

# Safety Guidelines

## Ethylene Oxide (EO) Gas Sterilization

STERIS®



Safe and effective use  
of Amsco® Ethylene Oxide Sterilizers,  
Aerators, and Sterilizer/Aerators



**WARNING: Failure to follow the guidelines in this booklet may result in serious health hazards from exposure to ethylene oxide.**



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## Glossary

EL	Excursion Limit
EPA	Environmental Protection Agency 401 M Street, SW Washington, D.C. 20460
EO	Ethylene Oxide
FDA	Food and Drug Administration 5600 Fishers Lane Rockville, MD 20852
NIOSHA	National Institute for Occupational Safety and Health U.S. Public Health Service 4676 Columbia Parkway Cincinnati, OH 45226
OSHA	Occupational Safety and Health Administration U.S. Department of Labor 200 Constitution Avenue, NW Washington, D.C. 20210
PEL	Permissible Exposure Limit
STL	Short-Term Excursion Limit
TWA	Time-Weighted Average

# Ethylene Oxide Safety Guidelines

**DANGER:** Ethylene Oxide (EO) Used In This Area: Possible Cancer Hazard and Reproductive Hazard.  
Wear Personnel Protective Equipment When in Direct Contact with Ethylene Oxide

## Read These Instructions

### General

1. Complete training on the safe use of EO before working with equipment in this area. (Additional training may be required by federal law. Ask department supervisor for details.)
2. Follow manufacturer's written recommendations for using equipment
3. Follow the device manufacturer's recommendations for sterilization and aeration parameters.
4. Inform your supervisor immediately if you experience breathing difficulty, nausea, skin burns, headaches, or eye, nose, or throat irritation.
5. Do not inhale EO. Take every precaution to prevent liquid EO from coming in contact with any part of your body.
6. It is important to review carefully the entire contents of the Safety Guidelines Booklet.

### Operating

1. Make sure the sterilizer exhaust system and room exhaust system are [ON] when gas sterilizer is running.
2. Never open gas sterilizer door until cycle is complete.
3. In case of power failure, leave gas sterilizer door closed. When power returns, allow unit to finish cycle. If alarm sounds, contact your STERIS Service Representative and/or facility maintenance.
4. Do not turn gas sterilizer off while it is running - wait until after the exhaust phase has been completed.

### After Sterilization

1. After sterilization, when aeration is not available within the same unit, open sterilizer door approximately 2 inches and clear immediate 5 to 10 foot area for 15 minutes.
2. At the end of the 15-minute period, promptly transfer gas-sterilized items to aerator, following these safety precautions:
  - Never touch gas-sterilized items before they are aerated, unless you are wearing protective gloves. Butyl rubber gloves are highly recommended. Immediately after use, remove gloves and wash hands.

- To move items from gas sterilizer to aerator, use loading carts or metal baskets. Be sure to keep your gloves on.
- Pull loads to aerator - don't push them.
- Aerate items for full time and at temperature recommended by the manufacturer(s) of the article(s) being processed.

### Emergencies

1. In case of EO leak or other EO emergency, follow these procedures:
  - Leave or evacuate area
  - Extinguish all open flames
  - Close all doors
  - Notify designated safety personnel
  - Do not re-enter sterilizer room until EO levels have been reduced to a safe level
2. Know where your facility's emergency procedures are posted. Become familiar with them.
3. In the event of building exhaust shutdowns, all EO sterilizers should be shut down.

### Emergency Care

1. If liquid ethylene oxide comes in contact with the eyes, immediately flush them with large amounts of water. Call a physician to see the patient.
2. If liquid ethylene oxide contacts skin, immediately remove any contaminated clothing and shoes. Then thoroughly wash contaminated skin. Do not wear clothing again until it has been laundered and/or aerated. Discard all leather items.
3. If EO vapor is inhaled, immediately seek fresh air.
4. If nausea and vomiting develop, keep person quiet and warm and call a physician.
5. If breathing is difficult, give oxygen and call a physician.
6. If breathing has stopped, perform cardiopulmonary resuscitation (CPR) and call a physician.

**WARNING:** Failure to follow the guidelines contained in the STERIS Safety Guidelines booklet may result in serious health hazards from exposure to ethylene oxide.

These instructions are provided by STERIS Corporation, 5960 Heisley Road, Mentor, OH 44060.

For more information, please contact your local STERIS Representative or call STERIS Customer Service at 800-548-4873 or 440-354-2600.



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## Introduction

In recent years, there has been a great increase in lifesaving diagnostic and therapeutic devices and supplies that must be sterilized prior to use on patients. Many of these are made of materials that cannot stand the high temperatures of conventional steam sterilization.

Designed for invasive and other uses, many of these products (such as rigid or flexible endoscopes, respiratory therapy devices, and others) are made of plastics or rubber which are unable to withstand the 250°F (121°C) and higher temperatures that are standard with steam sterilization.

Because sterilization can be accomplished with ethylene oxide (EO) at low heat and moisture levels, it continues to be recognized as the method of choice for most heat- and moisture-sensitive medical devices.

EO has been used to sterilize heat- and moisture-sensitive medical devices for more than a half century.

However, because of its toxic nature, EO must be used with caution and only by individuals properly trained in its safe use.

STERIS Corporation, therefore, has developed and published these guidelines -- based on the most current data and OSHA regulations -- to assist in the safe use of EO as a sterilant.

STERIS believes that occupational exposures to ethylene oxide can be minimized by utilizing properly designed, installed, and functioning equipment, in conjunction with:

- trained personnel
- correct work practices
- adequate ventilation
- routine sterilizer maintenance
- appropriate emergency procedures, and
- periodic environmental and daily personnel monitoring.

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## Background

The possible adverse health effects of exposure to EO have been, and will continue to be, investigated and studied by the medical and scientific communities. The research data generated to date have led the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor to conclude that human exposure to ethylene oxide can present serious health hazards, including carcinogenic and reproductive health hazards.

In order to minimize the risk of worker exposure to EO, OSHA has adopted EO exposure limits and has periodically reviewed and lowered those limits as it has received scientific data about possible adverse health effects of EO exposure. The 1988 OSHA regulation about EO exposure includes a Permissible Exposure Limit (PEL) and an Excursion Limit (short-term exposure limit) (EL), both of which must be met in order for an employer to comply with the regulation. The PEL for occupational exposure to EO is one part of EO per million parts of air (1 ppm) as an eight-hour time weighted average. In 1988, OSHA mandated an Excursion Limit of five parts of EO per million parts of air (5 ppm) averaged over a maximum sampling period of fifteen minutes.

The OSHA regulation contains specific requirements about methods of exposure control, measurement of employee exposure, training, medical surveillance, signs, emergency procedures, regulated areas, record keeping, and personnel protective equipment. The regulation, therefore, must be read and understood by those persons responsible for supervising the use of EO. Furthermore, because research and regulatory actions are evolving continuously, STERIS urges its customers to constantly monitor regulatory and research activity and to secure the most current information about EO.

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## WARNING:

The Occupational Safety and Health Administration has concluded that chronic or acute exposure to EO, or both, may increase the risk of serious adverse health effects.

OSHA has concluded that EO is, or may be, associated with the following: cancers of the blood (leukemia), brain, and other organs; mutations, increases in the rate of chromosomal aberrations and sister chromatid exchanges and other undesirable changes in the DNA of mammalian cells; adverse reproductive effects in both men and women; central nervous system depression and other adverse neurologic effects; sensitization and irritation of human tissues, including the eyes and the respiratory tract; pulmonary edema; bronchitis; headaches; nausea; vomiting; diarrhea; cyanosis; drowsiness; weakness; and incoordination.

In addition, OSHA has concluded that contact between human skin and liquid EO can cause swelling and burns; frostbite; eye irritation; and injury to the cornea. Possible health effects of exposure to EO are continuously being investigated by the medical and scientific communities, and it is possible that in the future, OSHA might conclude that EO may be associated with other adverse health effects.

STERIS strongly recommends that its customers review current OSHA regulations pertaining to EO exposure in order to obtain a thorough understanding of the methods prescribed by OSHA to reduce the risks of worker exposure to EO.

EO is highly flammable and combustible in certain concentrations, and presents an explosion and fire hazard. All necessary precautions should be taken to reduce the risk of explosion and fire.

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# Recommended Guidelines for the Use of Ethylene Oxide

**Note:** References to “sterilizers,” “aerators,” and “sterilizer/aerators” in this bulletin refer to those manufactured by STERIS. Guidelines for equipment from other manufacturers may differ.

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## Training and Supervision

1. All ethylene oxide (EO) sterilization procedures must be supervised by personnel trained and well informed in the safe use of EO.
2. All personnel working with EO must have a complete orientation in the EO process. This orientation must cover the health hazards of EO, methods for safe use, methods to detect EO, and the OSHA standard.
3. Regular in-service programs on the EO process must be conducted, and an attendance record and demonstration of understanding should be kept for each employee.
4. Before a sterilizer, aerator, or sterilizer/aerator is put into operation, an in-service program on the operation and safe use of this equipment must be conducted by the manufacturer. All personnel who operate the equipment must attend the in-service training program.

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## Correct Work Practices

1. EO sterilizers, aerators, and sterilizer/aerators must be located in a controlled area for access by authorized, trained personnel only. Dedicated containment rooms and sterilizer/aerators with remote controls are preferred.
2. Traffic patterns around EO gas sterilization equipment should be designed to reduce incidental or passive occupational exposure to EO.
3. EO sterilization of supplies in a single, centralized location is strongly encouraged to insure proper work practices and controls.
4. Employee workstations, pack preparation areas, desks, washing areas, lounges, and other personnel support areas must be situated away from EO sterilizers, aerators, and EO storage areas.
5. Supplies should not be stored in the immediate vicinity of sterilization/aeration equipment, or equipment access areas.
6. Operators of EO sterilizers, aerators, and sterilizer/aerators must be instructed to follow the manufacturer’s written instructions and recommendations.
7. Items that are to be processed in the sterilizer, aerator, or sterilizer/aerator should be placed on a loading cart or in metal baskets to eliminate handling of individual packs.
8. Occupational exposure to EO can occur at the end of the sterilization cycle during transfer of items to the aerator. Exposure can also occur on removal of biological indicators from the sterilizer prior to aeration. The exposure can be reduced by observing the following recommendations:
  - At the conclusion of a STERILIZE cycle (AERATE not selected or not available), the door of the sterilizer should be cracked open 2 inches for 15 minutes. During this time, personnel must remain away from the immediate vicinity of the sterilizer. This waiting period permits further EO reduction within the chamber and load. Failure to follow this cracked door procedure will allow time for EO levels to build up in the chamber, caused by out gassing from sterilized items.
  - Whenever possible, utilize a combined sterilizer/aerator unit, such as is available from STERIS. This microcomputer-controlled unit and precise control system permits aeration of the load without removal from the chamber, eliminating handling of EO-processed items.
  - The sterilized load should be pulled to the aerator, **not pushed** from behind. Otherwise, when a load is pushed, the flow of air over the load/cart/basket would be toward the employee’s breathing zone.
  - EO-sterilized goods must be fully aerated prior to use. Recommended aeration times for typical goods are as follows:

In a sterilizer/aerator:	In an aeration cabinet:
130°F -- 12 hours	140°F -- 8 hours
100°F -- 32 hours	120°F -- 12 hours
	100°F -- 20 hours

**Follow the recommendations by the manufacturer of the article being sterilized for the required sterilization/aeration temperature and time.**

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## Monitoring

1. In order to establish compliance with OSHA limits on occupational exposure to EO, the healthcare facility must monitor worker exposure to EO. Determinations of employee exposure must be made from breathing zone air samples that are representative of the 8 hour time weighted average (TWA) of each employee, expressed in parts per million (ppm). The 1988 standard calls on employers to insure that no employee is exposed to an airborne concentration of EO in excess of 1 ppm as an 8 hour TWA. Also, the permissible short-term excursion limit is 5 ppm averaged over a 15 minute sampling period.
2. Monitoring equipment must meet 1988 OSHA requirements for accuracy. (See 53 Federal Register 66, at 11437.)
3. Specific requirements for monitoring, record keeping, and notification of personnel of monitoring results are included in the OSHA standard 29 CFR 1910.1047. If EO levels are found to exceed permissible exposure limits or the excursion limit, corrective action must be taken and medical surveillance may be required. (Refer to OSHA standard for details.)
4. Areas in which employee exposure to EO may exceed the PEL and EL must be posted as such, and access must be limited to authorized personnel. (See p. 10 for information on warning signs available from STERIS.)
5. An effective EO monitoring program must include personnel monitoring and area monitoring to alert personnel of an emergency situation.
  - Daily personnel monitoring is recommended to determine individual employee exposure. Badges should be worn to reveal exposure to EO resulting from poor work practices or equipment problems, so that corrective action can be taken to reduce further employee exposure. Badges that supply same-day results, such as STERIS STELSCAN™ and SELFSCAN™ monitoring products, are available from your STERIS sales or service representatives.
  - Area monitoring - OSHA requires a method to alert employees of an emergency situation [OSHA Standard 29 CFR, 1910.1047, Section (h) (2)]. To prevent false readings due to interfering compounds and accurate to levels specified in the OSHA standard, it is recommended that a monitor designed specifically for tracing EO levels be used. This monitor should also provide documented readings for record retention.

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## Regulated Areas

1. A regulated area is to be established where airborne concentrations of EO would normally exceed the 8-hour PEL or the 15 minute excursion limit (EL).
2. This regulated area must be clearly identified to prevent employees from unknowingly entering a high exposure area without the proper respiratory equipment. In addition to alerting employees to the possible need to wear respirators, signs on the regulated area would also warn employees to keep out if they have no need to be present. (See page 10 for information on warning signs available from STERIS.)

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## Sterilizer Maintenance

**Note:** Following the correct procedures in maintaining EO equipment is as important as observing work practice recommendations in EO sterilizer operation. In case of a known or suspected ethylene oxide leak, respirators and protective clothing should be worn.

1. Each EO sterilizer, aerator, and sterilizer/aerator must have, at minimum, a quarterly preventive maintenance program managed or supervised by a well-trained person.
2. Compressed air or an approved substitute should be used when servicing EO sterilizers and running test cycles. EO sterilizing mixtures should be used only when sterilizing loads.
3. Service functions should be conducted after the sterilizer exhaust cycle has been completed; they must not be performed when the sterilizer is exhausting ethylene oxide.
4. When working near liquid ethylene oxide, maintenance personnel must wear protective gloves and splash goggles. Any other area of the body which could come in contact with liquid EO should be covered with protective clothing.
5. The recess or access area behind wall-mounted sterilizers should be locked. The area should be clearly identified by a posted sign (see p. 10) stating that authorized service personnel only are permitted in this area. ***No one should be in the recess or access area when an EO sterilizer is in the exhaust phase of its cycle.***
6. No equipment or supplies, other than EO gas sources in use or EO disposal equipment, should be stored in a recess or access area behind wall-mounted sterilizers.

## Maintenance of Gas Cylinders (Tanks) and Gas Charging Lines

1. Cylinders of EO gas mixtures must be stored in a designated area that meets building codes and at a temperature not exceeding 100°F (38°C). The tanks should not be stored outdoors in direct sunlight. Also, prolonged storage of cylinders (longer than 6 months) should be avoided. The designated area must be away from the traffic flow in the area.
2. Tanks must be stored upright and must be securely fastened to a solid structure by suitable straps or chains.
3. Tank weight at the time of shipment should be certified by suppliers. Then, tanks should be weighed routinely when received, prior to bringing them into the building. Any reduction below shipment weight indicates leakage, which can occur during transit and storage.
4. Ethylene oxide gas tanks must be transported on mobile equipment which is able to hold tanks and cylinders firmly secured.
5. Respirators as required by OSHA must be worn during tank changes.
6. Before changing cylinders, the ventilation (exhaust system) should be checked to assure that it is working properly. *During changing of gas cylinders, caution should be exercised to avoid contact with liquid sterilant that may remain in the connecting lines, and also, to avoid prolonged or acute exposure to sterilizing gas vapor.* To minimize the quantity of EO gas leaking into the atmosphere during cylinder changeover, a shutoff valve, or other means of temporarily isolating the EO cylinder from the connecting lines, and a vent line, must be installed and used. When the cylinder connecting line is open, local exhaust should be used to capture the release of EO.
7. Periodic servicing of components in the EO supply line is required. An EO cartridge-type filter is used in the sterilizer to capture any contaminants in the gas mixture that may be present and can affect the gas charging valve operation. Replacement elements are available from STERIS. To avoid exposure to EO when servicing the EO supply line (including filter element replacement), the line must be drained and flushed by following these steps:
  - Wear protective gloves, clothing, and splash goggles.
  - Make sure the local ventilating system is operating properly.
  - Immediately after closing the tank shut-off valve, relieve the pressure in the charging line using an appropriate venting line that has an outlet to an operating, non-recirculating atmospheric exhaust. Any questions about this procedure should be directed to your STERIS service representative.
  - Remove the EO supply tanks and connect compressed air or an approved substitute through charge line with adapter kit (STERIS's part# P-764320-362 or equivalent).
  - Purge compressed air or an approved substitute through charge line filter(s) by initiating a sterilization cycle and allowing sterilizer to proceed through a conditioning (vacuum) phase into a charge phase until the chamber pressure rises to atmospheric or higher.
  - Abort the cycle and initiate a vacuum purge to remove any EO which was flushed from the filter during the previous step.
  - Turn off the supply of compressed air or an approved substitute, drain the pressure from the supply line as outlined above, and then disconnect line.
  - Perform the necessary service procedure. For filter element replacement, disassemble filter housing. Place used filter element in EO-impermeable bag (STERIS's part# P-764320-694 or equivalent). Install new element and reassemble housing. Dispose of bagged filter element in a manner approved for hazardous wastes.
  - Reconnect compressed air tank and re-pressurize system.
  - Check the entire system for leaks, and repair leaks if present.
  - Follow the tank change procedure to remove compressed air and reinstall EO tanks.
8. Contact your gas supplier for recommendations on over-pressure protection installations using materials not supplied by STERIS (e.g. tanks, tank manifolds, remotely located gas supply, etc.).

**Special Note:** STERIS also has published maintenance guidelines for EO cylinder/supply maintenance. These are available under part# P150828-105.

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## Storage and Handling of 100% Ethylene Oxide Gas Cartridges

1. The 100% Ethylene Oxide used in some equipment is highly flammable and presents an explosion and fire hazard. Keep all sources of ignition, such as matches, lighted cigarettes, sparks, and static discharge away from the sterilizer and cartridges. Never put electrical items containing batteries in the load to be sterilized.
2. EO cartridges must be stored at a temperature less than 100°F (38°C).
3. Maintain only one day's supply or a maximum of 12 EO cartridges in the immediate sterilizer area, having a minimum of ten (10) air changes per hour.
4. Store additional EO cartridges in an approved flammable liquid storage compartment or cabinet which is vented to an outside exhaust system. Check the local fire protection codes for additional requirements.
5. Never place a leaking EO cartridge in a standard aeration cabinet.

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## Emergency Procedures

All facilities operating EO sterilizers and aeration equipment have the responsibility to establish an emergency plan and to assure its implementation.

The emergency plan must include evacuation and first aid procedures. It must also include training of employees in the procedures to be put into effect in the event that:

- There is ethylene oxide leakage from a sterilizer, EO storage tanks, or EO cartridges.
- Employees show symptoms associated with EO exposure, such as watery eyes, headache, skin burns, sore throat, or nausea.

The employer must also provide a supply of respirators and protective clothing that are readily available in case of an emergency. These should be readily accessible, but not in an area likely to be affected by a leak.

Regular training on the use of respirators is necessary to avoid dangers associated with inadequate or improper use.

The emergency plan and first aid procedures must be practiced so employees know how to carry out emergency measures should they become necessary.

In case of an emergency:

1. Only personnel trained in handling EO are allowed to enter areas where there is a risk of exposure to, or contact with, persistent concentrations of EO.
2. In case of EO spill, leak, or release, follow these procedures:
  - Immediately evacuate all personnel from area.
  - Extinguish all open flames, including hot water and furnace pilots, if without risk.
  - Close all doors.
  - Notify designated safety personnel.
  - Before re-entering area, check atmosphere with appropriate ethylene oxide monitoring device.
3. If exposed to EO, seek medical attention immediately. When notified of a leak or spill, the trained emergency team will take these measures:

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## Emergency Action

1. Ventilate the area by increasing local exhaust in order to decrease EO concentrations by dilution with air. This can be done by opening louvers or dampers.
2. If the area must be entered before high EO concentrations are reduced, the following protective clothing and equipment must be used:
  - EO-impermeable clothing, providing complete body coverage to prevent skin contact with liquid EO or EO-containing solutions.
  - Splash-proof safety goggles or face shield.
  - Work shoes impermeable to EO. Leather shoes should be avoided.
  - Butyl rubber work gloves.
  - An air-supplied positive-pressure, full-facepiece respirator with a joint label of approval from the Mine Safety and Health Administration (MSHA) and National Institute for Occupational Safety and Health (NIOSH) for use with ethylene oxide.
3. Any symptoms of acute exposure to EO should be treated according to accepted medical procedures.

## Ventilation of Sterilizer Equipment

1. All EO sterilization and aeration equipment must be provided with dedicated exhaust ventilation which includes the gas scavenging system and associated ductwork.
  - A. Typical blend EO sterilizers (see figure 1)  
These are usually equipped with a scavenging system over the door and at the drain. Also, the safety valve should be connected to the ductwork as shown. Units may be equipped with a fan located at the sterilizer, however, a roof mounted fan should also be used to ensure a negative air pressure in the exhaust duct. These systems are available from the OEM. STERIS can provide a kit to retrofit early Amsco brand units not factory equipped.
  - B. Typical 100% EO sterilizers (see figure 2)  
These units are usually equipped with a door scavenger and a connector on top for connection to the facility exhaust. A fan is not typically used so the facility must provide a roof mounted blower to provide the necessary air flow within the duct system.
2. EO can escape from the discharge point of sterilizers that exhaust to the sanitary sewer. Auxiliary/local ventilation must be installed at this discharge point in accordance with the sterilizer manufacturer's recommendation. Most plumbing codes also require an air gap. The sanitary sewer must be sealed to minimize the potential for EO release. Each floor drain should be individually trapped to prevent EO migration through other non-sealed floor drains.
3. Site ventilation and plumbing documentation should be kept permanently on file in the office of the sterilizer department head.

## General Area Ventilation

1. Ventilation must be adequate to ensure that environmental levels for EO comply with OSHA requirements.
2. The gas sterilization process should be confined to a separate containment room, whenever possible.
3. General area ventilation for gas sterilization must be designed by a competent ventilation engineer to ensure compliance with all pertinent standards including proper location of all room air intakes and exhaust. Proper air volume and direction should be considered and measured for adequacy in the immediate sterilizer area to avoid "dead" air spaces. Ventilation design flows shall be based on a minimum of 10 air changes per hour.
4. Rooms where EO equipment is installed should be at a negative air pressure with respect to adjacent areas.
5. Air must be exhausted to the outside and all terminations of the exhaust duct must be located at least 25 feet away from any source of building air intake. Consult local building ventilation codes as required.
6. A permanent record of any ventilation system modification and performance signed by the professional person doing the examination shall be maintained.

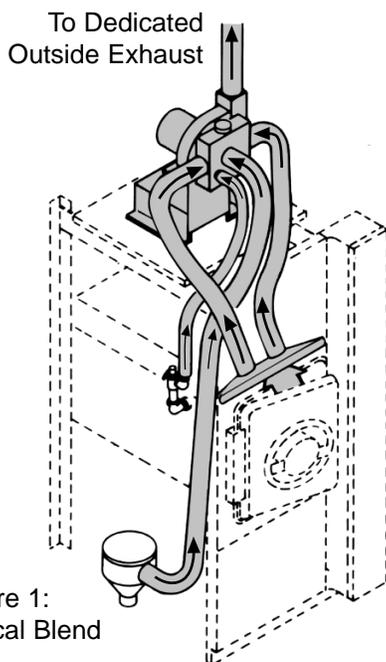


Figure 1:  
Typical Blend

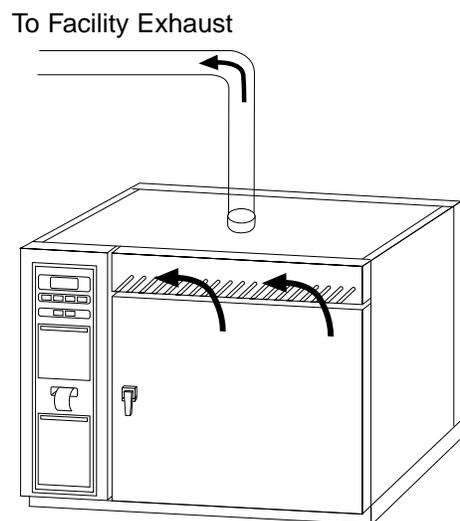


Figure 2:  
Typical 100% Sterilizer

# General Installation Requirements

## Ethylene Oxide Gas Sterilizers

### Introduction

These general installation requirements are intended to *complement STERIS equipment drawing(s)* and thereby further assist in achieving satisfactory installation of the equipment. Each equipment drawing pertains to the sterilization equipment as specified and purchased. The information on this and the applicable drawing(s) is based upon the design and construction of the equipment as of the date of the drawing. Thoroughly read the preceding pages to also become familiar with recommendations for the proper use of this equipment.

### Space Considerations

#### Clearances

The clearance dimensions shown on each drawing are the minimum considered necessary to allow space for servicing and operating the equipment.

Clearance in front of sterilizer, for comfortable loading and unloading operations, should approximately equal twice the inside length of the sterilizer chamber.

#### Dimensions

Attention must be given to the printed dimensions shown on each drawing, since they are not held to a specific scale.

### Mounting Details

#### Wall Thickness - Recessed Sterilizer

The purchaser must advise STERIS of the total finished thickness of the wall or walls through which the sterilizer will extend.

#### Wall Dimensions - STERIS Modular Wall

If the drawing pertains to a *STERIS Modular Wall*, the purchaser must advise STERIS of the overall width and height of the wall opening that the unit is to cover.

#### Recessing Cubicle

**Ventilation.** The recess area should be adequately ventilated and at negative air pressure with respect to adjacent areas. This is best accomplished by using exhaust ducts which provide a minimum of 10 air changes per hour. Temperature should not exceed 100°F (38°C).

**Illumination.** Ceiling illumination designed to afford 50 to 100 foot candles of total illumination, evenly distributed in principal areas of the recessing cubicle, should be provided. Also, at least one convenience outlet (110-120 volts) is recommended for power tools.

**Drainage.** An individually trapped floor drain is recommended for each cubical. A separate trapped floor drain is recommended for each sterilizer.

#### Space Between Recessed Sterilizer(s)

For a multiple (composite) sterilizer installation through a constructed wall (*not STERIS Modular Wall*), a minimum of 10 inches of clearance between the sterilizer front panels is recommended. A space of at least 20 inches between sterilizers is required for service access.

#### Cabinet Enclosed Sterilizer

Cabinet enclosed units should be located in a well-ventilated room (minimum recommended ventilation is 10 air changes/hour) from which gas vapors may be dispelled rapidly when load is being removed from the sterilizer.

An individually trapped separate floor drain, located within the confines of the sterilizer framework is necessary for each cabinet-enclosed sterilizer.

### Utility Service Requirements

#### Roughing-In

All lines should be dropped from overhead supply lines or short-stubbed through the floor or wall far enough to allow for pipe coupling. Provisions must be made for short-swing connections to equipment terminals. Piping outlets (stubbing) for equipment mounted in combination (composite installations) should be combined in one common set at the rear of equipment.

It is recommended that pipes and conduit NOT be stubbed through the floor under the chamber of the sterilizer. This recommendation would not preclude the stubbing of pipes and conduit through the floor within the confines of the panels on a cabinet-enclosed sterilizer.

#### Floor Drains

A 3-inch diameter (minimum) trapped floor drain should be provided by the user for each blend EO sterilizer. For sterilizers equipped with a STERIS Envirogard drain funnel, pipe the outlet of the sterilizer drain funnel to the floor drain. Seal all connections from the funnel outlet to the floor drain. (**Note:** The STERIS Envirogard drain funnel incorporates an air gap, as required by most plumbing codes.) *For blend sterilizers not equipped with Envirogard funnel, a suitable capture box must be provided to exhaust residual EO vapor from the drain area.*

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## **General Installation Requirements (cont'd)**

### **Utility Service Requirements**

#### ***Terminal Fittings***

Unless otherwise specified in the contract or purchase order, piping and other appurtenances between terminal fittings on the equipment and wall or floor outlets (stubbing) are not furnished by STERIS.

#### ***Pipe Sizes***

Pipe sizes shown on each drawing indicate terminals only. To ensure adequate service, the lines leading to the equipment should be increased by one pipe size.

#### ***Shutoff Valves***

To enable servicing of the unit without interruption of supply to other equipment, separate shutoff valves with lock-out capabilities should be installed in steam and water supply lines near each piece of equipment.

#### ***Chamber Relief Valves (Blend Sterilizers)***

All chamber relief valves must be piped to an atmospheric exhaust providing negative pressure. Caution must be exercised not to reduce the discharge capacity of the relief valve. Plumbing kit for valve to Envirogard system is available. (Recommended piping practices for relief valve piping can be found in ASME Boiler and Pressure Vessel Code, Section VIII, par. UG-135).

#### ***Pressure Reducing Valves/Backflow Preventer***

Local codes requiring a reduced pressure principle device on water supply line shall be provided by others.

#### ***Exhaust***

The building exhaust must be non-recirculating and directed to atmosphere. The outlet of the building exhaust should be remote from air-intake ports. A procedure should be in place for immediate shutdown of EO sterilizers in the event of building exhaust shutdowns. A dedicated atmospheric exhaust for EO sterilizers and aerators is required. The building exhaust must maintain negative pressure following hookup of powered sterilizer venting systems. Consult the Technical Data document for sterilizer exhaust flow rate and static pressure specifications.

#### ***Steam Return Lines***

Steam-return lines, if required, should be connected to a gravity system piped to a vented receiver; avoid any piping arrangement that could cause back-pressure in the return line. (This would not apply if steam-return lines were specified to be piped into the sterilizer condenser system or waste line.)

#### ***Steam and Water Pressures (Blend Sterilizers)***

Steam and water pressures indicated on each drawing are to be dynamic at the sterilizer.

Steam should be at least 97% vapor quality to prevent wetting of the load.

Sterilizer is adequately equipped to operate on these pressures. If supply line pressure exceeds those shown, reducing valves are needed. These are not furnished by STERIS unless specifically called for in the contract or purchase order.

#### ***Wiring***

**Terminals.** Wiring on sterilizer terminates at a junction box or boxes as shown on each drawing. Wiring and other appurtenances between junction box(es) and building service lines are not furnished by STERIS.

**Disconnect Switches.** (furnished by customer) Should be installed in electric supply lines near each sterilizer.

**Motors.** In providing electric service for motors, conductors should be sized to conform to the National Electrical Code specifications as to the rated motor current and motor branch circuit capacity, adjusted for ambient temperature conditions (for 3/4 hp and over) and voltage drop.

#### ***Survey Analysis***

Following installation of the sterilizer or sterilizer/aerator, an environmental analysis should be conducted by a competent trained and certified STERIS technician, using gas chromatography.

An on-going environmental analysis conducted on a periodic basis is suggested. This survey should include checking the gas sterilizer for leaks and performance; providing a ventilation evaluation of air flow rates and patterns; and measurement of EO concentrations at specific locations, including the employees' breathing zone.

## Warning Signs

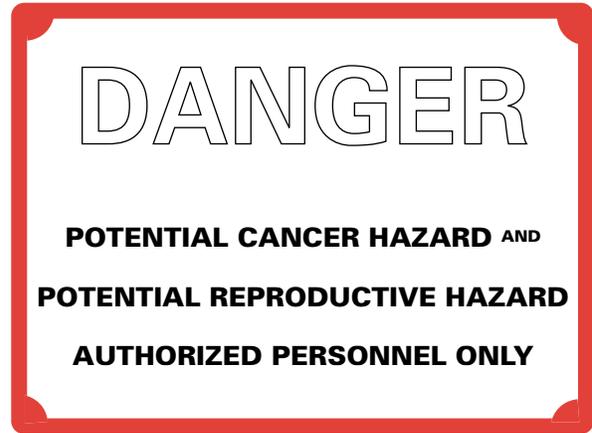
The warning signs illustrated on this page are available from STERIS (please order by part no.).

1. The employer must warn employees of EO hazards by posting legible signs clearly identifying regulated areas and doors, entrances, or accessways to regulated areas.



This sign is based on language in the OSHA, 1988 regulations.

Part no. P755715-467



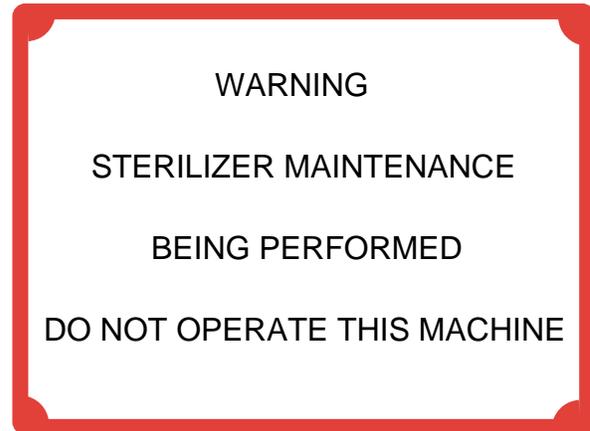
This sign is based on language in the Canadian Standards Association (CSA) standard Z314.9 (draft June, 1988). The reverse side of this sign is printed in the French language

Part no. P755715-859

2. Service technicians must post one of these signs when they are working on a gas sterilizer:



Part no. P755715-465



This sign is based on language in CSA standard Z314.9 (draft June, 1988).

Part no. P755715-851

3. Post near gas sterilizer:



Part no. P755715-466

4. Post on designated locker:



Part no. P755715-464

# Checklist on EO Guidelines

A checklist such as the following may be helpful in carrying out these EO guidelines. The checklist is designed as an informal tool to insure that responsibilities are assigned and completed. You may wish to adapt it to suit your operation, and it may be useful to update this checklist record each year.

Description	Responsibility Assignment	Frequency (Once, Daily, Weekly, Monthly Quarterly, Yearly)	Date to be Completed
<b>1. Personal Training</b>			
a. Sterilizer Operation			
b. Sterilizer/Aerator Operation			
c. Aerator Operation			
d. EO Health Hazards			
e. EO Emergency Procedures			
f. EO Work Practices			
g. OSHA Regulations			
h. Canadian Standards			
<b>2. Equipment</b>			
a. Sterilizer Preventive Maintenance			
b. Sterilizer/Aerator Preventive Maintenance			
c. Aerator Preventive Maintenance			
d. Emergency Equipment in Place			
e. EO Leak Checks			
f. EO Scavenging Systems Checks			
<b>3. Environment</b>			
a. Monitoring Techniques Established			
b. Ventilation and Exhaust Analysis			
c. EO Environmental Analysis			
d. EO Warning Signs Posted			
e. EO Warning Labels In Place			
f. EO Safety Guidelines Posted			

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