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# ALERT

## Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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NIOSH ❖ EPA ❖ EOSA

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### ATTENTION WORKERS!

**Explosions may result from improper venting of ethylene oxide into oxidizing emission control devices (OECDs).**

***Workers*** *should take the following steps to protect themselves while working in ethylene oxide (EtO) sterilization facilities:*

### Prevent overfeeding of the OECD

- Make sure that all interlocks and other safeguards are in place before sterilization begins.
- Periodically wash or vent sterilized products that sit idle in a sterilizer or aeration room to prevent EtO buildup.
- Monitor EtO concentrations in the sterilizer before the back vents are activated to avoid venting high EtO concentrations to the oxidizing emission control device (OECD).
- Vent confined spaces such as the sterilizer and the aeration room to the outside after a power loss.
- Do not purge EtO lines to an OECD.
- Perform regular preventive maintenance.
- Obtain management approval before changing the process or safety interlocks.

### Store and handle EtO properly

- Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion-proof area.
- Do not smoke at work.
- Do not use electrical devices or create open flames where EtO is handled, used, or stored.
- Use nonsparking tools when opening or closing metal containers of EtO or whenever EtO might be present.
- Keep containers individually bonded and grounded to the earth when liquid EtO is poured or transferred.

### Deal with leaks and spills

- Leave a leak or spill area immediately.
- If a catastrophic or large release of EtO occurs, do not enter the area. Evacuate the building and notify the fire department immediately.
- Do not enter an area where there is a small EtO leak until you have put on personal protective equipment (PPE), including a self-contained breathing apparatus (SCBA) that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.
- ***Do not use an SCBA unless you have received proper training and are current on its safe use.***

### Be prepared for rescue

- Know emergency rescue steps and where emergency equipment is located.
- ***Do not participate in emergency response without an SCBA and proper training***. If you do not have an SCBA and proper training, let the local fire department conduct the rescue.
- Before rescuing anyone in a leak or spill area, notify another person and put on an SCBA. Do not use a canister-type respirator for emergency response.

**Please tear out and post. Distribute copies to workers.**

**See back of sheet to order complete Alert.**

- If someone stops breathing because of EtO inhalation, immediately remove the person from the exposure area and perform cardiopulmonary resuscitation (CPR) while someone else calls for medical help. Keep the victim warm.

## Prevent skin and eye contact

- If liquid EtO contacts your skin, rinse it immediately under a heavy shower. Remove any contaminated clothing. Get medical attention.
- If EtO gets into your eyes, flush them immediately with a steady stream of water for at least 15 minutes. Lift the upper and lower eyelids and direct the stream of water under the eyelids. Get medical attention.
- Do not wear contact lenses in an area where EtO exposure might occur.

## Use respiratory protection and other PPE

- Use the respiratory protection recommended in the complete Alert during emergencies, maintenance work, vessel cleaning, and whenever engineering controls cannot be implemented. (See ordering information for the Alert at the bottom of this sheet.)
- Use PPE such as chemical-resistant gloves, eye-splash protection, and liquid-tight protective clothing whenever liquid EtO might be present.

For additional information, see ***NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities*** [DHHS (NIOSH) Publication No. 2000–119]. Single copies of the Alert are available free from the following:

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## Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities

### ATTENTION EMPLOYERS!

**Explosions may result from improper venting of ethylene oxide into oxidizing emission control devices (OECDs).**

***Employers*** *should take the following steps to prevent ethylene oxide (EtO) explosions:**

### Analyze and develop written procedures

- Conduct a process hazard analysis that emphasizes safety procedures for the entire sterilization system.
- Establish written procedures to cover all steps of EtO sterilization.
- Evaluate the advantages and disadvantages of each control technology.

### Prevent overfeeding of the OECD

- Make sure that all interlocks and other safeguards are in place before sterilization begins.
- Periodically wash or vent sterilized products that sit idle in a sterilizer or aeration room to prevent EtO buildup.
- Monitor EtO concentrations in the sterilizer before the back vents are activated to avoid venting high EtO concentrations to the oxidizing emission control device (OECD).
- Install an OECD bypass for emergency use if allowed by State or local environmental regulations.
- Vent confined spaces such as the sterilizer and the aeration room to the outside after a power loss.
- Do not purge EtO lines to an OECD.
- Perform regular preventive maintenance.

### Store and handle EtO properly

- Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion-proof area.
- Do not permit smoking, use of electrical devices, or open flames where EtO is handled, used, or stored.
- Use nonsparking tools when opening or closing metal containers of EtO or whenever EtO might be present.
- Keep containers individually bonded and grounded to the earth when liquid EtO is poured or transferred.

### Deal with leaks and spills

- Make sure that all workers leave a leak or spill area immediately.
- If a catastrophic or large release of EtO occurs, do not permit workers to enter the area. Evacuate the building and notify the fire department immediately.
- If a small leak occurs, do not permit workers to enter the area until they have put on personal protective equipment (PPE), including a self-contained breathing apparatus (SCBA).
- ***Do not permit workers to use SCBAs unless they have received proper training and are current on their safe use***.

*This list is not all-inclusive and may not be equally applicable to all sterilization and repackaging facilities. Employers should identify and use the controls and procedures that are relevant to their facilities. They should also be aware that no fail-safe control technique exists to guarantee that fires and explosions will not occur at their facilities.

## Implement engineering controls

- Provide an abort cycle (with diluent) in the sterilizer control system.
- Establish and follow a cycle approval process for all test cycles.
- Provide limited access to override controls.
- Eliminate back vents through appropriate equipment and cycle design.
- Interlock the sterilizer door to prevent opening before the cycle is complete.
- Interlock the gas inlet (shut-off) valve.
- Make sure that regular preventive maintenance is performed.
- Install a flow-limiting device on the vacuum pump inlet (controls or orifice).
- Install valve position sensors on critical valves.
- Install real-time area monitors that will alert workers to unsafe EtO concentrations.
- Use redundancies or other safeguards on all critical valves.
- Use damage control devices in the EtO supply lines and the OECD feed lines to limit explosion damage.
- Make sure that all other equipment has proper safety controls.

## Install emergency equipment

- Equip the facility with a type 2, 3 carbon dioxide or dry chemical fire extinguisher. Train workers annually in their safe use.
- Provide emergency eye-wash facilities.

## Provide respiratory protection and PPE

- Provide workers with the respiratory protection recommended in the complete Alert during emergencies, maintenance work, vessel cleaning, and whenever engineering controls cannot be implemented. (See ordering information for the Alert at the bottom of this sheet.)
- Provide workers with chemical-resistant gloves, eye-splash protection, and liquid-tight protective clothing whenever liquid EtO might be present.

## Provide training

- Fully train all operations, maintenance, and engineering workers in the dangers of EtO-rich evacuations to an OECD.
- Train all workers who will be responding to emergencies (including managers and supervisors) in the proper use of safety equipment and in emergency procedures for all EtO plant operations.

## Prepare workers for rescue

- Make sure that workers know emergency rescue steps and where emergency equipment is located. Be sure that they comply with Occupational Safety and Health (OSHA) regulations.
- ***Do not permit workers to participate in emergency response without SCBAs and proper training***. If workers do not have SCBAs and proper training, let the local fire department conduct the rescue.
- Design, develop, and practice emergency evacuation and rescue procedures.

For additional information, see ***NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities*** [DHHS (NIOSH) Publication No. 2000–119]. Single copies of the Alert are available free from the following:

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# ALERT

## Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities

**WARNING!**

**Explosions may result from improper venting of ethylene oxide into oxidizing emission control devices (OECDs).**

**The National Institute for Occupational Safety and Health (NIOSH), the U.S. Environmental Protection Agency (EPA), and the Ethylene Oxide Sterilization Association (EOSA) request assistance in preventing explosions at industrial ethylene oxide (EtO) sterilization facilities and EtO repackaging plants. EtO is a flammable gas. During sterilization procedures, EtO can easily form explosive mixtures when it is vented to certain types of emission control devices such as catalytic oxidizers.**

**Between 1994 and 1998, EtO was involved in 10 explosions at industrial EtO sterilization facilities and EtO repackaging plants. One of these explosions caused 1 death and 59 injuries among workers. All of these incidents caused damage to the plants, most of which used catalytic oxidizers to control EtO emissions.**

**This Alert informs owners, managers, supervisors, engineers, safety professionals, and workers about the explosions, injuries, and deaths that may occur at industrial EtO sterilization facilities and repackaging plants. Steps are recommended for preventing these explosions.**

## BACKGROUND

According to EPA, EtO is among the top 3% of high-volume chemicals produced in the United States. Less than 1% of all EtO produced in the United States is used as an industrial sterilant or fumigant [LaMontagne and Kelsey 1998a]. For sterilization applications, EtO is supplied in cylinders as a pure liquid—under pressure or mixed with other carriers.

Industry has long recognized the value of safe, effective, and efficient sterilization using EtO. The health care and food industries depend on the EtO sterilization industry for sterile products. More than 50% of all sterile medical devices sold are sterilized using EtO [Kroschwitz and Howe-Grant 1994].

Oxidizing emission control devices (OECDs) are integrated into some sterilization systems. They remove or destroy small amounts of EtO remaining in a vent stream through oxidation or burning. In most cases, OECDs replace acidified wet scrubber systems that are slightly less efficient in controlling low-concentration EtO emissions (see Appendix B). However, the

use of OECDs alone increases the potential for fire and explosion. Most recent explosions in the EtO sterilization industry are associated with OECDs. Since EtO vapors are highly flammable and explosive, the EtO concentration in the vent stream to the OECD must remain well below the flammable or explosive range because thermal or catalytic OECDs provide a source of ignition that could trigger an explosion in the vent system.

Nearly all such explosions are associated with overfeeding of the system. Such overfeeding occurs when

—a back vent is opened while a high concentration of EtO is in the sterilizer,

—no valve is used to control the flow rate of EtO to the OECD, and

—an EtO-rich stream reaches the device.

Overfeeding the OECD usually involves one or more of the following: (1) opening a sterilizer door that triggers back vent operation, (2) using a manual switch to trigger back vent operation, or (3) triggering back vent operation through a sterilizer controller (see Appendices C and D for more information about overfeeding). The high flow rate of the back vent exhausts could emit EtO at a rate that exceeds the safe design limits of the OECD if a valve or orifice is not used to control the flow of EtO or the EtO concentration sent to the OECD.

## Properties of EtO

EtO ($C_2H_4O$, epoxyethane, oxirane) is a colorless gas at room temperature with an ether-like odor at concentrations above 500 to 700 parts per million (ppm). The odor threshold for EtO is 260 ppm. EtO has a vapor density of 1.49 and is thus approximately 1.5 times heavier than air [Clayton and Clayton 1993]. The boiling point of EtO is 51 $^{o}$F, and the liquid has a flash point of 0 $^{o}$F. The gas has an autoignition temperature of 805 $^{o}$F. The vapor pressure of EtO is 1,095 mm Hg. EtO is soluble in water and reacts with acidified water to produce ethylene glycol. This process is one method for controlling EtO emissions. EtO is reactive with strong acids, alkalis and oxidizers, chlorides of iron, aluminum or tin, and oxides of iron and aluminum [Lewis 1996]. Highly flammable, EtO poses a dangerous fire and explosion risk. The flammability limits in air are 3% (30,000 ppm) to 100% [Lewis 1996]. Pure EtO can be ignited in the absence of air. EtO is more dangerous than hydrogen and should be treated with the same care as hydrogen and acetylene. Once ignited, it can flash back to the fuel source with velocities of 1,800 to 2,400 m/sec.

## EtO Health Effects

EtO irritates the eyes and skin; it may also irritate mucous membranes and cause a strange taste in the mouth. EtO may cause allergies, adverse reproductive effects, and possibly asthma. At high concentrations, it can cause nausea and vomiting [LaMontagne and Kelsey 1998a,b]. EtO can be detected by odor only when it has already reached the dangerous concentration of 260 ppm. Olfactory fatigue may limit a person's ability to smell EtO, but perception at concentrations below the odor threshold may occur because of mucous membrane irritation and a peculiar taste in the mouth. In 1984, the Occupational Safety and Health Administration (OSHA) classified EtO as a carcinogen

and regulated it as such [29 CFR* 1910.1047]. In 1994, the International Agency for Research on Cancer (IARC) classified EtO as a Group 1 human carcinogen [IARC 1994].

## INDUSTRIAL STERILIZATION PROCESS

Although the sterilization process and emission controls vary greatly among facilities, most industrial sterilization processes involve placing the products to be sterilized in a large chamber, injecting the chamber with EtO, flushing the EtO out of the chamber, and removing the sterilized products. Steps include product conditioning (preconditioning), sterilization, and sterilant gas removal (aeration). The sterilization stage consists of an initial purge, sterilant injection, sterilant gas dwell, and post-sterilization purge. Stages vary with the type of products to be sterilized and the equipment used.

In the typical process, EtO vapors from the sterilizer chamber and other areas of the facility are sent to an acidified wet scrubber before emission to the air. However, the scrubber may not keep the EtO concentration low enough to meet the emissions standard. Furthermore, sterilizer operators are left with ethylene glycol solutions for disposal. Consequently, sterilizer operators have added OECDs either after or in place of the wet scrubber. In OECD systems, EtO vent streams are mixed with dilution air to ensure that the EtO concentration that reaches the OECD is kept below 7,500 ppm (one-fourth of the 30,000-ppm lower flammability limit) or the manufacturer's specification under normal operating conditions. A key factor in sterilizer operation is ensuring that workers are not exposed to toxic concentrations of EtO.

One feature of the sterilizer chamber is a back vent, which consists of a large-diameter valve and a blower at the back of the sterilizer chamber. The blower creates a large-volume air flow through the chamber when the chamber door is opened at the end of a sterilization cycle. When this door is opened, the valve in the back vent automatically opens, and the OECD unit throttles up to capture and destroy EtO. This process keeps EtO concentrations below the OSHA permissible exposure limit (PEL) for workers who must enter the chamber to remove sterilized products. Figures 1 and 2 depict the typical process and emissions flow of industrial EtO sterilization facilities with and without an OECD.

## SAFETY CONCERNS†

Overfeeding increases the risk of EtO explosion. Possible causes for various types of overfeeding are listed here.

### A. Overfeeding the OECD from back vents containing high concentrations of EtO

***Causes:***

1. The back vent was turned on with EtO-rich gas present because

   —safety interlocks were bypassed,

   —the EtO valve leaked,

**Code of Federal Regulations*. See CFR in references.

†See also Appendix D.

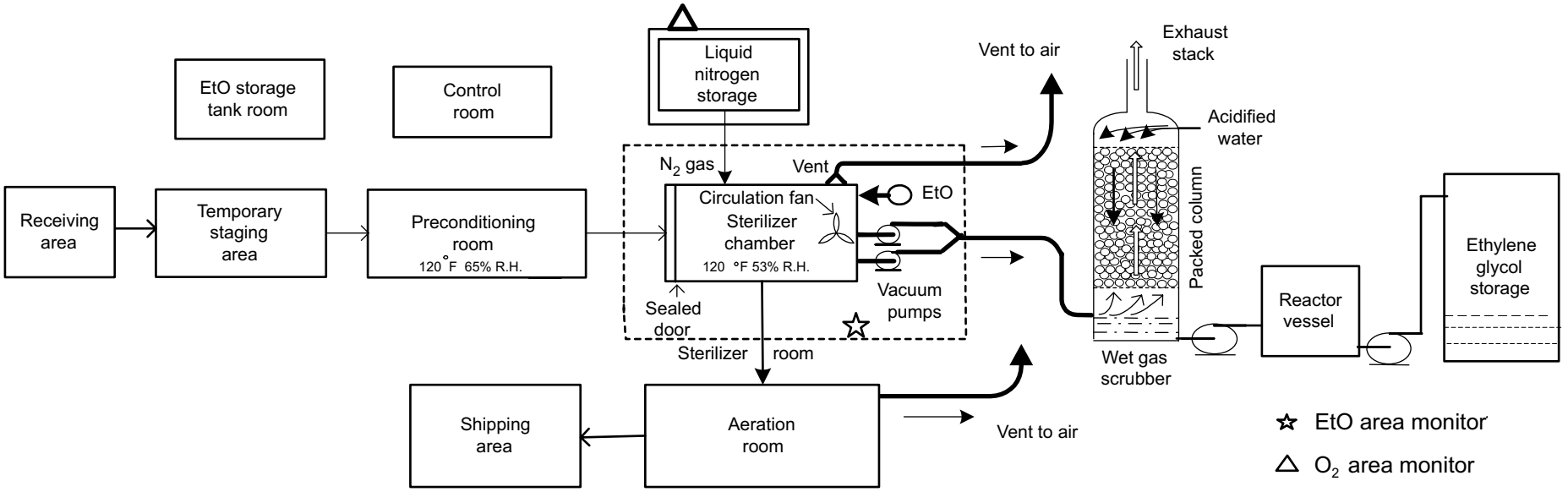


Figure 1. Typical process and emissions flow of an EtO sterilization facility using a wet scrubber.

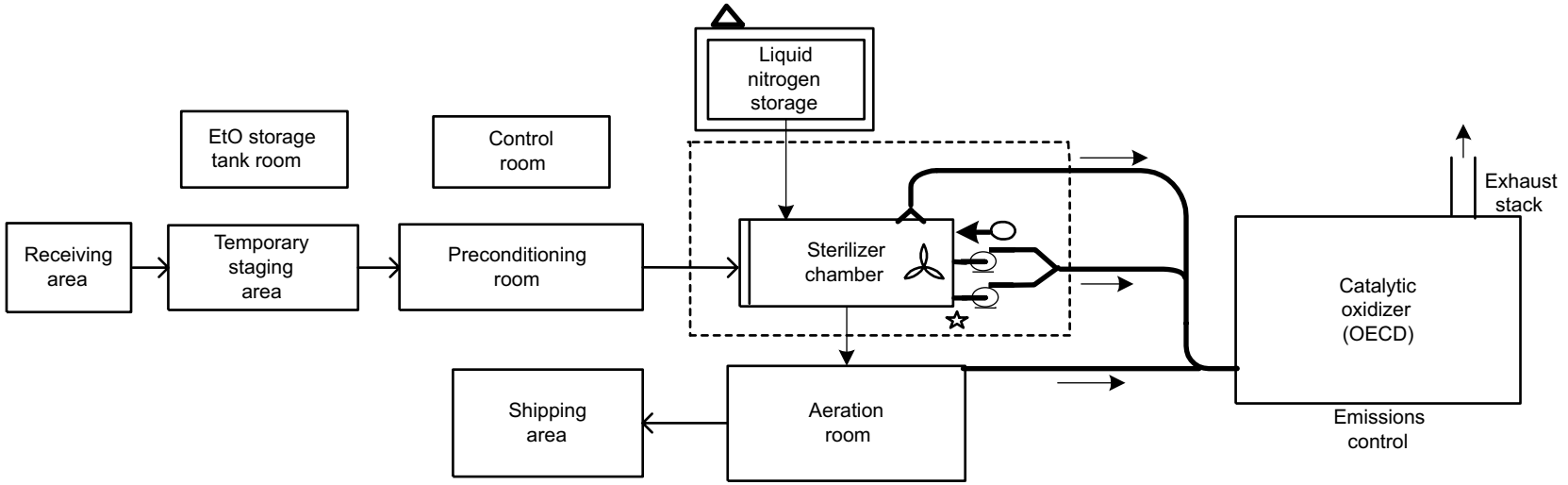


Figure 2. Typical process and emission flow using an OECD.

—the product degassed too long in the sterilizer after cycle completion, or

—the computer system, controller, or instrumentation failed.

2. The product was not adequately washed or flushed of EtO before the door was opened.

3. The incorrect cycle was used for the product.

4. The lower flammability limit sensors and the flow sensors had slow response times.

5. Test cycles explored process capability limits (resulting in an unexpected EtO-rich environment).

### B. Overfeeding from vacuum pumps

***Causes:***

1. Too many vacuum pumps were operating.

2. Discharges were misdirected.

3. Incoming flows were not interlocked or controlled.

4. EtO feed valves failed or malfunctioned.

5. Safety interlocks were bypassed.

### C. Overfeeding from lack of adequate dilution air

***Causes:***

1. Aeration exhaust or dilution source was lost.

2. Makeup dilution was lost.

### D. Overfeeding from other sources

***Causes:***

1. Spills or drum leaks occurred near vents to the OECD.

2. No interlock was present between the EtO valve and the sterilizer.

3. The air in-bleed valve failed or malfunctioned.

4. Valves became stuck and resulted in misdirected flow.

5. EtO cylinders were purged with EtO delivery valves in the wrong position.

6. The upstream scrubber was operated improperly.

7. The sterilizer control system was inadequate.

8. Cabinet locks were not present, allowing easy access to the manual sterilizer switches.

## CURRENT STANDARDS

### NIOSH

The NIOSH recommended exposure limit (REL) for EtO is 0.1 ppm as an 8-hr time-weighted average (TWA) with a 10-min ceiling limit of 5 ppm [NIOSH 1983]. NIOSH has determined that 800 ppm is the EtO concentration that is immediately dangerous to life and health (IDLH) [NIOSH 1994, 1997].

## OSHA

The OSHA PEL for EtO is 1 ppm as an 8-hr TWA with a 15-min excursion limit of 5 ppm [29 CFR 1910.1047]. Because of OSHA regulations, back vents were installed to reduce worker exposure to EtO.

## EPA

EPA has developed acute exposure guideline levels (AEGLs) for high-priority, acutely toxic chemicals. The AEGL is the concentration at or above which the general population could experience serious, long-lasting health effects or impaired ability to escape (because of health effects). The AEGL for EtO is 110 ppm for 1 hr [62 Fed. Reg.[‡] 58839 (1997)].

On December 6, 1994, EPA promulgated its final standard under the Clean Air Act (Subpart O—Ethylene Oxide Emissions Standards for Sterilization Facilities [40 CFR 63.360]). Because of public health concerns about EtO emissions to the air, this standard required that by December 6, 1997, all sterilization and fumigation facilities using more than 10 tons of EtO per year increase emission removal efficiency from 95% to 99% and add controls to certain vent streams. Many facilities selected and installed OECDs to meet these requirements (see Appendix B for more information about emission control devices). When several facilities using EtO and OECDs experienced explosions, EPA delayed the compliance deadline for 3 consecutive years so that facilities could reassess the safety of their processes and emission control systems.

[‡]*Federal Register*. See Fed. Reg. in references.

## ACGIH

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends for EtO a threshold limit value (TLV) of 1 ppm as an 8-hr TWA [ACGIH 1999].

## AIHA

The American Industrial Hygiene Association (AIHA) writes emergency response planning guidelines (ERPGs) for toxic chemicals involved in emergency situations such as releases to the community. The ERPG-2 for EtO is 50 ppm—the concentration below which nearly all persons can be exposed for up to 1 hour without experiencing irreversible or other serious health effects [AIHA 1998]. The ERPG-3 for EtO is 500 ppm—the concentration below which nearly all persons can be exposed for up to 1 hour without experiencing life-threatening health effects [AIHA 1998].

# CASE REPORTS

The following case reports briefly describe the EtO explosions at sterilization or repackaging facilities.

## Case 1

At an EtO sterilization facility, an operator noted an overfeed of EtO in one of the chambers during sterilization. The operator tried to correct the problem by adding dilution air and bringing the chamber to atmospheric pressure. When the front door of the sterilizer was opened, a valve opened at the back of the sterilizer (the back vent), causing EtO to bypass the wet scrubbers and go directly to the OECD. An

ignition occurred in the OECD on the roof of the facility. EtO gas in the ductwork flashed back and over-pressured the ductwork and the sterilizer. As a result, the roof of the building, walls, ductwork, and OECD were severely damaged. No workers were injured, and no chemicals were released to the environment [EPA 1997a].

### Case 2

An explosion occurred recently at a commercial EtO sterilization facility. This facility handles the bulk sterilization of medical kits using 100% EtO. The sterilization chambers are connected to two 400-lb EtO cylinders. Before the incident, the facility had replaced an acidified wet scrubber system with a new OECD to control EtO emissions. During a test run of the OECD at Chamber 1, an explosion occurred following primary evacuation of the chamber—about 15 sec after the back vent fan exhausted the chamber. Later it was determined that the ignition had occurred at the OECD. The ensuing explosion caused a flame front from the oxidizer back to the mixing plenum, completely destroying the plenum box. The explosion continued upstream toward the sterilizer, blowing out 14-gauge steel ducting along the way. The door blew off the sterilizer and shot through the building, damaging the de-gas room. The 50,000-lb chamber was moved 3 ft off its foundation. About 7% EtO (15 to 20 lb) was in the sterilizer at the time of the explosion. No worker injuries were reported [EPA 1997b].

### Case 3

At an EtO repackaging facility, an explosion occurred during a test run on the inside of a thermal oxidizer. Testing probes had been placed at the inlet and outlet sides of the thermal oxidizer. At the beginning of the test, the inlet concentration was in the expected range of 1,000 ppm EtO. But just before the explosion, the inlet EtO concentration rose to 35,000 ppm. Within 16 sec, the explosion occurred in the thermal oxidizer. The thermal oxidizer bed and production equipment were damaged, and the filling room was destroyed. No worker injuries were reported [EPA 1998].

## CONCLUSIONS

All incidents described in the case reports occurred during operations in which an OECD was used as the only emission control device (that is, when acidified wet scrubbers were not used or were bypassed). Sterilization facilities using an OECD typically have the chamber door interlocked with the back vent system to protect workers from EtO exposure when they are loading or unloading products. When the back vent system is activated, it vents a high-volume flow directly to the OECD. The intention is to activate the back vent only when the concentration of EtO in the chamber is well below the lower flammability limit (3% or 30,000 ppm EtO)—typically in the range of several hundred parts per million. OECDs are designed to operate at concentrations well below the lower flammability limit to avoid igniting the sterilant gas. Some EtO explosions have been caused by incomplete evacuation cycles, and others have been caused by improper operation. **In all cases, overfeeding resulted when a high concentration of EtO was inadvertently sent to the OECD.**

Investigation and analysis of the incidents described here and a review of the sterilization process by EOSA and EPA resulted in the following conclusions:

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

# RECOMMENDATIONS

## Workers

Workers should take the following steps to prevent EtO explosions:

### *1. Prevent overfeeding of the OECD*

- Make sure that all interlocks, safeguards, and other preventive measures are in place before a sterilization cycle begins.
- Periodically wash or vent sterilized products that sit idle in a sterilizer or aeration room to prevent EtO buildup.
- Monitor EtO concentrations in the sterilizer before the back vents are activated to avoid exhausting high concentrations of EtO through the back vent to the OECD.
- Vent confined spaces such as the sterilizer and the aeration room to the outside after a power loss to prevent EtO buildup and overfeeding of the OECD.
- Do not purge EtO lines to an OECD: an incorrect valve lineup or a leak in the storage area is likely to lead to overfeeding.
- Perform regular preventive maintenance.
- Obtain management approval before changing the process or safety interlocks.

See Appendix C for more details about steps to prevent overfeeding of the OECD.

### *2. Store and handle EtO properly*

- Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion-proof area. Store cylinders or tanks away from heat, sparks, flames, strong oxidizers, alkalines, acids, and acetylide-forming metals such as copper, silver, mercury, and their alloys. The storage room should be explosion-proof according to the definition of the National Fire Protection Association (NFPA 560) [NFPA 1995].
- Do not smoke, use electrical devices, or create open flames where EtO is handled, used, or stored.
- Use nonsparking tools when opening or closing metal containers of EtO or whenever EtO might be present.
- Keep containers individually bonded and grounded to the earth when liquid EtO is poured or transferred.

### *3. Deal with leaks and spills*

- Leave a leak or spill area immediately.
- If a catastrophic or large release of EtO occurs, do not enter the area. Evacuate the building and notify the

fire department immediately. ***Note***: *A large release of EtO is any release other than the type of small leak that would occur (for example) from a loose connection or valve. A catastrophic release is one that would occur if (for example) a forklift pierced a 400-lb EtO cylinder*.

- Do not enter an area where there is a small EtO leak until you have put on personal protective equipment (PPE), including a self-contained breathing apparatus (SCBA) that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

- **Do not use an SCBA unless you have received proper training and are current on its safe use.**

### *4. Be prepared for rescue*

- Know emergency rescue steps and where emergency equipment is located. Be sure that you comply with OSHA regulations regarding emergency response, PPE, and rescue in confined spaces [29 CFR 1910.38, 1910.120(q), 1910.132–138, 1910.146].

- **Do not participate in emergency response without an SCBA and proper training.** If you do not have an SCBA and proper training, let the local fire department conduct the rescue.

- Before rescuing anyone in a leak or spill area, notify another person and put on an SCBA. Do not use a canister-type respirator for emergency response; such respirators provide no protection in case of leaks or spills.

- If someone stops breathing because of EtO inhalation, immediately remove the person from the exposure area and perform cardiopulmonary resuscitation (CPR) while someone else calls for medical help. Keep the victim warm.

### *5. Prevent skin and eye contact*

- If liquid EtO contacts your skin, rinse it immediately under a heavy shower. Remove any contaminated clothing. Get medical attention.

- If EtO gets into your eyes, flush them immediately with a steady stream of water for at least 15 min. Lift the upper and lower eyelids and direct the stream of water under the eyelids. Get medical attention.

- Do not wear contact lenses in an area where EtO exposure might occur.

### *6. Use respiratory protection and other PPE*

- Use appropriate respiratory protection[§] during emergencies, maintenance work, vessel cleaning, and whenever engineering controls cannot be implemented. At a minimum, such protection must comply with OSHA requirements in 29 CFR 1910.1047 and 1910.134.

- Use PPE such as chemical-resistant gloves, eye-splash protection, and liquid-tight protective clothing whenever liquid EtO might be present. At a minimum, such equipment must comply with OSHA requirements [29 CFR 1910.1047].

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[§]For detailed information about respiratory protection for workers exposed to EtO, see *NIOSH Current Intelligence Bulletin 52: Ethylene Oxide Sterilizers in Health Care Facilities* [DHHS (NIOSH) Publication Number 89–115].

## Employers

The following list of recommendations presents engineering controls and safety procedures for preventing fires and explosions at EtO sterilization and repackaging facilities. This list was identified by the EOSA Safety Committee and was revised by NIOSH. The list is not all-inclusive and may not be equally applicable to all sterilization and repackaging facilities. Employers should identify and use the controls and procedures that are relevant to their facilities. They should also be aware that no fail-safe control technique exists to guarantee that fires and explosions will not occur at their facilities.

### *1. Analyze and develop written procedures*

- Conduct a process hazard analysis that emphasizes safety procedures for the entire sterilization system (chambers, aeration rooms, EtO delivery and evacuation, and emission control). This analysis will minimize the possibility that flammable concentrations of EtO will enter the oxidizer (see Appendix E).
- Establish written procedures to cover all steps of EtO sterilization.
- Evaluate the advantages and disadvantages of each control technology.

### *2. Prevent overfeeding of the OECD*

- Prevent overfeeding of the OECD by following the steps listed on page 8.
- Install an OECD bypass for emergency use if allowed by State or local environmental regulations.

### *3. Store and handle EtO properly*

- Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion-proof area. Store cylinders or tanks away from heat, sparks, flames, strong oxidizers, alkalines, acids, and acetylide-forming metals such as copper, silver, mercury, and their alloys.
  - —Make sure that the storage room is explosion-proof according to the definition of the National Fire Protection Association (NFPA 560) [NFPA 1995].
  - —Make sure that the storage room meets National Electrical Code requirements to prevent ignition and explosion.
- Do not permit smoking, use of electrical devices, or open flames where EtO is handled, used, or stored.
- Use nonsparking tools when opening or closing metal containers of EtO or whenever EtO might be present.
- Keep containers individually bonded and grounded to the earth when liquid EtO is poured or transferred.

### *4. Deal with leaks and spills*

- Make sure that all workers leave a leak or spill area immediately.
- If a catastrophic or large release of EtO occurs, do not permit workers to enter the area. Evacuate the building and notify the fire department immediately. ***Note***: *A large release of EtO is any release other than the type of small leak that could occur (for example) from a loose connection or valve. A catastrophic release is one that would occur if (for example) a forklift pierced a 400-lb EtO cylinder*.
- If a small leak occurs, do not permit any worker to enter the area until

he or she has put on PPE, including an SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

- Do not permit workers to use SCBAs unless they have received proper training and are current on their safe use.

### *5. Implement engineering controls*

- Provide an abort cycle (with diluent) in the sterilizer control system.
- Establish and follow a cycle approval process for all test cycles.
- Provide limited access to override controls.
- Eliminate back vents through appropriate equipment and cycle design.
- Interlock the sterilizer door to prevent opening before the cycle is complete.
- Interlock the gas inlet (shut-off) valve.
- Make sure that regular preventive maintenance is performed.
- Install a flow-limiting device on the vacuum pump inlet (controls or orifice).
- Install valve position sensors on critical valves.
- Install real-time area monitors that will alert workers to unsafe EtO concentrations.
- Use redundancies or other safeguards on all critical valves. For example, install redundant control valves on the EtO line (use double-block valves with leak check).
- Use damage control devices to limit explosion damage:
  - —install flow-control checkvalves in the EtO supply lines.
  - —install flame arresters and checkvalves in OECD feed lines from the vacuum pumps to eliminate flame propagation back into and throughout the system.
- Make sure that all other equipment has proper safety controls.

### *6. Install emergency equipment*

- Equip the facility with a type 2, 3 carbon dioxide or dry chemical fire extinguisher. Train workers annually in their safe use.
- Provide emergency eye-wash facilities.

### *7. Provide respiratory protection and PPE*

- Provide workers with appropriate respiratory protection** for use during emergencies, maintenance work, vessel cleaning, and whenever engineering controls cannot be implemented. At a minimum, such protection must comply with OSHA requirements in 29 CFR 1910.1047 and 1910.134.
- Provide workers with chemical-resistant gloves, eye-splash protection, and liquid-tight protective clothing whenever liquid EtO might be present. At a

**For detailed information about respiratory protection for workers exposed to EtO, see *NIOSH Current Intelligence Bulletin 52: Ethylene Oxide Sterilizers in Health Care Facilities* [DHHS (NIOSH) Publication Number 89–115].

minimum, such equipment must comply with OSHA requirements [29 CFR 1910.1047].

### *8. Provide training*

- Fully train all operations, maintenance, and engineering workers in the dangers of EtO-rich evacuations to an OECD.

- Train all workers who will be responding to emergencies (including managers and supervisors) in the proper use of safety equipment and in emergency procedures for all EtO plant operations. Training should include

  —instruction about spill and control procedures,

  —information about the OSHA hazard communication standard [29 CFR 1910.1200],

  —training in the use of SCBAs and other PPE, and

  —instructions in following OSHA requirements for preventing EtO exposure and for decontamination [29 CFR 1910.1047].

### *9. Prepare workers for rescue*

- Make sure that workers know emergency rescue steps and where emergency equipment is located. Be sure that they comply with OSHA regulations regarding emergency response, PPE, and rescue in confined spaces [29 CFR 1910.38, 1910.120(q), 1910.132–138, and 1910.146]. ***Note***: *29 CFR 1910.119 applies if a facility possesses 5,000 lb EtO or more at any given time*.

- **Do not permit workers to participate in emergency response without SCBAs and proper training.** If workers do not have SCBAs and proper training, let the local fire department conduct the rescue.

- Design, develop, and practice emergency evacuation and rescue procedures.

## Manufacturers

Manufacturers should develop reliable, high-speed EtO monitoring sensors to be installed and integrated into the EtO sterilization process.

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We greatly appreciate your assistance in protecting the health of U.S. workers.

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# SOURCES OF ADDITIONAL INFORMATION

## Organizations

The Ethylene Oxide Sterilization Association, Inc. (EOSA)
Washington, DC
Telephone: 202–296–6300

ISEA—The Safety Equipment Association
Arlington, VA
Telephone: 703–525–1695

National Institute for Occupational Safety and Health (NIOSH)
Washington, DC
Telephone: 1–800–35–NIOSH
(1–800–356–4674)

U.S. Environmental Protection Agency (EPA)
Chemical Emergency Preparedness and Prevention Office
Washington, DC
Telephone: 202–260–9781

U.S. Chemical Safety & Hazard Investigation Board
Washington, DC
Telephone: 202–261–7600

## Internet Resources

EOSA Web site: www.eosa.org

EPA Chemical Emergency Preparedness and Prevention Office Web site: www.epa.gov/ceppo

ISEA Web site: www.safetycentral.org/isea

NIOSH Web site: www.cdc.gov/niosh

OSHA Web site: www.osha.gov

OSHA Regulations for Ethylene Oxide (29 CFR 1910.1047) Web site: www.osha-slc.gov/OshStd_data/1910_1047.htm

Right-to-Know Web site: www.rtknet.org

U.S. Chemical Safety & Hazard Investigation Board Web site: www.chemsafety.gov or www.csb.gov

# APPENDIX A
# ABBREVIATIONS AND GLOSSARY

## Abbreviations

| | |
|---|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AEGL | acute exposure guideline level |
| AIHA | American Industrial Hygiene Association |
| Btu | British thermal unit |
| CFR | *Code of Federal Regulations* |
| CPR | cardiopulmonary resuscitation |
| EOSA | The Ethylene Oxide Sterilization Association |
| EPA | U.S. Environmental Protection Agency |
| ERPG | emergency response planning guideline |
| EtO | ethylene oxide |
| °F | degrees Fahrenheit |
| Fed. Reg. | *Federal Register* |
| ft | foot (feet) |
| HAZOP | hazardous operational study |
| hr | hour(s) |
| IARC | International Agency for Research on Cancer |
| IDLH | immediately dangerous to life and health |
| L | liter(s) |
| lb | pound(s) |
| m | meter(s) |
| mg | milligram(s) |
| min | minute(s) |
| mm Hg | millimeters of mercury |
| NESHAP | National Emission Standards for Hazardous Air Pollutants |

| | |
|---|---|
| NFPA | National Fire Protection Association |
| NIOSH | National Institute for Occupational Safety and Health |
| OECD | oxidizing emission control device |
| OSHA | Occupational Safety and Health Administration |
| PEL | permissible exposure limit |
| PPE | personal protective equipment |
| ppm | parts per million |
| REL | recommended exposure limit |
| SCBA | self-contained breathing apparatus |
| scfm | standard cubic feet per minute |
| sec | second(s) |
| STEL | short-term exposure limit |
| TLV | threshold limit value |
| TWA | time-weighted average |
| % | percentage |

## Glossary

**Algorithm**: The "logic" programmed into a computer that controls the process on the basis of inputs from sensors, switches, or other devices. A typical algorithm may control how many pumps can be operating or when a valve is turned on or off or is repositioned.

**Back vent**: A large-diameter valve and blower at the back of the sterilizer. The vent creates a high-volume evacuation of the sterilizer when the sterilizer entrance door is opened to reduce operator EtO exposure during unloading. Most back vents pull in air at a rate equal to one sterilizer volume per minute. Most back vents are automatically triggered when an operator opens or attempts to open the sterilizer door, regardless of conditions within the chamber.

**Cycle**: Treatment of a product with EtO in a sterilizer designed to render the product free of all forms of viable microorganisms. EtO concentrations in the sterilizer range between 100 and 800 mg/L or between 5.5% and 44.4%. The cycle includes removing air from the sterilizer, conditioning with temperature and humidity (if used), injecting EtO, exposing the product to EtO, removing EtO, and flushing the sterilizer. A diluent gas (such as nitrogen) is generally injected and evacuated as part of air removal at the beginning of the cycle and during flushing after EtO exposure. These diluent injections and evacuations have become prominent safety additions for OECD operation because they decrease the flammability of the environment within the sterilizer. After completion of the cycle, the back vent is run before unloading. (***Note***: *Cycle parameters vary widely among facilities. Most facilities operate several different cycles, depending on customer needs*.)

**Emission control device and OECD**: A device designed to reduce the EtO content in the exhaust stream (source). Generally, OECD refers to an oxidizing emission control device (catalytic or thermal) (see also Appendix B).

**Exhaust stream**: The sum of all gases exiting from the facility (source) that is directed to the inlet of the emission control device or OECD.

**Gas delivery system**: The system that delivers EtO from its protective storage drum through automated valves into a vaporizer. The vaporizer converts the liquid EtO to gas as it is injected into the sterilizer. The correct amount of EtO injected may be determined by measuring the change in weight of the EtO tank, by measuring the change in pressure within the sterilizer, or both.

**Interlock**: A mechanical device or computer algorithm that ties one action into another action (response). An interlock may be as simple as a mechanical limit switch that is tied to a motor starter, or it may be a computer program that electrically or mechanically "locks out" a valve or motor until certain conditions have been met. Effective interlocks provide a safer, but not foolproof, method of assuring that an objective or procedure is met before an action is taken. A complete review of all normal and abnormal operating conditions (using a hazard analysis) is necessary when assessing an interlock's effectiveness. Startup and testing of safety-related interlocks is important and requires extreme caution.

**Lower flammability limit**: The lowest concentration of a substance in air that will sustain combustion when elevated to its ignition temperature. The lower

flammability limit for EtO is about 3% or 30,000 ppm at standard conditions. This limit can be lower under elevated temperature or pressure. Note that EtO is also flammable at 100%, indicating that oxygen is not required to have a flammable event.

**Manual intervention**: The ability of an operator to manually override the sterilizer controller by (1) accessing the sterilizer controller and manually initiating an action before completion of a cycle step or (2) opening the sterilizer door (and thus triggering the operation of a back vent) before completion of the cycle.

**Operator**: A person who is responsible to initiate, monitor, and control a cycle. The operator may manually intervene and may also load and unload product from the sterilizer.

**Overfeeding**: Introducing EtO to an emission control device or OECD at a rate greater than the manufacturer's design limitation.

**Sterilizer**: A sealed chamber in which a product is subjected to a cycle that renders it free of all forms of viable microorganisms. A sterilizer generally consists of a chamber with one or more doors, a vacuum pump, a back vent valve with a blower, a heating system, a gas delivery system, a sterilizer controller, and various parameter gauges and instruments.

**Sterilizer controller**: A computer system that controls and monitors the cycle. The system controls (1) the appropriate valves, pumps, blowers, and heaters according to a planned sequence (algorithm) and (2) rates of pressure changes to achieve the desired environment within the sterilizer. The system monitors sterilizer pressure, sterilizer temperature, possibly EtO cylinder weight and EtO temperature, evacuation rates, and vacuum depths. Redundant sensors or methods contribute to increased reliability of operating parameters.

**Vacuum pump**: A device that withdraws gases from a sealed sterilizer. It generally consists of a liquid ring pump capable of pulling a vacuum in a sealed sterilizer. Vacuum pumps are rated in cubic feet per minute at the pump inlet. Most pumps have a rated capacity between 0.1 and 0.25 sterilizer volumes per minute.

# APPENDIX B
# TYPES OF EMISSION CONTROL DEVICES

The following describes the different technologies used to treat EtO emissions and the common ranges of operation for these control devices.

## Wet Scrubbers

Wet scrubbers have been installed on many sterilizer primary vacuum pump discharges. A wet scrubber absorbs EtO into a recirculating water-acid solution, converting the EtO to ethylene glycol. It operates effectively with higher concentrations of EtO in air or nitrogen. The most common size for sterilizer primary discharges (vacuum pumps) is between 200 and 400 standard cubic feet per minute (scfm) (600 to 600,000 ppm EtO). Wet scrubbers can have capacities of up to 20,000 scfm, though these are generally for lower EtO concentrations (50 to 8,000 ppm). Wet scrubbers operate at ambient temperature. Overfeeding generally results in recovery efficiencies below the required 99% NESHAP[††] but is generally not detrimental to the system.

## Catalytic OECDs

Catalytic OECDs operate by oxidizing or burning EtO to form the end products of carbon dioxide, water, and heat. The inlet gas is preheated to the needed activation temperature of the catalyst, about 300 F. The preheating is generally accomplished with a direct-fired burner, indirect-fired burner, steam coil, or electric element. The oxidation causes the temperature in the catalyst to rise. EtO has a fuel value of about 12,000 British thermal units (Btu)/lb. Catalytic OECDs can have up to 30,000 scfm rated flow capacity. The most common sizes currently in use fall between 6,000 and 14,000 scfm. The maximum inlet concentration of EtO should be limited to 3,000 to 6,000 ppm or to the manufacturer's specification.

Overfeeding produces even higher temperatures in the catalyst and gas stream, potentially damaging the catalyst or shortening its useful life. If the inlet gas has an EtO concentration greater than the explosive limit, an explosion can result. If the inlet gas has a concentration above the explosive limit, an explosion can result either from the high temperature of the catalyst or from the direct-fire burner. Exhaust gases containing EtO should never be passed through a catalytic OECD under cold conditions, because the catalyst will adsorb and destroy the EtO. The exothermic EtO destruction will increase the temperature of the system and an explosion may result.

[††]National Emission Standards for Hazardous Air Pollutants.

## Thermal OECDs

Thermal OECDs operate with the same end result as the catalytic OECDs. They operate without a catalyst at a higher temperature than catalytic OECDs and generally have a higher EtO concentration limit. Inlet concentration limits vary by manufacturer. Recuperative thermal OECDs and regenerative thermal OECDs provide heat recovery for facility uses. Recuperative and regenerative thermal OECDs have flow rates of up to 20,000 and 100,000 scfm, respectively. Thermal OECDs provide an ignition source for vapor containing concentrations greater than the lower flammability limit of EtO.

## Dry-Bed Reactors

Dry-bed reactors eliminate EtO by causing it to bind permanently to the reactant. They operate at ambient temperatures and do not require preheating of the exhaust gas. They are most commonly used for removing low concentrations of EtO from high-volume exhaust streams. Occasionally, they are used for emergency containment of a catastrophic event (emergency responses) where they handle a short burst with a high concentration of EtO. Dry-bed systems can be furnished for any flow capacity. Typical operating concentrations vary from 5 to 300 ppm with spikes up to 10,000 ppm. Overfeeding these reactors increases the temperature and may cause a fire or explosion.

# APPENDIX C
# PREVENTIVE MEASURES AND SAFETY CONSIDERATIONS

The EOSA Safety Committee has identified the following preventive measures and safety considerations for the sterilization process. The list was revised by NIOSH.

**A. Interlock the sterilizer door and gas valve.**

Mechanically or electrically lock the gas valve out of operation if the sterilizer door is opened. This measure prevents an EtO-rich environment from entering a sterilizer while a cycle is not running.

**B. Use interlocks to prevent the opening of a sterilizer door before a cycle is complete.**

Be sure interlocks, safeguards, or other preventive measures are in place to prevent the opening of a sterilizer door during a sterilization cycle. Since several sterilizer installations have the back vent interlocked with the sterilizer door for worker safety considerations, the door must remain shut when EtO-rich concentrations are present in the chamber.

**C. Wash or vent periodically while the sterilizer is idle with the product.**

If a sterilized product sits idle in a sterilizer or aeration room, wash or vent it periodically to prevent buildup of EtO.

**D. Monitor the EtO concentration in the sterilizer before back vents are activated.**

Use direct analysis of the sterilizer gas content in conjunction with lockout of the back vent to prevent exhausting high concentrations through the back vent. Direct analysis and the air-flow rate of the back vent and vacuum pump provide real-time information that can be used to limit EtO flow to the OECD below design limits. (The accuracy, reliability, resolution, and availability of current EtO measurement devices is questionable.)

**E. Use redundant control valves (double-block, with leak check) on the EtO line.**

Use redundant control valves on the EtO line to prevent overfeeding if one valve fails or develops a leak.

**F. Install valve position sensors on critical valves.**

Valve position sensors provide continuous feedback of a valve's open or closed status. Consider the types of position indicators installed and whether they can be used as a mechanical, electrical, or software interlock with the OECD.

**G. Install a flow-limiting device on the vacuum pump inlet (controls or orifice).**

Install software or mechanical flow-limiting devices on vacuum pump inlets to prevent overfeeding of the OECDs.

**H. In an emergency, disconnect the back vents and bypass the OECD (if legally allowed).**

In an emergency, removal of the back vents from the OECD can eliminate this stream as a source of overfeeding. However, this measure may be illegal because of the environmental impact.

**I. Use redundancies or other safeguards for all critical valves.**

Redundant valves, sensors, or systems prevent overfeeding if one valve fails or develops a leak.

**J. Vent confined spaces to the outside atmosphere after a power loss.**

Since high-EtO concentrations can accumulate in a confined space after a power loss, vent the confined space to the outside atmosphere to prevent buildup of EtO concentrations and overfeeding of the OECD.

**K. Do not purge EtO lines to an OECD.**

Avoid purging EtO drums or venting EtO storage systems to an OECD, since an incorrect valve lineup or a serious leak in the storage area is likely to lead to overfeeding. Do not install a vent in the gas storage or charging area that feeds the OECD. Instead, consider using spring-closed valves.

**L. Assure proper controls of other equipment.**

Systematically evaluate the integration of the OECD into the facility under all operating conditions during a process hazard analysis. The OECD relies on the correct operation of other sterilization equipment that may fail periodically. Failure of any single piece of equipment should not result in the unsafe operation of the OECD.

**M. Provide limited access to override controls.**

Avoid overriding or bypassing safeguards or interlocks. Overrides of safety interlocks should not be allowed without proper review of their consequences by qualified personnel.

**N. Provide an abort cycle (with diluent) in the sterilizer control system.**

If the sterilization cycle is aborted after EtO gas has been injected into the chamber, the sterilizer controller should automatically run an abort cycle. The abort cycle typically consists of evacuations and diluent washes to bring the gas content of the chamber below the lower flammability limit.

**O. Fully train all operations, maintenance, and engineering personnel on the dangers of EtO-rich evacuations to an OECD.**

Proper safety training is essential for all workers involved in operating the sterilization equipment.

**P. Follow a cycle approval process for all test cycles.**

When testing is performed using sterilization equipment or the OECD, an administrative approval process is recommended to ensure safe operation. During testing, the design limits of systems are often approached and safeguards are bypassed.

**Q. Perform regular preventive maintenance.**

A sound preventive maintenance program reduces the number of failures of critical equipment and therefore reduces the risk associated with operating the sterilization equipment.

**R. Eliminate back vents through appropriate equipment and cycle design.**

Through appropriate equipment and cycle design, back vents may be eliminated as an input stream to the OECD. Worker safety issues should be fully assessed when this preventive measure is implemented to ensure a safe working environment.

**S. Obtain management and administrative approvals.**

Proper management and administrative approvals are also needed before any changes are made to the process or safety interlocks. This approval process needs to include proper review of the consequences associated with any changes.

**T. Use damage control devices.**

Incorporate safety engineering devices such as flame or detonation arresters and explosion vents to minimize equipment and facility damage. Install the flame arresters or detonation arresters and check the valves in the EtO supply lines. Also, install flame arresters and check valves in the OECD feed lines from the vacuum pumps to eliminate flame propagation back into and throughout the system.

# APPENDIX D

# SAFETY CONSIDERATIONS FOR THE INTEGRATION OF OECDs

The EOSA Safety Committee has identified the safety concerns and good engineering design for the catalytic and thermal emission control devices listed in this appendix. Most of the recent explosion incidents in the EtO sterilization industry are associated with the use of OECDs, and nearly all are associated with opening a back vent. The following section provides information to consider in the design and integration of an OECD with a sterilizer. This section does not replace a typical process hazard analysis that should be conducted on the entire sterilization process before installing an OECD. Nor should this section replace the normal good engineering guidelines that should be used in the design of the equipment. The purpose of this section is to provide each facility with ideas for the process design and operation.

## Good Engineering Design

Good engineering practice requires that the designer use proper engineering guidelines and codes in the design and operation of the sterilizer and associated equipment (including the OECD equipment). This includes adherence to proper electrical and mechanical codes throughout the sterilization system. Furthermore, the designer needs to ensure that the equipment can safely accommodate maximum operating conditions (including EtO feed rates, temperature, pressure, etc.). Any startup, shutdown, or abnormal operating condition must be reviewed before the system is installed.

The designer should look at EtO inventories at every step of the process and determine the minimum and maximum rates (including EtO rate), minimum and maximum temperatures, minimum and maximum pressures, and other operating conditions. Good engineering practice should also include the review of all failure modes (such as a sticking EtO feed valve or smart valve failure) to see if the equipment selected can safely handle the resulting flow conditions. If more than one sterilizer is used, this review must include all possibilities of “simultaneous” sources to ensure that the entire system is within the design limits. For safety concerns, the designer should look at atmospheric venting for emergency conditions (such as vessel over pressure). Good engineering practice should include redundant instrumentation of critical operating parameters (such as flow rates, EtO weights, etc.). In addition, position indicator sensors should be included on any valves that are critical to the process and safe operation of the system. The control algorithm should include checking the alarm and sensor operation and its integrity during both normal and abnormal operating conditions.

Other good engineering practices include installing manual valves for equipment isolation. A dual path may be desirable because it allows connection of a backup pump or sensor until a broken item can be repaired. Safety must be considered in the design of engineering equipment.

## Integration of Emission Control Device with the Sterilization Process

If an OECD is used, it needs to be properly integrated with the sterilization process, possibly with a scrubber system. The design and operation of both the OECD and the sterilization system must be considered, as the two processes are connected. All operating conditions of the sterilization process, including those during startup, shutdown, and test phases, must be analyzed for potential failure points. Abnormal process conditions pose the most serious safety challenges.

Only after the OECD limitations have been established can the entire operating and control system be devised and reviewed to ensure that these limitations cannot be exceeded under any circumstance. EtO concentrations in the explosive range must never be allowed to enter the device that can create a temperature rise sufficient to ignite the gas stream. The design of the emission control system must take into account the potential for release of EtO from all EtO sources in the facility. The design may vary substantially, depending on the limitations of the control device selected. Since the gas that is initially discharged from the sterilizer by the vacuum pump is always concentrated, dilution is necessary.

## Safety Concerns Associated with Catalytic or Thermal OECDs

Most emission control devices have two limitations: (1) the maximum volumetric flow capacity (commonly expressed in cubic feet per minute), and (2) the maximum quantity of EtO it can process (commonly expressed in pounds per minute). However, if the system has a variable flow capacity, it will most likely have a variable EtO capacity, which will be expressed as a concentration limit—commonly, ppm.

The most immediate safety concern associated with catalytic or thermal OECDs is to prevent overfeeding the system. The most severe result of overfeeding occurs when a quantity of EtO is released that is greater than the lower flammability limit. In this case, the exhaust stream can be ignited by the burner flame (if the OECD has a burner) or by an increase in the catalyst temperature. This would cause an explosion throughout the OECD, the exhaust ducting, and connected sterilizers.

The following four conditions might overfeed an OECD and cause an explosion. Included are references to preventive measures from Appendix C.

### *1. Overfeeding the OECD from back vents containing high concentrations of EtO*

Nearly all of the known explosions associated with OECDs occurred when a sterilizer back vent was opened while a high concentration of EtO was in a sterilizer. This condition generally involves a worker's (a) opening a sterilizer door that triggers back vent operation, (b) using a manual switch to trigger back vent

operation, or (c) triggering back vent operation through a sterilizer controller. The high flow rate of the back vent exhausts could send EtO at a rate that exceeds the safe design limitation of the OECD. An explosion could result.

Each sterilization facility should be examined to determine every condition in which a back vent could be opened while a sterilizer contains an EtO-rich mixture. Appropriate measures should then be taken to prevent opening of the back vent when these conditions exist. Employee error has been a significant cause of overfeeding events. Errors have resulted from allowable procedure changes, test conditions, use of improper procedures, and inadequate process control systems. Since EtO operators can make mistakes, the process hazard analysis must address possible human errors and identify safeguards to protect against and prevent them. Bypassing interlocks should never be allowed without specific permission based on extensive evaluation and knowledge of the possible consequences by designated, qualified personnel.

Sterilization requires an EtO-rich environment during part of the overall cycle. The EtO-rich gas is removed from the sterilizer by the vacuum pump (see item 2 on page 28). A normal cycle includes post-vacuum flushing or purges that successively dilute the EtO concentration in the sterilizer before opening the back vent. In all cases, the normal number of post-vacuum purges should be completed before initiating the back vent. If operations do not go as planned, back vents may be activated during the following unplanned situations:

- **Sterilizer back vent turned on with EtO-rich gas present**—This situation may be caused by the following:

  - *Bypassing safety interlocks*—Even in the best engineered systems, bypassing of safety interlocks by operators or maintenance personnel can result in overfeeding an OECD through the back vent. Aborting cycles after EtO gas is added without adequate diluent washes is an example of improper bypassing of safety interlocks (review preventive measures A, B, C, D, H, and N in Appendix C).

  - *EtO valve leak*—This condition involves a leak of EtO into the sterilizer anytime before a back vent operation. While a pressure rise would generally be observed during the sterilization control portion of a cycle, a person could misdiagnose the cause of the pressure rise. When a cycle is not running, a leak could also fill a sterilizer before a door is opened, triggering back vent operation (review preventive measures A, B, C, D, E, F, H, and Q in Appendix C).

  - *Product degasses too long in sterilizer after cycle completion*—Significant degassing can occur as a load sits in a nonvented sterilizer, resulting in an EtO-rich environment (review preventive measures C, D, H, and J in Appendix C).

  - *Computer system/controller failure*—Computer systems or controllers that directly interface with the sterilization process or OECD control can fail from power bumps, age, software bugs, etc. Since these systems are critical to interlock mechanical equipment properly, their failure can result in an EtO-rich environment in a sterilizer (review preventive measures A, B, D, H, J, and Q in Appendix C).

- *Instrumentation failure*—The sterilizer controller relies on signals from sensors and transmitters to control and monitor the cycle, and these can fail. In addition, lower flammability limit sensors are considered unreliable for use in EtO environments and should not be relied on for quantitative decisions in controllers associated with OECDs (review preventive measures H and Q in Appendix C).

- **Inadequate washing before opening the door**—Cycle design that does not provide for a sufficient number of diluent washes after EtO exposure generally results in an EtO-rich environment before back vent operation (review preventive measures D and H in Appendix C).

- **Incorrect cycle used for product**—Because of variable absorption and desorption rates by different products, a cycle that does not finish with an EtO-rich environment for one product may finish with an EtO-rich environment for other products (review preventive measures D, H, O, and P in Appendix C).

- **Slow response time**—Some lower flammability limit and flow sensors could have slow response times that would not properly identify an EtO-rich stream going to the OECD (review preventive measures D, H, I, and R in Appendix C).

- **Test cycles**—Test cycles often explore process capability limits, and unexpected EtO-rich environments can result (review preventives measures A, B, C, D, H, O, and P in Appendix C).

***2. Overfeeding from vacuum pumps***

Unless an OECD is sized to accept the peak flow of every system exhausting to it, a control algorithm will be necessary to sequence (queue) the number of vacuum pumps evacuating to the OECD. The algorithm may have to monitor what point in the cycle every sterilizer is operating. The control can be very complex and must be thoroughly evaluated. OECD manufacturers rely on the facility personnel to control the maximum amount of EtO flow to OECD. The following are ways design limits can be exceeded:

- **Too many vacuum pumps operating (design and control issue)**—An expanding facility can exceed design limits by (1) adding sterilizers, aeration rooms, or an EtO-rich cycle to a sterilizer not previously considered in the design of the queue controller, or (2) incorrectly computing EtO concentrations being evacuated (review preventive measures G, H, I, L, and O in Appendix C).

- **Misdirecting discharges**—Directing an EtO-rich exhaust stream into a duct system faster than the duct can move it to the OECD can deliver EtO-rich gas to another idled sterilizer or aeration room. This situation creates a “temporary inventory” that is later sent unknowingly to the OECD (review preventive measures D, G, H, I, J, and L in Appendix C).

- **Failure to interlock or control incoming flows**—Proper queue control of all flows must be considered to prevent overfeeding the OECD. Inaccuracies or failures in the queue controller could allow evacuations at a flow rate exceeding the limits of the OECD. Although OECD

manufacturers generally have safety cut-off systems that react to some overfeeding conditions, the reaction is generally too late to prevent an explosion if the exhaust stream is above the lower flammability limit (review preventive measures G and I in Appendix C).

- **Failure or malfunction of the EtO feed valves**—Failure of an EtO feed valve can result in an unexpected EtO-rich environment in a sterilizer. When the vacuum pump is activated, it delivers more EtO than planned (review preventive measures E, F, G, I, and Q in Appendix C).

- **Bypassing safety interlocks**—Even on the best-engineered systems, bypassing safety interlocks by operations, maintenance, or engineering personnel can result in a back overfeeding of the OECD by the back vent. Aborting cycles after EtO gassing without adequate diluent washes is an example of improper bypassing of safety interlocks (review preventive measures A, B, C, D, H, M, N, and O in Appendix C).

### *3. Overfeeding from lack of adequate dilution air*

- **Loss of the aeration exhaust or dilution source**—Some OECD installations rely on the aeration room exhaust to dilute the high concentrations from EtO-rich sources to a safe concentration (review preventive measures I and Q in Appendix C).

- **Loss of make-up dilution**—OECDs generally have one or more fans, various valves, one or more filters, a diffuser, and a catalyst bed. The failure or plugging of any of these items decreases the flow of air. Discharging an otherwise acceptable EtO-rich stream may cause overfeeding because of insufficient dilution (review preventive measures I and Q in Appendix C).

### *4. Overfeeding from other sources*

- **Spills or drum leaks near vents to OECD**—Spills or drum leaks near any vent flowing to an OECD can result in an unplanned EtO-rich flow delivered to an OECD. Spills most generally occur from a leaky valve or damage to an EtO line (review preventive measures E, K, O, and Q in Appendix C).

- **Lack of interlock between EtO valve and sterilizer**—Most chamber installations do not have interlocks preventing the opening of a sterilizer door when the EtO valve is open. If the back vent is interlocked to trigger when the chamber door is opened, an EtO-rich mixture can be delivered to an oxidizer (review preventive measures A, B, D, H, O, and M in Appendix C).

- **Failure or malfunction of the air in-bleed valve**—Failure of the air in-bleed valve can cause a nonflammable cycle to change to an EtO-rich flammable cycle that might exceed an OECD's safe operating conditions (review preventive measures D, F, and Q in Appendix C).

- **Sticking valves that result in misdirected flow**—A multiport control valve designed to send exhaust either to an OECD or to the atmosphere can fail,

allowing the operator to deliver EtO-rich gas to the OECD rather than to the atmosphere (review preventive measures F and Q in Appendix C).

- **Purging EtO cylinders with EtO delivery valves in wrong position**—If an EtO delivery system is piped to allow purging of EtO cylinders to an OECD, an operator could empty an entire cylinder into the OECD line when valves are left in the wrong position (review preventive measures G, K, L, and O in Appendix C).

- **Improper operation of upstream scrubber**—If an OECD relies on an upstream scrubber to reduce EtO concentrations, malfunction of the upstream system can overfeed the OECD. A scrubber can be considered a safeguard ONLY when operating properly (review preventive measures I, L, and Q in Appendix C).

- **Sterilizer control systems inadequate**—Older sterilizer controllers may not support the safe operation of an OECD. Systems requiring periodic manual intervention are of particular concern (review preventive measure L in Appendix C).

- **Lack of cabinet locks**—Many older sterilizer control systems allow easy access to the manual sterilizer switches. If manual intervention is allowed, there is high danger that a person will trigger a wrong switch and send an EtO-rich flow to an OECD (review preventive measures G, L, M, and O in Appendix C).

# APPENDIX E
# PROCESS HAZARD ANALYSIS

## Background and Regulatory Requirements

A process hazard analysis is an effective tool that provides a systematic analysis of hazards associated with the sterilization process and the integration of environmental controls with this process. The chemical industry has been using process hazard analyses successfully for the past several years to identify and correct hazards associated with their processes. The sterilization industry should also use a process hazard analysis as a risk assessment tool to identify and correct hazards associated with EtO and their equipment.

Recent regulations from OSHA and EPA may require the industry to conduct such process hazard analyses on a regular basis. In 1992, OSHA promulgated the process safety management regulation that requires companies to establish a process safety management system for any process that contains more than 5,000 lb of EtO. The process safety management system includes several key elements (e.g., procedures, training, maintenance, and management of change) and requires that process hazard analyses be conducted and updated or revalidated on a regular basis. All process hazard analyses were to have been completed by May 1997; several sterilization facilities are subject to these requirements. In June 1996, EPA promulgated its risk management program regulation, which requires any company that handles more than 10,000 lb of EtO to implement a risk management program and prepare a risk management plan. The risk management program builds on the OSHA process safety management standard (compliance with the OSHA process safety management standard will basically meet EPA requirements as long as off-site consequences are included). The risk management program also requires process hazard analyses or hazard reviews as part of an accident prevention program. Information about the program is documented in a risk management plan that must be submitted to EPA in June 1999. Finally, the Clean Air Act Amendments of 1990 include a general duty clause that states that “any facility handling any extremely hazardous substance must identify hazards using appropriate hazard assessment techniques, design and maintain a safe facility taking such steps as necessary to prevent accidental releases and minimize the consequences of accidental releases that do occur.”

Several different process hazard analysis methodologies are available to help assess the hazards associated with the sterilization process. The above regulations

do not specify the process hazard analysis methodology to use, but they do have process hazard analysis requirements. These process hazard analysis requirements stipulate that a multifunctional team familiar with the process must be used for a process hazard analysis. Also, the process hazard analysis leader must be knowledgeable in the particular methodology being used for the analysis. They also require that workers be involved and made aware of this study and its recommendations.

The company must select the proper process hazard analysis methodology for the sterilization process and their analysis goals. The methodology selected should allow the process hazard analysis team to adequately review the failure modes of all equipment and instrumentation, potential operator errors, adequacy of the control system and interlocks, previous industry incidents, and any other process hazard. For an overall review of the hazards associated with the entire sterilization process, a gross hazard analysis (including what-if) or hazardous operability study (HAZOP) is probably the most appropriate methodology type. Other methodology types may be used for other analysis purposes (such as accident investigation or quantitative reviews).