Safe Use of Ethylene Oxide

NANCY CHOBIN, RN, CSPDM

STERILE PROCESSING UNIVERSITY LLC

Ethylene Oxide

- Chemical agent used for the sterilization of heat, pressure and/or moisture sensitive items.
- A member of the ether family also known as an epoxide.
- A liquid that, at room temperature, becomes a gas.

Uses of EtO

- A sterilant.
- A fumigant and pesticide.
- To control molds and fungi in processing fruits, nut meats, egg powders, spices and tobacco.
- In the production of antifreeze, polyester fibers & films.

Types of EtO Used for Sterilization

- 100% undiluted in unit dose cartridges.
  - Most commonly used in hospitals since the ban of CFC's in 1995 because of their ozone depleting action.
- Mixtures with inert gasses such as HCFC's and Carbon Dioxide.
  - HCFC's banned after 2023.
  - Stability and pressure issues with CO2 mixtures.

Differences

- 100% Ethylene oxide systems operate under a vacuum. If a leak occurs it will be vacuumed out through the exhaust.
- The EtO mixtures operate under pressure. If a leak occurs, the leak will leak into the department from the door gasket, pressure relief valve or drain.

Characteristics of 100% EtO

- Completely soluble in water at 50ºF
- In presence of an acid or alkaline catalyst it **REACTS WITH WATER TO FORM ETHYLENE GLYCOL OR ETHYLENE CHLORHYDRIN** (characterized by brown residue)
- **FLAMMABLE** in both the liquid and gaseous state.

Characteristics of 100% EtO

- Has the ability to be **ABSORBED by many materials.**
- Colorless.
- Liquid form **CAUSES SEVERE BURNS.**
- **In the gaseous state it is MODERATELY TOXIC UNDER THE CONDITIONS OF PROPER USE.**

Characteristics of 100% EtO

- **Most people can not detect the odor until it reaches levels of 700 ppm.**
- **EXPLOSIVE in mixtures of air from 3% to 80%**
  - The explosiveness can be eliminated by mixing EtO with inert gases.

Storage/Handling of 100% EtO

- Provided in unit dose cartridges.
- Stored, and used, in well ventilated area with **minimum of 10 air exchanges/hour**.
- Not more than one days supply, not to exceed 12 cartridges in the department unless in a flammable cabinet
- Cartridges should be aerated at the end of the cycle along with the gloves used to handle the cartridge.

Storage and Handling of 100%

- Neoprene gloves should be used.
- Goggles are also recommended when transferring items to an aerator.
- Storage of bulk supply of gas (excess of 12 cartridges) should be as a Class I flammable liquid.

Storage/Handling of EtO Mixtures

- Supplied in large cylinders or tanks.
- Cylinders must be secured.
- Should be stored at room temperature.
- Storage areas must be well ventilated with 10 air exchanges/hour.
- Care must be taken when changing cylinders to avoid accidental exposures

Achieving Sterility With EtO

- Items must be clean before sterilization.
- Materials to be sterilized, and packaging, should be maintained in an environment with a relative humidity of at least 50%.
- Items to be sterilized must be completely dry.

Achieving Sterility With EtO

- All traces of lubricants must be removed.
- Select appropriate packaging materials.
  - Most wrappers acceptable for steam also acceptable for EtO.
  - Can use polyethylene (may not exceed 3 mils in thickness) and Tyvek.™
  - **Do not use** nylon, polyester (mylar), pvc (plastic) films, or styrofoam.

Packaging for EtO Sterilization

- Make sure packaging is performed in a manner that conforms with the standards for packaging products for sterilization:
  - Packages must be wrapped in a manner that provides for aseptic handling and protection of package contents until use.
- The following materials are compatible with ETO sterilization:
  - **Textiles, nonwovens, polyolefin wraps, paper–plastic pouches and rolls, Tyvek® (all-plastic) pouches, polyethylene, most rigid sterilization containers**

Packaging for EtO Sterilization

- If using trays for containing items make sure they are perforated and lay flat in the sterilizer.
- If using rigid containers make sure they are biologically tested in YOUR sterilizer.
- Packaging materials and items for ETO sterilization should be maintained at a humidity level of 50%.

Loading the Sterilizer

- DO NOT OVERLOAD
- Load in a manner that allows for the sterilant to circulate and reach all surfaces of the packages easily.
- When using paper/plastic pouches:
  - Place them on edge. If working with large chamber sterilizers place them in basket.

Loading the Sterilizer

- When using paper peel pouches:
  - Use a pouch separator device or place in a metal mesh basket. The plastic side of one pouch should face the paper side of the pouch next to it.
  - Do not stack pouches on top of each other.
- If using polyethylene (plastic pouches) place cloth or paper between them to create an air space.

Monitoring the Sterilization Process

- A chemical indicator must be included with each item sterilized.
  - Must be a product specific to EtO
- A lot label (number) must be on each package sterilized.
- Biological testing must be performed for each load processed.
  - ***Bacillus atropaeus* used as the spore.**

Sterilization Cycle Parameters for EtO Sterilization

- The parameters vary significantly from sterilizer manufacturer to manufacturer.
- OSHA regulations require that operators of the sterilizers must demonstrate competence in all of the parameters of EtO sterilization, as well as a comprehensive knowledge of the system in use (100% or mixture).

Sterilization Cycle Parameters for EtO Sterilization

- Gas Concentration:
  - 450mg/l to 1500mg/l
- Exposure Time
  - 48 minutes to 12 hours
- Humidity
  - 50% to 80%
  - Critical to the penetration of bacterial cells and successful sterilization.

Sterilization Cycle Parameters for EtO Sterilization

- Temperature
  - Ambient (room temperature)
  - 70°F to 149°F
- Pressure
  - Only ETO mixture systems require pressure.
  - 5 psig to 28psig.

Most Common Cycle Parameters for EtO Sterilization

- The cycle parameters most commonly found in hospitals today are:
  - Exposure Time - 105 mins or 1 Hr. 45 mins
  - Temperature – 130^{o}F
  - Concentration - 600 to 700 mg/l
  - Humidity - 55%
  - Pressure - 8 psig (mixtures only)

EtO Kills by Alkylation

- Alkylation changes the chemical structure of the microorganism by taking hydrogen from it. In order to accomplish this the EtO must penetrate the cell wall.
- Prevents the organism from normal metabolism causing the organism to die.

Cycle Phases of the EtO Sterilizer

- Vacuum
- Humidification
- Introduction of the sterilant
- Exposure period - load held at time, temp, and concentration. (Pressure if applicable.)
- Final Vacuum (repeated purges in some units.)
- Aeration

Unloading the EtO Sterilizer

- The Environmental Protection Agency (EPA) **no longer permits transfer of ETO loads.**
- **Load cannot be removed until fully aerated.**
- ALL items EtO sterilized must be aerated.
  - Packaging and goods absorb EtO.
  - Materials release EtO at different rates.
  - Residuals must be removed for patient and staff safety.

EPA

- For facilities that do NOT abate EtO before release into the environment, the EPA requires that all EtO cycles be full.
- Anytime a load must be run that is not full, a statement of “medical necessity” must be noted on the Sterilization Log form signed by the SPD/CS Director.

EPA

- Sterilization “records must be in a form suitable and readily available for expeditious review” and kept for 5 years.
- The rule specifies that records must be kept onsite for 2 years.
- Additionally, hospitals should keep a copy of their Initial Notification of Compliance Status on file.

Unloading the EtO Sterilizer

- Unloading the sterilizer (prior to aeration) represents one of the greatest hazards for potential employee exposure.
  - The other is while changing cylinders.
- Because of the various sterilizers in use today aeration may be accomplished in several ways.

Unloading the EtO Sterilizer

- Sterilizers with aeration cycles.
  - Unit will first go into a 3 hr aeration cycle during which the unit cannot be opened.
  - The unit will continue with aeration. The elapsed time of aeration will be displayed.

Unloading the EtO Sterilizer

- If unit dose cartridges are used they should remain in the sterilizer so they are aerated with the load.
- After complete aeration, the empty cartridges can be discarded in the regular trash.

Aeration

- Mechanical aeration cabinet.
  - **Dedicated exhaust.**
  - **Continuous, filtered air washes.**
    - **Temperature controlled at either 122º F. for 12, 130º F. for 10 hours or 140º F. for 8 hours.**
- Check with the manufacturer of the item you are aerating for recommendations.
  - Never ASSUME you know the answer to how long you should aerate an item

Problems Associated With EtO

- The benefits of EtO outweigh the risks.
- The problems associated with EtO sterilization appear to stem from lack of knowledge - the risks are controllable

Problems Associated With EtO

- EtO residuals.
  - Caused by improper or inadequate aeration.
  - Can cause death or irreversible tissue damage products used before aeration is complete.
  - Solution - PROPER AERATION OF PRODUCT after sterilization.

Problems Associated With EtO

- Ethylene oxide by-products.
  - Ethylene glycol (antifreeze) - chemical reaction with water.
    - **Characterized by the presence of a brown oily film.**
    - **Poisonous and toxic**

Problems Associated With EtO

- Ethylene chlorhydrin
  - **Water must be present for this to occur.**
  - **Occurs when items are improperly aerated and they are exposed to saline or body fluids.**
- Solution
  - **Items for EtO sterilization must be dry.**
  - **Proper aeration.**

Problems Associated With EtO Toxicity

- Result from exposure by inhalation, ingestion or direct contact with tissue.
  - Acute toxic effects.
    - **Respiratory, eye irritation and headache (early symptoms).**
    - **Skin sensitization.**
    - **Vomiting and diarrhea.**
    - **Peculiar taste in mouth.**
    - **Drowsiness.**

Problems Associated With EtO Toxicity

- Chronic toxic effects.
  - **Respiratory irritation.**
  - **Secondary respiratory infection.**
  - **Anemia.**
  - **Altered behavior.**
  - **Sub-acute polyneuropathy.**
- Classified by OSHA as a carcinogen and a reproductive hazard.

Safe Use of Ethylene Oxide

- EtO must be used with extreme care and only when recommended by a device manufacturer.
- Sterilizer operators must be able to demonstrate a complete understanding of the properties and hazards of the gas and the sterilization process.

Safe Use of Ethylene Oxide

- Act responsibly.
- Follow procedures prescribed by the manufacturers of your equipment and of the products you process

Safe Use of Ethylene Oxide

- Adhere to strict procedures and controlled conditions such as:
  - Proper equipment.
  - Proper training.
  - Proper preparation.
  - Proper packaging.
  - Proper sterilization conditions.
  - Proper aeration.

Regulations Relative to EtO Use

- Regulatory agencies.
  - OSHA, FDA and the EPA
    - **OSHA supersedes all others unless the others are more stringent.**
- OSHA regulations include employee exposure measures, sterilization installation and engineering controls, medical surveillance, emergency situations, as well as other aspects

OSHA Regulations
Employee Exposure Levels

- Determined by sampling the air from the “breathing zone” of employees during a work day which includes the processes of EtO sterilization.
- Three levels.
  - **PEL Personnel Exposure Level**
  - **Action Level**
  - **STEL Short Term Excursion Level**

OSHA Regulations
Employee Exposure Levels

- Employee exposure levels determine whether or not additional practices must be adhered to.
- PEL - Personnel Exposure Level
  - 1 ppm for an 8 hr TWA (time weighted average)
  - Determined on the basis of one or more samples representing full shift exposure.
  - Levels between 0.5 and 1 ppm monitoring must be done semi-annually.

OSHA Regulations
Employee Exposure Levels

- If initial monitoring reveals levels above 1 ppm, monitoring must be done every 3 months until two consecutive results are below 1 ppm.
- "*Whenever there may be occupational exposures*" in excess of 1 ppm there must be regulated areas and precautionary signs.

OSHA Regulations
Employee Exposure Levels

- Action Level
  - 0.5 PPM for an 8 hr TWA
  - The level at which point additional monitoring and/or action must be taken.
  - If initial monitoring reveals exposure levels at or below the action level no further monitoring is required (unless other circumstances come into play).

OSHA Regulations
Employee Exposure Levels

- Additional training must be conducted if levels are above 0.5 ppm.
  - Medical surveillance must be initiated for exposure levels above the action level for 30 days or more per year without the use of respirators.
- STEL Short Term Excursion Level
  - 5 ppm over a 15 minute period during the performance of specific tasks.

OSHA Regulations
Employee Exposure Levels

- Additional monitoring is required when:
  - **There is a change in the production process.**
  - **There is a change in personnel.**
  - **When there is a change in control measures.**
  - **After sterilizer repairs.**

OSHA Regulations
Employee Exposure Levels

- When the employer has reason to suspect that a change may result in new, or additional exposure.
- "*The employer shall, within 15 days after the receipt of any monitoring performed under this standard, notify the affected employee of these results in writing either individually or by posting.*"

OSHA Regulations
Employee Exposure Levels

- If the PEL is exceeded the notification must include a written plan of action for the reduction of the exposure levels.
- Monitoring data, as well as medical surveillance data, is to be recorded and maintained for thirty years.

OSHA Regulations
Emergency Plan

- Must have a written plan for emergency situations.
  - *"OSHA has defined 'Emergency Situations' as an occurrence such as, but not limited to: equipment failure, rupture of containers, or failure of control equipment that may result in an unexpected, significant release of EtO."*

OSHA Regulations
Emergency Plan

- You must have a visual and audible alarm to alert employees of a potential “emergency” situations.
- The written Emergency plan should include:
  - Under what conditions would an EtO emergency occur.

OSHA Regulations
Emergency Plan

- What to expect, and what action to take if there is a liquid exposure.
- What to expect and what action to take if gas inhalation (exposure) should occur.
- What to expect and how to react to a ventilation system failure or leak should occur.

OSHA Regulations
Engineering Controls

- Local exhaust hoods are required when specific sterilizer parts are located in the work area:
  - Sterilizer door.
  - EtO storage tanks (cylinders).
  - Drains from the sterilizer.
  - Sterilizer safety valves.

OSHA Regulations
Engineering Controls

- There must be a dedicated exhaust for EtO systems and areas.
  - There must be a minimum of 10 air exchanges per hour.
- Sterilizers and aerators must be vented to the outside.
  - The vent can not end within 25 feet of any opening into the building.

OSHA Regulations
Medical Surveillance

- All employees who are exposed at, or above, the action level, without regard to the use of a respirator, for at least 30 days per year.
- Employees exposed to an “emergency situation”.
- To be done by, or under the supervision of, a licensed physician.

OSHA Regulations
Medical Surveillance

- Provided without cost to the employee, without loss of pay, and at a reasonable time and place.
- To be done:
  - Prior to assignment to the work area.
  - At least annually.
  - At termination of employment.
  - As medically appropriate after any overexposure.

OSHA Regulations
Medical Surveillance

- The content of the surveillance should include:
  - Medical and work history.
  - Physical exam.
  - Complete red and white blood count.
  - Any other lab tests deemed necessary by the physician.

OSHA Regulations
Precautionary Signs & Labels

- Required for regulated areas where EtO is in use.
- Specific wording required:
  - **"Danger - Contains Ethylene Oxide - Cancer and Reproductive Hazard - Authorized Personnel Only. Respirators and protective clothing may be required in this area."**

OSHA Regulations
Precautionary Signs & Labels

- Must contain a warning statement against breathing airborne concentrations of ethylene oxide.
- Tanks must have a warning statement regarding breathing airborne concentrations and a **green DOT label.**

OSHA Regulations
Leak Detection

- Should be performed, and recorded, every two weeks – for pressurized systems only
- Make sure your detector is specific to the type of EtO you are using.
  - 100% - EtO specific.
  - Mixtures - detect HCFCs
- Should be done during sterilizer operation.

OSHA Regulations
Leak Detection

- Leak detection should be performed:
  - Around the sterilizer door gaskets.
  - Around the vacuum piping hose.
  - Around filters.
  - Around safety valves and other valves such as tank valves.
  - After changing cylinders to be sure connections are tight.

OSHA Regulations
Training

- **Employees exposed at, or above, the action level of 0.5 ppm.**
- Content should inform employees of:
  - The hazards of an EtO exposure.
  - Steps to protect themselves from and during exposure.
  - Limitations and proper use of respirators and other equipment.

OSHA Regulations
Training

- Medical examinations and their purpose.
- Implementation of work practices.
- Use of available engineering controls.
- Contents of the OSHA Standard.

OSHA Regulations

- Employers to provide changing rooms and emergency showers in areas ***"where the eyes or body of any person may be exposed to injurious corrosive materials".***

OSHA Regulations Summary

- The extent to which the regulations apply is dependent upon employee exposure levels.
- OSHA States you may discontinue monitoring if your levels are documented below the action level of 0.5 ppm on two consecutive occasions at least seven days apart.

OSHA Regulations
Summary

- OSHA further says you must initiate monitoring again for a change in the production process, control equipment, personnel and whenever the employer has reason to suspect an increase in employee exposure.
- **Therefore .....**
- Periodic monitoring is the only way to assure you are continuing to meet this ruling.

The End

- Use caution
- Follow all safety rules at all times
- EtO will continue to be used
- Do NOT fear EtO but **RESPECT** it!