Ethylene Oxide Sterilization

One Integrated Approach to Healthcare.
Continuing Education Contact Hours

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Objectives

Upon completion of this course, you will be able to:

Describe Ethylene Oxide (EO) as a low temperature method of sterilization

Review recommended procedures when performing EO sterilization
What is Ethylene Oxide?

- \( \text{C}_2\text{H}_4\text{O} \)
- Colorless gas
- Smells like ether
- Sporicidal
- Non-corrosive
- Readily permeates
- Small percentage used in healthcare to sterilize heat and ethylene oxide molecule and moisture sensitive devices
Historical Perspective

1859
EO discovered (fumigation)

1929
EO/CO₂ patented for insecticide and microbial properties

1930
Fumigant for spices, gums, cereals
1940
100% EO patented as agricultural fumigant

1949
EO identified as a sterilant (Ft. Detrick)

1950
100% EO used for heat sensitive medical devices

1960’s
EO blends available
1980’s: Safety issues surface (OSHA)

1990’s: Environmental issues

Today: 100% EO
Advantages

• Effective at low temperature/low moisture levels
• Excellent penetration with no lumen restrictions
• Widely accepted by device manufacturers
  – Material compatibility
  – Non-corrosive
• Relatively low capital equipment cost
• Effective on a wide range of microorganisms
Limitations

- Long cycle times with aeration
- Expensive installation requirements
- EtO monitoring required
- Toxicity
  - Known health hazard and carcinogen to humans
- Installation requirements: dedicated exhaust, disposer, etc.
- Refer to AAMI ST 41
Ethylene Oxide (EO)

- Kills by alkylation
- Combines with genetic material in cell, destroys ability to metabolize and reproduce
- Effects: irreversible, causes cell death
- Used in industry and hospitals
- Mixed blends now outlawed
100% EO

- Single-use cartridges
- Reduced flammability
- Increased productivity and cost savings
- Safety features minimize operator exposure
EO Sterilizer Key Components

- Cycle Selector
- Touch Pads & Display
- Gasket
- Single-use Cartridge
- Impact Printer
- Envirogard
- In Chamber Aeration
- 5 Cubic Foot Chamber
100% EO

- Increased productivity and cost savings
- Higher concentration of EO
- Not paying for expensive inert gases
- Safety features minimizes operator exposure:
  - In-chamber placement
    - Vacuum cycles
    - In chamber aeration
- Chamber operates under negative pressure
100% EO Sterilization Phases

- Preconditioning
- Conditioning
- Exposure
- Exhaust
- Aeration
EO Sterilization Parameters

- EO gas concentration
  - 740-100 mg/L

- Relative humidity
  - 40-80% (critical to penetration of bacterial cells and successful sterilization)

- Temperature
  - High 145 F (63 C)
  - Low 98 F (37 C)

- Exposure
  - Varies between 1-6 hours
Preconditioning

- Chamber is sealed
- Vacuum is pulled
- Chamber begins to heat devices to preselected temperature (usually 100 or 130° F)
Conditioning

• Humidification – steam in
• Vacuum pulls and moisture purges
• Humidity at preset range
• EO sterilant and pressure rises
Exposure

- Sterilization
  - 1 hour at 130 F
  - 4.5 hours at 100 F
- Chamber maintained at selected:
  - EO concentration
  - Temperature
  - Humidity
  - For prescribed time
Exhaust

• Vacuum is drawn
• Filtered air wash
• Aeration
Aeration Requirements

- Removes residual EO before use or storage
- Device manufacturer provides parameters
- Single-chamber process required
- Sterilization and aeration must occur in the same chamber
  - 12 hours at 130 F (37.8 C)
  - 36 hours at 100 F (54.4 C)
- The load cannot be physically moved until aeration is complete
What Happens to Aerator Exhaust?

- Most Common
  - Non-recirculating
  - Dedicated exhaust to atmosphere
- Clean Air Act of 1990
- EPA regulates EO
- Some states require emission control systems to treat aerator exhaust
Safe Work Practices are Essential

Carelessness can be hazardous to your health!
EO Must Be Used With Care

- Known human carcinogen
- Improper use hazard
- Acute exposure
  - Irritation, CNS depression
- Chronic inhalation
  - Cataracts, cognitive impairment, neurologic dysfunction
- Occupational exposure
  - Hematologic changes, some cancers
EPA EtO National Emission Standards

March 2008
• Sterilize full loads
• Demonstrate and submit compliance status with management practice standard

Record keeping
• Compliance status
• Sterilizers not equipped with air pollution control devices

March 2010
• Single chamber process – no separate chamber
Preparing Devices for EtO

Follow manufacturer IFUs
- Cleaning/decontamination
- Packaging/loading/unloading
- Aeration
Items Must Be Clean And Dry!

- $H_2O + EO = \text{Ethylene Glycol}$
Packaging Materials

- Must be validated
- Allows penetration
- Removal during aeration
- Withstands rapid air removal during vacuum
- Withstands normal handling
- Economical
- Readily available
Packaging Materials

• Natural or synthetic woven textiles
• Non-woven, disposable, flat wrappers
• Polypropylene, cellulose fibers, cellulose-polyester
• Plastic/paper peel pouches
• Tyvek
• Rigid containers
• Limit use of absorbent surgical towels in sets
Inappropriate Packaging Materials

- Nylon/Teflon
- PVC (Saran Wrap)
- Mylar
- Cellophane
- Aluminum foil

STOP
Accessories
Loading Peel Pouches

- Verify package integrity
- Place peel pouches on edge
- Arrange plastic to paper
- Use perforated, wire mesh bottom trays
Loading Carts or Baskets

- Use metal baskets only
- Load in loose fashion
- No contact with walls of chamber
- Load to avoid contact if transferring for aeration
Aeration

• Removes toxic EO residues
• Same temperature as sterilization
• Series of pulses introduced, vacuum pulled, cycle repeated

• Factors determining aeration time
  • Sterilization/aeration system used
  • Wrapping materials/containers
  • Design/weight of devices
  • Size/arrangements of packs
Why is Aeration Essential?

• With premature removal, EO exposure can occur
• Adverse health effects through long term exposure
  – ‘ambient air’ aeration is not recommended
• No one is off the hook by signing a waiver
Quality Assurance

- Physical monitors
- Chemical indicators
- Biological indicators
- Environmental monitors
Chemical Indicators

- Indicator of sterilant conditions present
- External indicators
- Internal indicators
  - Placed in most challenging area for sterilant penetration
Biological Indicators

• Sterilization verification
• Bacillus atrophaeus (subtilis)
• Control biological
• Follow BI manufacturer instructions
• Routine monitoring
  – Test EVERY sterilization cycle

Installation Testing

• Verification of sterilizer efficacy
  – After installation of new sterilization
  – After major repairs
  – Relocation
  – Unexplained sterility failure
  – Change in gas supply, chamber load patterns

• Three consecutive cycles – negative results
• Utilize challenge pack (AAMI ST 41)
Record Keeping

• Load record
• Cycle documentation
• Chemical and biological indicator results
• Preventive maintenance/service records
• Records kept according to state and local statutes
• Sterilization malfunction
  – Remove sterilizer from service
  – Determine sterility of load
Occupational Exposure Limits

- Occupational Safety Health Administration (OSHA)
- Established limits, 1984
- Updated limits, 1987
- Limits at breathing zone of worker
Occupational Exposure Limits

- **Time Weighted Average (TWA)**
  - Average personnel exposure during specific period of time

- **Permissible Exposure Limit (PEL)**
  - Maximum EO exposure allowed in 8 hours
  - 1 ppm EO is the 8 hour TWA

“Code of Federal Regulations” (CFR)
(Section 1910, Subpart Z, Toxic and Hazardous Substances)
Occupational Exposure Limits

• Action Level – AL
  – EO exposure level above which OSHA requirements apply
  – 0.5 ppm is 8 hour TWA

• Excursion Limit – EL
  – OSHA term to define short-term exposure limit
  – 5 ppm is 15 minute TWA
Environmental Monitors

Area monitoring

Personnel monitoring
Action Item

Your policy and procedures should be in-line with recommended standards (AAMI ST 41/EPA National Emission Standards).

Also, ensure your team understands the policy and procedures. This will ensure your facility’s compliance and safe practice.
References

- Association for the Advancement of Medical Instrumentation, Ethylene Oxide Sterilization in Healthcare Facilities: Safety & Effectiveness AAMI ST41:2008 Arlington, VA

- Association of periOperative Registered Nurses, Recommended Practice for Sterilization in the Practice Setting, Denver, CO, 2010, AORN


- Occupational Safety and Health Administration, (OSHA), Occupational Exposure to Ethylene Oxide, Final Standard (29 CFR 1910.1047)

- Ball, KA, Endoscopic Surgery, St. Louis, MO, 1997, CV Mosby, Inc.

- Reichert, M and Young, J, Sterilization Technology for the Health Care Facility, Gaithersburg, MD, 1997, Aspen Publishers, Inc.

- United States Environmental Protection Agency (EPA), Re-registration Eligibility Decision for Ethylene Oxide, March 31, 2008
Questions
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Ethylene Oxide

- **AAMI/ANSI 41**
- Devices are clean and dry
  - ETO is sensitive to the presence of residual soil
- Low pressure (vacuum) systems
  - Venting cap required
- Sterilization parameters validated by endoscope manufacturer
  - Conditioning, sterilization and aeration
- Post-sterilization aeration is essential
  - Processing time typically >18 hours
- May have a limited number of cycles before requiring extensive repair