HEALTHCARE STERILIZATION ASSUMING THE ROLE OF INDUSTRIAL STERILIZATION ETHYLENE OXIDE
TYPES OF STERILIZATION

- High Temperature
- Low temperature chemical

Ethylene Oxide
TYPES OF LOW TEMPERATURE STERILIZATION
MAJOR DIFFERENCES BETWEEN HEALTH CARE AND INDUSTRIAL STERILIZATION

- Industrial sterilization pre-conditions loads for days in environmentally controlled rooms, health care facilities do not
- Sterilization cycles differ
- Loading patterns differ
- Aeration differs
- Manufacturers sterilize using a standard load configuration
- Industrial loads are scheduled
- Healthcare facilities require IFU to process
ETHYLENE OXIDE STERILIZATION

Healthcare EO sterilizer

Industrial

Accessed 10/14/19 EO vacuum sterilization chambers STERISYS
INDUSTRIAL ETHYLENE OXIDE STERILIZATION

- S
- A
- A
- S

Medical sterilizer / for the pharmaceutical industry / ethylene oxide / horizontal

Accessed 10/14/2019
OCCUPATIONAL EXPOSURE TO EO

• An occupational monitoring program must be in place to comply with the OSHA requirements
• Employee records must be kept for 30 years after leaving healthcare
• Monitoring methods available
  • Badges
  • Area monitors
EMPLOYEE EXPOSURE LIMIT

<table>
<thead>
<tr>
<th>Compound</th>
<th>Current OSHA PEL (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene Oxide</td>
<td>1</td>
</tr>
<tr>
<td>Hydrogen Peroxide</td>
<td>1</td>
</tr>
<tr>
<td>Ozone</td>
<td>0.1</td>
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</tbody>
</table>

Staff require a great deal of chemical safety training
PACKAGING PRODUCTION

- Manufacturers automated process
- Healthcare facilities
  - Staff package each item
  - Staff have frequent interruptions
  - Chemical indicators placed into each package
STERILIZATION LOADING STANDARDS

- Paper–plastic pouches placed on edge, with the paper side of one pouch next to the plastic side of the next pouch
- Properly spaced in the sterilizer for adequate sterilant contact and drying.
- Placed in holding racks or baskets specifically designed for paper–plastic pouches.

ANSI/AAMI ST79:2019
PROCESS MONITORS

Physical

Chemical

Biological
EFFECTS OF ADDITIONAL VOLUME ON HEALTH CARE FACILITIES
SPACE CHALLENGES

- Additional space needed for sterilizers
- Additional space needed for preparation
- Additional space needed for inventory holding
- Additional space needed for load quarantine
- Many older facilities unable to accommodate needed space and transformations
- In many healthcare facilities sterile processing is located close to or adjacent to surgery
- Space in healthcare facilities limited
## STERILIZER CAPACITY

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Time Ranges in minutes</th>
<th>Weight Ranges in pounds</th>
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</thead>
<tbody>
<tr>
<td>V Pro Max 2</td>
<td>11-51</td>
<td>11-50</td>
</tr>
<tr>
<td>V Pro</td>
<td>28-35</td>
<td>Up to 50</td>
</tr>
<tr>
<td>V Pro S2</td>
<td>19-60</td>
<td>4-25</td>
</tr>
</tbody>
</table>
HEALTHCARE ETHYLENE OXIDE INFRASTRUCTURE REQUIREMENTS

- Dedicated exhaust
- Ventilation rates should be monitored & documented
- Vent system alarms
- Separate room
- Environmental monitoring
- Many jurisdictions require engineering controls to reduce emissions

ANSI/AAMI ST41:2008
TRANSPORTATION IN AND OUT

- Logistics many sterile processing departments are located very close, adjacent to or within surgery
  - Very little space
  - Effects on patient transport
- Volume
- Additional costs
  - Transport equipment
  - Labor
  - Documentation
MEDICAL DEVICE FAILURES

- Who is liable for medical device failures?
- Manufacturer recalls difficult since the lot number may not be readily visible
- Unclear how UDI will fit into the change
CHALLENGES

- Staffing
  - Obtaining funds to hire techs
- Competency level of staff of current SP
  - Expert to entry level
  - Staff turnover
- High stress
- Low wages
Range of Services Supported

- Decontamination
  - Disassembly

- Inspection
  - Assembly

- Prep & Packaging

- Sterilization or Disinfection
  - Surgery
    - General
    - ENT
    - Orthopedic
    - Neuro
    - Peripheral Vascular
    - Robotics
    - Cardiovascular
    - GYN
    - Plastic
    - Cysto/GU
    - Eye
  - Cardio Vascular Lab
  - Endoscopy
  - Labor & Delivery
  - Emergency
  - Dental Clinic
  - Outpatient Clinics
  - Nursing Units
    - Critical Care
    - General
    - Specialty Carts
Range of Medical Devices

- Implants
- Scopes
  - Flexible
  - Rigid
- Power Equipment
- Specialty Inst
- General Instrumentation
- Loaners

- Robotic
- Cameras
- Eye Instruments
- Laparoscopic
- Diagnostic
- Cords
- Nursing Units
  - Equipment
  - Instrument sets
  - Specialty carts
Medical devices and processes in sterile processing are becoming more complex. A method to reduce errors has been to remove noncomplex tasks such as inventory tasks so the SP staff can focus on processing.
HUMAN FACTORS

- Constant interruptions
- Noisy
- Typically not enough space
- Ergonomics
UNCONTROLLED INPUTS HIGH DEMAND OUTPUTS
STRATEGIES/TRENDS TO ENHANCE SP FUNCTIONS

- Noncomplex tasks removed from SP
  - Inventory
  - Equipment rounds
- Review items processed to convert to disposable
ADDITIONAL HEALTHCARE COSTS

- New sterilizers
- Process monitoring
- Environmental monitoring
- Personal monitoring
- Abatement systems
- Labor

- Additional space
- Infrastructure requirements for ethylene oxide
- Assembly accommodations
- Cost to re-validate supplies
- Transport
- Sterilant
MORE QUESTION THAN ANSWERS

- How to track UDI?
- How to track medical devices recalled by the manufacturer?
- How can additional sterilizers be placed into a SP?
- What about healthcare facilities that do not have space for sterilizers?
- How to obtain funds for additional sterilizers?
- Who will be responsible for a medical device failure?
- How will healthcare facilities fund new increase cost to daily operations?
- Will other SP activities be impacted?
- How will healthcare facilities manage internal logistics (pts/supplies)?
MORE QUESTION THAN ANSWERS

- What will be the cost increase to re-validate medical devices?
- How will healthcare facilities fund the increase in daily operations?
- Will other SP operations be impacted?
- If additional low temperature sterilizers are added, will that increase emissions at the facility?
- Who will be responsible for a medical device failure?
- How will healthcare facilities fund new increase cost to daily operations?
- Will other SP activities be impacted?
- How will healthcare facilities manage internal logistics? Especially not to interfere with patient transport
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