water.

D. Impact of the Proposed Amended ATCM

1. Are the proposed amendments likely to result in any significant adverse environmental impacts?

Public Resources Code section 21159 of the California Environmental Quality Act (CEQA) requires the ARB to conduct an environmental analysis which includes, at a minimum, all of the following: (1) an analysis of the reasonably foreseeable environmental impacts of the methods of compliance, (2) an analysis of the reasonably foreseeable feasible mitigation methods, and (3) an analysis of the reasonably foreseeable alternative means of compliance with the regulations. Those analyses are summarized below.

(1) There will be no reasonably foreseeable environmental impacts. The amended ATCM is designed to achieve the same emission reductions as the existing ATCM. Therefore, the proposed amendments will result in the same emissions as before. The principle difference will be greater flexibility in terms of compliance options and testing requirements for noncommercial facilities, and additional monitoring, recordkeeping and reporting requirements for commercial facilities.

(2) There are no reasonably foreseeable mitigation measures, because the ARB's environmental analysis concludes that the amended ATCM will have no significant adverse impacts on the environment.

(3) The amended ATCM will retain the same performance standard at the current ATCM. It will improve the effectiveness of the current ATCM by allowing greater flexibility during testing of both traditional and new technology. It will also incorporate the federal monitoring, recordkeeping and reporting requirements. Since the alternative to using the amended ATCM is to continue using the existing ATCM and to comply with the NESHAP, ARB staff expects that no significant adverse impacts will occur due to the "reasonably foreseeable alternative means of compliance."

2. Are the proposed amendments likely to result in any impacts on air quality?

The conclusion reached during the development of the existing Ethylene Oxide ATCM was that the ATCM would result in a significant improvement to air quality and the environment by reducing emissions of ethylene oxide. This reduction represents an overall 99 percent decrease in emissions from ethylene oxide sterilizers and aerators prior to the implementation of the ATCM. Because the proposed amendments will not result in any change in EtO emissions relative to the existing ATCM, there are no expected air quality impacts.

3. Are the proposed amendments likely to result in any significant impacts on water quality and landfills?

Impacts on water quality were analyzed during the development of the existing ATCM. The Board agreed that no significant environmental impact would occur on water quality. Because the proposed amendments embody equivalent emission standards, these same conclusions hold true for the amended ATCM. There are no foreseeable impacts on landfills from these proposed amendments.

4. Are the proposed amendments likely to result in an adverse economic and cost impacts on California businesses, including small businesses?

No. Businesses which uses ethylene oxide are subject to the requirements of the current ATCM. In addition, six commercial facilities must also comply with NESHAP which requires additional monitoring, recordkeeping and reporting compared to the existing ATCM. Incorporating the clarified and simplified NESHAP requirements will reduce the impact of the federal requirements on California businesses.

5. Are the proposed amendments likely to result in any adverse impact on interstate business competitiveness?

The amended ATCM will have no adverse impact on interstate business competitiveness. The amendments to the ATCM simplify and provide additional flexibility to the existing requirements, and incorporate the NESHAP requirements for commercial facilities into the ATCM. Out-of-state commercial facilities will now be subject to similar requirements due to the NESHAP.

6. Are the proposed amendments likely to result in any adverse impact on employment?

The amended ATCM will have no adverse impact on employment. Some additional effort will be in the monitoring, recordkeeping, and reporting aspects of compliance with the amended ATCM for commercial facilities. Whether the amendments are adopted or not, the same facilities remain subject to the NESHAP and must comply with the monitoring, recordkeeping, and reporting requirements. For non-commercial facilities, the amendments provide flexibility in compliance demonstration and are expected to either have no effect or to reduce the cost of compliance with the ATCM.

7. Are the proposed amendments likely to result in any adverse impact on business creation, elimination, and expansion?

The amended ATCM will have no adverse impact on business creation, elimination, and expansion. Very small additional effort arising from the proposed amendments are attributable to changes in the monitoring, recordkeeping, and reporting provisions. These requirements must be met under the NESHAP whether or not the amendments to the ATCM are adopted.

The amended ATCM will make it easier, and to a degree less costly, for facilities with reclamation-based control technology to demonstrate compliance. For large commercial facilities affected by the NESHAP-driven changes, the control equipment is the same is currently in place. Therefore, business creation, elimination, and expansion are not expected to be adversely impacted.

E. Alternatives

Staff considered the following alternatives to the proposed amendments. None were found to be as effective as the recommended amendments in providing enhanced flexibility and streamlining compliance for the facility operators, and protecting public health.

1. No change to current ATCM

If the ATCM is not amended to incorporate the combined sterilizer/aerator control efficiency performance standard, the ethylene oxide discharge limits, and the test method changes, compliance with the ATCM will be more costly than necessary because of the more complex testing necessary to demonstrate compliance, and the required case-by-case approval for alternative test procedures.

If there is no change to the ATCM, there would be two significant opportunities forgone to streamline requirements for the facilities, and simplify and provide flexibility to facilities now in compliance with the ATCM.

If the ATCM is not amended to incorporate the NESHAP requirements, the NESHAP would be enforced directly on affected facilities. Because we have simplified some of the NESHAP requirements, this approach would cause an additional recordkeeping and reporting burden on the six facilities subjected to the NESHAP as well as an additional administrative burden on any district in which a commercial facility is located.

2. Incorporate changes to the ATCM for non-commercial and small commercial facilities, and delete ATCM requirements applicable to the NESHAP-subject facilities

This alternative would result in the direct application of the NESHAP to large commercial facilities. It would result in more complex requirements for the NESHAP-subject facilities than under the proposed amendments. We have simplified and clarified the NESHAP requirements that we propose to include in the ATCM, and believe that the revision of the ATCM to include the simplified NESHAP requirements represents a reduced regulatory burden on facility operators.

3. Incorporate changes to the ATCM for non-commercial and small commercial facilities, and incorporate the NESHAP verbatim in the ATCM

This would provide for a greater convenience to facility operators than alternative 2, in that the requirements could be found in a single document. However, the simplification and clarification of the NESHAP requirements achieved in the amended ATCM will (if adopted) reduce the regulatory burden on facilities, and so represent the preferred alternative.

F. Plain Language Summary of the Proposed Amendments

We are proposing to change the State regulation for ethylene oxide sterilizers and aerators. The proposed changes do not affect the emission limits in the regulation. The proposed changes will make it simpler for facility operators to show that they meet the emission limits of the regulation. The proposed changes involve four areas. These areas are discussed below.

1) We are proposing to separate the requirements for non-commercial and small commercial facilities from the requirements for large commercial facilities. Commercial facilities are manufacturers of products or equipment that sterilize what they make, or are facilities whose main business it is to sterilize products or equipment. A large commercial facility is one that uses 2,000 pounds or more of ethylene oxide in a 12 month period.

We propose to add additional requirements for large commercial facilities. These requirements are for monitoring operation of the control equipment, keeping records, and reporting information to the government. We propose to include these requirements to our regulation because the U.S. EPA has enacted a federal regulation that requires these things to be done. A few facilities in California will have to comply with the federal regulation. It will be simpler for these facilities to have to meet only one regulation.

2) We are proposing to change some of the compliance testing requirements for non-commercial and small commercial facilities. These changes--like being able to calculate instead of measure the ethylene oxide coming out of the sterilizer chamber--are intended to make it easier to test emissions. We are also proposing to make other changes that clarify and improve the effectiveness of the regulation.

3) We are proposing to add an optional emission limit. This is a combined sterilizer and aerator limit. It is equivalent to the separate limits, but will make it easier for some facilities operators to show that their meeting the requirements.

4) We are eliminating the prohibition on discharge of wastewater from the sterilizer exhaust vacuum pump (that contains ethylene oxide), and substituting a limit for ethylene oxide in liquid discharge. This means that a discharge of liquid is O.K. if the ethylene oxide is removed from it to meet the discharge limit.

APPENDIX A

PROPOSED REGULATION ORDER
ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

TABLE OF CONTENTS

Part 1

NON COMMERCIAL STERILIZERS AND AERATORS AND COMMERCIAL STERILIZERS AND AERATORS USING LESS THAN 2,000 POUNDS OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

Part 2

COMMERCIAL STERILIZERS AND AERATORS USING 2,000 POUNDS OR MORE OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

PROPOSED REGULATION ORDER

ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

The Air Resources Board staff is proposing to amend section 93108, title 17, California Code of Regulations and to add section 93108.5 title 17, California Code of Regulations. These changes are proposed to simplify and clarify the ATCM and emission test method to reflect implementation experience practices and, for large commercial ethylene oxide sterilizers, to integrate the State requirements with the new United States Environmental Protection Agency's promulgation of the National Emission Standards for Ethylene Oxide Commercial Sterilization And Fumigation Operations. Additions are shown in underline; deletions are shown in strikeout.

17 CCR, Section 93108. Ethylene Oxide Airborne Toxic Control Measure--Sterilizers and Aerators.

PART 1

NON COMMERCIAL STERILIZERS AND AERATORS AND COMMERCIAL STERILIZERS AND AERATORS USING LESS THAN 2,000 POUNDS OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

(a) Definitions. For the purposes of this section, the following definitions shall apply:

(1) "Acute care facility" means any facility currently licensed by the California Department of Health Services as a general acute care hospital (as defined in title 22, CCR, section 70005), or any military hospital.

(2) "Aeration" is the process during which residual ethylene oxide dissipates, whether under forced air flow, natural or mechanically assisted convection, or other means, from previously sterilized materials after the sterilizer cycle is complete.

(3) "Aeration-only facility" means a facility which performs aeration on materials which have been sterilized with ethylene oxide at another facility.

(4) "Aerator" means any equipment or space in which materials previously sterilized with ethylene oxide are placed or remain for the purpose of aeration. An aerator is not any

equipment or space in which materials that have previously undergone ethylene oxide sterilization and aeration can be handled, stored~~;~~, and transported in the same manner as similar materials that have not been sterilized with ethylene oxide.

(5) "Aerator exhaust stream" means all ethylene oxide-contaminated air which is emitted from an aerator.

(6) "Back-draft valve exhaust stream" is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.

(7) "Commercial sterilizer" means facility which as its principal business sterilizes products or equipment manufactured elsewhere, or a facility which sterilizes products or equipment it manufactures. A commercial sterilizer is also a non-medical facility that sterilizes items used in conducting its business.

(~~7~~ 8) "Control device" means an article, machine, equipment, or contrivance which reduces the amount of ethylene oxide between its inlet and outlet and which is sized, installed, operated, and maintained according to good engineering practices, as determined by the district.

(~~8~~ 9) "Control efficiency" is the ethylene oxide (EtO) mass or concentration reduction efficiency of a control device, as measured with ARB Test Method 431 (title 17, CCR, section 94143) according to the source testing requirements herein, and expressed as a percentage calculated across the control device as follows:

$$\frac{\sum (\text{EtO in} - \text{EtO out})}{\sum \text{EtO in}} \times 100 = \%\ \text{Control Efficiency}$$

(~~9~~) ~~"Date of compliance" means the time from district adoption of regulations enacting this control measure until a facility must be in compliance with specific requirements of this rule.~~

(10) "District" means the local air pollution control district or air quality management district.

(11) "Ethylene oxide (EtO)" is the substance identified as a toxic air contaminant by the Air Resources Board in 17 CCR, section 93000.

(12) "Facility" means any entity or entities which: own or operate a sterilizer or aerator, are owned or operated by the same person or persons, and are located on the same parcel or contiguous parcels of land.

(13) "Facility-wide pounds of ethylene oxide used per year" is the total pounds of ethylene oxide used in all of the sterilizers at the facility during a one-year period.

(14) "Leak-free" refers to that state which exists when the concentration of sterilant gas measured 1 cm. away from any portion of the exhaust system of a sterilizer or aerator, during conditions of maximum sterilant gas mass flow, is less than:

(A) 30 ppm for sterilant gas composed of 12% ethylene oxide/88% chlorofluorocarbon-12 by weight; and
(B) 10 ppm for other compositions of sterilant gas,

as determined by ARB Test Method 21 (title 17, CCR, section 94124) using a portable flame ionization detector or a non-dispersive infrared analyzer, calibrated with methane, or an acceptable alternative method or analytical instrument approved by the district. A chlorofluorocarbon-12 specific audible detector using a metal oxide semi-conductor sensor shall be considered an acceptable alternative for exhaust systems carrying a sterilant gas mixture of ethylene oxide and chlorofluorocarbon-12.

(15) "Local medical emergency" means an unexpected occurrence in the area served by the acute care facility resulting in a sudden increase in the amount of medical treatments which require a significant increase in the operation of a sterilizer or aerator.

(16) "Non-commercial sterilizer" means a facility other than a commercial facility at which ethylene oxide is used for sterilizing or fumigation, or at which aeration occurs.

(~~16~~ 17) "Sterilant gas" means ethylene oxide or any combination of ethylene oxide and (an)other gas(es) used in a sterilizer.

(~~17~~18) "Sterilizer" means any equipment in which ethylene oxide is used as a biocide to destroy bacteria, viruses, fungi, and other unwanted organisms on materials. Equipment in which ethylene oxide is used to fumigate foodstuffs is considered a sterilizer.

(~~18~~19) "Sterilizer cycle" means the process which begins when ethylene oxide is introduced into the sterilizer, includes the initial purge or evacuation after sterilization, and subsequent air, steam or other washes, and ends after evacuation of the final ~~air-~~wash.

(~~19~~20) "Sterilizer door hood exhaust stream" is the air stream which results from collection of fugitive ethylene oxide emissions, by means of an existing hood over the sterilizer door, during the time that the sterilizer door is open after the sterilizer cycle has been completed.

(~~20~~21) "Sterilizer exhaust stream" is all ethylene oxide-contaminated air which is intentionally removed from the sterilizer during the sterilizer cycle.

(~~21~~22) "Sterilizer exhaust vacuum pump" means a device used to evacuate the sterilant gas during the sterilizer cycle, including any associated heat exchanger. A sterilizer exhaust vacuum pump is not a device used solely to evacuate a sterilizer prior to the introduction of ethylene oxide.

(b) Applicability. Any person who owns or operates a non-commercial sterilizer or aerator or any person who owns or operates a commercial sterilizer or an aerator that uses less than 2,000 pounds of EtO per consecutive 12-month period after December 6, 1996, must comply with Part I of this regulation, section 93108.

(c) Notification. Any person subject to this regulation must provide the district with the following information, in writing, within 30 days of the date of district adoption:

(1) the name(s) of the owner and operator of the facility, and

(2) the location of the facility, and

(3) the number of sterilizers and aerators at the facility, and

(4) an estimate of the total pounds of ethylene oxide and sterilant gas used by the facility, in all sterilizers, during the previous calendar year, as determined by a method approved by the district.

A district may exempt a source from this requirement if the district maintains current equivalent information on the source.

(d) Reporting. Any person who owns or operates a sterilizer shall furnish a written report to the district annually on the date specified by the district, or, at the district's discretion, shall maintain such a report and make it available to the district upon request. This report shall include one of the following, as determined by the district:

(1) the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer during the reporting period, as determined by a method approved by the district; or

(2) the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the previous calendar year, as determined by a method approved by the district.

(e) Requirements. No person shall operate a sterilizer or aerator ~~after the applicable date shown in column (d), Table I~~, unless all of the following requirements are satisfied:

~~(1) there is no discharge of sterilizer exhaust vacuum pump working fluid to wastewater streams, and~~

(~~2~~ 1) the exhaust systems and EtO supply system including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide-contaminated air is conveyed ~~from~~ between the sterilizer, ~~and aerator to the outlet of~~, aerator and the control device ~~are~~ shall be leak-free; and

(~~3~~2) all of the control requirements shown in Table I below for the applicable control category are met; and

(3) the concentration of ethylene oxide shall not exceed:

- (A) 30 μg/ml in any liquid discharge associated with the sterilization cycle; and
- (B) 10 μg/ml in any liquid discharge associated with the aeration cycle for those facilities where Table I requires aeration control;

Table I
Control and Compliance Requirements

Control Category (Facility-wide Pounds of Ethylene Oxide Used Annually)	Requirements			
	(a) Exhaust Streams to be Controlled	(b) Exhaust Streams to be Tested	(c) Control Efficiency (%)	~~(d) Date of Compliance (months)~~
Less than or equal to 25	None	None	None	~~None~~
More than 25 and less than or equal to 600	Sterilizer	Sterilizer	99.0	~~24~~
More than 600 and less than or equal to 5,000	Sterilizer Aerator Sterilizer/Aerator Back-draft Valve	Sterilizer Aerator Sterilizer/Aerator	99.9 95.0 99.7 N/A*	~~18~~
More than 5,000	Sterilizer Aerator Sterilizer Door Hood & Back-draft Valve	Sterilizer Aerator	99.9 99.0 N/A* N/A*	~~12~~
Aeration-Only Facilities	Aerator	Aerator	95.0	~~18~~
*Not Applicable				

(4) for facilities using more than 600 pounds of ethylene oxide per year, the back-draft valve is ducted to the control device used to control the sterilizer exhaust stream or the aerator exhaust stream; and

(5) for facilities using more than 5,000 pounds of ethylene oxide per year, the sterilizer door hood exhaust stream is ducted to the control device used to control the aerator exhaust stream.

(f) Exemptions.

(1) The requirements set forth in subsection (e) above do not apply to any facility which treats materials in a sterilizer and which uses a total of 25 pounds or less of ethylene oxide per calendar year.

(2) The district hearing board may grant an emergency variance from items (a) and (c) in Table I of Part 1 subsection (e), Requirements, to a person who owns or operates an acute care facility if response to a local medical emergency requires increased operation of a sterilizer or aerator such that the requirements cannot be met.

The demonstrated need for such increased operation shall constitute "good cause" pursuant to Health and Safety Code Section 42359.5. The emergency variance shall be granted in accordance with this section and any applicable district rule regarding the issuance of emergency variances for such occurrences, including the requirement that the emergency variance shall not remain in effect longer than 30 days; however, the emergency variance shall be granted only for the period of time during which increased operation of a sterilizer or aerator is necessary to respond to the local medical emergency.

(g) Compliance. ~~The facility shall be in compliance with all provisions specified in subsection (e), Requirements, no later than the date specified in column (d) of Table I.~~

~~(1)~~ For the purpose of determining compliance with the control efficiency requirement ~~shown~~ set forth in column (c) of Table I, subsection (e), if a reduction in the amount of ethylene oxide across the control device is demonstrated, but the control efficiency cannot affirmatively be demonstrated because the concentration of ethylene oxide measured in the outlet of the control device is below 0.2 parts per million ethylene oxide, the facility shall be considered to be in compliance with this requirement.

~~(h) Alternate Compliance Date. The owner or operator of any facility which uses more than 600 pounds of ethylene oxide per year may choose this alternate compliance option which addresses the date for compliance with the requirements of subsection (e). If this compliance option is chosen, the owner or operator shall:~~

~~(1) within 3 months of the date of district adoption of regulations enacting this control measure, comply with the requirements shown in subsections (e)(1) and (e)(2) and demonstrate a control efficiency of 99.9% for the sterilizer exhaust stream, in accordance with the source testing requirements set forth in subsection (i);~~ and

~~(2) within 6 months of the date of district adoption of regulations enacting this control measure, submit to the district a plan to discontinue operation of all sterilizers and aerators or comply with the district requirements to submit a plan to comply with the requirements of subsections (e)(3), (e)(4), and (e)(5),~~ and

~~(3) within 18 months of the date of district adoption of regulations enacting this control measure, do one of the following:~~

~~(A) demonstrate to the satisfaction of the district that operation of all sterilizers and aerators at the facility has been permanently discontinued; or~~

~~(B) demonstrate compliance with the requirements of subsections (e)(3), (e)(4), an (e)(5), in accordance with the source testing provisions set forth in subsection (i), below.~~

(~~i~~ h) Source Testing. Source testing shall be conducted according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district in consultation with the Executive Officer of the Air Resources Board. Specific requirements for application are given below:

(1) ~~The test on a control device for a sterilizer exhaust stream shall be run with a typical load, as approved by the district, in the sterilizer.~~ All ethylene oxide emission points shall be sampled during the entire testing period.

(2) ~~The test on a control device for an aerator exhaust stream shall be run with a typical load, as approved by the district, in the aerator.~~ If the efficiency is being determined by inlet and outlet sampling, the inlet and outlet of the control device shall be sampled simultaneously during testing.

~~(3) the inlet and outlet of the control device shall be sampled simultaneously during testing to measure the control efficiency.~~

(~~4~~ 3) The efficiency of each control device shall be determined under conditions of maximum ethylene oxide mass flow to the device, under normal operating conditions. To measure the control efficiency of the control device on the sterilizer exhaust stream, sampling shall be done during the entire duration of the first sterilizer evacuation after ethylene oxide has been introduced. To measure the control efficiency of the control device on an aerator exhaust stream with a constant air flow, sampling shall be done during a period of at least 60 minutes, starting 15 minutes after aeration begins. To measure the control efficiency of the control device on an aerator exhaust stream with a non-constant air flow, sampling shall be done during the entire duration of the first aerator evacuation after aeration begins.

(~~5~~ 4) There shall be dilution of the air stream between the inlet and outlet test points during testing.

NOTE: Authority cited: Sections 39600, 395601, and 39666, Health and Safety Code.
Reference: Sections 39650, 39665, and 39666, Health and Safety Code.

17 CCR, Section 93108.5. Ethylene Oxide Airborne Toxic Control Measure--Sterilizers and Aerators.

PART 2

COMMERCIAL STERILIZERS AND AERATORS USING 2,000 POUNDS OR MORE OF ETHYLENE OXIDE PER 12 CONSECUTIVE MONTHS

(a) Definitions. For the purposes of this section, the definitions set forth in section 93108 (a) shall apply unless otherwise specified below:

(1) "Administrator " means the Administrator of the United States Environmental Protection Agency or his or her authorized representative (e.g., a district that has been delegated the authority to implement any of the provisions of this part).

(2) "Back-draft valve /chamber exhaust stream" is the air stream which results from collection of ethylene oxide-contaminated air which may be removed from the sterilizer through a back-draft valve or rear chamber exhaust system during unloading of the sterilized materials.

(3) "Baseline temperature" means the range of temperatures at the outlet point of a catalytic oxidation control device or at the exhaust point from the combustion chamber for a thermal oxidation control device established during the performance test at which the unit achieves at least 99 percent control of ethylene oxide emissions.

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

(5) "Maximum ethylene glycol concentration" means the 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.

(6) "Maximum liquor tank level" means the 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.

(7) "Modification" means either (A) any physical change in, method of operation of, or addition to, an existing permit unit that requires an application for a permit to construct

and/or operate. Routine maintenance and/or repair shall not be considered a physical change. A change in the method of operation of equipment, unless previously limited by an enforceable permit condition, shall not include:

(i) an increase in the production rate, unless such increases will cause the maximum design capacity of the equipment to be exceeded; or

(ii) an increase in the hours of operation; or,

(iii) a change in ownership of a source; or,

(B) the addition of any new permit unit at an existing source; or,

(C) the replacement of components if the fixed capital cost of the components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source.

(8) "Oxidation temperature" means the temperature at the outlet point of a catalytic oxidation device or at the exhaust point from the combustion chamber for a thermal oxidation device.

(9) "Parametric monitoring" means monitoring of a specific operating parameter or parameters of a control device established to demonstrate that the control device is operating under conditions that meet a performance standard.

(b) Applicability. Any person who owns or operates a commercial sterilizer or an aerator using 2,000 pounds or more of ethylene oxide in any 12 consecutive month period after December 6, 1996 must comply with Part 2 of this regulation, section 93108.5, effective the date that the National Emission Standard For Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization And Fumigation Operations (Code of Federal Regulation 40, Part 63, subpart O) becomes effective. Until that time the requirements in Part I, section 93108, are applicable to all sterilizer and aerators.

(c) Initial Notification. Any person subject to this regulation must provide the district with the following information, in writing, within 30 days after the source becomes subject to the regulation. Facilities must also provide the information to the Administrator unless the Administrator has waived this requirement.

(1) The name(s) and address of the owner and operator of the facility;

(2) The location of the facility;

(3) The number of sterilizers and aerators at the facility;

(4) An estimate of the facility-wide pounds of ethylene oxide used per year;

(5) A brief description of the nature, size, design, design operating capacity, expected control efficiency, and method of operation of the source, and control equipment, including operating design capacity, bypass valves, and an identification of each point of emission;

(6) Facilities complying with this regulation with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers must provide information describing the design and operation of the air pollution control system including recommendations for the operating parameters to be monitored that will indicate proper operation and maintenance. The site specific operating, reporting and monitoring parameters will be determined during the performance test.

(7) A statement of whether the source is a major or area source to the Administrator. If the source is a new major source or a major source undergoing modification, it must receive written approval in advance from the Administrator. The source may use the "Application for Construction or Modification" in Appendix 2 to satisfy the initial notification requirements; and

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

(d) Requirements. No person subjected to these standards shall operate a sterilizer or aerator, unless all of the following requirements are satisfied:

(1) all ethylene oxide released from the sterilizer and aerator shall be controlled to meet the requirements shown in Table I for the applicable control category:

Table I
Emissions Standards for Commercial Facilities

Control Category (Facility-wide Pounds of Ethylene Oxide used per 12 consecutive months)	Requirements for Ethylene Oxide Sterilizer Facilities		
	(a) Emission Streams to be Controlled	(b) Emission Streams to be Tested	(c) Control Efficiency (%) or Outlet Concentration
equal to or greater than 2,000 and less than 5,000	Sterilizer	Sterilizer	99.9
	Aerator	Aerator	95.0
	Back-draft Valve		*
	Aeration Only		95.0
equal to or greater than 5,000 and less than 20,000	Sterilizer	Sterilizer	99.9
	Aerator	Aerator	99.0
	Sterilizer Door Hood		*
	&		
	Back-draft Valve		*
	Aeration Only		95.0
Equal to or more than 20,000	Sterilizer	Sterilizer	99.9
	Aerator	Aerator	99.0 or 1 ppm max
	Sterilizer Door Hood		*
	Back-draft Valve		99.0*
	Aeration Only		99.0

* Sources may show compliance by manifolding emissions to control device used to comply with sterilizer or aerator requirement.

(2) the exhaust systems and EtO supply including, but not limited to, any piping, ducting, fittings, valves, or flanges, through which ethylene oxide is conveyed to and from the sterilizer, aerator and the control device shall be leak-free; and

(3) Facilities must obtain a title V permit from the Administrator.

(e) Compliance Procedures

(1) Compliance Testing Notification

The facility shall notify the Administrator 60 days before the date and time of any performance tests and monitoring system evaluations. In the event the source is unable to conduct the test on the date specified in the notification, the source shall notify the Administrator within 5 days prior to the scheduled performance test date.

(2) Compliance Testing

(A) Source testing conducted for the purpose of demonstrating compliance must be according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district in consultation with the Executive Officer of the Air Resources Board, and the Administrator. Before conducting a required source test, the source shall develop a site-specific test program summary, the test schedule, data quality objectives, and both an internal and external quality assurance program.

(B) The following procedures shall be used to determine the monitored parameters for acid-water scrubbers:

(i) 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 (1988).

(ii) 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.

(C) The following procedures shall be used to demonstrate the baseline temperature for catalytic oxidation units or thermal oxidation units and to continuously monitor the oxidation temperature as required by this measure.

(i) The baseline temperature for the sterilization chamber vent shall be the temperature for the catalytic oxidation unit or oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in U. S. EPA Test Method 18, section 7.2.

(ii) The baseline temperature for the aeration room vent shall be 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 U.S. EPA Test Method 18, section 7.2.

(iii) The baseline temperature for the chamber exhaust vent shall be the temperature for the catalytic oxidation unit or oxidation temperature at the exhaust point from the thermal oxidation unit averaged over three test runs using the procedures in U.S. EPA Test Method 18, section, 7.2 or 7.3.

(D) A facility seeking to demonstrate compliance with the standards with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit shall submit: a description of the device; tests results collected in accordance with the test method cited within or an approved method verifying the performance of the device for controlling ethylene oxide emissions 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 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.

(E) A facility seeking to demonstrate compliance with the standards 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.

(3) Compliance Testing Report

(A) The facility shall send the district and the Administrator an initial statement of compliance and test results within 60 days following the performance test.

(B) The facility shall submit (before a title V permit is issued) to the Administrator:

(i) The methods that were used to determine compliance;

(ii) The results of any performance tests, continuous monitoring system (CMS) performance evaluations, and/or other monitoring procedures or methods that were conducted;

(iii) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods.

(iv) A statement by the owner or operator of the affected existing, new, or modified source as to whether the source has complied with the relevant standard or other requirements.

(f) Monitoring Requirements. The owner or operator of a sterilizer or aerator shall monitor the parameters of the control system specified in this section to show compliance with the provisions of this regulation. If continuous monitoring systems are required, Appendix 1 should be consulted for their application. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters which affect emissions from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include, at a minimum, completion of the manufacturer's written specifications or recommendations for installation, operation, maintenance, and calibration of the system.

(1) For sterilization facilities complying with the emissions standard through the use of an acid-water scrubber, the owner or operator shall either:

(A) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration using the test procedures in subsection (e)(2)(B)(i). Monitoring is required only if the scrubber unit has been operated during that week; or

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

(C) Operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum liquor tank level shall constitute a violation of the chamber exhaust vent standard for sources using 20,000 pounds or more of ethylene oxide per 12 consecutive months.

(2) For sterilization facilities complying with the emissions standards 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 a temperature monitor. The temperature monitor shall be installed, calibrated, operated, and maintained to an accuracy within ±5.6°C (±10°F). 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) standard, or with 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.

For sources using more than 20,000 pounds of ethylene oxide per 12 consecutive months, 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.

(A) 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) and a three-cycle block average every third cycle.

(B) 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.

(C) For the back draft valve (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).

(3) For sterilization facilities complying with the emission standards with 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.

(4) For facilities continuously measuring the ethylene oxide concentration from the aeration room (after a control device) or in the sterilization chamber immediately prior to the operation of the chamber exhaust, the owner or operator shall follow either paragraph (A) or (B) of this subsection:

(A) 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. 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 to measure ethylene oxide. The daily calibration requirements are required only on days when ethylene oxide emissions are vented to the control device from the aeration room vent.

(B) Measure and record the ethylene oxide concentration in the sterilization chamber immediately before the chamber exhaust is activated. The owner or operator shall install, calibrate, operate, and maintain a gas chromatograph to measure ethylene oxide concentration. The daily calibration requirements are required only on days when the chamber exhaust is activated.

(5) At facilities using 20,000 pounds or more of ethylene oxide per consecutive 12 months, seeking to comply with the standard by manifolding emissions from the chamber exhaust vent to a control device controlling emissions from another vent type (sterilization chamber vent and/or aeration room vent), shall monitor the control device to which emissions from the chamber exhaust vent are manifolded.

(g) Recordkeeping.

(1) The owner or operator of a sterilizer or aerator subject to the emissions standards in subsection (d) Table I shall maintain records of all reports and notifications (including compliance notifications) in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report or record. At a minimum the most recent 2 years of data shall be retained on site. The files shall contain:

(A) The occurrence and duration of each malfunction of the air pollution control equipment;

(B) All required measurements needed to demonstrate compliance with the standard (including, but not limited to, 15-minute averages of CMS data, raw performance testing measurements, and raw performance evaluation measurements, that support data that the source is required to report);

(C) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;

(D) Any information demonstrating whether a source is meeting the requirements for a waiver of recordkeeping or reporting requirements.

(2) The source may apply for a waiver of recordkeeping or reporting requirements by submitting a written application to the Administrator. Until the waiver is granted, the source remains subject to the requirements of this section. The application must contain at a minimum:

(A) A request for an extension of compliance (if applicable);

(B) All required compliance progress reports or compliance status reports;

(C) Any excess emissions and CMS performance report;

(D) Information to convince the administrator that a waiver of recordkeeping or reporting is warranted.

(h) Reporting. Any person who owns or operates a sterilizer shall furnish the following written report to the Administrator and to the district within thirty days after the date specified by the district.

(1) An annual report that demonstrates that the facility is a major or area source. The report shall contain at a minimum:

(A) the number of sterilizer cycles and the pounds of ethylene oxide used per cycle for each sterilizer during the consecutive 12-month reporting period from the district permit; or

(B) the total pounds of sterilant gas and the total pounds of ethylene oxide purchased, used, and returned in the consecutive 12-months from the date of the permit.

(2) Facilities shall provide semi-annual compliance reports to the Administrator that contain information on the compliance status of the source. This report should also contain the summary report in Appendix 1, (i). The report shall be signed by the responsible official who shall certify its accuracy.

(i) Construction or Modification.

The requirements of this section apply to sources subject to the emission standards in Table I. No person may construct or modify a source, without obtaining written approval, in advance, from the district and from the Administrator. For major sources, the application for approval of construction or modification may be used to fulfill the notification requirements. For specific requirements, see Appendix 2. In lieu of complying with requirements in Appendix 2, a facility may fulfill these requirements by complying with the permitting agency's new source review rule or policy, provided similar information is obtained.

NOTE: Authority cited: Sections 39600, 395601, and 39666, Health and Safety Code.
Reference: Sections 39650, 39665, and 39666, Health and Safety Code.

Appendix 1
Requirements for Continuous Monitoring Systems (CMS)

(a) General Requirements

(1) When the effluent from a single source, or when two or more sources are combined before being released to the atmosphere, the owner or operator shall install an applicable CMS on each effluent.

(2) When the effluent from one source is released to the atmosphere through more than one point, the owner or operator shall install an applicable CMS at each emission point unless the installation of fewer systems is approved by the Administrator.

(3) If more than one Continuous Emission Monitoring System (CEMS) is used to measure the emissions from one source, the owner shall report the results as required for each CEMS.

(4) The date and time during which a CMS is malfunctioning or inoperative, except for zero (low level) and high level checks. Also records of all required CMS measurements (including monitoring data recorded during unavoidable CMS breakdowns and out-of-control periods) shall be maintained.

(b) Recordkeeping

(1) All results of performance tests, and CMS performance evaluations;

(2) All CMS calibration checks;

(3) All adjustments and maintenance performed on CMS (including the nature and cause of any malfunction and the corrective action taken or preventive measures adopted). Records of the total process operating time during the reporting period shall be maintained as well;

(4) For facilities using more than 20,000 pounds of ethylene oxide per 12 month consecutive period, records shall be maintained for all procedures that are part of a quality control program developed and implemented for CMS.

(5) The specific identification (i.e., the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, as defined in the standard, that occurs during periods other than startups, shutdowns, and malfunctions of the affected source;

(6) The total process operating time during the reporting period.

(c) Additional Reporting The owner or operator shall submit to the Administrator a semiannual summary report. The summary report shall contain, at a minimum, the information in (h) of this subsection. In addition if the duration of excess emissions or process or control system parameter exceedances for the reporting period exceeds 1 percent or the total CMS downtime exceeds 5 percent of the reporting period, an excess emissions and continuous monitoring system performance report shall be submitted semiannually as well. The performance report shall contain, at a minimum, all information required in (h) of this subsection.

(d) Operation and maintenance of continuous monitoring systems. Each CMS shall be maintained and operated as specified in this subsection, and in a manner consistent with good air pollution control practices.

(1) All CMS shall be installed such that representative measurements of emissions or process parameters are obtained.

(2) All CMS shall be installed, operational, and the data verified either prior to or in conjunction with conducting performance tests. Verification of operational status shall, at a minimum, include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(e) Quality control program. (Sources using 20,000 pounds or more EtO per 12 consecutive months)

(1) The owner or operator shall develop and implement a CMS quality control program. As part of the quality control program, the owner or operator shall develop and submit upon request by the Administrator, a site-specific performance evaluation test plan for the CMS performance evaluation. In addition, each quality control program shall include, at a minimum, a written protocol that describes procedures for each of the following operations:

(A) Initial and any subsequent calibration of the CMS;
(B) Determination and adjustment of the calibration drift of the CMS;
(C) Preventive maintenance of the CMS, including spare parts inventory;
(D) Data recording, calculations, and reporting;
(E) Accuracy audit procedures, including sampling and analysis methods; and
(F) Program of corrective action for a malfunctioning CMS.

(2) The owner or operator shall keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this section, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator shall keep previous (i.e., superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision to

the plan.

(f) Performance evaluation of continuous monitoring systems.

(1) If the Administrator requests a performance evaluation, the evaluation shall be conducted according to the applicable specifications and procedures described in this subsection.

(2) Notification of performance evaluation. The owner or operator shall notify the Administrator in writing of the date of the performance evaluation simultaneously with the notification of the performance test date or at least 60 days prior to the date the performance evaluation is scheduled to begin if no performance test is required.

(3) Submission of site-specific performance evaluation test plan. (A) Before conducting a required CMS performance evaluation, the owner or operator shall develop and submit a site-specific performance evaluation test plan to the Administrator for approval. The performance evaluation test plan shall include the evaluation program objectives, an evaluation program summary, the performance evaluation schedule data quality objectives, and both an internal and external QA program. Data quality objectives are the pre-evaluation expectations of precision, accuracy, and completeness of data.

(B) The internal QA program shall include, at a minimum, the activities planned by routine operators and analysts to provide an assessment of CMS performance. The external QA program shall include, at a minimum, systems audits that include the opportunity for on-site evaluation by the Administrator of instrument calibration, data validation, sample logging, and documentation of quality control data and field maintenance activities.

(C) The owner or operator shall submit the site-specific performance evaluation test plan to the Administrator (if requested) at least 60 days before the performance test or performance evaluation is scheduled to begin, or on a mutually agreed upon date, and review and approval of the performance evaluation test plan by the Administrator will occur with the review and approval of the site-specific test plan (if review of the site-specific test plan is requested).

(D) In the event that the Administrator fails to approve or disapprove the site-specific performance evaluation test plan within the specified time period, the following conditions shall apply:

(i) If the owner or operator intends to demonstrate compliance by using an alternative to a monitoring method specified in this measure, the owner or operator shall refrain from conducting the performance evaluation until the Administrator approves the use of the alternative method. If the Administrator does not approve the use of the alternative method within 30 days before the performance evaluation is scheduled to begin, the performance evaluation deadlines may be extended such that the owner or operator shall conduct the performance evaluation within 60 calendar days after the Administrator approves the use of the alternative method. Notwithstanding the requirements in the preceding two sentences, the owner or operator may proceed to conduct the performance evaluation as required in this section (without the Administrator's prior approval of the site-specific performance evaluation test plan) if he/she subsequently chooses to use the specified monitoring method(s) instead of an alternative.

(4) Neither the submission of a site-specific performance evaluation test plan for approval, nor the Administrator's approval or disapproval of a plan, nor the Administrator' failure to approve or disapprove a plan in a timely manner shall:

(A) Relieve an owner or operator of legal responsibility for compliance with any applicable provisions of this part or with any other applicable Federal, State, or local requirement; or

(B) Prevent the Administrator from implementing or enforcing this part or taking any other action under the Act.

(5) Conduct of performance evaluation and performance evaluation dates. The owner or operator of an affected source shall conduct a performance evaluation of a required CMS during any performance test required in accordance with the applicable performance specification as specified in the standard. If a performance test is not required, or the requirement for a performance test has been waived, the owner or operator of an affected source shall conduct the performance evaluation not later than 180 days after the appropriate compliance date, or as otherwise specified in the standard.

(6) Reporting performance evaluation results. The owner or operator shall furnish the Administrator a copy of a written report of the results of the performance evaluation simultaneously with the results of the performance test within 60 days of completion of the performance evaluation if no test is required, unless otherwise specified in the standard. The Administrator may request that the owner or operator submit the raw data from a performance evaluation in the report of the performance evaluation results.

(g) Use of an alternative monitoring method. Until permission to use an alternative monitoring method has been granted by the Administrator under this paragraph, the owner or operator of an source remains subject to the requirements of this section and the standard.

(1) Request to use alternative monitoring method. (A) An owner or operator who wishes to use an alternative monitoring method shall submit an application to the Administrator. The application may be submitted at any time provided that the monitoring method is not used to demonstrate compliance with the standard or other requirement. If the alternative

monitoring method is to be used to demonstrate compliance with the standard, the application shall be submitted not later than with the site specific test plan (if requested), with the site-specific performance evaluation plan (if requested), or at least 60 days before the performance evaluation is scheduled to begin.

(B) The application shall contain a description of the proposed alternative monitoring system and a performance evaluation test plan, if required. In addition, the application shall include information justifying the owner or operator's request for an alternative monitoring method, such as the technical or economic infeasibility, or the impracticality, of the affected source using the required method.

(C) The owner or operator may submit the information required in this paragraph well in advance of the submittal dates to ensure a timely review by the Administrator in order to meet the compliance demonstration date specified in this section or the standard.

(2) After receipt and consideration of written application, the Administrator may approve alternatives to any monitoring methods or procedures of this part including, but not limited to, the following:

(A) Alternative monitoring requirements when installation of a CMS specified by the standard would not provide accurate measurements due to liquid water or other interferences caused by substances within the effluent gases;

(B) Alternative monitoring requirements when the affected source is infrequently operated;

(C) Alternative locations for installing CMS when the owner or operator can demonstrate that installation at alternate locations will enable accurate and representative measurements;

(D) Alternate procedures for performing daily checks of zero (low-level) and high-level drift that do not involve use of high-level gases or test cells;

(E) Alternatives to the American Society for Testing and Materials (ASTM) test methods or sampling procedures specified by any relevant standard;

(F) Alternative monitoring requirements when the effluent from a single affected source or the combined effluent from two or more affected sources is released to the atmosphere through more than one point.

(3) Status of request to use alternative monitoring method.

(A) The Administrator will notify the owner or operator of approval or intention to deny approval of the request to use an alternative monitoring method within 30 calendar days after receipt of the original request and within 30 calendar days after receipt of any supplementary information that is submitted. Before disapproving any request to use an alternative monitoring method, the Administrator will notify the applicant of the Administrator's intention to disapprove the request together with:

(i) Notice of the information and findings on which the intended disapproval is based.

(ii) Notice of opportunity for the owner or operator to present additional information to the Administrator before final action on the request. At the time the Administrator notifies the applicant of his or her intention to disapprove the request, the Administrator will specify how much time the owner or operator will have after being notified of the intended disapproval to submit the additional information.

(B) If the Administrator approves the use of an alternative monitoring method for a source, the owner or operator shall continue to use the alternative monitoring method until he or she receives approval from the Administrator to use another monitoring method.

(4) If the Administrator finds reasonable grounds to dispute the results obtained by an alternative monitoring method, requirement, or procedure, the Administrator may require the use of a specific method, requirement, or procedure. If the results of the specified and alternative method, requirement, or procedure do not agree, the results obtained by the specified method, requirement, or procedure shall prevail.

(h) Monitoring data recorded during periods of unavoidable CMS breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level adjustments shall not be included in any data average computed.

(1) A CMS is out of control if:

(A) The zero (low-level), mid-level, or high level calibration drift (CD) exceeds two times the applicable performance specification; or

(B) The CMS fails a performance test audit, relative accuracy test audit, or linearity test audit.

(i) Summary Report - Gaseous and Continuous Monitoring System Performance

The summary report shall contain the following information:

(1) The company name and address of the source;

(2) The date of the report, and the beginning and ending dates of the reporting period;

(3) A brief description of the process units;

(4) The emission and operating parameter limitations specified in the standard;

(5) The monitoring equipment manufacturer(s) and model number(s);

(6) The date of the latest CMS certification or audit;

(7) The total operating time during the reporting period;

(8) An emissions data summary, including the total duration of excess emissions during the reporting period (recorded in hours), the total duration of excess emissions expressed as a percent of the operating time during the reporting period, and a breakdown of the total duration of excess emissions during the reporting period into those that are due to startup/shutdown, control or monitoring equipment problems, process or process equipment problems, quality assurance, quality control calibrations, other known causes, and other unknown causes;

(9) A CMS performance summary, including the total CMS downtime recorded in hours, the total duration of CMS downtime expressed as a percent of the total source operating time during that reporting period, and a breakdown of the total CMS downtime during the reporting period into periods that are due to monitoring equipment malfunctions, nonmonitoring equipment malfunctions, quality assurance, quality control calibrations, other known causes, and other unknown causes;

(10) A description of any changes in CMS, processes, or controls since the last reporting period.

(11) The name, title, and signature of the responsible official who is certifying the accuracy of the report.

(j) Excess Emissions and Continuous Monitoring System Performance Report

The excess emission report shall contain the following information:

(1) The name, title, and signature of the responsible official who is certifying the accuracy of the report;

(2) The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;

(3) The date and time the identifying each period during which the CMS was out of control;

(4) The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during periods other than startups, shutdowns, and malfunctions;

(5) The specific identification (i.e. the date and time of commencement and completion) of each period of excess emissions and parameter monitoring exceedances, that occurs during startups, shutdowns, and malfunctions;

(6) The nature and cause of any malfunction if known;

(7) The corrective action taken or preventive measures adopted;

(8) The nature of the repairs or adjustments to the CMS that was inoperative or out of control;

(9) The total process operating time during the reporting period.

Appendix 2
Application for Construction or Modification

(a) General requirements.

An owner or operator shall submit to the district and Administrator an application for approval of the construction of a new affected source, or the modification of an existing source. Each application for approval of construction or modification shall include at a minimum:

(1) The applicant's name and address;

(2) A notification of intention to construct a new affected or make any modification as defined in subsection (a)(7);

(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 modification;

(6) The expected completion date of the construction or modification. Facilities undergoing modification shall provide a brief description of the components that are to be replaced;

(7) The anticipated date of (initial) startup of the source,

(8) The mixture (100%, 12/88, 8/92 etc.,) and quantity of ethylene oxide 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 ethylene oxide expected to be emitted by the source reported in units and averaging times specified in the standard. The owner or operator may submit percent reduction information. Operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance; and

(9) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis 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."

(b) Application for construction. Each application shall include technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source, including an identification of each point of emission for ethylene oxide 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 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.

(c) Application for modification. Each application shall include in addition to the information in (a) above of this section the following:

(1) A brief description of the affected source and the components that are to be replaced;

(2) A description of present and proposed emission control systems (i.e., equipment methods) that will be used to comply with the standard in Table I. The description of the equipment to be used for the control of emissions shall include 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;

(3) An estimate of the fixed capital cost of the replacements and of constructing a comparable entirely new source;

(4) The estimated life of the affected source after the replacement.

APPENDIX B

SUMMARY COMPARISON OF THE EXISTING ATCM, NESHAP, AND PROPOSED AMENDED ATCM

APPENDIX B

Summary Comparison of the Existing ATCM, NESHAP, and Proposed Amended ATCM

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM	
			Part 1 **(Small Commercial and Non-Commercial)**	**Part 2** **(Large Commercial)**
Applicability	Facility using less than 25 pounds EtO annually--reporting required. Facility using 25 pounds or more of EtO annually--emission standards and other requirements apply also.	Commercial facilities using more than 2,000 pounds per 12 consecutive months--emission standards and other requirements apply.	Facility using less than 25 pounds EtO annually--reporting required. Non-commercial facilities using 25 pounds or more EtO annually and commercial facilities using 25 or more annually but less than 2,000 pounds per 12 consecutive months--emission standards and other requirements apply also.	Commercial facilities using 2,000 pounds or more EtO per 12 consecutive months--emission standards and other requirements apply.
Emissions Standards	**Sterilizer emissions** 99% control for any facility using more than 25 but less than 600 pounds EtO annually. 99.9% control for any facility using 600 pounds or more EtO annually.	**Sterilizer emissions** No control for facilities using less than 2,000 pounds of EtO per 12 consecutive months. 99% control for commercial facilities using 2,000 pounds or more EtO per 12 consecutive months.	**Sterilizer emissions** 99% control for non-commercial and commercial facilities using more than 25 but less than 600 pounds EtO annually. 99.9% control for non-commercial and commercial facilities using 600 pounds or more EtO annually.	**Sterilizer emissions** 99.9% control for commercial facilities using 2,000 pounds or more but less than 5,000 pounds EtO per 12 consecutive months. 99.9% control for commercial facilities using 5,000 pounds or more EtO per 12 consecutive months.

APPENDIX B

Summary Comparison of the Existing ATCM, NESHAP, and Proposed Amended ATCM

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM	
			Part 1 (Small Commercial and Non-Commercial)	Part 2 (Large Commercial)
Emissions Standards (continued)	**Aerator emissions** 95% control for any facility using more than 600 but less than 5,000 pounds EtO annually. 99% control for facilities using 5,000 pounds or more EtO annually. 95% control of Aeration - only facilities using 600 pounds or more EtO annually.	**Aerator emissions** No control for facilities using less than 20,000 pounds of EtO per 12 consecutive months. 1 ppm maximum outlet concentration or 99% control for facilities using 20,000 pounds or more of EtO per 12 consecutive months. No control for aeration-only facilities using less than 20,000 pounds of EtO per 12 consecutive months. 99% control for aeration-only facilities using more than 20,000 pounds of EtO per 12 consecutive months.	**Aerator emissions** 95% control for non-commercial facilities using 600 or more but less than 5,000 pounds EtO annually. 99% control for non-commercial facilities using 5,000 or more pounds of EtO annually. 95% control for commercial facilities using 600 or more pounds EtO annually. 95% control for non-commercial and commercial aeration-only facilities.	**Aerator emissions** 95% control for commercial facilities using 2,000 pounds or more but less than 5,000 pounds EtO per 12 consecutive months. 1 ppm maximum outlet concentration or 99% control for commercial facilities using 5,000 pounds or more of EtO per 12 consecutive months. 95% control for aeration only facility using 2,000 pounds or more EtO but less than 20,000 pounds of EtO per 12 consecutive months. 99% control for aeration only facilities using 20,000 pounds or more EtO per 12 consecutive months.
Monitoring	Facilities subject to emission standards must maintain leak-free system.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must monitor key operating parameters of control equipment, such as temperature, liquid levels, etc.	Facilities subject to emission standards must maintain leak-free system.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must monitor key operating parameters of control equipment, such as temperature, liquid levels, etc.
Recordkeeping	All facilities must maintain record of EtO use.	Facilities using more than 2,000 pounds of EtO per 12 consecutive months must maintain records of EtO use, breakdown data, continuous monitoring performance report, and compliance data for five years.	All facilities maintain record of EtO use.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must maintain records of EtO use, breakdown data, continuous monitoring performance data, and compliance data for five years.

APPENDIX B

Summary Comparison of the Existing ATCM, NESHAP, and Proposed Amended ATCM

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM Part 1 (Small Commercial and Non-Commercial)	 Part 2 (Large Commercial)
Reporting	All facilities must report annual EtO use.	Facilities using more than 2,000 pounds of EtO per 12 consecutive months must submit semi-annual compliance report, annual report of EtO use, and monitoring and breakdown data.	All facilities must report annual EtO use.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must submit semi-annual compliance report, annual report of EtO use, and monitoring and breakdown data.
Testing	ARB Method 431	U. S. EPA Test Methods in 40 CFR part 60 appendix A	ARB Method 431 equivalent to U.S. EPA Method. In addition, added to ARB Method 431 a test procedure to quantify concentration of EtO in water. Added procedure for calculating mass of EtO to the control device.	ARB Method 431 equivalent to U.S. EPA Method. In addition, added to ARB Method 431 a test procedure to quantify concentration of EtO in water. Added procedure for calculating mass of EtO to the control device.

APPENDIX C

PROPOSED TEST METHOD 431, DETERMINATION OF ETHYLENE OXIDE EMISSIONS FROM STATIONARY SOURCES

California Environmental Protection Agency

Air Resources Board

PROPOSED

Method 431

Determination of Ethylene Oxide Emissions from Stationary Sources

Adopted: September 12, 1989
Amended: July 28, 1997
Amended: __________

Note: this document consists of the text of the proposed amendment to Method 431. Proposed deletions are noted by graphic screen and proposed additions are noted by underline.

Method 431 **Ethylene Oxide**

PROPERTIES:

gas at room temp
M.W.: 44.05 B.P.: 10.7 ; V.P.: 146 kPa (20 °C)
vapor density: 0.98 (air = 1); explosive range: 3% to 80+% v/v in air

SAMPLING

Actual monitoring at the inlet of control devices, where concentrations of EtO are extremely high and may even be in the explosive range, may pose a significant safety hazard. In the very recent past there have been explosions at several EtO sterilization facilities in other states. These explosions may have been associated with catalytic oxidation control devices. Due to these concerns it is strongly recommended that the estimation calculations (Appendix B) be used instead of actual monitoring measurements to determine the mass of EtO delivered to the inlet of the control unit.

The calculations described in Appendix B may be used to estimate the mass of EtO delivered to the inlet of the control device, or: the direct interface sampling and analysis procedure described in Appendix A may be used to continuously monitor ethylene oxide concentrations at the outlet (and inlet) of the control device using a gas chromatograph with flame ionization detector (GC/FID) or photo-ionization detector (PID).

OPTION: Where appropriate, integrated Tedlar bag sampling may be used to monitor the ethylene oxide concentrations. Refer to Appendix I for sampling procedures.

MEASUREMENT

TECHNIQUE:	Gas Chromatography, Flame Ionization detector (PID optional).
ANALYTE:	Ethylene Oxide (EtO)
INJECTION:	0.5 cc to 2cc; sampling loop.
TEMPERATURE:	- INJECTION: 100 cc - DETECTOR:220 cc - COLUMN: isothermal 80 °C
CARRIER GAS:	UHP Helium or Nitrogen 30 cc/minute
COLUMNS:	6 to 9 foot 1% SP-1000 on 60/80 mesh Carbopack B
CALIBRATION:	compressed gas cylinder standard,
ANALYTICAL RANGE:	0.20 ppmV to 0.50% v/v

PRINCIPLE: The mass (or concentration) of ethylene oxide delivered to a control unit (inlet) during a sterilization cycle will be estimated (i.e., calculated) using the procedures in Appendix B or measured using the sampling/analysis procedures described above. The mass (or concentration) of ethylene oxide delivered to the control unit (inlet) during an aeration cycle and the mass (or concentration) of ethylene oxide emitted from the control unit (outlet) during a sterilization or aeration cycle will be determined using the sampling/analysis procedures described above and the calculations described in Appendix F.

APPLICABILITY: This method is applicable to the measurement of ethylene oxide in emissions from hospital equipment sterilization and aeration chambers, and appropriately configured commercial sterilizers.

LIMITATIONS: Refer to Appendix H for limitations associated with Tedlar bag and direct interface sampling/analysis of ethylene oxide.

INTERFERENCES: The diluent gas (such as Freon-12, HCFC-124, or others) may interfere with the EtO peak when testing low EtO emissions concentrations. GC operating conditions should be adjusted to provide baseline resolution between EtO and any diluent gas.

REFERENCED METHODS: This method is based on the EPA rule for EtO emissions from sterilizers (December 6, 1994, CFR 40, Part 63.63, pg. 689).

Ethylene oxide METHOD: 431

REAGENTS:

1. Ethylene oxide in compressed gas cylinders at levels bracketing the sample concentrations. Sterilant diluent gas may be included in the gas mixtures at levels expected in the emission matrix.
2. Helium, 99.999%, and FID grade hydrogen and air.
3. Air, purified, to be used for dilutions, blank preparation, and standard preparation.

EQUIPMENT:

1. Gas chromatograph, flame ionization detector, integrator, and columns.
2. Sample loops .50, 1.0, and 2.0 cc.

** SPECIAL PRECAUTIONS: Ethylene Oxide is a potential carcinogen. Work should be performed in a well ventilated fume hood. For specific regulatory requirements refer to the California Labor Code, Part 10, Section 9020; Title 8, California Code of Regulations, Section 5220.

Actual monitoring at the inlet of control devises, where concentrations of EtO are extremely high and may even be in the explosive range, may pose a significant safety hazard. In the very recent past there have been explosions at several EtO sterilization facilities in other states. These explosions may have been associated with catalytic oxidation control devices. Due to these concerns it is strongly recommended that the estimation calculations (Appendix B) be used instead of actual monitoring measurements to determine the mass of EtO delivered to the inlet of the control unit.

CALIBRATION AND QUALITY CONTROL:

Refer to Appendix E for multipoint and daily calibration and quality control procedures. Refer to Appendix E for calibration procedures specific to the direct-interface gas chromatography.

LIST OF APPENDICES:

Appendix A: Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units

Appendix B: Procedures for Estimating Mass of EtO at the Control Unit Inlet

Appendix C: Testing Procedures for Aeration Chambers

APPENDIX A
TESTING PROCEDURES FOR STERILIZERS WITH CATALYTIC OXIDATION OR HYDROLYTIC SCRUBBER TYPE CONTROL UNITS

The following procedures shall be used to determine the efficiency of catalytic oxidation and hydrolytic scrubber types of control devices used in controlling emissions from an ethylene oxide sterilizer. The following aspects of the ethylene oxide compliance test are discussed below in this Appendix:

-Stack gas moisture determination.
-Stack gas volumetric flow rate determination.
-Determination of ethylene oxide concentration.

The procedures described herein are used to provide control unit inlet and outlet mass or concentration values to be used in calculating a control efficiency, as specified in the Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators (17 CCR, Section 93108). As described below, stack gas moisture and volumetric flow rate determination may not be required for many control unit configurations. In such cases the control efficiency will be based solely on the concentration reduction across the control device.

Stack Gas Moisture

For catalytic oxidation units, the atmospheric moisture dominates the resulting average moisture from the sterilization chamber humidification process and of the moisture created by the destruction of EtO. This is due to the fact that ambient air is used in great excess (normally >100:1) to dilute the chamber sterilant gas before passing across the catalyst bed. Thus the "stack" gas moisture content may be assumed to be the same as that of the ambient air. The wet/dry bulb method may be used for determination of the ambient moisture content.

For hydrolytic scrubber units, the outlet gas may be assumed to be saturated with moisture (i.e., the temperature of the outlet stream must be obtained for the calculation).

At the discretion of the Source Test Protocol reviewer the moisture content of the exhaust gas may be measured using ARB Method 4 during the evacuation and wash stages of at least one cycle (out of the three).

Stack Gas Flow Rate

If volumetric flow measurements are required, measure the volumetric flow rate of the control device exhaust continuously during the evacuation and wash cycles using the procedures found in ARB test methods 2, 2A or EPA Method 2C or 2D, as appropriate. Following are the recommended procedures for flow rate measurements for hydrolytic scrubber and catalytic oxidation type control devices.

<u>Hydrolytic scrubber type control units</u>: ARB Method 2A is required for measuring flow rates from hydrolytic scrubber type control units. It may be necessary to have multiple meters available in order to cover the expected range of flow rates. To calculate the molecular weight of the gas, assume that the composition of the sterilant gas is delivered unchanged from the chamber to the control unit and that the balance of the control unit emission gas is sterilant balance gas (if any) plus the moisture content. If there is any dilution of the sterilant gas though, the diluent gas concentration will have to be measured along with the concentration of EtO in the gas streams for volumetric flow to be calculated correctly. 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. (The purpose here is to measure flow rates concurrently with the bag samples or on-site GC). Correct the flow to standard conditions (68°F and 1 atm) and determine flow rate in units of standard cubic feet per minute for the run as outlined in the test methods listed in this paragraph.

Catalytic oxidation type control units: Volumetric flow measurements may not be necessary for compliance testing of catalytic oxidation control units. In those systems that meet the following criteria the destruction efficiency calculation can be based solely on the EtO concentration measurements (not applicable where the inlet estimation technique is used).

1. no dilution between inlet and outlet sampling locations,

2. identical flow at inlet and outlet sampling locations, and

3. constant flow throughout the duration of the compliance test.

However, volumetric flow measurements may be required by the Districts in order to determine yearly mass emissions for inventory or facility risk assessment purposes. In those cases the following procedures shall be followed. Note that flow measurements need only be obtained at one of the sampling locations, either inlet or outlet, if the above conditions are met.

CARB Method 2 (type S pitot tube) should be used to determine stack gas velocity and volumetric flow rate of stacks greater than 12 inches in diameter. Testing stacks/ducts having cross-sectional diameters less than 12 inches and equal to or greater than four inches, must be conducted according to United States Environmental Protection Agency (USEPA) Stationary Source Sampling Methods 1A and 2C. The differential pressure gauge used to measure velocity head (delta P) must meet the requirements of ARB Method 2, Section 2.2 (also USEPA Method 2, Section 2.2). Pitot tube dimensions and specifications must be demonstrated to meet the requirements of ARB Method 2, Sections 2.7 and 4.2 (also USEPA Method 2, Sections 2.7 and 4.2). The source test reports must (1) include reasonably accurate as-installed drawings of the stack from the sterilizer to the point of emission, and (2) identify sampling locations, including dimensions, for each facility. Volumetric flow measurements will be conducted in the following manner: 1. A complete velocity traverse of the exhaust duct will be conducted in a manner consistent with applicable ARB or USEPA reference methods for flow determinations. 2. An average velocity pressure will be calculated from the individual pressure measurements made at each velocity traverse point as specified in the ARB/EPA reference method. 3. A traverse point, where the measured velocity pressure corresponds to the calculated average pressure, will be used to make single point pressure measurements during direct sampling and analysis of EtO emission. 4. Velocity pressure measurements will be made concurrently with each direct sample drawn out of the exhaust duct for analysis. The emissions flow rate will be determined from the set of pressure measurements made at the single traverse point and compared to the flow rate calculated from the initial, "complete" flow rate measurement procedure. The two flow rates must compare within 10% for the test run to be valid.

Typical cat-ox units operate at 50 and 100 scfm. The exhaust ducting of a typical control unit is 4 to 6 inches and occasionally up to 10 inches in diameter. The larger size ducting gives very low linear gas velocities (e.g., less than 10 ft/sec.) which are difficult to measure using standard pitot tube/manometer techniques. A practical solution is to reduce the diameter of the oversize stack to a temporary 4 inch stack during the test. Also, because low flow/low velocity pressure conditions are anticipated for the exhaust duct emissions from some control units, use of a pressure transducer whose sensitivity is applicable for low magnitude pressure measurements and whose performance is traceable to a National Institute of Standards and Technology (NIST) reference standard is acceptable. Calibrations of the pressure transducer must be routinely conducted and calibration curves maintained in the company's file.

Determination of Ethylene Oxide Concentration at the Inlet of Control Units

Actual monitoring at the inlet of control devices, where concentrations of EtO are extremely high and may even be in the explosive range, may pose a significant safety hazard. In the very recent past there have been explosions at several EtO sterilization facilities in other states. These explosions may have been associated with catalytic oxidation control devices. Due to these concerns it is strongly recommended that the estimation calculations (Appendix B) be used instead of actual monitoring measurements to determine the mass of EtO delivered to the inlet of the control unit.

Two options are provided, as outlined below, for determination of the mass of ethylene oxide delivered to the control unit inlet.

Option 1, Inlet Estimation: (sterilization cycle only, cannot be used for aeration tests) The mass of ethylene oxide emitted from the sterilization chamber and delivered to the control unit inlet, during a sterilization cycle, may be calculated using the estimation technique detailed in Appendix B. The procedures shall be performed, on an empty sterilizer, for the duration of the post-evacuation/wash stages under normal operating conditions. A short "soak" (exposure) stage, e.g., manually aborted after no more than ten minutes, should be used to minimize leak and chamber losses. For those sterilization systems where sterilant gas is also added as "make-up" during the exposure stage, the cycle shall be aborted and the chamber exhausted before such "make-up". The use of the inlet estimation technique is not allowed for sterilizer systems using water ring seal pumps (flow through or recirculating) for chamber evacuations. All test conditions must be characterized and reported with the final test results.

Option 2, Inlet Measurement: (must be used for aeration tests)
The mass of ethylene oxide emitted from the sterilization or aeration chamber and delivered to the control unit inlet may be determined by monitoring the chamber exhaust volumetric flow rate and EtO concentration (as described in the Measurement Methods section below) at the control unit inlet. If using this inlet measurement procedure, only the "entire duration of the first evacuation", as defined by the ATCM, must be tested for compliance purposes. The inlet and outlet of the control unit must be tested simultaneously. A loaded chamber must be used when performing compliance tests of sterilization cycles if using this inlet measurement option. If the chamber load is to be used for compliance testing of an aeration run, the "soak" (or exposure) stage may not be shortened, e.g., manually aborted. This inlet measurement procedure must be used for compliance testing of aeration cycles. All test conditions must be characterized and reported with the final test results.

Measurement Methods

The mass of ethylene oxide delivered to the control unit inlet during an aeration cycle and the mass of ethylene oxide emitted from the control unit outlet during a sterilization or aeration cycle must be determined by using one of the following sampling/analysis procedures and the calculations found in Appendix F. For catalytic oxidation control units, if the mass of EtO at the inlet is measured rather than estimated, testers must report documented evidence that the inlet probe is placed such that the sampled gases are completely mixed (i.e., chamber exhaust and ambient make-up). This documentation may be obtained by following the steps outlined in Appendix D.

<u>Tedlar bag sampling/analysis procedure:</u> The Tedlar bag sampling procedure specified in Appendix I may be used to collect samples of sterilizer/aerator and control unit exhaust gas for subsequent analysis by GC/FID. The sampling quality assurance procedures detailed in Appendix I must be followed. In addition, the following procedures must be followed.

If Option 1, Inlet Estimation, is used then the entire 1st evacuation and wash period must be monitored for EtO emissions at the outlet of a control system. Sampling will be initiated for the first evacuation when the pressure in the sterilizer is released.

If Option 2, Inlet Measurement, is performed then the inlet and outlet monitoring will be conducted simultaneously. Sampling will be initiated for the first evacuation when the pressure in the sterilizer is released.

ARB staff recommends that one of the test personnel monitor the sterilizer chamber pressure during the run and communicate, with walkie-talkies, the sampling start and stop times to the sampling test crew.

Excess EtO shall be bubbled through a sulfuric acid (1 N solution) impinger before discharge, or alternatively can be routed back into the control unit inlet gas stream. Ensure that the excess sample gas which has passed through the acid filled impinger is discharged to a safe location and will not imperil test personnel.

The Tedlar bag samples must be analyzed within 24 <u>8</u> hours (of the sample stop time) by the procedures listed herein. The mass of EtO associated with each bag sampling interval is calculated as outlined in Appendix F.

Repeat the procedures three times (three cycles). The arithmetic average percent efficiency (see Appendix F: Calculations) of the three runs shall determine the overall efficiency of the control device.

<u>Direct Interface Sampling Analysis:</u> As an alternative to the Tedlar bag sampling procedure described above, a gas chromatograph (with FID or PID) interfaced directly to the emission source may be used to continuously monitor ethylene oxide concentration at the outlet (and inlet) of the control device. For catalytic oxidation type control units, this procedure shall only be used if the sampling frequency is less than 2 minutes. For hydrolytic scrubber units, this procedure shall only be used if the sampling frequency is less than 1 minute. In addition, the following procedures must be followed.

If Option 1, Inlet Estimation, is used then the entire 1st evacuation and wash period must be monitored for EtO emissions at the outlet of a control system. Sampling will be initiated for the first evacuation when the pressure in the sterilizer is released.

If Option 2, Inlet Measurement, is performed then the inlet and outlet monitoring will be conducted simultaneously. For cat-ox control units, direct GC sampling will be conducted for at least the duration of the entire 1st evacuation. For acid scrubber control systems, sampling will be conducted during the 1st evacuation and for the duration of any additional evacuation/wash periods (up to the point where aeration begins). Sampling will be initiated for the first evacuation when the pressure in the sterilizer is released.

ARB staff recommends that one of the test personnel monitor the sterilizer chamber pressure during the run and communicate, with walkie-talkies, the sampling start and stop times to the sampling test crew.

When testing 3M sterilizer systems, or other systems with pulsed chamber exhaust, if the inlet mass is measured using the direct-GC approach, testers must use a one liter Greenburg-Smith impinger (empty) in the GC sampling train. The impinger shall be placed between the catalyst bed control unit and the on-site GC. This impinger will be connected by a Teflon line (less than 2 feet) to the catalyst bed's inlet sample port and by a Teflon line (less than 1 foot) to the heated sample line to the GC analyzer. The insertion of this impinger into the sample train will function as a mixing chamber for the sampled sterilizer exhaust gas prior to introduction into the GC analyzer. Sterilizers with pulsed exhaust will be continuously sampled through the modified sample train. The impinger geometry will mix the sampled gas and "smooth out" the variable concentrations associated with the pulsed exhaust gas flow. The impinger must be included in the system leak check, field blank and field spike.

The sample train is leak checked by plugging the sample line at the stack end and running the sample pump. Flow indicated by the rotameter should fall to zero. If it does not, seek and correct loose connections and other potential sources of leakage, then repeat the leak check.

Maintain a constant flow rate of approximately 2 liters per minute through the sample probe and transfer lines. If the sample transfer line is more than 10 feet long it should be heated to approximately 150 °F.

Excess EtO shall be bubbled through a sulfuric acid (1 N solution) impinger before discharge, or alternatively, route the excess gas back into the control unit inlet gas stream. Ensure that the excess sample gas which has passed through the acid filled impinger is discharged to a safe location and will not imperil test personnel.

Repeat the procedures three times (three cycles). The arithmetic average percent efficiency (see Appendix F: Calculations) of the three runs shall determine the overall efficiency of the control device.

APPENDIX B

PROCEDURES FOR ESTIMATING MASS OF ETO AT THE INLET

The amount of ethylene oxide, in pounds, loaded into the sterilizer shall be determined by one of the following three procedures. These estimation procedures are valid only if there are no significant leaks or loss of EtO before the control unit. These estimation procedures shall be performed using an empty sterilization chamber. A short exposure stage, e.g., manually aborted, should be used to minimize leak and chamber losses. For those sterilization systems where sterilant gas is also added as "make-up" during the exposure stage, the cycle shall be aborted and the chamber exhausted before such "make-up". These estimation procedures may not be used with sterilization systems using recirculating water ring seal pumps for evacuation of the chamber if the "correction" procedures outlineded in section 4 below are followed. Use of flow through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO ATCM.

1) For small sterilizer operations using disposable sterilant cartridges, weigh the cartridge to the nearest .5 gram before and after use. Multiply the total mass of gas charged by the weight percent ethylene oxide present in the sterilant mixture. Alternatively, if the cartridge supplier has certified the weight of EtO contained in the cartridge then this weight may be used for the estimation calculation. Or,

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

3) Calculating the mass based on the conditions of the chamber immediately after it has been charged and using the following equation. A calibrated differential pressure gauge shall be used to monitor the chamber pressure.

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

where:

W_c = weight of ethylene oxide charged to the chamber, in pounds (grams)

MW = Molecular weight of ethylene oxide, 44.05 lb/mol (gr/gr-mole)

M = mole fraction of ethylene oxide

P = chamber pressure, psia (atm)

V = chamber volume, ft^3 (L)

R = gas constant, 10.73 $(psia*ft)^3/(mol*°R)$ ((.08205 L*atm)/(g-mole*°K))

T = temperature, °R (°K)

S = standard conditions are 68°F (°R or °K) and 1 atm.

4. For sterilization systems using a recirculating water ring seal pump to evacuate the chamber after the exposure stage (primary evacuation) a correction must be applied to the estimated inlet EtO mass. The amount of EtO retained in the pump water resorvoir must be subtracted from the amount calculated by the above techniques. Follow the procedures specified in Appendix L to collect 2 aliquot water samples from the resorvoir immediately before and after the sterilizer exhaust compliance test (i.e., water sampling times must directly correspond to start and stop times of the exhaust test). The pump resorvoir may need to be fitted with a sampling port for this purpose. Determine the volume of water in the resorvoir both before and after the exhaust test. Analyze the samples as per Appendix L and calculate the mass of EtO retained in the water, and the corrected inlet EtO mass, using the calculations shown below.

$$W_{cc} \equiv W_c - W_w$$

where:

W_{cc} ≡ weight of ethylene oxide charged to the chamber and delivered to the control unit, corrected for EtO loss to the water, in pounds (grams)

W_w ≡ weight of ethylene oxide retained in the pump resorvoir water, in pounds (grams)

where:

$$W_w \equiv (EtO_{after})(Vol_{after}) - (EtO_{before})(Vol_{before})$$

Where:

EtO_{after} ≡ concentration of EtO in the pump resorvoir water after the exhaust test

EtO_{before} ≡ concentration of EtO in the pump resorvoir water before the exhaust test

Vol_{after} ≡ volume of water in the resorvoir after the exhaust test

Vol_{before} ≡ volume of water in the resorvoir after the exhaust test

APPENDIX C

TESTING PROCEDURES FOR AERATION ROOMS

The following procedures shall be used to determine the efficiency of a control device used to control ethylene oxide emissions from an aeration room. An aeration room is defined as any facility used for the dissipation of ethylene oxide residue from equipment previously sterilized in a sterilizer. The procedures are identical to those used to test sterilization chamber/control units (Appendix A) with the exception of the following.

The test shall be performed by placing a normal load of previously-sterilized equipment into the aeration room. The exposure stage cannot be shortened or aborted.

The measurement procedures in Appendix A shall be used to determine the volumetric flow rate and EtO concentration at the inlet and outlet of the control device. (The inlet estimation technique cannot be used.)

If using the direct GC sampling and analysis procedure, sample and analyze a slipstream of the outlet concentration of EtO once every 3 minutes continuously for 1 hour.

The emissions test shall be conducted in the hour immediately following the loading of the aeration room. The test shall consist of one aeration cycle run. The test engineer and/or test administrator shall insure that the aeration room is being tested under normal operating conditions and equipment load. These conditions shall be documented and reported with the final test results.

Testers must have documented evidence that the inlet probe is placed such that the sampled gases are completely mixed (i.e., chamber exhaust and make-up air). Procedures for insuring the correct probe position are listed in Appendix D. This documentation shall be reported along with the test final results.

APPENDIX D

DOCUMENTATION OF INLET PROBE POSITION FOR CATALYTIC OXIDATION UNITS

For catalytic oxidation control units, if the mass of EtO at the inlet is measured rather than estimated, testers must report documented evidence that the inlet probe is placed such that the sampled gases are completely mixed (i.e., chamber exhaust and ambient make-up). This documentation may be obtained by the following steps:

1. Install the sampling probe in the control unit inlet.
2. During a sterilizer chamber evacuation monitor the volumetric flow rate of the control unit exhaust. Also monitor the concentration of ethylene oxide, using the procedures outlined below, at the control unit inlet (e.g., after dilution in the control unit). Monitor both the flow rate and EtO concentration for the duration of the sterilization chamber exhaust (first evacuation and following washes).
3. Calculate the total amount of EtO delivered to the control unit. These calculations are outlined in Appendix F.
4. Calculate the estimated amount of EtO delivered to the control unit by following the procedures in Appendix B.
5. Perform the above operations 3 times.
6. The concentration of EtO measured at the control unit inlet must be within 10 % of the estimated amount for the probe to be documented as correctly positioned.

The above test must be performed every time the probe is replaced or moved. The documentation showing correct positioning of the inlet probe must be included in the test report.

APPENDIX E

CALIBRATION AND QUALITY CONTROL PROCEDURES FOR ANALYSIS

1 INTRODUCTION

Each laboratory that uses this procedure is required to operate a formal quality control program. The minimum quality control requirements of this program consists of an initial demonstration of laboratory capability and an ongoing program of routine calibration and analysis of performance check samples to evaluate and document data quality. Two options are provided for routine calibration; calculation by linear regression or average response factor. The laboratory must maintain records of all performance checks to document the quality of generated data.

2 APPARATUS

2.1 Flowmeter, 100 sccm.

2.2 Tedlar bags, 10 L.

3 REAGENTS

3.1 Calibration standards can be obtained commercially in specially treated compressed gas cylinders. Concentrations of the minor components in each mixture must be traceable to the National Institute of Standards & Technology (NIST) or to a national measurement system approved by the Executive Officer of the Air Resources Board. NIST traceability may be accomplished by the specialty gas vendor via several methods:

(1) By analyzing the gas mixture directly against a NIST Standard Reference Material (SRM). This alternative can be utilized when an SRM with the proper component is available and the concentration is within a factor of two (2) from the gas mixture concentration.

(2) If SRMs are not available, analyzing the gas mixture against well characterized Gas Manufacturer Primary Standards (GMPS). These GMPS mixtures are analyzed against internal laboratory standards, gravimetric or volumetric, traceable to NIST.

4 INITIAL PERFORMANCE DEMONSTRATION

The following steps must be followed before the analytical method may be used. The performance evaluation must be repeated at least every six months. NOTE: Two options are provided for daily calibration (see Section 5). If response factor method (5.2) is used, both Option 1 and 2 (4.1.2 and 4.1.4) must be conducted during initial performance evaluation. Peak area integration, and not peak heights, must be used for the determination of instrument response.

4.1 Multipoint calibration

4.1.1 Standards are analyzed at least three times at four different concentrations. The concentration levels should be five times the limit of detection on the low end, approximately midway in the linear response range of the method, and near the high concentration end of the linear response limit. Results of the multipoint analyses must be documented and shall include data on intercept, slope, correlation of fit, relative standard deviations, range of concentrations tested, response factor and limit of detection calculations.

4.1.2 Option 1, Least Squares Fit. The least squares analysis of the data should produce a correlation coefficient of at least 0.99. Blank values shall not be subtracted from the raw data and the origin (0.0, 0.0) will not be used in the calculations. If the intercept deviates significantly from zero, the analysis must be reviewed for possible system contamination or other problems.

4.1.3 Standard deviation of the GC responses (area counts) are calculated at each level of the multipoint and must be included in the analytical report.

4.1.4 Option 2, Response Factor. For each calibration target compound, calculate the pooled mean response factor (RF) from the set of four multipoint levels. Calculate the standard deviation and the percent relative standard deviation. The laboratory must demonstrate that RF values over the working range for the target compounds are constant. The percent relative standard deviations of the mean RF's must not exceed 15%. The equation for calculating the pooled mean response factor is listed below.

$$Rf_{pooled} = (RF_{1a} + RF_{1b} + RF_{1c} + RF_{2a} + \ldots\ldots RF_{4b} + RF_{4c}) / 12$$

where 1a through 4c represent the individual response factors calculated from the 12 multipoint runs.

4.1.5 Analytical Limits of Detection (LOD) must be calculated. The LOD for each method must be calculated by the following equation:

$$LOD = |A| + 3S$$

where:

A is the least squares x-intercept, in units of ppmV, calculated from the multipoint data (section 4.1.1).

S is the standard deviation of replicate determinations of the lowest standard, in units of ppmV, calculated from the multipoint data by the following equation:

$$S = (Y - b) / m$$

Where:

Y = the standard deviation of the GC response, in area counts, of replicate determinations of the lowest standard.

b = the least squares Y intercept

m = the least squares slope

At least 3 replicates are required. The lowest standard must be run at 1 to 5 times the estimated detection limit. If data is not available in the concentration range near the detection limit, S may be estimated by:

$$S = RSD \times A$$

where RSD is the relative deviation of the lowest standard analyzed.

4.1.6 The Limit of Quantitation (LOQ) must be calculated by the following equation:

$$LOQ = 3.3 \times LOD$$

No analysis results will be reported below the LOQ.

5 ROUTINE CALIBRATION PROCEDURE

Routine users of the method will use one of the following options for calibrations and result calculations. Compound concentrations used in the calibration curves must bracket levels found in stationary source emission samples. Peak area integration, and not peak height, must be used for determination of instrument response.

5.1 Option 1, Least Squares Fit

A least squares fit, i.e. as determined with the initial multipoint calibration, must be used for sample quantitative calculations. A calibration check must be performed every ten hours, or every ten sample analyses, whichever is more frequent. Use the midpoint calibration as a check. The GC response must be within 10% of the mean values established in the multipoint calibration or a new calibration curve must be prepared. The GC responses are recorded and inspected to check for trends which indicate the degradation of standards or instrument performance.

5.2 Option 2, Response Factor

The average response factors, i.e. as determined with the multipoint calibration, must be used for sample quantitative calculations. A calibration check must be performed every ten hours, or every ten sample analyses, whichever is more frequent. Use the midpoint calibration (see section 4.1) as a check. The measured RFs must be within 10% of the mean values established in the multipoint calibration or a new calibration curve must be prepared. The response factors are recorded and inspected to check for trends which indicate the degradation of standards or instrument performance.

For non-routine users of the method, ie. 1 test per month or less, calibration involves generation of at least a 3 point curve during each analysis day and a midpoint calibration check after every 10 samples. Either linear regression or mean response factor calculations can be used. The initial performance evaluation is still required.

6 ROUTINE QUALITY CONTROL

6.1 Laboratory Blanks

A laboratory method blank is a volume of ultra high purity gas carried through the entire analytical scheme. The gas used for blank runs should be certified by the gas supplier or laboratory to contain less than the analytical limit of detection (LOD) of the analytes of interest. The laboratory blank volume must be equal to the sample volumes being processed. Laboratory blanks are analyzed each shift before the analysis of samples may proceed. A blank is also analyzed after the analysis of a sample containing components with concentrations greater than the most concentrated standard used. The laboratory blank results will be reported along with raw sample data in final reports. Sample results should not be corrected for blank contribution. Note that a field blank analysis may be used in place of the laboratory blank. However, if the results of the field blank are greater than LOQ, a laboratory blank will be run to isolate the source of contamination.

6.2 Laboratory Replicate Samples

Replicates serve to measure the precision of an analysis. Ten percent of all samples, or at least one sample per batch, will be analyzed in duplicate to indicate reproducibility of the analysis and to monitor such conditions as instrument drift. The precision ($(|\text{Ave.} - X_1|/\text{Ave.}) \times 100$) of duplicate analyses must fall within predetermined limits, i.e, 3 x RSD as established during the initial performance evaluation.

6.3 Calibration Check Sample

The midpoint standard used in multipoint calibrations must be analyzed every eight hours, or every ten samples, whichever is more frequent, to check instrument performance. The GC response of all analytes must be within 10 % of the mean values established in the multipoint calibration or a new calibration curve must be generated. The GC responses are recorded and inspected to check for trends which indicate the degradation of standards or instrument performance.

6.4 Performance Evaluation Samples

To demonstrate data quality, performance evaluation samples may be analyzed periodically. At the discretion of the Executive Officer, periodic analysis of performance evaluation samples may be required. If analysis of performance evaluation samples is required by the Executive Officer, the analyses shall be conducted in the following manner. The performance evaluation material shall be used to evaluate both sampling and analytical systems. Performance evaluation samples shall be analyzed at a frequency dependent on how often the method is used. If the method is used on a daily basis, the performance evaluation sample must be analyzed twice a month. If the method is used less frequently, the performance evaluation sample must be analyzed once a month or whenever the method is used (whichever is less). A value of ±10% of the stated concentration of the performance evaluation sample must be recovered for the analyte of interest. The results of these analyses must also be recorded and placed on permanent file for at least three years and shall be made available to the Executive Officer upon request. All performance evaluation samples will be labeled with an expiration date and may be re-certified by the vendor if they contain sufficient volume (i.e. greater then 60% residual).

6.5 Qualitative Analysis Criteria

The retention time of the target compound must be within 0.06 RRT units of the standard RRT.

6.6 Quantitation Criteria

The column resolution criteria of 20% valley (as measured from the baseline to valley minimum) between a target compound and an interfering compound must be achieved before any quantitation can be allowed. When a compound interferes with the target compound and the degree of the interferences exceeds the column resolution criteria the compound can still be quantified if the following criteria is met. Set the reporting limit for the lowest amount that can be quantified high enough such that the interfering compound accounts for less than 10% of the area of the target compound.

7 ANALYTICAL REPORTING REQUIREMENTS

Each report of analyses shall be in the following format and will include the following information. Refer to Appendix F for result calculations format.

7.1 Complete identification of the samples analyzed (sample numbers and source). Pertinent information should be submitted to the analytical laboratory via a chain of custody record.

7.2 Date of submittal of the sample, date and time of GC analysis. The latter should appear on each chromatogram included with the report.

7.3 The raw and calculated data which are reported for the actual samples will also be reported for the duplicate analyses, laboratory and field blank analyses, the field spike sample analyses, and any other QA or performance evaluation samples analyzed in conjunction with the actual sample set(s).

7.4 The calibration data, including average response factors calculated from the calibration procedure described in Section 5. Include the relative standard deviation, and data showing that the midpoint response factors have been verified at least once during each 10-hour period of operation or with each separate set of samples analyzed.

7.5 All relevant data used to define the reporting limit will be reported. This will include parameters such as sampling volumes, sample injection volume, chromatographic interferences, and Tedlar bag contamination levels. In no case will results be reported below the established reporting limit. Test reports should include a table summarizing reporting limits (per sample) including a description of causes of variation.

8 DIRECT SAMPLING CALIBRATION AND QUALITY CONTROL PROCEDURES

Due to the nature of direct sampling, routine calibration procedures are somewhat different. The sequence of in-field calibration, quality control, and sample runs listed below is recommended when performing on-site analyses.

1. Run a 3 point calibration (triplicate runs at three levels) bracketing the expected sample concentration before each compliance test. The calibration curve prepared from the averages shall be used for quantitation of the cycle samples as well as determination of the limit of quantitation.

2. Run a field blank, through the entire sampling train, using zero air (ambient air normally can be used for this purpose for ethylene oxide sampling).
3. Run a field spike, through the entire sampling train, using the calibration standard closest to the sample concentrations. The spike gas introduced at the transfer line inlet should be at ambient pressure.
4. Analyze the field samples.
5. Run standard checks after sample analyses are complete for each cycle test. Standard check results must be within 10% of the pretest average values.

APPENDIX F

CALCULATIONS

For all of the monitoring options listed below the procedures and calculations will be repeated three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

For Tedlar Bag Sampling: Calculate the mass of EtO emitted from the control unit during each bag sampling period by using the following equation. Throughout the calculations, sufficient significant figures will be carried to round off to the required destruction efficiency. For example, if the rule requires 99.9% destruction efficiency, the calculations will be carried to 4 significant figures with the result rounded to 3 significant figures.

$$W_b = C \times V \times 44.05 \text{ lb/mol} \times \text{mol}/385.32\text{scf} \times 1/10^6$$

where:

W_b = the mass of EtO emitted corresponding to each bag

C = concentration of EtO in ppm

V = volume of gas exiting the control device corresponding to each bag sample, ft^3. The volume is determined by integration of the area under the curve of volumetric flow rate (corrected) versus time for the period each bag was sampled.

Add the mass corresponding to each bag, W_b, (i.e., mass emitted during the 1st evacuation plus the mass emitted during washes) used during the evacuation for the total mass (W_o).

$$W_o = (\text{Sum})W_b$$

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

$$\% \text{ Eff.} = (W_i - W_o)/W_i \times 100$$

where:

W_i = the total mass of EtO delivered to the control unit; this value can either be estimated using the procedures in Appendix ~~A~~ B or measured using the procedures in Appendix ~~B~~ A along with the calculations listed above (for W_i). Note that where appropriate, as described in Appendix A, the mass values in the control efficiency equation may be replaced with the corresponding EtO concentration averages.

For Direct GC Sampling: If the direct GC approach is used, instead of Tedlar bag sampling, plot a concentration versus time curve. Calculate the mass flow at each sampling interval ($\leq$ 2 minutes for catalytic oxidation units, $\leq$ 1 minute for hydrolytic scrubbers) by selecting the concentration, C, and volumetric flow rate, F_v, at each interval. (Concentration and flow measurements must be synchronized.) Use the following equation to determine the mass flow rate W_t of EtO exiting the control device.

$$W_t = C \times F_v \times 44.05 \text{ lb/mol} \times \text{mol}/385.32 \text{ scfm} \times 1/10^6$$

where:

C = EtO conc (ppm)
F_v = flow (scfm)
44.05 = molecular weight of EtO lb/lb-mole (g/g-mole)
385.32 = 359 scf/mole ideal gas law constant corrected to 68° F and 1 atm. (24.054 l/mole at 68° F).

Plot a curve of mass flow rate versus time and integrate for total mass of EtO for the control device outlet (W_o) (or inlet W_i). Use the equation listed above for sterilizer control device efficiency calculation.

Repeat the procedures and calculations three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

APPENDIX G

REPORTING REQUIREMENTS

The following outline of reporting requirements is meant to be used as a general guide for EtO source test report reviewing purposes.

Sterilizer: manufacturer and model number, volume of the chamber, the type of sterilant gas used, the type of materials sterilized, a cycle process diagram, e.g., a plot of chamber pressure vs. time including footnotes regarding start and stop points of cycle stages and including a detailed explanation of the evacuation flow discharge path (water and vapor) during all stages of the cycle. If pressure/volume calculations are used to determine the weight of EtO charged to the chamber then chamber pressure sensor calibration data shall be included in the report.

Control Unit: type of chamber evacuation pumps used, type of control unit, manufacturer and model number, the size or capacity of the control unit, the operating temperature, a diagram of the control unit and sampling locations. If monitoring is conducted at the inlet of a catalytic oxidation unit then the test report shall include documentation of the correct positioning of the inlet sampling probe.

Test Data: plots of volumetric flow rate versus time (the reviewer should determine whether integrated sampling is appropriate), results of moisture determinations, a plot of the multipoint calibrations used for quantitative calculations, calculations for limit of detection and reporting limits, tables of raw data, final results, and all chromatograms (refer to Appendix E, section 7 of this document for more detailed "Analytical Reporting Requirements"). If the direct GC approach is used then plots of EtO concentration vs. time should be included in the report along with the integrated total mass emission result.

Quality Control: The test report shall include complete identification of the samples analyzed (sample numbers and source), date of submittal of the sample, date and time of GC analysis. The raw and calculated data which are reported for the actual samples will also be reported for the duplicate analyses, laboratory and field blank analyses, the field spike sample analyses, and any other QA or performance evaluation samples analyzed in conjunction with the actual sample set(s).

APPENDIX H

METHOD LIMITATIONS

Alternative sampling and analytical methodologies that are demonstrated to be substantially equivalent may be used if approved by the Executive Officer. The term Executive Officer as used in this document shall mean the Executive Officer of the Air Resources Board or his or her authorized representative. The Executive Officer may require the submission of test data or other information showing that the alternate method is equivalent to Method 431. Any modifications to the sampling and analytical procedures described must also be approved in writing by the Executive Officer.

Tedlar Bag Sampling

Tedlar bag samples must be analyzed within 24 8 hours of end of the sampling period.

Tedlar bags with fittings other than those listed may not be suitable for EtO sampling. The appropriate recovery and stability tests should be conducted before using other fitting types (especially for bags with stainless steel fittings).

CARB staff have not conducted bag stability studies for EtO in dilute-acid hydrolytic scrubber emissions.

The integrated Tedlar bag sampling procedure is not applicable for testing of sources where both the emission gas volumetric flow rate and target compound concentration are variable. The test engineer and/or the reviewing agency will determine whether integrated sampling is appropriate.

Ethylene oxide may decay if exposed to sunlight. Thus, Tedlar bag samples and standards should be protected from sunlight exposure.

On-Site GC

At many hospitals, the control unit is not accessible from parking areas (i.e., with 150 foot heated lines to a parked GC-van). Thus, the GC, gas cylinders and associated support equipment must be physically moved to a location near the control unit, which may prove inconvenient. Also, adequate power may be difficult to get at some facilities. In addition to the equipment required, performance of on-site GC requires that an experienced chemist be involved in the field operations.

Inlet Estimation

The inlet estimation procedure assumes that there is no loss of EtO to the chamber, chamber contents, transfer plumbing or pumps and that there are no leaks before the control unit.

Use of the inlet estimation technique assumes that the composition of the sterilant gas is accurately defined and consistent in individual cylinders/cartridges. Thus, at the discretion of the District, a sample from the gas cylinder(s) used during the test may be analyzed to verify the exact sterilant gas composition for the inlet estimation.

Accurate estimates rely on accurate volume measurements and calibrated pressure gauges. Thus, manufacturer's chamber volume specifications should always be double checked and system pressure monitoring devices should be evaluated for accuracy.

Some sterilization systems add sterilant gas as needed to the chamber during the exposure stage because the chamber pressure may decrease slightly after initial pressurization. This addition of make-up gas would, if significant, invalidate the inlet estimation calculation since with existing systems it would be quite difficult to estimate the amount of make-up gas added. To minimize this source of error, when using the inlet estimation technique, the test should be conducted with an empty chamber and the exposure stage should be aborted after no more than 10 minutes.

Since the estimation technique can only be used for empty chamber tests, an exposed chamber load will not be available if subsequent aeration tests are to be performed. There must be an exposed load in the aerator for a valid test. Thus, an additional sterilization cycle with unaborted exposure stage would have to be run to provide the materials to be aerated. Furthermore, the inlet EtO concentrations must be physically measured with Tedlar bags or direct GC for aeration tests since estimation is not possible. Thus, where aeration tests must be conducted in addition to sterilizer tests, inlet estimation may not provide any time or cost benefit.

The inlet estimation technique should not be used with sterilization systems using water ring seal pumps, either flow through or recirculating.

Acid Scrubber

The stability of ethylene oxide in hydrolytic scrubber unit emission matrix, in Tedlar bags, has not yet been demonstrated (by ARB staff). Stability studies for ethylene oxide in this matrix should be conducted and results included in the test report.

This method allows the option to measure inlet concentrations (e.g., with bag sampling or by direct GC) instead of using the estimation technique outlined in Appendix B. However, the concentration of EtO at the inlet of hydrolytic scrubber units will be approximately 27% and 100% by volume for systems using 12/88 and 100% EtO sterilant gases, respectively. Due to the safety concerns associated with the high inlet EtO concentrations, it is recommended to use the calculation procedure in Appendix B. Anyone conducting tests at the inlet of a hydrolytic scrubber should use extreme caution to avoid exposure to personnel and explosions.

The direct interface option may only be used to test hydrolytic scrubber units (inlet or outlet) if sample frequencies are 1 minute or less.

Quantitation of the diluent gas may be necessary at facilities using a sterilant mixture in order to calculate corrected volumetric flow rate.

Catalytic Oxidation

If the control unit inlet total mass is measured rather than estimated, testers must have documented evidence that the inlet probe is placed such that the sampled gases are completely mixed, i.e., chamber exhaust and make-up air (refer to Appendix D). This documentation shall be reported along with the test final results.

When testing 3M sterilizer systems, or other systems with pulsed chamber exhaust, if the inlet mass is measured using the direct-GC approach, testers must use a one liter Greenburg-Smith impinger (empty) in the GC sampling train. The insertion of this impinger into the sample train will function as a mixing chamber for the sampled sterilizer exhaust gas prior to introduction into the GC analyzer.

The direct interface option shall only be used to test catalytic oxidation units (inlet or outlet) if sample frequencies are 2 minutes or less.

Many sterilization systems use recirculating water ring seal pumps to evacuate the chamber. Some EtO will be retained in the water as the sterilant gas passes through the pump. Depending on system design, recirculating water ring seal pumps can cause a shift in EtO emission from the initial chamber purge to the air washes and even into the aeration cycle. Because of this emission shift, the inlet estimation technique ~~should not~~ may only be used with systems using water ring seal pumps if the "correction" outlined in Appendix B is applied. Use of flow through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO ATCM.

Testers have speculated that EtO concentrations may, in some cases, be stratified in the exhaust duct flow from catalytic oxidation control units. Further investigation is necessary to define this problem. However, if stratification does occur, some sort of sample averaging probe would be required to obtain valid test results.

APPENDIX I

STANDARD OPERATING PROCEDURE FOR THE SAMPLING OF ETHYLENE OXIDE EMISSIONS FROM STATIONARY SOURCES INTO TEDLAR BAGS

INTRODUCTION

This method should not be attempted by persons unfamiliar with source sampling, as there are many details that are beyond the scope of this presentation. Care must be exercised to prevent exposure of sampling personnel to hazardous emissions.

1 APPLICABILITY

This sampling method uses a Tedlar bag to collect ethylene oxide (EtO) samples from applicable source emissions.

2 LIMITATIONS

2.1 Refer to Appendix H.

3 EQUIVALENCY

Alternative sampling methodologies that are demonstrated to be substantially equivalent may be used if approved by the Executive Officer or his or her authorized representative. The Executive Officer may require the submission of test data or other information showing the alternate method is equivalent to Method 431.

4 APPARATUS

Apparatus required for sampling is described below. It is recommended that all equipment which comes in contact with sampled gas be made of Teflon or Tedlar unless these materials are found unsatisfactory and other materials demonstrated suitable in specific situations.

4.1 Sample line. Teflon tubing, 6.4 mm (1/4 inch) outside diameter, of minimum length sufficient to connect the probe to bag and not longer than 10 feet. If the sample line must be longer than 10 feet, then the sample line shall be heated and insulated and capable of operation at above 100 °C (212°F).

4.2 Teflon valves or fittings shall be used to connect sample train components. Mininert Teflon valves are recommended.

4.3 Sample bags. Bags shall be made of Tedlar film, at least 0.002 in. thick.

4.3.1 Mininert Teflon valves are recommended.

4.3.2 Refer to Section 7 for this Appendix for apparatus used in Tedlar bag manufacture, cleaning, and contamination testing.

4.4 Rigid container(s) for filling sample bags by application of vacuum.

4.4.1 The container shall be airtight when sealed.

4.4.2 The container shall be opaque except that a small window to check the condition of the bag within is permissible.

4.4.3 The container shall be fitted with couplings to mate with sample bags, sample line and vacuum line and a flow control valve capable of shutting off flow to the bag.

4.4.4 Sample bags may be fabricated with rigid containers as an integral unit.

4.4.5 An appropriate vacuum relief valve is suggested to protect bags and rigid container.

4.5 Pump, leak free, with capacity of at least 2 liters per minute.

4.6 Flow meter, rotameter type or equivalent, with measurement range of 0.05 to 1.0 liters per minute for observing sampling rate.

4.7 Shipping containers to protect bags in transport shall be opaque to protect bags from ultraviolet light. Containers shall have no staples, sharp edges or metal closures which might damage bags. The rigid container for filling bags may be used for bag transport; any window in the container shall be covered with opaque material during such transport.

4.8 Expendable Materials

4.8.1 Standard gas mixture for field spikes. Appropriate cylinder gases containing the pollutant(s) of interest in known concentration.

4.8.2 99.999% N_2 or zero air

5 PROCEDURE

The following describes the procedure for collecting samples from stacks. A field blank and a field spike must be obtained for each source test (Refer to section 6 for discussion).

5.1 (Optional) Determine stack moisture content by ARB Method 4; if moisture content is above the 60°F saturation level, then dilution of the sample bag may be required. If moisture content of stack gas is not determined, then Tedlar bag shall be monitored for condensation during sampling (see Section 5.7).

5.1.1 Procedure for Sample Bag Dilution. Bags should be pre-filled with 99.999% nitrogen or zero air to approximately one-third the final sample volume. The exact volume of dilution gas must be recorded to allow for correction of data. If condensation still occurs, increase dilution as necessary.

5.2 Assemble the sampling train at the sampling site as shown in Figure 1.

5.3 Leak check the sample train. To start the leak check, connect the sample line to the bag, making sure the valve on the bag is closed. Place the bag in the rigid container and close as if for sampling. Turn on the vacuum pump until a reading of 15 inches H_2O is maintained. Make sure that the probe line is **not** plugged and that the ON/OFF valve is open. If a leak greater than 5% of the sampling flow rate is found, then the problem must be located and fixed before the leak check continues. Turn the pump off, break the vacuum on the rigid container and open the mininert valve on the Tedlar bag. Place the bag back in the container and close as if for sampling. Plug (leak tight) the end of the probe. Turn on the vacuum pump and adjust until a reading of 15 inches H_2O is maintained. If a leak greater than 5% of the sampling flow rate is found, then the problem must be located and fixed before sampling continues.

5.4 Break the vacuum on the rigid container. Unplug the end of the probe and place the end of the probe in the stack away from the walls. Care should be taken to avoid dilution of the stack gas sample with ambient air by sealing the open port area around the probe, especially in stacks with negative static pressure.

5.5 Make sure the sampling train is configured correctly, the valve on the sample bag is open and the ON/OFF valve is closed. Turn the vacuum pump on and adjust until a reading of 15 inches H2O is maintained. Begin sampling by opening the ON/OFF valve. Record the sample start time on the field data sheet.

5.6 Monitor the container vacuum and sample flow rate and adjust as necessary. After sampling for the planned interval, close the ON/OFF valve noting the time on the field data sheet. Bags should be filled no more than half full. If condensation occurs, discard sample and resample as per 5.1.1.

5.7 After sample purge is complete, close the ON/OFF valve, turn the pump off, break the vacuum on the rigid container and close the mininert valve on the bag.

5.8 Attach a label to each Tedlar bag sample (and impinger if used) containing the following information:

Job #
Date
Time
Sample/Run #
Plant Name
Sample Location
Log #
Initials of Sampler Operator

5.9 Promptly place the sealed bag in a shipping container; close the container to prevent possible degradation of the sample by ultraviolet light. Several bags may be placed in the same shipping container.

5.10 Fill out the Chain of Custody-Sample Record, Log Book Data sheets, and Field Data sheets. Copies of these forms are attached as Figures 2, 3 and 4.

5.11 Sample Bag Transport Procedure

5.11.1 Transport sample bags in opaque shipping containers.

5.11.2 Airborne transport could potentially result in rupturing of bags containing toxic samples. Surface shipment is advised. If airborne transport is unavoidable then bags should not be filled more than half way to avoid bag rupture.

5.11.3 Deliver bags to laboratory for analysis promptly. The maximum hold time is 24 hours.

6 QUALITY CONTROL

6.1 Sampling Runs, Time and Volume

6.1.1 Sampling runs. The number of sampling runs must be sufficient to provide minimal statistical data and in no case shall be less than three (3) runs per source test.

6.1.2 Sample time. Integrated bag sampling. The sampling must be of sufficient duration to provide coverage of the average operating condition of the source as specified by the ATCM or as directed by the District.

6.2 Routine Sampling Quality Control. This section outlines the minimum quality control operations necessary to assure accuracy of data generated from samples collected in Tedlar bags. These QC operations are as follows:

- Field blank samples
- Field spike samples
- Collocated samples (optional)
- Tedlar bag contamination checks

6.2.1 Field blank samples. At least one field blank sample will be taken per source test. At the discretion of the tester, more blank samples may be taken. Air or nitrogen from a compressed gas cylinder (ambient air may also be used) is collected in the bag in the manner described in section 5 of this method. This blank sample is transported and analyzed along with the stack gas samples. If field blank values are greater than 20 % of the stack gas values, then the data will be flagged. Field blank values will be reported along with the stack gas results.

6.2.2 Field spike samples. At least one field spike sample will be taken per source test. At the discretion of the field engineer, more spike samples may be taken. Pure air or nitrogen containing known concentration(s) of EtO is drawn from one bag to another through the sampling apparatus. The spiked sample is transported and analyzed along with the stack gas samples. Spike sample recoveries will be reported along with the source test results.

6.2.3 Collocated samples. Collocated sampling will be performed at the discretion of the tester. Samples are collected through two identical sampling systems simultaneously from the same stack sampling port. The analysis results of collocated samples are used to estimate method precision.

6.2.4 Tedlar bag contamination checks. Tedlar bags will be tested for contamination as outlined in Section 10 of this Appendix.

FIGURE 1
TEDLAR BAG SAMPLING TRAIN

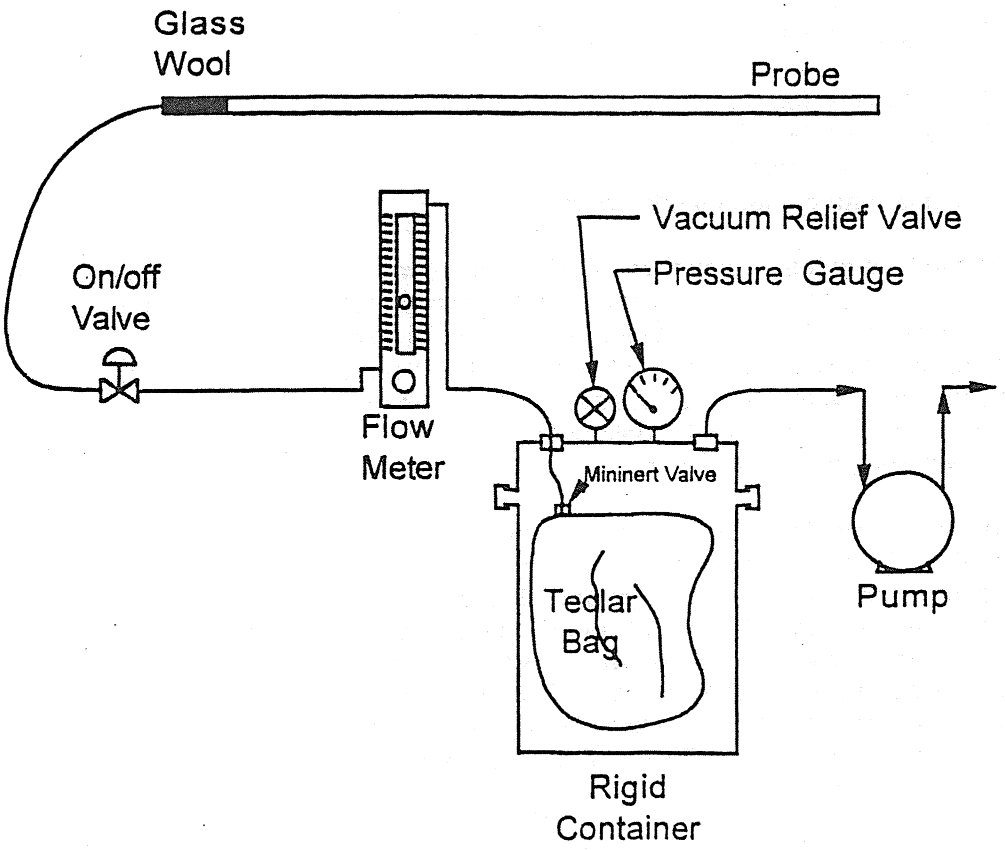

FIGURE 2

CHAIN OF CUSTODY

SAMPLE RECORD

Job ________________ Date: ________________ Time: ____________________

Sample/Run# ______________________________________

Sample Location ____

Type of Sample ____

Log # ________________ Fitting # ______________ Initials __________________

Action Taken	Start Date	Time	Given By	Taken By

Related I.D. #s	Description

FIGURE 3

CHAIN OF CUSTODY
LOG BOOK

PROJECT NO. ________

Log No.	Sampl e I.D.	Date	Time	Comment	Valve I.D. Bag Sample	Given By	Taken By

FIGURE 4

FIELD DATA SHEET

Project Name ____________________

Date ____________________ Sample ID: ____________________

LOG ID: ____________________

Sample Type: ____________________

BAG QUALITY ASSURANCE

Bag ID No. __________ Initial Bag Leak Check __________

Bag Check Analysis (List Results of Bag check Analysis)

FLOWMETERS

Flowmeter ID ____________________

Date of Flow Meter Calibration Check ____________________

Sampler ID ____________________ Sampler Leak check __________

SAMPLE TIME

Time					Total time

Flowrate					Average Flow

COMMENTS ____

____

7 Production of Tedlar Bags

New bags are recommended for each sample. Previously-used bags may be used again if cleaned andchecked for leaks and contamination as specified below. Tedlar bags may also be purchased already assembled, but must be certified to specified contamination levels before use.

7.1 Materials and Equipment

7.1.1 Tedlar, 0.002 inch thickness.

7.1.2 Fittings for connection to sample line. Mininert Teflon valves are recommended. Quick-disconnect Swagelock fittings are commonly used, but are suspected of possible interferences at low ppb concentrations. Fittings should be composed of inert materials, teflon and stainless steel are recommended.

7.1.3 Septum fitting for injection of surrogates or removal of sample by syringe.

7.1.4 Cork borers for installation of fittings.

7.1.5 Lay-out Table to measure and cut Tedlar to size.

7.1.6 Heat-Seal Apparatus for making seams in Tedlar. Vertrod Thermal Impulse Heat Sealing Machinery or similar device. May require compressed air cylinder.

7.1.7 Pump for evacuation of bags during purging operations, together with fittings or manifold system to connect pump to bags.

7.1.8 Ultrasonic bath for cleaning fittings.

7.1.9 Oven for drying fittings

7.1.10 99.999% Nitrogen for purging bags.

7.1.11 Distilled water.

7.2 Clean Fittings

Use of organic solvents is not recommended due to possible contamination of bags.

7.2.1 Clean fittings by placing them in soapy water in ultrasonic bath for about one hour. Rinse fittings thoroughly with clean water, followed by a rinse with distilled water.

7.2.2 Bake fittings in a 100 °F oven for at least 8 hours.

7.3 Manufacture of Tedlar Bag

Tedlar bags should be constructed in a clean area, with care taken to avoid contamination such as exposure to chemical fumes, solvent vapors or motor exhaust.

7.3.1 Cut one piece of Tedlar film from roll on lay-out table using a razor blade. A sheet of Tedlar measuring about 54" by 30" will make about a 30 Liter capacity bag (15 L at half-full).

7.3.2 Fold the Tedlar sheet in half and make two seams using heat-seal apparatus. Seams should be at least ½ inch from edge.

7.3.3 Place piece of cardboard inside bag. Use cork borer to make appropriate size hole for fittings, using cardboard to protect other side of bag. Tedlar film should fit snugly around base of fitting.

7.3.4 Attach previously cleaned sample line fitting. Use Teflon washers on inside and outside of bag to secure fitting.

7.3.5 Attach septum fitting if necessary. (Mininert valves have septum and sample line connections all on one fitting).

7.3.6 Seal remaining seam using heat-seal apparatus.

8 Leak Test

Check all sample bags for leaks by inflating with 99.999% nitrogen to a pressure of 2 to 4 inches of water. Good bags should hold constant pressure as indicated by a manometer for 10 minutes or (alternative test) should remain taut and inflated overnight. A small weight (e.g. Kimwipe box) may be placed on top of bag for the overnight leak check. Report bag acceptability on field data sheet (figure 4); destroy or repair and retest defective bags.

9 Bag Cleaning

Purge the bag with 99.999% nitrogen repeatedly until acceptable contamination values are attained. ARB staff experience has shown that 3 to 8 purges are needed to meet the target contamination levels of <1 ppb for most VOCs of interest.

10 Bag Contamination Check

10.1 Check bags for contamination by filling them halfway (so that check volume approximates actual sample volume) with 99.999% nitrogen, allow to equilibrate for 24 hours, then analyze for EtO.

10.2 Acceptable contamination levels may vary depending on the expected sample concentration. However, bags which contain contaminants at levels greater than the LOD will be rejected.

10.3 Label bags and record contamination levels. Also record contamination levels on field data sheets.

APPENDIX J

DEFINITIONS AND ABBREVIATIONS

Response Factor

The response of the gas chromatograph detector to a known amount of standard.

Performance Evaluation Sample

A sample prepared by EPA, ARB or other laboratories containing known concentrations of method analytes that has been analyzed by multiple laboratories to determine statistically the accuracy and precision that can be expected when a method is performed by a competent analyst. Analyte concentrations are usually known to the analyst.

Calibration Check Sample

A standard, normally the midpoint of multipoint calibrations (see section 422.199.4.1), which is analyzed each shift (or cycle) to monitor detector drift. The values of all analytes must be within 10% of the mean values established in the multipoint calibration or a new calibration curve must be prepared.

Analytical Limit of Detection (LOD)

The lowest level at which detector response can be distinguished from noise. Refer to Appendix E for more detail.

Analytical Limit of Quantitation (LOQ)

The lowest level at which a compound can be accurately quantified. This value is 3.3 times the Limit of Detection.

Reporting Limit (RL)

The reporting limit (RL) is the lowest level that can be reliably quantitated within specified limits of precision and accuracy during routine analyses of source samples. Reporting limits will be based on parameters such as sampling volumes, dilutions, sample injection volume and chromatographic interferences.

Field Blank

A field blank is taken in the same way as a sample is taken except that pure air or nitrogen is used as a sample. The field blank is used to determine background levels in the sampling system. The gas used for blank runs should be certified by the gas supplier or laboratory to contain concentrations less than the limit of detection for the analytes of interest.

Field Spike

A standard gas containing ethylene oxide at known and certified concentration is introduced at the sampling probe inlet and transferred through the entire sampling train to be analyzed exactly as a normal stack emission sample. The standard gas used for the field spike should be the calibration standard closest to the actual sample concentrations. The spike gas introduced at the probe inlet should be at ambient pressure. The use of a Tedlar bag provides a simple procedure for introduction of the spike gas into the sample probe. The spike/standard gas can be transferred from a compressed gas cylinder into the Tedlar bag and the bag then attached (leak-tight) to the probe inlet. Spike gas can then be pulled through the sample train as under normal conditions.

Laboratory Replicate Samples

Replicates serve to measure the precision of an analysis. Ten percent of all samples are analyzed in duplicate to indicate reproducibility of the analysis and to monitor such conditions as instrument drift.

APPENDIX K

TESTING PROCEDURES FOR STERILIZERS WITH JOSLYN RECOVERY TYPE CONTROL UNITS

Identified points of EtO emission from Joslyn system include:

1. Recovery compressor "burps" which are routed to an acid scrubber. These burps are short-duration (e.g., 3 seconds) recovery compressor pressure relief emissions which occur on an irregular basis (infrequent according to manufacturer). Recovery compressor "burps" are routed to an acid scrubber. These burps would only occur while the recovery compressor is in operation during sterilizer exhaust stage (i.e., the recovery compressor is not in operation during the detoxification-B and preconditioning stages). For the purpose of occupational safety, the composition of the emission from these burps should be assumed to be the same as the 12/88 sterilant mixture and appropriate precautions are taken.

2. An oil-sealed pump is used to evacuate the sterilization chamber during the primary exhaust and detox-A stages. The oil is held in an oil/water separator where oil and water intermingle. Moisture from the chamber collects in the separator and is discharged from the pump several times per cycle. Volume of the discharge would normally be approximately 2 liters and normally has EtO concentrations in excess of 5000 mg/liter. The Joslyn system was modified to attempt to abate this waterborne EtO emission. The EtO-contaminated water collected during the exhaust and detox-A stages is transferred to a "heater" for hydrolysis followed by transfer to the heated sterilizer chamber water jacket, which is discharged to the floor drain.

3. A water ring seal pump is used to evacuate the chamber during the preconditioning and the detox-B stages. The pump working fluid (water) is discharged to the floor drain and vapors are discharged to a floor drain vent. The aeration stage (the manufacturer calls this stage "detoxification-B") discharges of EtO must be controlled/compliance tested at those facilities permitted for use over 600 pounds of EtO per year (as per the statewide ATCM) or as dictated by the District Rule.

The following general test procedures are recommended:

Sterilization Exhaust

1. Use of the inlet estimation technique, as described in Appendix B, to calculate the mass of EtO delivered to the inlet of the recovery/control system. The sterilizer/control system must have been used on each of the 2 days just preceding the compliance test-day. This practice is to insure that the emissions from the heated chamber water jacket are representative of "in-use" conditions. Documentation of sterilizer/control system use on the preceding 2 days must be included in the report.

2. Capture the total exhaust from the acid scrubber with a small volume Tedlar bag. Do not manually induce a compressor emission. This testing must be conducted in such a manner that no back pressure and/or leaks are produced in the acid scrubber. If the system does not off-gas during testing then the district may ask the facility to provide an engineering estimate (worst plausible case calculations) of mass of EtO emitted from the acid scrubber. This emission estimate could be used in calculating the system control efficiency.

3. Follow the Tedlar bag sampling and analytical quality control procedures described in Appendix I. In particular, follow the Initial Performance Demonstration, Routine Calibration Procedures and Routine Quality Control Procedures.

4. Repeat the above procedures and calculations (Appendix F) three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device. Run three cycles with the sterilization chamber empty and average the results.

5. Collect and analyze water samples for the first cyle tested from the outlet of the heated sterilization chamber water jacket. Collect the entire discharge of the heated chamber jacket in separate ½ hour samples for a 2 hour period starting at the beginning of the chamber evacuation. The ½ hour samples should be collected in graduated glass containers and the total volume included in the report. Follow the procedures specified in Appendix L to immediately collect 2 aliquot water samples from each of the ½ hour samples. Analyze the samples as per Appendix L and report the average EtO concentration for each of the four ½ hour samples. Collect field quality assurance samples as specified by Appendix L.

Aeration Exhaust

1. Use the measurement methods described in Appendix A to determine the mass air concentration of EtO delivered to the inlet of, and emitted from, the aeration exhaust control system: of EtO in the drain vent associated with the water ring seal pump used during the aeration (detoxification) stage. Monitor the vent emissions for 1 hour following the start of aeration. Do not abort or shorten the exposure stage. Report the average or integrated concentration of EtO.

2. If required by the District, use the volumetric flow measurement procedure appropriate for the facility's stack diameter, configuration and flow characteristics.

3. Collect and analyze the water discharge of the control system associated with the water ring seal pump used during the detoxification (aeration) stage. The pump is on, evacuating the chamber, for 5 minutes every 20 minutes. Collect the entire discharge of the water ring seal pump in separate 5 minute samples for a 1 hour period starting at the beginning of the aeration stage. The water sample collection must be coordinated with the 5 minute "pump-on" times. The 5 minute samples should be collected in graduated glass containers and the total volume of each included in the report. Follow the procedures specified in Appendix L to immediately collect 2 aliquot water samples from each of the 5 minute samples. Analyze the samples as per Appendix L and report the average EtO concentration for each of the three 5 minute samples. Collect field quality assurance samples as specified by Appendix L.

4. Run one cycle (exposure stage may not be aborted early) with a normal load in the aeration chamber.

APPENDIX L

Method 431 **Ethylene Oxide in Water**

PROPERTIES: gas at room temp
M.W.: 44.05 B.P.: 10.7 °C; V.P.: 146 kPa (20 °C), water sol.: completely miscible
vapor density: 0.98 (air = 1); explosive range: 3% to 80+% v/v in air

SAMPLING	MEASUREMENT
Section 6010B, Standard Methods for the Examination of Water and Wastewater, APHA, latest edition	TECHNIQUE: Gas Chromatograph, Flame Ionization detector ANALYTE: Ethylene Oxide (EtO) and Ethylene Glycol INJECTION: 2 μL TEMPERATURE - INJECTION: 250 °C - DETECTOR: 250 °C - COLUMN: 50 °C for 2 minutes, 10 °C/min to 250 °C, hold for 1 minute CARRIER GAS: Helium, 30 cc/min COLUMNS: 30m DB - WAX megabore, 0.53 mm i.d., 1.0 μm film thichness with 2-3 ft. deactivated fused silica guard column CALIBRATION: EtO standards in water at 500 or 1000 μg/mL ANALYTICAL RANGE: approx. 1.0 ppm to 100 ppm, sample dilution will extend the range

PRINCIPLE: The mass of ethylene oxide contained in water associated with ethylene oxide control units is determined using the sampling analysis procedures described herein. Ethylene glycol, a hydrolysis product of EtO, is also quantitated and reported.

APPLICABILITY: This method is applicable to the measurement of ethylene oxide in water samples from sterilization chamber water jacket, water discharge associated with water ring seal pumps and other similar locations where possibility of EtO transfer to water exists.

LIMITATIONS: A minimum sample volume of 15 mL is required to avoid EtO losses during sample clean-up. No headspace should be present in field samples. Samples should be analyzed within _____ hours of collection to minimize EtO volatilization losses.

INTERFERENCES: Sample clean-up is required for samples contaminated with process oils.

REFERENCED METHODS:

REAGENTS:

1. EtO and ethylene glycol stock standards in solvent
2. Methanol, HPLC grade
3. Distilled water
4. Crushed ice

EQUIPMENT:

1. GC/FID with split/splitless injector, detector, integrator and columns
2. Reverse-phase cartridges - Baker Analyzed, Bakerbond, octadecylsilane bonded to silica gel (C-18), 40 μM APD160A, P/N 7020-03 with gas syringes adaptor
3. 15 mL test tubes with teflon-lined screw caps
4. Liquid and gas syringes

** SPECIAL PRECAUTIONS: Ethylene Oxide is a potential carcinogen. Work should be performed in a well ventilated fume hood. For specific regulatory requirements refer to the California Labor Code, Part 10, Section 9020; Title 8, California Code of Regulations, Section 5220.

CALIBRATION AND QUALITY CONTROL:

Refer to Appendix E for multipoint and daily calibration and quality control procedures.

STANDARD PREPARATION:

1. Aliquot 12 mL of d. water into a 15 mL vial or test tube with a teflon lined screw cap and place it into a container with crushed ice to chill.
2. Prepare a 10 ppm (w/w) standard by adding 120 μL of a 1000 μg/mL (1 μg/μL) ethylene oxide standard to the 12 mL of chilled water, cap, and shake vigorously for 1 minute. Return the vial to the ice and allow enough time for solvent in the standard to partition. If the standard solvent is miscible with water then gentle mixing is sufficient. With a disposable-pipet transfer from the bottom of the vial (to minimize the immiscible solvent pick-up) some the standard to an auto-sampler (a/s) vial and store on ice or in a refrigerator until rready to analyze.
3. Prepare a 5 ppm standard by adding 500 μL of water in an autosampler vial, chill, and from the bottom of the vial add 500 μL of the 10 ppm standard. Chill.
4. Prepare a 1 ppm standard by adding 1 mL of water to an a/s vial, remove 100 μL, chill, add 100 μL of the 10 ppm standard.

5. Prepare a blank by adding d.water to an a/s vial.

SAMPLE CLEAN - UP

1. Using the gas syringe and the adaptor, activate the C-18 cartridge by flushing with 3 to 4 mL of methanol. Immediately wash out the methanol with repeated flushing of distilled water to minimize the methanol peak when the sample is analyzed. Ten flushings of 3 to 4 mL are sufficient.

2. Add water to the cartridge but do not immediately flush through the column. The C-18 must be kept wet prior to sample application.

3. Pass the sample through the cartridge into a clean vial. Use at least 15 mL or more than 3 times the cartridge volume. Discard the first 5-8 ml to waste and collect the remainder. Use slight air pressure from the syringe to increase the processing speed.