Control of CRE transmissions and the use of Ethylene Oxide Sterilization

by Larry Talapa, MS, CQE

A s a Technical Service Representative for 3M’s Infection Prevention Division, I have the honor of talking with Sterile Processing professionals and leaders on a daily basis. In recent months our Technical Service team has received an increasing number of calls from around the U.S. asking for assistance, understanding, and advice on how to implement changes in response to the events related to duodenoscopes used to perform endoscopic retrograde cholangiopancreatography (ERCP) procedures and the deadly transmission of CRE. Many of the Sterile Processing leaders we have talked with have asked by their facility to provide expertise and guidance on reprocessing of endoscopes, although for many, reprocessing endoscopes was not part of their department’s responsibility. Nonetheless, with a positive team approach, these leaders accepted the call-to-action and are reaching out for expertise and the best information to begin their journey of understanding and implementing change.

A substantial number of questions emerged from Sterile Processing professionals regarding the use of ethylene oxide (EO) sterilization, which is not unexpected in light of the measures several hospitals have taken to control the outbreak of CRE in their facilities. As reported in peer-reviewed published research papers, three facilities have controlled CRE outbreaks isolated to duodenoscopes by changing to EO sterilization as the terminal step in reprocessing these scopes. 2, 3, 4 EO sterilization has been used for reducing bioburden and for terminal sterilization since the 1930s and its use in U.S. healthcare facilities spans more than 50-plus years. Today EO is successfully used in a wide range of industries for microbial control and sterilization, including preservation of delicate artifacts, reducing the biolod on herbs and spices, sterilization of delicate powders, and for the terminal sterilization of more than 50 percent of the single-use devices that are used daily in our U.S. healthcare facilities.

Many facilities have contacted 3M because they are changing to EO sterilization for all of their duodenoscopes, after every procedure, to provide the highest level of sterility assurance. These facilities are confident and knowledgeable; they understand the safe and effective use of EO sterilization and that most, if not all endoscope manufacturers (including Olympus, Pentax, and Fujifilm), provide documentation for EO as an option for sterilization of their scopes. The endoscopes in question (upper GI) have long lumen lengths and can have multiple small diameter inner channels. These scopes have been validated for EO sterilization by the endoscope manufacturer as evidenced by their reprocessing instructions, which includes EO sterilization as a terminal method.

In light of the increased use of EO as proactive risk mitigation implemented by many facilities who are concerned about transmission of CRE, this in-service article provides a summary of safe and effective EO use for end-users who may need a refresher.

As of January 1, 2015 the U.S. Clean Air Act banned the use of Hydrochlorofluorocarbons (HCFCs). This ban has effectively eliminated the use of mixed gas EO sterilization systems that were so common years ago in the U.S. healthcare market. These systems, installed in the 1970s and early 1980s and now outlawed in the U.S., required long EO delivery lines, large tanks of...
EO and risky tank changes coupled with emissions of greenhouse gases that are unfriendly to the environment.

The EO systems of today use single-dose cartridges of 100 percent EO, have a proven track record of safe and effective use, and are environmentally sustainable with the advancements of emissions control systems designed to protect our environment.

The use of 100 percent EO makes possible a sterilization process that remains totally in a vacuum (Figure 1). This is a substantial safety feature not found in the EO systems of yesterday which relied on mixed blend sterilants. If the system integrity is compromised while EO is in the chamber, room air will enter the chamber before EO escapes the system. The control system of the sterilizer will detect air entering the system (via a rise in pressure) and will safely cancel the cycle if the vacuum cannot be maintained. The control system will bring the sterilizer to a safe state by flushing the sterilizer with fresh air and exhausting any remaining EO through the pollution control device or directly to the outside. Unlike other low temperature sterilization systems, EO sterilization systems are never vented inside the room.

Let’s review some key points to remember regarding EO sterilization.

**EO sterilization cycle**

EO sterilization has evolved with a focus on three critical items: safety of operators, devices, and patients. In the U.S., EO sterilizers sold to healthcare facilities must be FDA-cleared for sale as a Class II medical device.

The FDA recognized consensus standard ANSI/AAMI ST41:2008 (R)2012, Ethylene oxide sterilization in health care facilities: Safety and effectiveness contains valuable recommended practices for the safe and effective use of EO and will be referenced and directly quoted throughout this article.

The typical EO sterilization cycle consists of 10 stages. After the sterilization cycle is complete, an aeration cycle is required to remove any residual EO from the medical devices per manufacturers’ instructions for use (IFUs). Figure 1 is a graph of a typical 100 percent EO sterilization cycle illustrating the process is maintained in a vacuum, i.e., operates below atmospheric pressure.

**Facility engineering controls**

Proper design of EO sterilization areas will provide increased protection in the work place as well as promote efficient work flow. All EO sterilizers should be located in a containment area that is physically separate from other work areas. The containment area should be large enough to ensure adequate ventilation and to accommodate the loading, unloading, and maintenance of the sterilizers. It should be actively ventilated to ensure that under normal conditions occupational safety requirements are routinely met. Air flow, air exchanges, and ventilation of sterilizer rooms or areas are vital engineering controls for all low temperature sterilization systems. The air flow, rate and direction of exhaust air flow in the immediate vicinity of sterilizers should be measured to verify that there is adequate air flow away from sterilizer operators and other personnel in the sterilization area (Figure 2).

**Ventilation monitoring:** Ventilation rates should be monitored and documented at least annually by the health care facility engineer, other qualified in-house personnel, or an outside contractor. Signs demarcating regulated areas and entrances to regulated areas must be posted and maintained. Such signs must be legible and must bear the following legend: Danger. Ethylene oxide Cancer hazard and reproductive hazard Authorized personnel only Respirators and protective clothing may be required to be worn in this area Regulated areas are defined as an area wherever it might be reasonable that occupational safety limits to airborne concentrations of EO may be exceeded.

Personnel not involved in sterilization processing should be routed around or away from all sterilization equipment. Such routing can be accomplished by signs and posters, floor paint or tape lines around the equipment area, or temporary or permanent partitions. Sterilizer access areas must have restricted personnel access as a regulated area.

The temperature in sterilization equipment access rooms should be controlled between 24°C and 29°C (75°F and 85°F) or as recommended by the equipment manufacturer. Relative humidity is a critical parameter of EO sterilization, an excessively dry environment could affect EO sterilization efficacy.

**EO area monitors**

EO area monitors measure one point of the immediate environment and are not a replacement for personal (breathing zone) monitoring. While OSHA doesn’t specify the use of an area monitor, it does require employers to have a method to alert employees to emergency situations. A wall-mounted EO monitoring system is an effective, practical method of satisfying this requirement.

Good practice would dictate that an EO area monitor be employed inside the EO sterilizer area in combination with annual or semi-annual personal (breathing zone) monitoring as described in the Health and safety of ethylene oxide section of this article on page 28.

**Preparing medical devices for sterilization**

Always follow the device manufacturer’s IFU, including device cleaning, drying, packaging, sterilization parameters, and aeration. Thorough cleaning is essential to achieve sterilization efficacy. Only sterilize medical devices that are manufactured with materials compatible with ethylene oxide sterilization processes. Do not sterilize leather, liquids, or materials that are reactive to EO. Do not sterilize devices with energy sources that could create a spark in the sterilization chamber during the sterilization cycle.

**Packaging medical devices**

Non-compatible packaging may compromise the sterility of the processed devices. Use packaging that has been cleared by the FDA for packing EO sterilized items and follow the packaging manufacturer’s IFU.

The following packaging types have been recommended for use with EO sterilization:

- Polyethylene plastic bags (designed for use as a sterile package and are not more than 5 mils thick)
- Peel pouches:
  - Spun-bonded olefin polyethylene-polyester laminate
  - Paper/polyethylene-polyester laminate
  - Paper/polypropylene-polyester laminate
- Wraps:
  - Woven textile
  - Nonwoven textile
  - Nonwoven polypropylene
  - Paper, coated and uncoated
  - Rigid sterilization container systems
- Plastic trays with paper or spun-bonded olefin lids
- Muslin

See SELF-STUDY SERIES on page 28.
**Self-Study Series**

**Loading the sterilizer**

Always use loading baskets or racks when loading an EO sterilizer. Do not overload the chamber. Arrange items in loading baskets such that water vapor and EO can circulate freely between them. Place peel pouches on their edges, if possible. Arrange sterilization pouches so that the transparent side of a pouch faces the opaque side of the adjacent pouch. Ensure no devices are touching the sterilizer chamber walls (Figure 3).

To the extent practical, sterilize full loads consisting of items having a common aeration time. A full load can be comprised of sterilization pouches, wrapped trays, and rigid containers or a combination of various packs.

In the U.S., the EPA National Emission Standards for Hospital Ethylene Oxide Sterilizers requires hospitals that do not have an air pollution control device to adopt the management practice of running full loads except under medically-necessary circumstances. The date and time of all EO sterilization cycles should be documented and any loads not containing a full load for medically-necessary reasons should be noted.

**Operation of the EO sterilizer**

It is facility management’s responsibility to ensure that all personnel who operate or maintain the EO sterilization equipment are trained in its operation and safe use. In addition, it is the facility management’s responsibility to assure safety inspections are complete on the sterilizer before routine use. Contact your service personnel for required safety inspections.

The responsibility for EO sterilization should be assigned to qualified individuals who have demonstrated competence in all aspects of sterilization processing: decontamination, preparation, packaging, sterilization, sterile storage, and distribution of sterile medical devices.

Before operating any sterilization equipment always read and follow the procedures described in the manufacturer’s Operator’s Manual. Warnings and precautions should be observed to avoid unsafe actions that could result in personal injury or damage to the sterilizer or instruments.

**Unloading the sterilizer**

Do not remove the load until the total elapsed aeration time meets or exceeds the aeration time recommended by the device and packaging manufacturers’ IFUs. The EPA requires U.S. healthcare facilities to complete full aeration within the sterilizer chamber (single-chamber process) prior to removing the load. This practice eliminates the potential for EO exposure that might occur if the load were transferred to a separate aeration chamber prior to full aeration.

If it is necessary to access the chamber during the aeration stage, for example to remove a BI PCD, routine BI Test Pack, or an instrument or item that requires minimal aeration, take all precautions to minimize exposure to EO and after opening the door. Retrieve the item or items promptly, minimize handling and sorting, and close the door to limit off-gassing of the load into the sterilizer room. When it is necessary to handle individually packaged items that are not fully aerated, butyl, neoprene, or nitrile gloves should be worn. The breathing zone of personnel should be monitored to verify the safety of the practices followed.

**Performance monitoring and routine load release**

Use chemical indicators and biological indicators for monitoring the performance of sterilization cycles as described in the sterilizer manufacturer’s Operator’s Manual. Chemical and biological indicators should be used according to device manufacturer’s IFU.

Monitoring recommended for routine load release per ANSI/AAMI ST41:2008 (R)2012 includes:

- **user verification of the physical parameters reported on the cycle report (i.e., print-out or electronic file): Do not use sterilizers that do not have a verifiable cycle report;**
- **the use of external and internal chemical indicators with each package, tray or containment device. Class 1 process indicators are recommended for the external CI while for internal CIs, Class 4 multi-variable or Class 5 integrating indicators are recommended; and**
- **a BI PCD, either the routine test pack described in ANSI/AAMI ST41:2008 (R)2012 or a commercially available equivalent, should be used in each load. The BI PCD “should be placed in the area of the chamber and load that is considered to be least favorable to sterilization (usually the center of the load unless otherwise indicated by the sterilizer manufacturer)” (Figure 3).**

**Health and safety of EO**

Users of EO, including those working in healthcare facilities, must follow the requirements of OSHA’s occupational exposure standard for EO (29 CFR 1910.1047). Commonly-referenced sections of the standard include those on exposure limits, employee exposure monitoring, emergency planning, and employee training.

OSHA has established two Permissible Exposure Limits (PELs) for EO: a 1 part per million (ppm) 8-hour time-weighted average and a 5 ppm excursion limit for any 15-minute period.

The employer must conduct initial monitoring to determine representative employee exposure for both time periods in their workplace and demonstrate compliance to the established exposure limits.

**Permissible Exposure Limits (PEL) for Ethylene Oxide (OSHA 29 CFR 1910.1047)**

<table>
<thead>
<tr>
<th>Action Level (8-hour average)</th>
<th>0.5 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration Limit (average exposure over a sampling period of 15 minutes)</td>
<td>5 ppm</td>
</tr>
<tr>
<td>8-hour time-weighted average (TWA)</td>
<td>1 ppm</td>
</tr>
</tbody>
</table>

**Storage and handling of 100 percent EO gas cartridges**

One hundred percent EO gas cartridges are classified as a Gas Under Pressure: Liquefied Gas. Liquefied gases are gases which can become liquids at normal (ambient or room) temperatures when they are under pressure inside cylinders. They exist inside the cylinder in a liquid-vapor balance or equilibrium.

Good practice recommendations for storing 100 percent EO gas cartridges are more stringent than those in the National Fire Protection As-

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**Figure 3. Placement of BI PCD in Center of the Load**

In addition to verifying satisfactory results for all monitoring tools, load release should include verification that the prescribed aeration time is complete. Any “packages containing implants should be quarantined until the results of the BI testing (early readout or spore growth) are available”5.

**Figure 4. 3M EO monitoring badge**

A written plan for emergency situations is also a required element of the OSHA standard. Refer to the OSHA standard for more details about the written plan for emergency situations.

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Circle the one correct answer:

1. Recent outbreaks of patient-to-patient transmission of CRE have been attributed to improperly cleaned and sterilized duodenoscopes.
   A. True B. False

2. No endoscope manufacturers have validated ethylene oxide as an option for sterilization.
   A. True B. False

3. The use of EO/HFCl sterilant blends is now banned.
   A. True B. False

4. In 100 percent EO sterilization cycles, the entire cycle operates below atmospheric pressure.
   A. True B. False

5. As an engineering control measure, EO sterilizers should be operated in a room with a minimum of 10 total air exchanges per hour.
   A. True B. False

6. Unless the exhaust from an EO sterilizer is connected to an air pollution control device, the U.S. EPA requires facilities to adopt the management practice of sterilizing full loads of items having a common aeration time.
   A. True B. False

7. Packaged items should be placed in EO sterilizer loading baskets such that water vapor and EO can circulate freely between items.
   A. True B. False

8. The U.S. EPA requires healthcare facilities perform EO sterilization and aeration in a single chamber.
   A. True B. False

9. ANSI/AAMI ST41:2008(R)2012 recommends that each EO sterilized load be monitored with a BI PCD.
   A. True B. False

10. One of OSHA’s Permissible Exposure Limits for EO is a 1 ppm 8-hour time-weighted average (TWA).
    A. True B. False

References:

2. JAMA October 8, 2014 Volume 312, Number 14 (Lauren Epstein, MD, MSc, et al) New Delhi Metallo-β-lactamase–Producing Carabapenem-Resistant Escherichia coli Associated with Exposure to Duodenoscopes.


4. GASTROINTESTINAL ENDOSCOPY Volume 81, No. 4: 2015, Transmission of carabapenem-resistant Enterobacteriaceae during ERCP: time to revisit the current reprocessing guidelines (Zachary L. Smith, et al), Milwaukee, Wisconsin, USA.


7. Federal Register / Vol. 72, No. 248 / Friday, December 28, 2007/