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Fundamentals of Ethylene Oxide Sterilization

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LEARNING OBJECTIVES

1. Describe the ethylene oxide sterilization process
2. Define the quality monitors used in ethylene oxide sterilization to demonstrate the sterilization process was effective
3. Describe the safety practices used for ethylene oxide sterilization

Ethylene oxide (EO) gas is a sterilant primarily used for heat- and moisture-sensitive medical devices that cannot undergo steam sterilization. It has been used in healthcare facilities for low-temperature sterilization for more than 60 years. Since its inception, the use of EO has transformed. EO is used in both healthcare facilities and medical device manufacturing. This lesson focuses on the use of EO in healthcare facilities.

Objective 1: Describe the ethylene oxide sterilization process

As with all sterilization methods, successful EO sterilization depends not only on the efficacy of the sterilization process but also on efficient facility design, good infection prevention and control practices, effective quality control, and adherence to other best practices of device processing prior to, during and following sterilization.

EO sterilization is unique in its excellent compatibility with many reusable medical devices and ability to reach hard-to-access areas. It can do this because EO is a small molecule that vaporizes easily and can permeate a wide range of materials to reach recessed areas. EO destroys microorganisms' ability to metabolize or reproduce by a process called alkylation, which leads to the organism's death.

EO must be used with care because of its toxicity, flammability and explosiveness. The sterilant gas is delivered in individual dose cartridges that are placed inside the chamber and automatically added to the sterilization cycle when needed. The basic EO sterilization cycle consists of five stages: preconditioning and humidification, gas introduction, exposure, evacuation and air washes. The cycle takes approximately 2½ to 3½ hours, excluding aeration time. Upon completion of the sterilization cycle, the items must go through an aeration process, which circulates warm air through the chamber to remove all residual EO, before the sterilizer can be unlocked and the items handled safely. The length of the aeration process depends on the temperature of the cycle and the items being aerated.

One of the benefits of EO sterilization is that it has excellent compatibility with

many reusable medical devices. As with all types of sterilization methods, SP technicians must follow specific device manufacturer recommendations for the appropriate sterilization process.

Sterilization areas should be designed to help minimize occupational exposure to EO as well as promote efficient workflow. The release of EO within a healthcare facility is a potentially serious problem. For that reason, EO sterilization is usually located in a centralized containment room with negative air pressure, adequate ventilation and environmental discharge controls.

All items undergoing sterilization must be thoroughly cleaned and then packaged. The packaging must be EO gas-permeable and allow for sterilization and proper aeration; as always, the packaging IFU should be reviewed for EO compatibility and followed carefully. EO sterilization is compatible with a variety of packaging materials, including paper/plastic (which are not typically permitted for sterilization using low-temperature hydrogen peroxide), Tyvek peel pouches, approved textile wrappers, medical crepe paper, polypropylene and most container systems. *Note: Packaging materials made from aluminum foil or nylon should not be used, as the EO molecule cannot penetrate these products.*

When loading the sterilizer, there must be adequate space for sterilant flow. Items should be placed loosely and well within the confines of the metal basket, shelf or cart. Metal is used since it does not absorb EO. Pouches should be placed on edge in wire baskets to promote air flow. Packaged items should not touch chamber walls, and instrument sets should not be stacked. An overloaded sterilizer impedes proper air removal, load humidification, sterilant penetration and aeration.

The U.S. Environmental Protection Agency (EPA) requires that EO sterilizers only be operated with full loads of items that share common aeration times. Although running a full EO load is preferred, there are occasions when an item must be sterilized immediately due to an emergency. Should an emergency or other situation arise that results in a less-than-full load, the Sterile Processing (SP) professional must record the reason in the sterilizer record. These records must be kept for five years with at least the most recent two years stored onsite.

Objective 2: Define the quality monitors used in ethylene oxide sterilization to demonstrate the sterilization process was effective

An essential element of sterility assurance is sterilization process monitoring. Documentation helps ensure that the sterilization process is monitored as it is occurring, and the cycle parameters have been met. It also establishes accountability.

Sterilization process monitoring devices include physical monitors, chemical indicators (CIs) and biological indicators (BIs). Each of these devices plays a distinct and specific role in sterilization process monitoring and is indispensable to sterility assurance. Used in combination, they help demonstrate the efficacy of the sterilization process.

Physical monitors verify that the parameters of the sterilization cycle have been met. They include operating pressure gauges, temperature control/measurement devices, timing recorders and humidity sensors. Physical monitoring is needed to detect malfunctions as soon as possible so appropriate corrective actions can be taken. Charts, graphs and printouts detailing the measurements made by physical monitors must be carefully examined to ensure the correct parameters were met before devices are removed from the sterilizer. Most temperature sensors indicate temperature at a single point in the chamber, not at the center of packages. Tightly loaded chambers or incorrect package composition can interfere with air evacuation and EO penetration, and these conditions will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to recommended packaging and loading procedures.

CIs verify that one or more conditions necessary for sterilization have been achieved on or within a package or at a specific location within the load. They are specifically designed and validated to respond with a chemical or physical change to one or more of the physical conditions within the sterilization chamber and should be used in accordance with their manufacturers' IFU. CIs assist in the detection of potential sterilization failures that could result from incorrect packaging or loading of the sterilizer, inadequate preconditioning, or sterilizer malfunction. The "pass" response of a CI demonstrates that the conditions for sterilization were met but does not prove that the item is sterile (there are no practical means of verifying the sterility of an individual item). A "fail" CI result, however, is an early warning sign that something may be wrong with some aspect of the sterilization process.

External CIs are used to differentiate between sterilized and unprocessed items. These process indicators, known as Type 1, come in the form of sterilizer indicator tape, indicating labels or indicating printed legends. External CIs should be affixed to or printed on each hospital-assembled package or rigid sterilization container except for those that allow visual inspection of an internal indicator such as paper-plastic pouches.

Internal CIs should be placed inside each package in the area considered most difficult for the sterilant to penetrate. In some cases, multiple CIs are needed if numerous areas pose a challenge. The internal CI's color will change when exposed to the specific sterilant it is designed to detect.

BIs are usually ampules that contain a paper strip impregnated with live microorganisms that are most resistant to the specific method of sterilization used, in this case EO. BIs demonstrate the lethality of the sterilization cycle by verifying that the conditions at a location within the load were adequate to kill the microorganisms.

BIs and Type 5 chemical integrating indicators are used within a process challenge device (PCD). Each PCD is designed and validated to simulate a predetermined set of conditions when used to test a sterilizing agent. BIPCDs are used for sterilizer qualification testing and after sterilizer installation, relocation, malfunction, major repair and sterilization process failure. BIPCDS are also used in each sterilization cycle.

Upon completion of the EO sterilization and aeration process, the BI and other components of the pack should be handled according to the healthcare facility's protocol for minimizing worker exposure to EO. For each test BI run, a BI that is from the same lot and that has not been exposed to the sterilant is also incubated as a control to verify the pre-sterilization viability of the test spores and the proper incubation temperature. The control BI should grow when incubated; the test BI should not. Upon completion of the incubation period, the test and control results are should be read and recorded.

Sterilizer records

For every EO sterilization cycle, the following information should be recorded and maintained:

- Lot number, sterilizer identification and cycle number
- Contents of the lot or load, including quantity, department, and a list or specific description of the items
- Exposure time and temperature
- Identification of the SP technician who processed the load
- Aeration time and temperature
- Results of the biological monitoring test
- Results of the internal CI (if placed in the BIPCD)
- Reports of inconclusive or nonresponsive CIs found later in the load

The recording chart, printer or tape should also be dated and maintained, and each cycle on the chart reviewed and signed by the SP technician who processed the load.

Objective 3: Describe the safety practices used for ethylene oxide sterilization

While EO is an effective sterilant, it is also a toxic gas classified by the Occupational Safety and Health Administration (OSHA) as a carcinogen and reproductive hazard. OSHA has established a permissible exposure limit (PEL) of 1 part per million (ppm) airborne EO in the workplace, expressed as a time-weighted average (TWA) for an 8-hour work shift in a 40-hour work week. OSHA also has defined an "action level" of 0.5 ppm, expressed as an 8-hour TWA, and an excursion limit (EL) of 5 ppm, expressed as a 15-minute TWA.

To protect SP professionals, EO sterilizers should be housed in a well-ventilated area with an air exchange rate of at least 10 changes per hour. EO sterilizers should be in negative-pressure rooms with contained ventilation systems venting to the outside. Qualified professionals should check EO ventilation systems, exhaust lines and floor drains at periodic intervals as specified in facility policies to ensure the system is working properly.

Today's EO systems are designed for safety and have numerous engineering safeguards to prevent personnel from encountering EO. The single-dose 100% EO cartridges must be stored in a ventilated flammable liquid storage cabinet that is exhausted outside and positioned away from heat, sparks and sunlight.

OSHA requires that facilities using EO sterilization have a procedure to immediately alert affected employees in case of a leak, spill or equipment failure. There are two types of safety monitoring methods to measure employee safety when working with EO: area monitoring and personnel monitoring devices. Area monitoring is used to measure the working area where EO sterilizers are used and alert personnel if an EO leak occurs. Personal monitoring devices should be affixed directly to the employee's clothing in the breathing zone (within one foot of the person's nose). The monitor should be analyzed

but the results will not be available until after the sampling period has ended. Again, OSHA requires that facilities immediately alert affected employees in the case of a leak, spill or equipment failure.

OSHA also requires that employers maintain an accurate record of all measurements taken to monitor employee exposure to EO. This information includes:

- Date of measurement
- Sampling and analytical methods used and evidence of their accuracy
- Number, duration and results of samples taken
- Type of protective devices worn, if any
- Names of employees whose exposures are represented

The employer shall maintain these records for at least 30 years. OSHA also requires that medical surveillance records for each employee exposed to high levels of EO be kept for the duration of employment, plus 30 years.

To minimize the safety risks associated with the use of EO, employees should be instructed about:

- EO hazards
- Sterilizer manufacturer and EO supplier IFU
- Processing procedures
- Storage and handling of EO cartridges
- Procedures to reduce employee exposure to EO
- Use of personal protective equipment (PPE) designated for EO sterilization
- Principles of EO monitoring and interpretation of results
- Handling of canceled cycles
- Applicable OSHA regulations
- Safety data sheets (SDS)
- EO emergency plans

Based on the Clean Air Act (CAA) and Clean Water Act (CWA), which are enforced by EPA regulations, some states have implemented emission control requirements that affect healthcare facilities. At this time, no federal EPA emission control regulations affect healthcare facilities. Healthcare facilities must comply with the OSHA standard and applicable EPA regulations.

Conclusion

EO is a sterilant that can be used to sterilize a wide range of materials. As with all sterilization methods, the IFU of the medical device, packaging and sterilizer must be followed. Specific safety regulations for EO must be followed to maintain employee safety. When regulations and standards are diligently followed, EO sterilization is safe and effective. P

RESOURCES

Healthcare Sterile Processing Association. (2023). *Sterile Processing Technical Manual*, 9th ed. Chicago: HSPA. See particularly "Ethylene Oxide," pages 257–260; "Quality Assurance Measures," pages 204–205; and "Biological Indicators," pages 287–288.

Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST41:2008/(R)2018 *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.*

CIS Self-Study Lesson Plan Quiz
Fundamentals of Ethylene Oxide Sterilization

Lesson No. CIS 304 (Instrument Continuing Education – ICE) · Lesson expires August 2027

1. What types of medical devices are sterilized by EO?
   a. Metal and plastic
   b. Motorized equipment
   c. Heat- and moisture-sensitive devices
   d. Devices with long lumens

2. What is a unique feature of EO sterilization?
   a. Its ability to penetrate throughout a wide range of materials
   b. Its ability to turn steam into gas
   c. Its ability to clean and sterilize
   d. That EO can be stored indefinitely

3. Why must EO be handled with care?
   a. It is very expensive
   b. Due to its toxicity, flammability and explosiveness
   c. It can turn into a liquid and be unable to be used
   d. EO glass canisters can break easily

4. Excluding aeration, how long does an EO cycle take?
   a. 1½ to 2½ hours
   b. 2½ to 3½ hours
   c. 3½ to 4½ hours
   d. 4½ to 5½ hours

5. When can the EO sterilizer be unlocked to remove items?
   a. At the end of the sterilization cycle
   b. Upon completion of the BI incubation
   c. After the items go through an aeration process to remove all residual EO
   d. When the EO aeration monitor turns color

6. During the loading of an EO sterilizer, what is a basic practice?
   a. Packages may be stacked but not more than four high
   b. Placing paper between each package to absorb the EO
   c. Placing packages an inch apart
   d. Leaving adequate space for sterilant flow

7. Why are metal baskets recommended for use during the EO loading process?
   a. Metal baskets do not rust
   b. Metal is easily cleaned
   c. Metal does not absorb EO
   d. EO can permeate the holes in the basket

8. Where should an EO sterilizer be located?
   a. In a centralized containment room
   b. By the steam sterilizer
   c. With the other low-temperature sterilizers
   d. In the preparation and packaging area

9. Which of the following packaging materials **cannot** be used in EO sterilization?
   a. Paper/plastic
   b. Tyvek peel pouches
   c. Aluminum foil
   d. Polypropylene

10. Which monitoring tool would be the first to detect a sterilizer malfunction?
   a. Internal chemical Indicator
   b. Physical monitor
   c. Biological monitor
   d. External chemical indicator

11. According to the U.S. Environmental Protection Agency (EPA), how should EO sterilizers be operated?
   a. Full loads of items that share common aeration times
   b. Partial loads to meet the needs of the productivity monitor
   c. Only packaged items can be sterilized
   d. There are no regulations

12. Which statement is true about a tightly loaded EO sterilizer chamber?
   a. It is an Occupational Safety and Health Administration (OSHA) requirement
   b. It saves money because the EO sterilant is expensive
   c. It can interfere with air evacuation and EO penetration
   d. It can cause packaging to tear

13. Where should 100% EO cartridges be stored?
   a. In sterile storage on a sturdy shelf
   b. Under the sterilizer in a cabinet
   c. In a ventilated flammable liquid storage cabinet that is exhausted outside
   d. In a locked, fire-resistant cabinet

14. Which EO safety monitor measures the sterilizer working area and can immediately alert personnel of an EO leak?
   a. Personnel monitor
   b. Area monitor
   c. Sterilizer physical monitor
   d. Aerator monitor

15. Who does OSHA require to keep records of all measurements taken to monitor employee exposure to EO?
   a. Employer
   b. Employee
   c. Employee Health
   d. Physician

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