

**Ethylene Oxide (ETO)  
Stakeholder Meeting Agenda Topics  
January 29, 2014**

- Introductions
- ETO Usage Overview
- Industrial ETO Sterilization
  - ETO Process Overview and Steps
  - ETO Sterilization Emission Controls
  - ETO Sterilization Worker Exposure Control Measures
- Hospital ETO Sterilization
  - Typical Hospital EO Sterilization Process
  - Hospital ETO Sterilization Emission Controls
  - Hospital ETO Worker Exposure Control Measures
- ETO Preliminary Work Plan -- Anticipated Data Needs or Requested Comments
  - Occupational Exposure
  - Residential Post-Application -- Inhalation
  - Ecological
  - Water Quality
  - Additional Information
- Open Discussion

**Meeting Summary**

EPA/Ethylene Oxide Stakeholders  
January 29, 2014, 1:00 PM to 2:30 PM  
Room S-9100, 2777 S. Crystal Drive, Arlington, VA 22202

Participants

**Stakeholders:** Lynn L. Bergeson (Bergeson & Campbell, P.C. – counsel to The Ethylene Oxide Sterilization Association, Inc. (EOSA)), Joanne Cashin (ARC Specialty Products/ Balchem Corporation), Kathleen Hoffman (Sterigenics), Suzanne Leung (3M), David Ludwig (ARC Specialty Products/ Balchem Corporation), Edward M. Ruckert, (McDermott, Will & Emery – counsel to the American Spice Trade Association), Larry Talapa (3M), Jake Vandevort ( B&C Consortia Management)

\*Mike Ebers (Steris), \*Anita Kore (3M), \*Resa Manson (Steris), \*Randy Viscomi (ARC Specialty Products/ Balchem Corporation), \*Ruey Dempsey (Advanced Medical Technology Association)

\* Indicates participation by conference call

**EPA:** Sandra O’Neill, Susan Bartow, Cathryn Britton, Thurston Morton, Jessica Kidwell, Michelle Ranville, Sujatha Sankula, Gabe Rothman, He Zhong, Srinivas Gowda, Tim Leighton, Donna Randall, Rose Kyprianou, Donna Kamarei, Philip Ross, Jeffrey Dawson, Len Yourman, Elissa Reaves, Najm Shamim, Ivan Nieves, Ed Odenkirchen

**EPA/Ethylene Oxide Stakeholders Meeting:** On Wednesday January 29<sup>th</sup>, 2014, members of AD, PRD, HED, BEAD, EFED, and OGC met with stakeholders of Ethylene Oxide (ETO) to discuss comments submitted by the stakeholders pertaining to the ETO Preliminary Work Plan (PWP). The stakeholders presented an overview on ETO usage and industrial and hospital ETO sterilization (typical ETO sterilization processes, emission controls and worker exposure control measures). Participants also discussed anticipated data needs, and comments on the ETO PWP and areas where the risk assessment could be refined with data from ETO stakeholders. (Donna Kamarei [Kamarei.donna@epa.gov](mailto:Kamarei.donna@epa.gov), Susan Bartow [bartow.susan@epa.gov](mailto:bartow.susan@epa.gov), Sandra O’Neill [oneill.sandra@epa.gov](mailto:oneill.sandra@epa.gov))

# REGISTRATION REVIEW OF ETHYLENE OXIDE

Stakeholder Meeting  
Arlington, VA  
January 29, 2014

Jake Vandevort  
B&C® Consortia Management, L.L.C.  
Washington, D.C.  
[www.bc-cm.com](http://www.bc-cm.com)

# Agenda

- **Introductions**
- **Summary of Key Points**
- **Ethylene Oxide (EO) Usage Overview**
  - **David Ludwig, ARC Specialty Products/Balchem**
- **Industrial and Spice EO Sterilization**
  - **Kathleen Hoffman, Sterigenics**
- **Hospital EO Sterilization**
  - **Larry Talapa, 3M**
- **EO Preliminary Work Plan (PWP)**
  - **Jake Vandevort, B&C<sup>®</sup> Consortia Management, L.L.C.**
- **Discussion**

# Introductions

## Summary of Key Points

- **The Ethylene Oxide Sterilization Association, Inc. (EOSA) believes the assumptions made concerning emissions do not reflect current usage and the perceived dangers due to those emissions are not reflective of the current situation**
- **EOSA is compiling industry data and wishes to provide it to the U.S. Environmental Protection Agency (EPA)**

## Summary of Key Points (cont'd)

- **Invitation to visit a sterilization facility**
- **EO sterilization plays a critical role in maintaining public health and we must get it right**
- **EOSA is committed to the registration review process and the products**
- **EOSA requests an opportunity to meet with EPA to discuss the PWP and anticipated data needs prior to the preparation of the Final Work Plan**

# EO Usage Overview

- **EO's Essential Public Health Applications**
- **Sterilized Medical Products**
- **Sterilization Market**
- **Sterilization Capacity**

# EO's Essential Public Health Applications

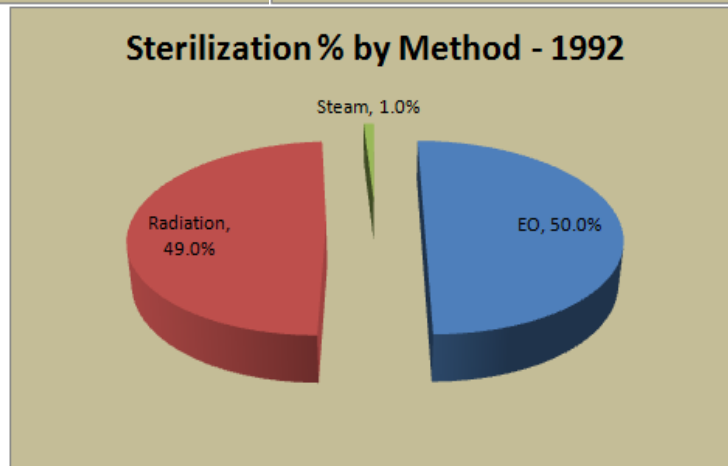
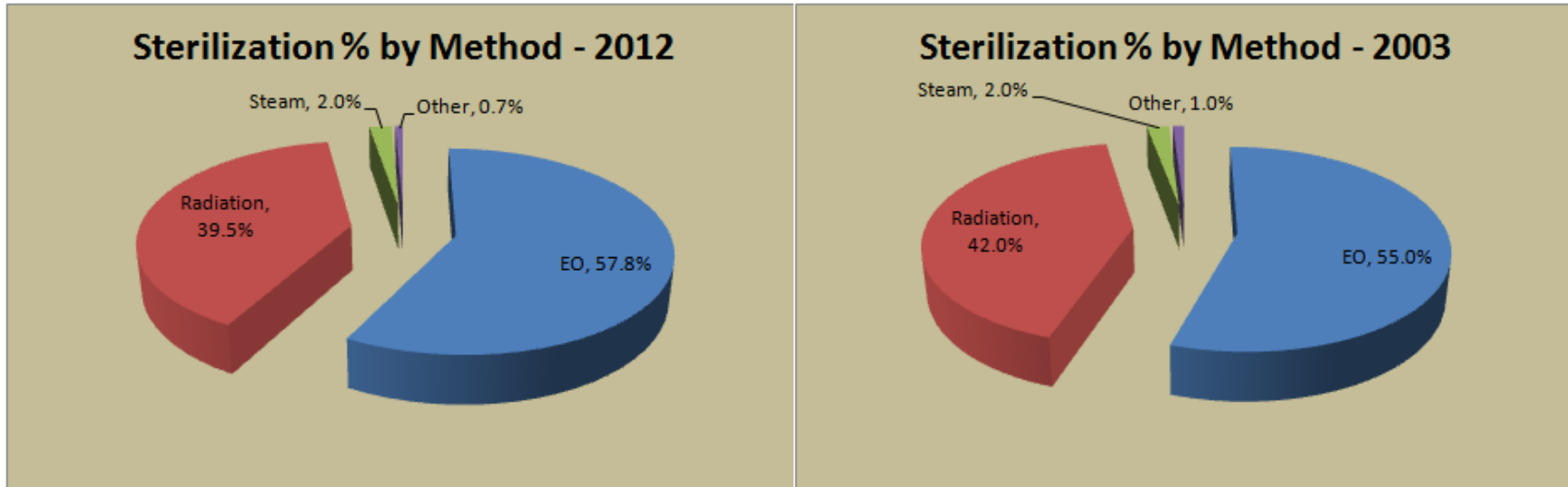
- **Certain materials can only be sterilized using EO -- materials that are heat-sensitive, materials that cannot withstand exposure to steam or gamma radiation**
  - **Sterilizes complex devices**
  - **Long history of device compatibility**
  - **Readily inactivates spores (most resistant life forms)**
- **Approximately 58% of medical products and 95% of surgical kits are processed with EO sterilization**



## EO's Essential Public Health Applications (cont'd)

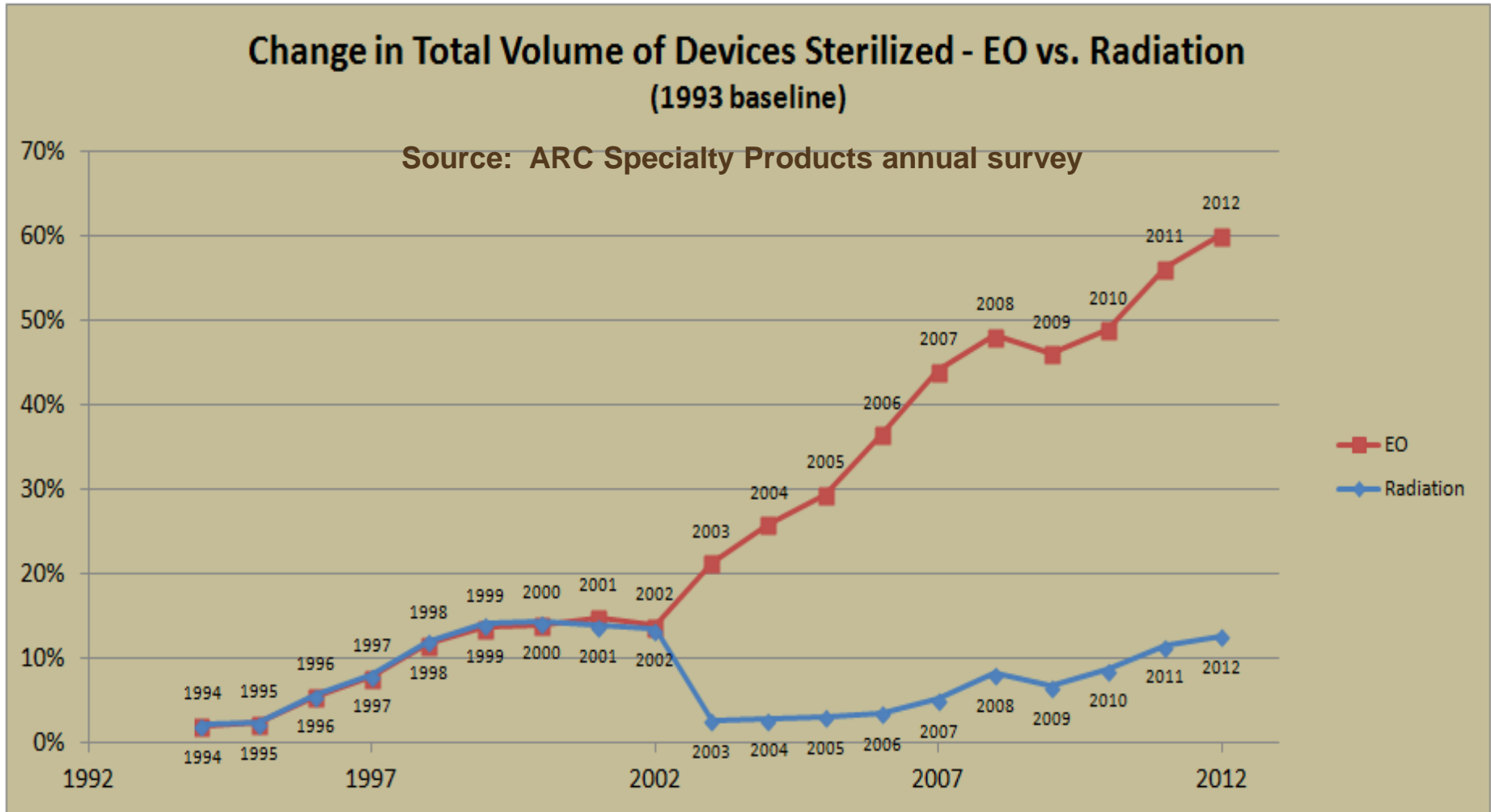
- **EO sterilization is also vital to the spice industry**
  - **Approximately 20% to 30% of spices in the U.S., most of which are imported, are treated with EO to reduce bioburden**
  - **EO is an essential tool in protecting public health**
  - **EO has consistently demonstrated its reliability in preventing the spread of dangerous pathogens, such as *Salmonella* and *E.coli*, and it does so without adversely affecting the quality or conditions of the spices**

# Total Sterilized Medical Products (Cubic Feet Processed)

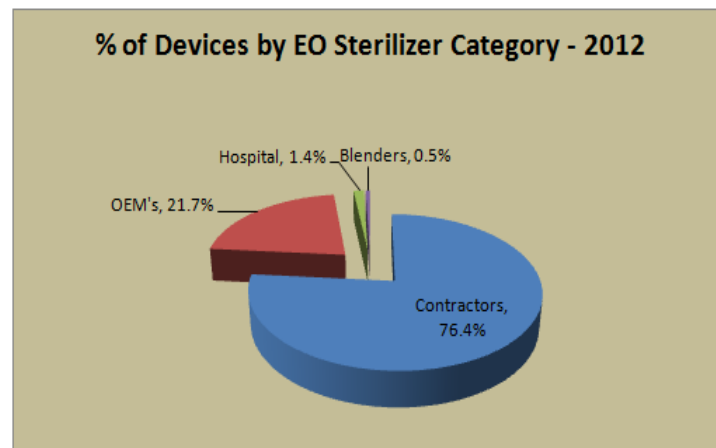
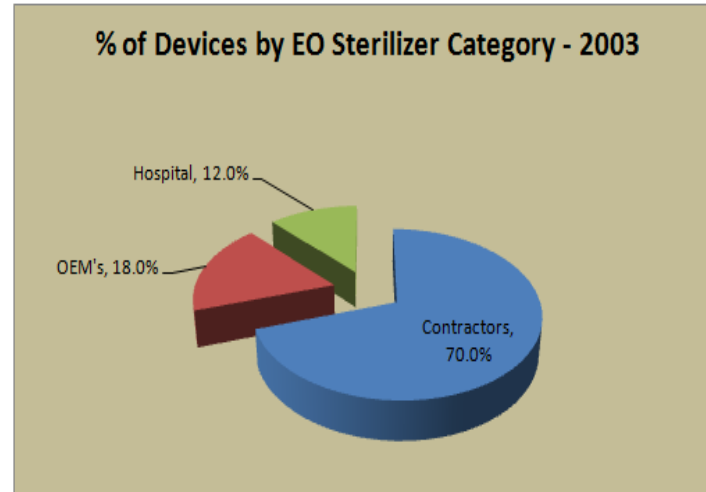
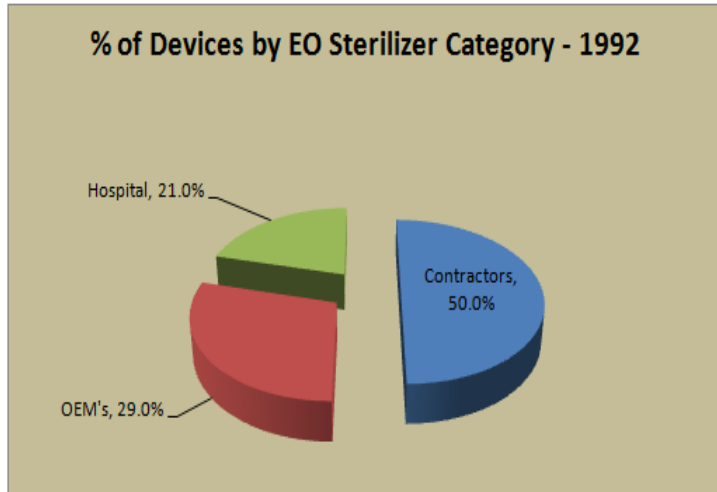


**Source: ARC Specialty  
Products annual survey**

# Historical Sterilization Market Trend (Cubic Feet Processed)

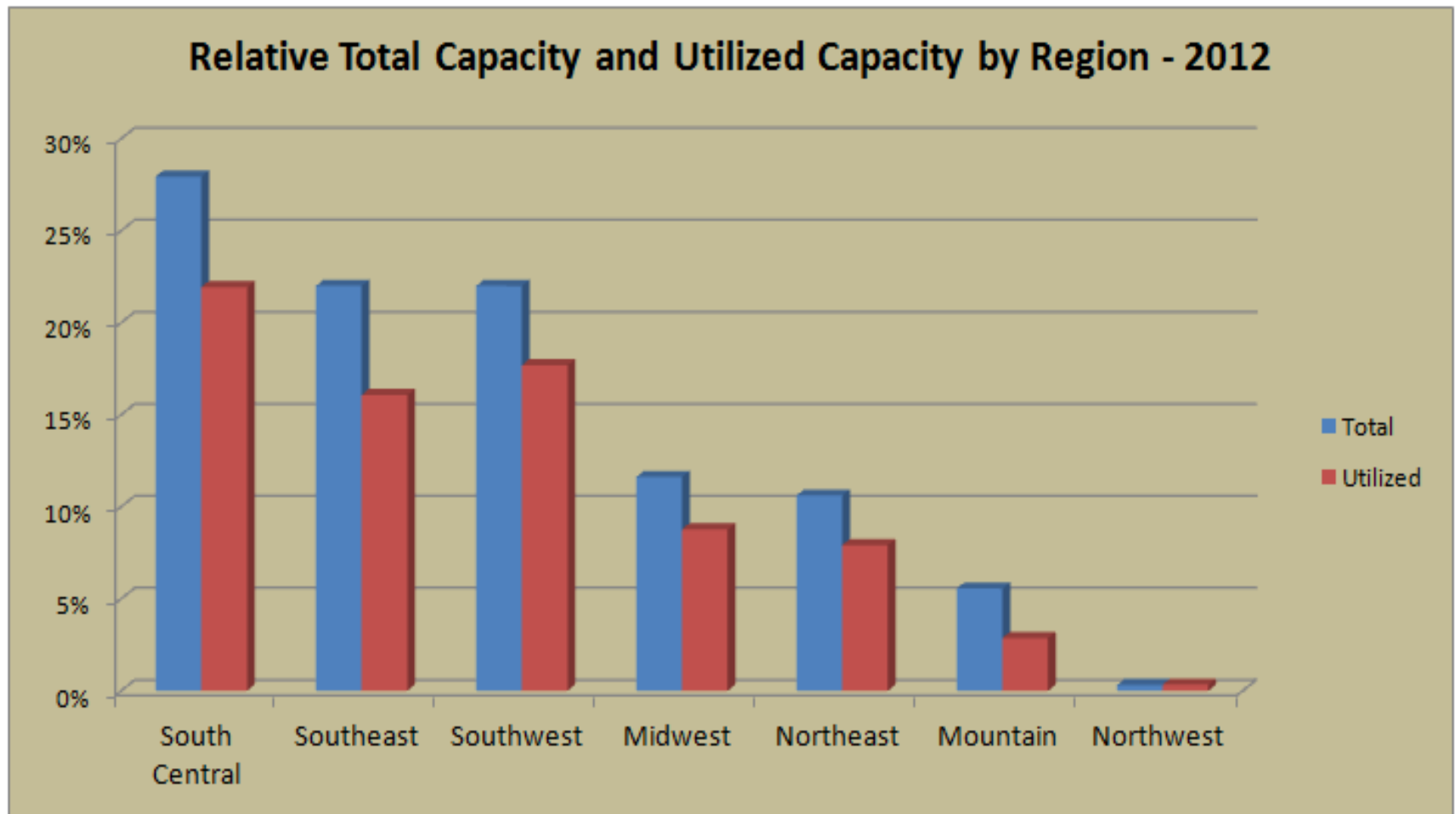


# EO Sterilization Market (Cubic Feet Processed)



**Source: ARC Specialty Products annual survey**

# Contract and OEM EO Sterilization Capacity

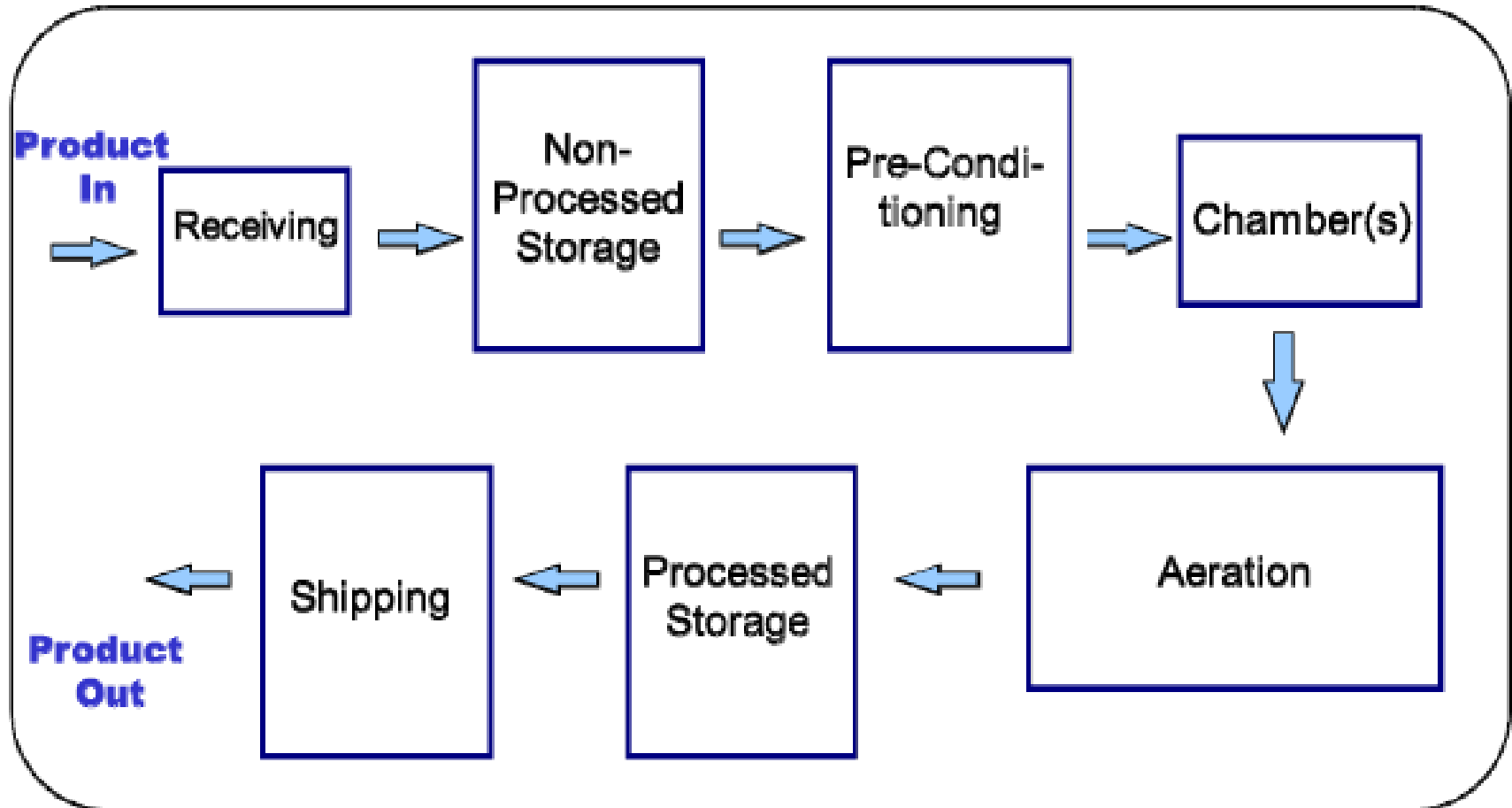


**Source: ARC Specialty Products annual survey**

# Industrial EO Sterilization

- **EO Sterilization -- Process Steps**
- **EO Worker Exposure -- Controls and Monitoring**
- **EO Emission Controls and Typical Emissions  
(compared to EPA's PWP)**

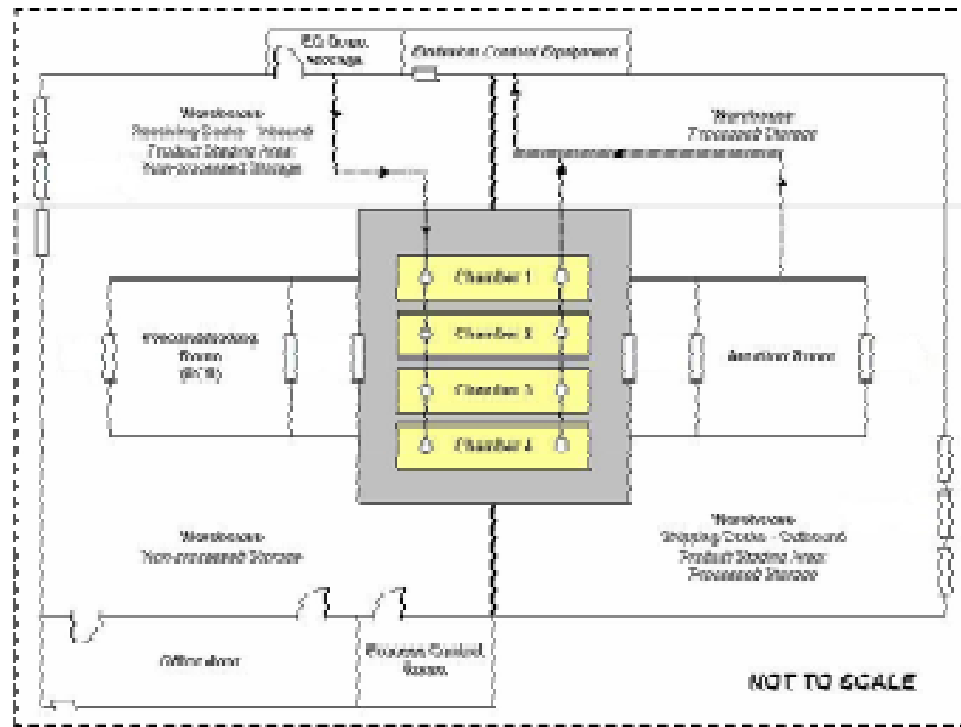
# EO Sterilization -- Product Flow



# EO Facilities Are Typically Split into Two Areas

**Unsterilized**

**Sterilized**





## Receiving and Non-Processed Storage

- The first step in sterilization is the receiving of material and storage in the non-processed area



## Receiving (cont'd)

- Product is received on pallets and is traced throughout the process
- Material is moved through sterilization facilities with forklifts



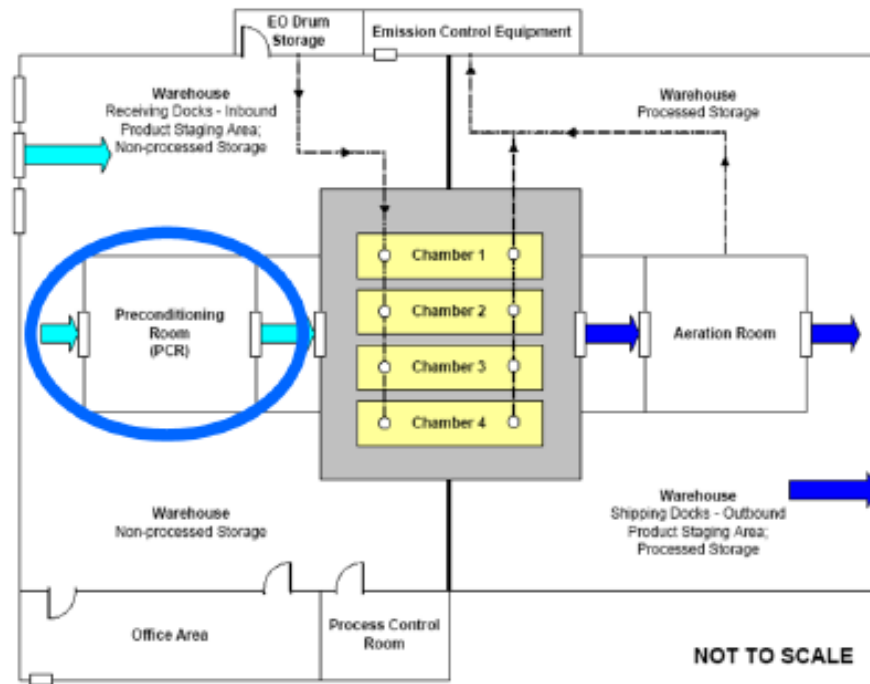
## Facility Area Labeling

- All areas of the facility are clearly labeled



# Pre-conditioning

- Before being sterilized, the material needs to be pre-conditioned. This step brings the product up to the desired temperature and humidity. This is usually done in a separate pre-conditioning room or cell



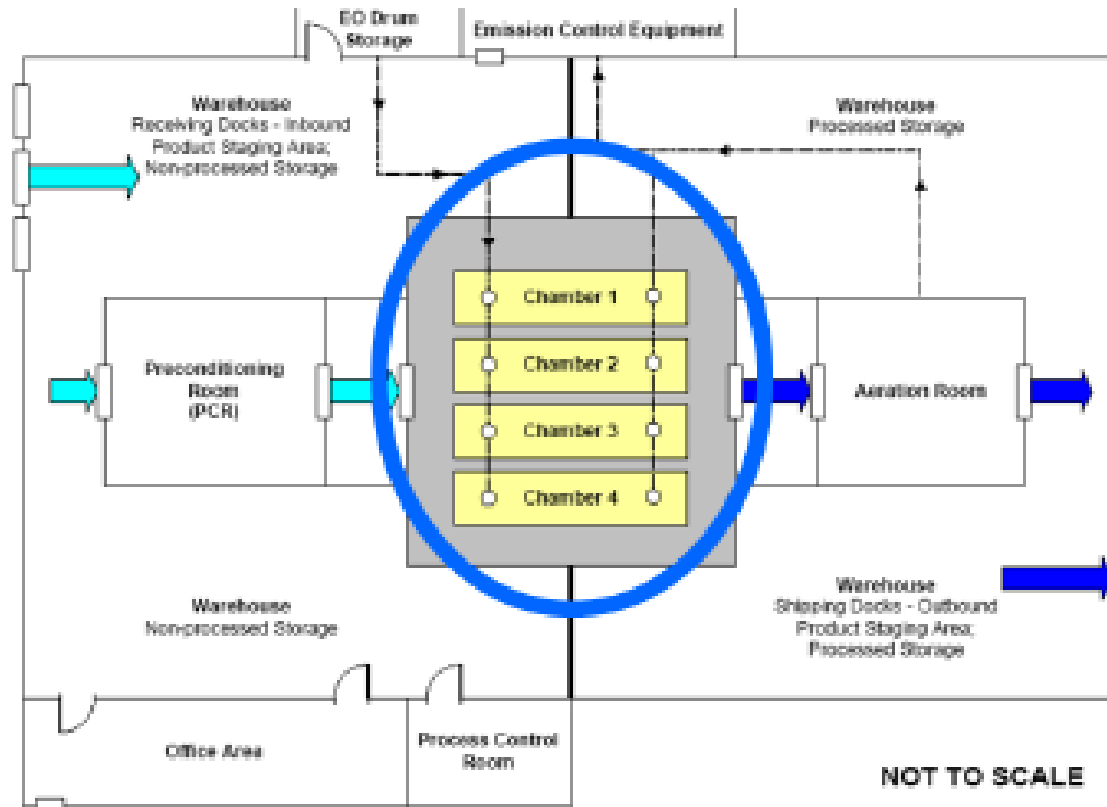
# Pre-conditioning

- **Product is stored in pre-conditioning room at elevated temperature and humidity for a prescribed time period**



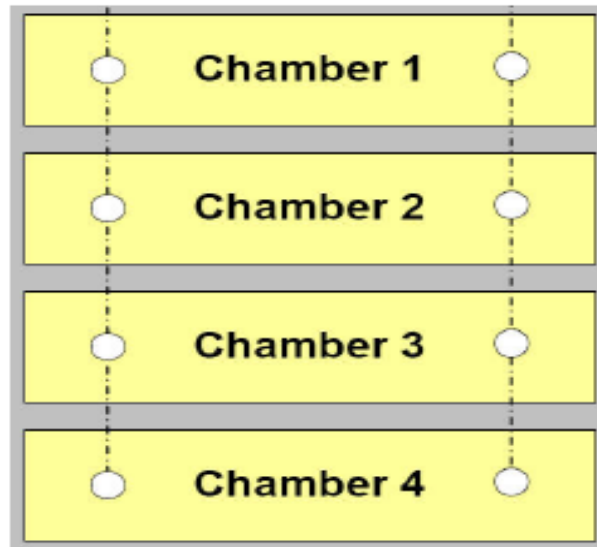
# Sterilization Chambers

- Following pre-conditioning, the material is ready to be sterilized and moved to an EO chamber



## Sterilization Chambers (cont'd)

- EO facilities typically have multiple sterilization chambers





# Multiple Chambers

- **Sterilization work aisle for a plant with multiple chambers**
- **Note the physical separation of chambers from the rest of the plant and ventilation systems**





## Sterilization Chambers (cont'd)

- Chambers are large, gas-tight, steel containers that are capable of holding vacuums



Steam or hot water is circulated through a jacket around the chamber to regulate the temperature of the material inside

## Sterilization Chambers (cont'd)



EO Sterilization  
Chamber with  
the Chamber  
door open

EO Chambers vary  
greatly in size to  
hold from one to  
30 pallets of  
customer product

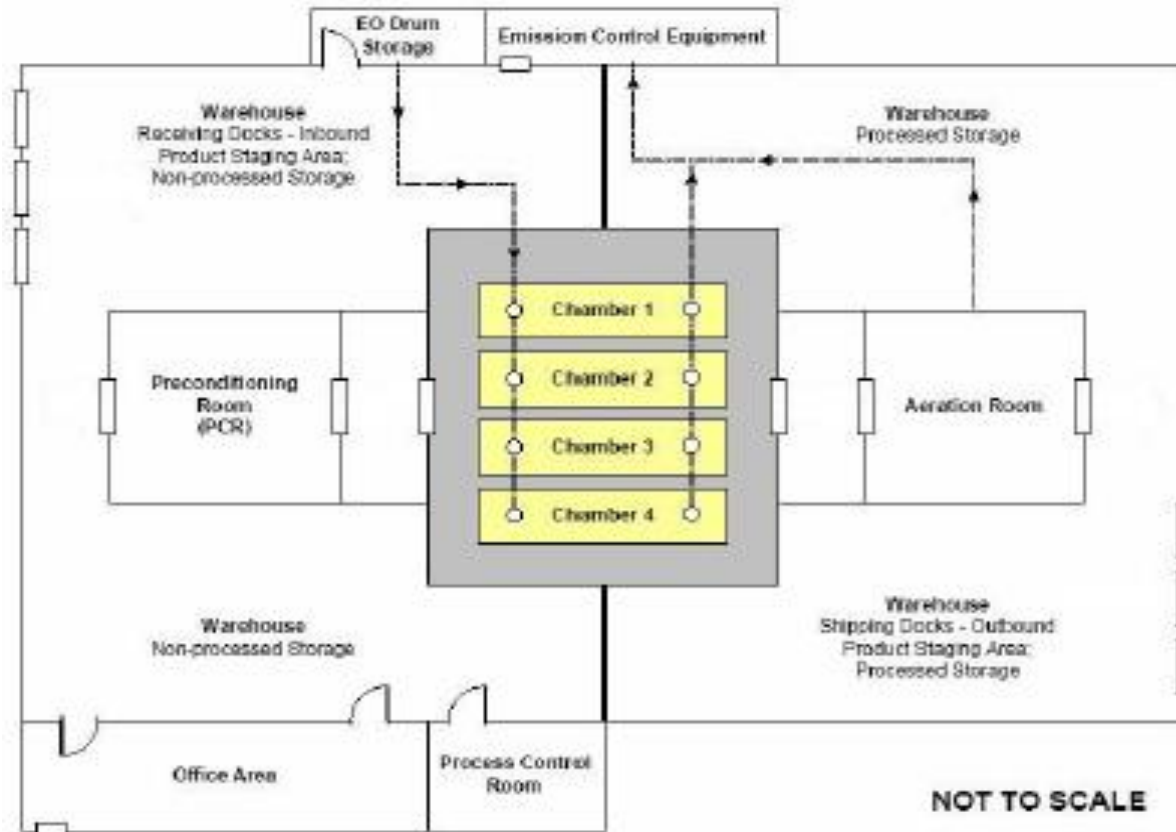
## Sterilization Chambers (cont'd)

- Some chambers have conveyors to assist with the loading of product



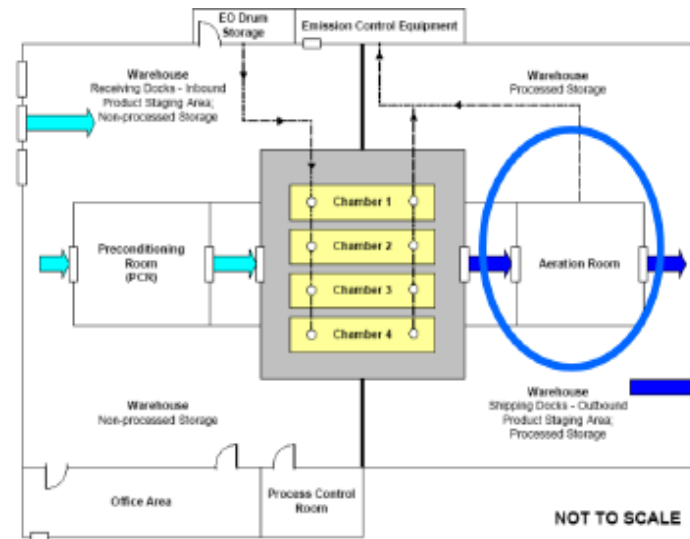
# Delivery and Removal from Chambers

- EO is delivered to and removed from the chambers through gas-tight pipes



# Aeration Areas

- In conventional sterilization facilities, product is removed from chambers and put in an aeration room or cell
- Aeration rooms allow product to aerate safely. The product gives off small amounts of EO after it is removed from the chamber



## Aeration Room (cont'd)

- **Aeration rooms undergo continuous air exchanges to provide a homogenous environment and route EO streams to emission controls**
- **Aeration rooms are considered restricted areas because of elevated EO concentrations. Operators are required to wear respirators when entering aeration rooms**
- **The elevated temperatures in aeration rooms helps speed the EO removal that is absorbed by the products**
- **Aeration is part of the sterilization process and subject to the same process control and Food and Drug Administration (FDA) validation as other sterilization steps**

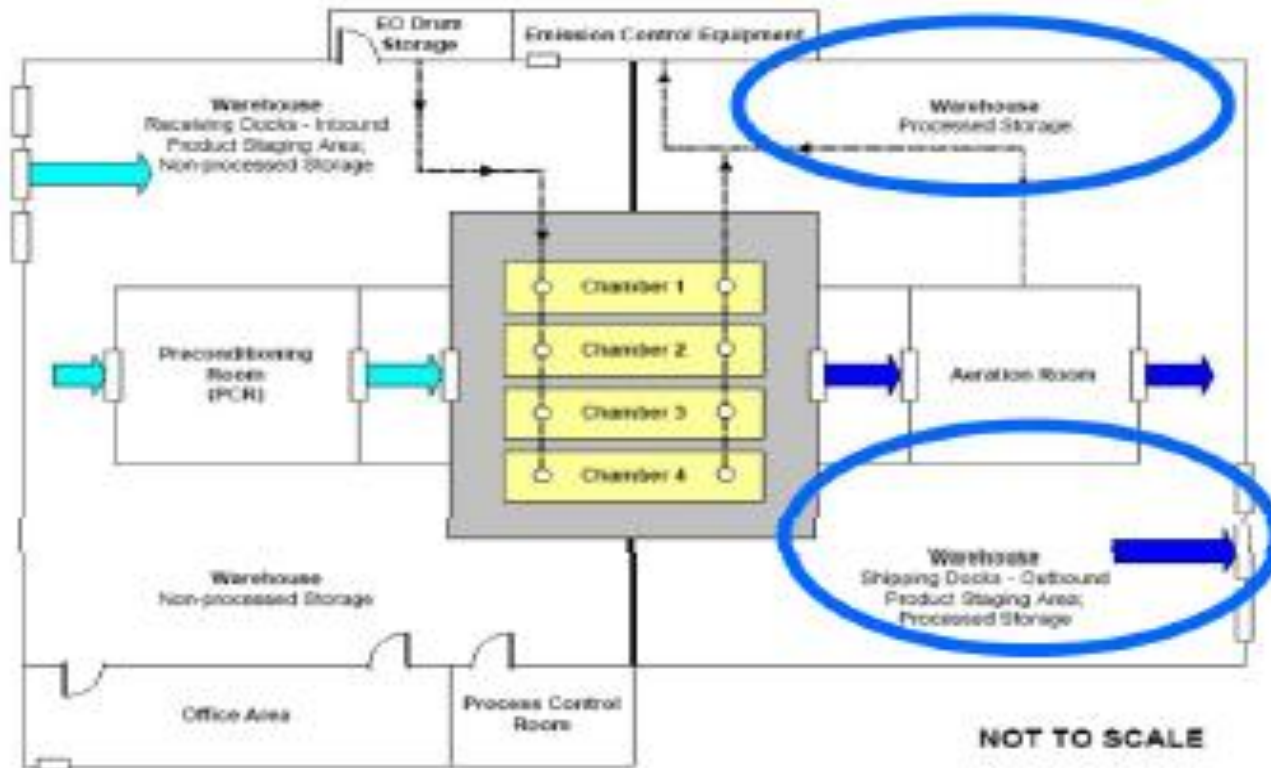


# Aeration



# Processed Storage and Shipping

- Following aeration, material is moved to processed storage. Once the product is released, it can be shipped





# Processed Product

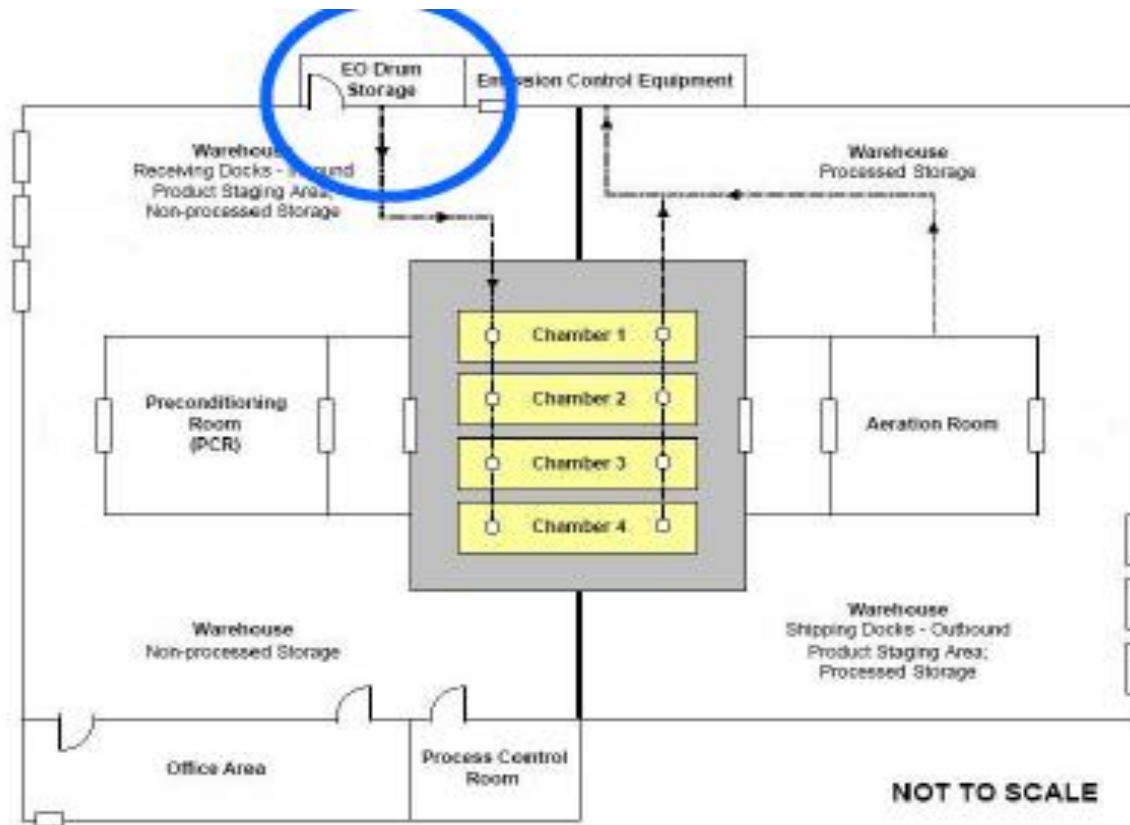


# Shipping



# EO Drum Storage

- EO is stored in a special drum storage area
  - Access to this area is restricted



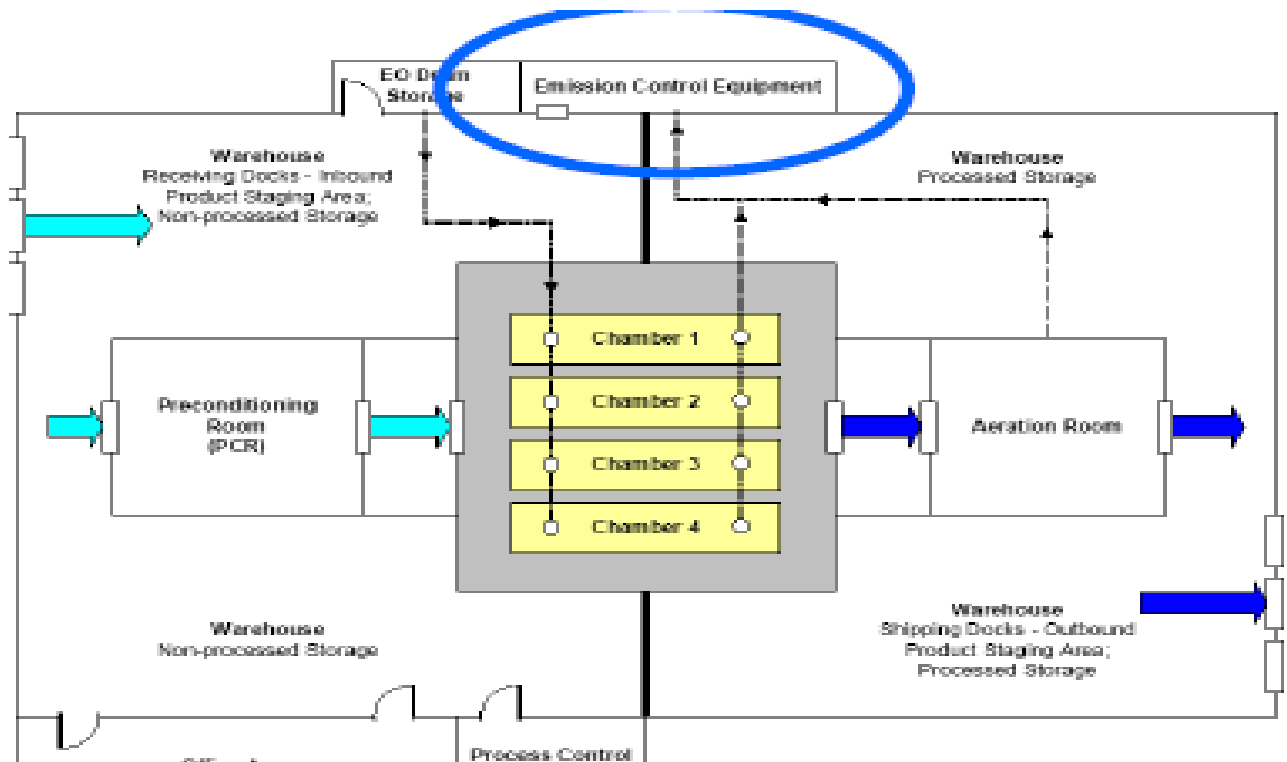
# Connecting and Disconnecting Drums

- Special precautions are taken when EO drums are connected and disconnected
- All connections and piping are gas-tight and leak-checked



# Emission Controls

- EO emissions must be controlled
- EO vapors are piped from the chambers and aeration rooms to emissions control equipment





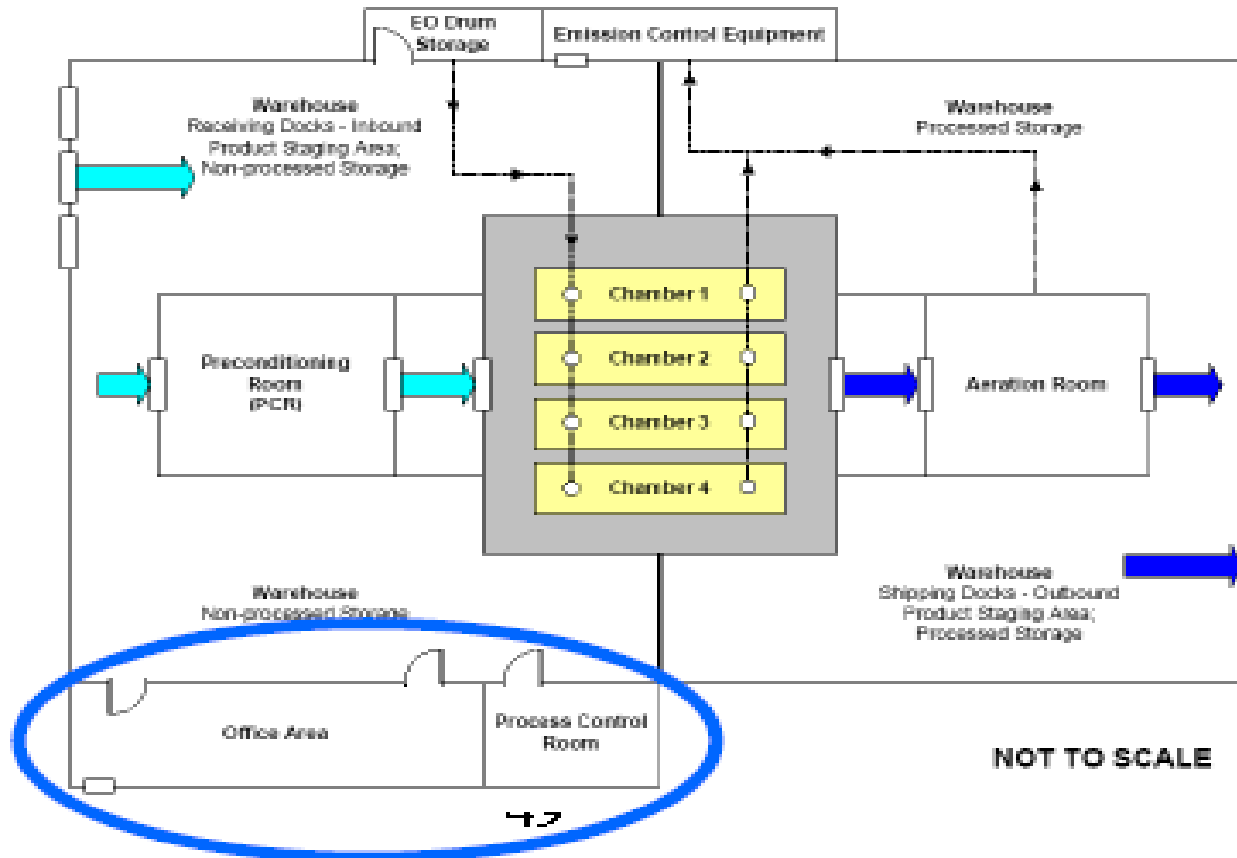
# Wet Scrubbers

- **Wet scrubbers are often used to control emissions. These devices convert EO to ethylene glycol**
- **Sterilization facilities must comply with federal and state environmental air emissions regulations**



# Control Room

- A control room and office area are also part of a facility



## Control Room (cont'd)

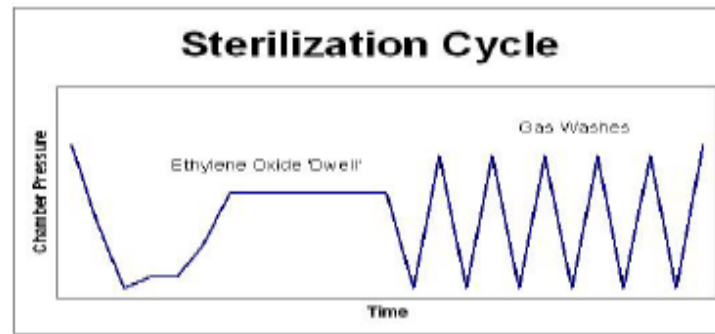
- A control room has computer equipment and instrumentation that allows operators to monitor and control every step of the sterilization process
- All computer software and control equipment must undergo FDA validation





# EO Cycle Designs

- **EO vapor is exposed to product inside of a sealed chamber through a controlled and FDA validated “cycle”**
  - **A cycle is composed of several steps, including removal of air by vacuum from the chamber, introduction of steam, nitrogen, and EO, and then the removal of EO**
  - **The EO removal is conducted through the use of “gas washes,” where gas in the chamber is repeatedly removed by vacuum and replaced with nitrogen**



## Typical EO Sterilization Cycle Phases

- **Initial Vacuum**
- **Nitrogen Dilution**
- **Steam Injection and Conditioning**
- **EO Gas Injection**
- **EO Gas Dwell**
- **After Vacuum**
- **Air/Nitrogen Washes**
- **Final Release (ready for aeration)**

## Cycle Design Considerations

- **Cycle design has been used in recent years as an important tool to reduce employee exposures when the cycle is complete**
- **FDA's EO residual requirements were recently reduced, which has also driven cycle designs that minimize EO left within the product**
- **The industry minimizes EO within the cycle**
- **All cycle design changes have resulted in lowering the number of employees potentially exposed**

## **EO Facilities Are Heavily Regulated**

- **The Occupational Safety and Health Administration (OSHA) EO Standard addresses worker exposure**
- **Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) standards regulate the sterilization process**
- **An industry-specific National Fire Protection Association (NFPA) Standard addresses EO fire hazards**
- **FDA Quality Systems Regulations address the operation of the entire sterilization process**
- **OSHA Process Safety Management applies to facilities that store more than 5,000 pounds of EO**
- **Homeland Security regulations regulate security requirements for EO facilities**

# OSHA Requirements

- Employee Exposure Monitoring
- Segregation of EO Regulated Area
- Respiratory Protection/Personal Protective Equipment (PPE)
- Emergency Planning
- Medical Surveillance
- Employee Communication
- Recordkeeping

OSHA's Action Level = 0.5 ppm  
OSHA's TWA Level = 1.0 ppm  
OSHA's EL = 5.0 ppm

## **Worker Exposure Issues -- Solutions**

- **Heavily Regulated Industry**
- **Segregated Process Areas per OSHA Standards**
- **Segregated Product Storage Areas**
- **Well-Designed Ventilation Systems**
- **Properly-Designed Aeration Rooms**
- **Chamber Back Vents**
- **Effective Emission Controls**

**(EOSA Best Practice Sharing)**

## **Worker Exposure Issues -- Solutions (cont'd)**

- **Improved Sterilization Cycles**
- **Thorough EO Training for Employees**
- **Procedures for Handling EO and Drums**
- **Lower Explosive Limit (LEL) Detection Devices**
- **Continuous EO Monitoring Systems**
- **Door Interlock System (with EO Measurement)**
- **Respirator Requirements for Certain Tasks**

## **Few Employees Per Facility**

- **EO sterilization is a capital-intensive process, not labor intensive**
  - **Industrial EO facilities typically have 5 to 30 EO employees**
  - **Further minimized number of employees within the facility that are potentially exposed to EO**



## **Typical Respirator-Required Tasks**

- **Unloading Sterilization Chambers**
- **Entering an Aeration Room or Cell**
- **Maintenance Tasks on EO Pipes or Equipment**
- **Sampling or Accessing Processed Product**
- **Changing EO Drums Connected to the Process**

## Types of Respirators Used

- **MSA Canister Masks (phased out)**
- **Forced-Air Negative Fit Masks**
- **Self-contained Breathing Apparatus (SCBA)**



# Safety-Limiting Worker Exposure



Continuous EO area monitors are installed throughout many facility

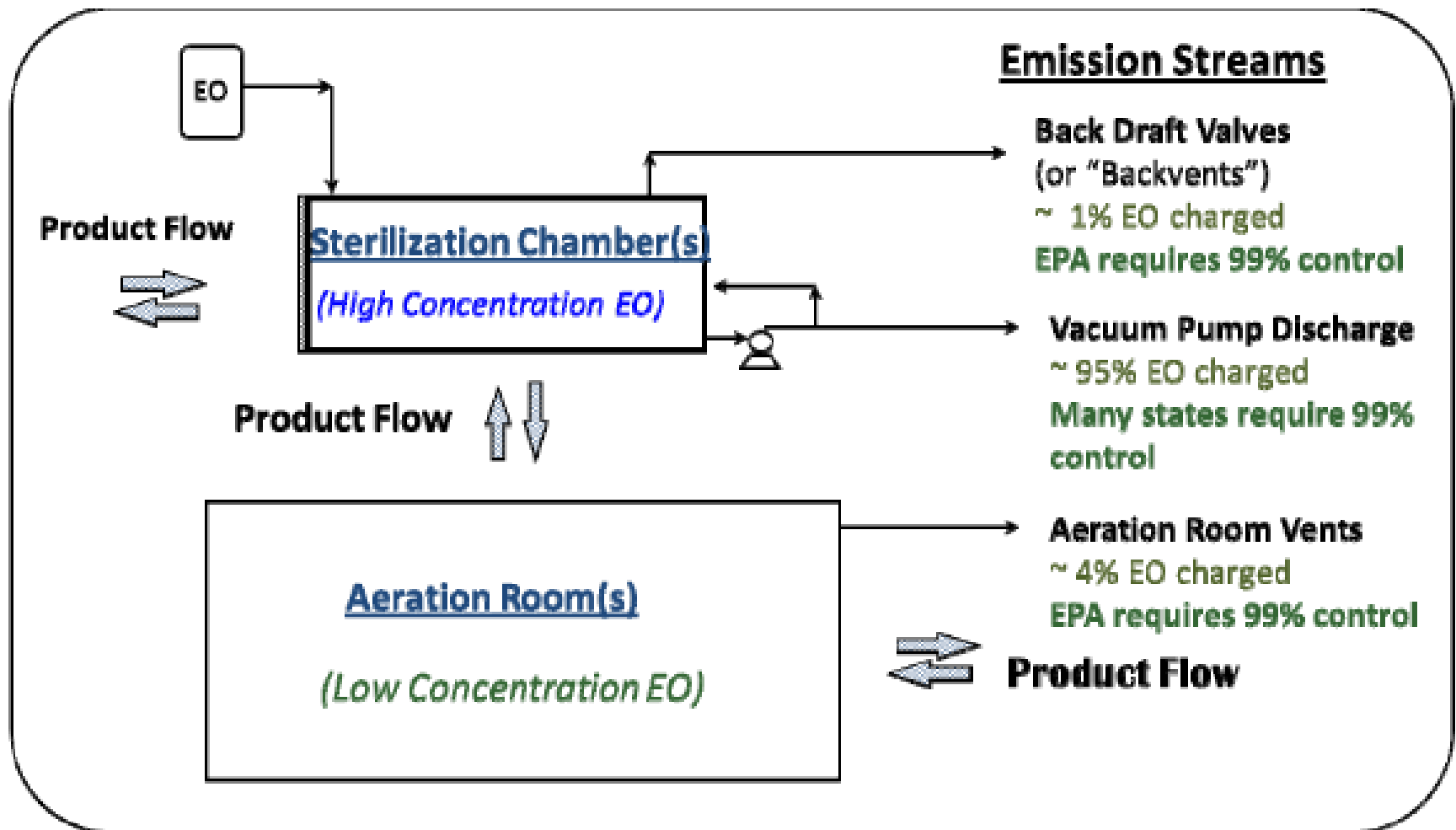


Employees exposure must be monitored using badges every six months (minimum)



Handheld monitors are used often

# EO Sterilization Emissions



## **EO Emissions -- EPA Assumptions**

- **Appendix E (PWP) -- Modeling input based on EO release scenarios for spices and herbs**
- **Spices and herbs are processed in an industrial sterilization facility like medical devices**
- **EPA requires emission controls in almost all of these facilities**
- **The PWP assumptions should be corrected**

## EO Emissions -- EPA Assumptions and Corrections

- Maximum Chamber Size is ~~40,000~~ **5,200** cubic feet
- Maximum Application Rate is 500 mg/L
- Emission Rate is ~~312.2~~ **162.3** lbs/hr. **(without controls)**
- **Emission Rate is 1.62 lbs/hr. (with controls and 99% efficiency)**
- Stack or Release Height is ~~5~~ **25-30** feet
- Stack Diameter is ~~39.6~~ **12** inches
- Distance between the stack and building center is ~~22.3~~ **100-300** feet

# EO Sterilization Is Needed -- The Gold Standard

- **Low temperature, moisture sensitive, device sterilization**
  - 50+ years of EO use in U.S. hospital setting
- **Efficacious -- inactivates spores, fungi, and viruses**
- **Superior ability to penetrate**
- **Long, large bore, multiple channel, flexible endoscopes**
  - Sterilizes complex geometries
  - No lumen restrictions
- **Materials compatibility**
  - Does not damage sterilized devices or materials
  - Long history of compatibility
  - Variety of packaging options
- **Cost-effective**
  - Cycle to cycle basis



Long, large bore, multiple channel, flexible endoscopes



# Increasing Critical Need to Sterilize Complex Instruments

CDC Home



Centers for Disease Control and Prevention  
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## Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)



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### Notes from the Field: New Delhi Metallo-β-Lactamase-Producing *Escherichia coli* Associated with Endoscopic Retrograde Cholangiopancreatography – Illinois, 2013

*Weekly*

January 3, 2014 / 62(51);1051-1051

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE)\* are increasing among patients in medical facilities (1). CRE that produce *Klebsiella pneumoniae* carbapenemase (KPC) have been responsible for much of the increase in the United States. However, New Delhi metallo-β-lactamase (NDM)-producing CRE have the potential to add to this burden. Since first reported in 2009, through 2012, 27 patients with NDM-producing CRE have been confirmed by CDC from isolates submitted by state laboratories. Since January 2013, 44 patients with NDM-producing CRE have been identified in the United States; 44 patients were from northeastern Illinois.

From March to July 2013, nine patients with positive cultures for NDM-producing CRE were identified in northeastern Illinois. An investigation was conducted to understand the source of the NDM-producing *E. coli* isolate, recovered from a patient in northeastern Illinois (PFGE) to the outbreak strain, detected after January 1, 2013. Of the nine case-patients, 7 were identified as having undergone ERCP. A case-control study was conducted. 27 controls were randomly selected from among 131 hospital A patients with no history of ERCP. At hospital A, exposure to ERCP was strongly associated with NDM-producing CRE (OR = 6.0, 95% confidence interval = 6.0 to >999.99).

After manual cleaning and high-level disinfection in an automated endoscope reprocessor, NDM-producing *E. coli* and KPC-producing *K. pneumoniae* were recovered from the ERCP device.<sup>5</sup> The *E. coli* isolate was highly related (>95%) to the outbreak strain by pulsed-field gel electrophoresis. The investigation did not identify lapses in protocol. Previous studies have shown that high-level disinfection does not eliminate resistant bacteria; the design of the ERCP endoscopes might pose a particular concern.

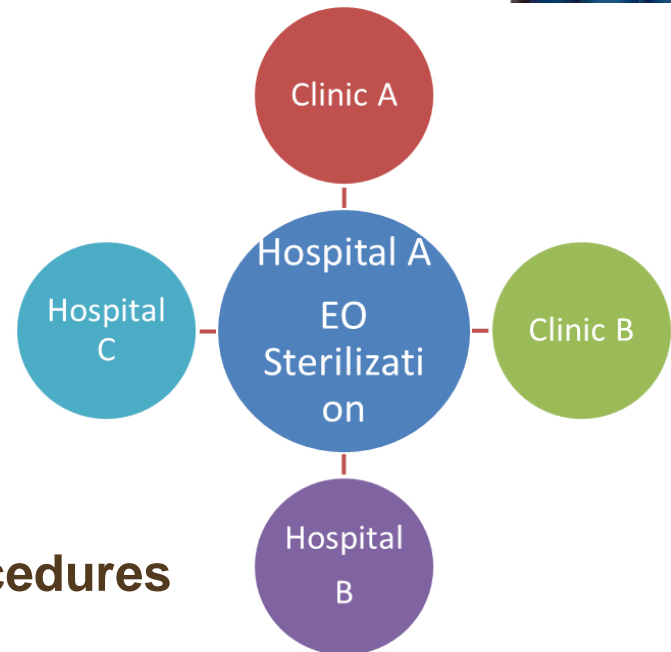
Among 91 ERCP patients who were initially notified that they had potential exposure to a culture-positive endoscope, 50 returned for rectal surveillance cultures. NDM-producing *E. coli* were recovered from 23 (46%). An additional 12 patients with NDM-producing CRE have been identified in northeastern Illinois, bringing the total during January–December 2013 to 44. In September 2013, as a result of the investigation, hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to gas sterilization with ethylene oxide; no new cases with exposure to a gas-sterilized ERCP endoscope have been identified.

In September 2013, as a result of the investigation, hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to gas sterilization with ethylene oxide; no new cases with exposure to a gas-sterilized ERCP endoscope have been identified.



# Hospital EO Sterilization -- Usage Profile

- **Reduced EO usage in U.S. health care facilities**
  - **Approximately 1% of EO sterilization usage in the U.S.**
  - **U.S. Clean Air Act -- Phase out of HCFC-based products**
  - **Consolidation of hospital EO sterilization sites**
  - **Long cycle times**
- **Sterile processing personnel**
  - **Small ambulatory surgery centers**
    - **1 - 2 operators**
  - **Large multi-system hospitals**
    - **1 - 3 operators**
  - **Most cross train all on safety and procedures**



# Recommended Practices

- **ANSI/AAMI ST41:2008/(R)2012 -- *Ethylene oxide sterilization in health care facilities: Safety and effectiveness***
  - Facility design
  - Personnel training, continuing education, personnel health
  - Sterilization and aeration
  - Installation and maintenance of equipment
  - EO PPE, storage, handling, leak, and spills
  - Area and personnel monitoring
  - OSHA (29 C.F.R. § 1910.1047)



FDA Recognized  
Consensus  
Standard

## FDA Cleared Sterilizers

- **ANSI/AAMI ST24:1999/(R)2013 -- *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities***
  - **Reaffirmed by AAMI in 2013**
    - **Sterilizer design requirements**
    - **Sterilant source requirements**
    - **Sterilant emissions control systems**



FDA Recognized  
Consensus  
Standard

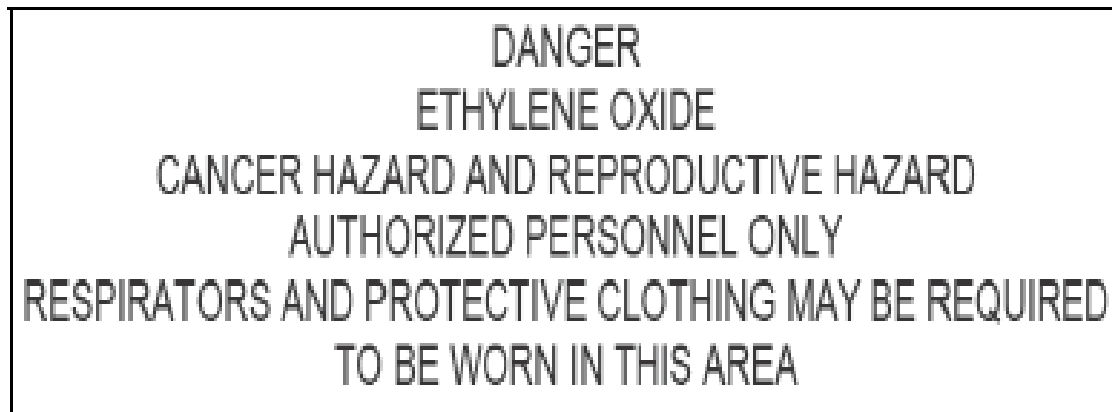
# User Certification

- **International Association of Healthcare Central Service Materials Management (IAHCSMM)**
  - **Central Service Technical Manual (7<sup>th</sup> ed) Chapter 16 includes EO and Chapter 21 EO Special Safety Procedures**
  
- **Certification Board for Sterile Processing and Distribution (CBSPD)**
  - **20% of Certification Exam Sterilization Knowledge includes EO**
  - **CE-credited EO In-services -- <http://www.spdceus.com/tests.htm>**



## Existing Controls -- Facility Layout and Work Flow

- Signs demarcating regulated areas and entrances
- EO sterilizers located in containment area
- Traffic routed around or away
- Restricted personnel access in accordance with OSHA



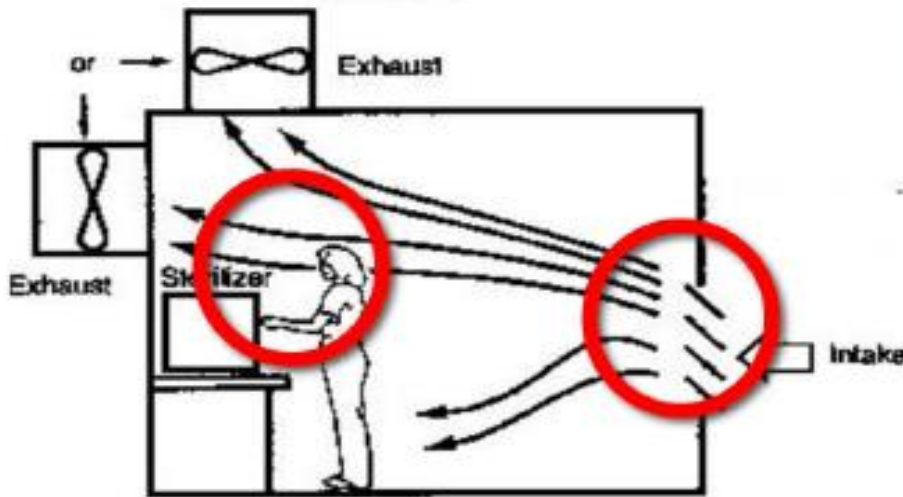
**(ref. ANSI/AAMI/ST41:2008)**

# Existing Controls -- Facility Layout and Work Flow (cont'd)



## Existing Controls -- Engineering Controls

- Air flow away from operator's breathing zone
- Minimum of 10 room air changes per hour (ACH)



(Ref. ANSI/AAMI/ST41:208)



## High Level Procedure

- Hospitals must follow device and sterilizer manufacturers instructions (IFU) created per obligations under FDA labeling regulations (21 C.F.R. Part 801)

Device Cleaning



Device Packaging

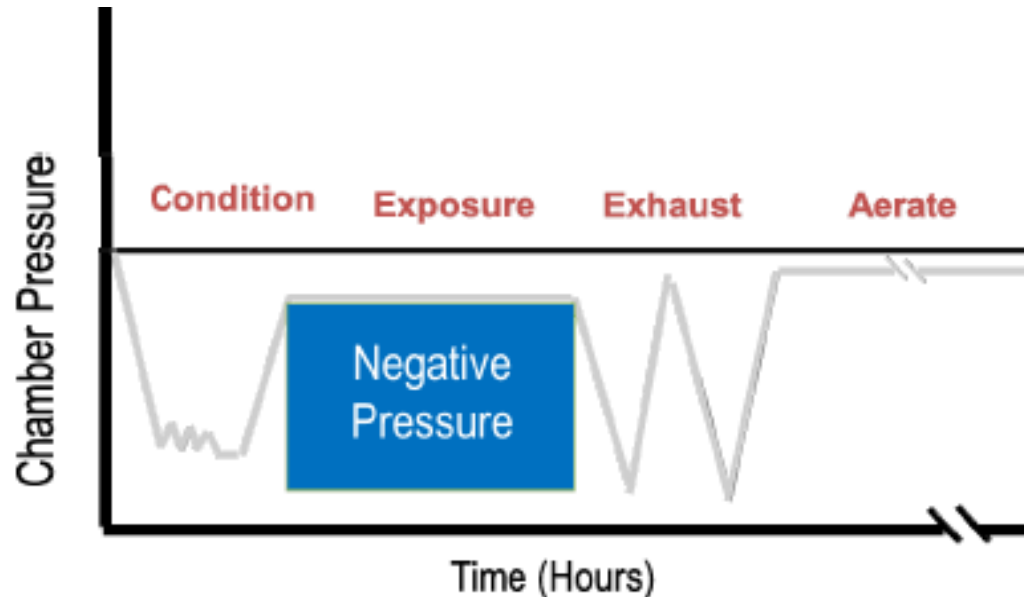


Loading and Sterilization





# Typical 100% EO Cycle



- EO delivered in single dose cartridges
- Entire process maintained in a vacuum
- Sterilizer doors are interlocked until process complete
- Aeration of load begins automatically



## Typical 100% EO Cycle (cont'd)

- EO is delivered in single dose cartridges



# Existing Controls -- OSHA Occupational Exposure Standard for EO

- **Employer required to monitor employee exposure**



- **What?**

- **Monitor for 8-hour time-weighted average (TWA)**
    - **15 minute sampling period**

- **How?**

- **Breathing zone air samples**

- **Who?**

- **Representative employee on each shift for each job classification**



- **If EO exposure  $\leq$  0.5 ppm AL, 8-hr TWA**

- **Monitoring of those employees can be discontinued (ref. OSHA 29 C.F.R. § 1910.1047)**

# Existing Controls -- OSHA Occupational Exposure Standard for EO (cont'd)



- **Emergency planning**
  - **Facilities using EO must have a written emergency plan**
  - **Means to alert employees of emergencies promptly**
    - **Area monitors in fixed locations with continuous sampling**
    - **Alerts employees to leak or spill using visible and audible alarm**  
(ref. OSHA 29 C.F.R. § 1910.1047)



EO Area Monitor  
Photo courtesy of chemDAQ

# Existing Controls -- EPA Reregistration Eligibility Decision (RED)



- RED: *“determine that the benefits of continued use outweigh the associated occupational risks, provided that risk mitigation measures specified by the Agency are adopted and reflected on product labeling”*
- In hospitals, required risk mitigation, effective February 28, 2010:
- Use of a single chamber process (*i.e.*, sterilization and aeration occur in the same chamber)



## Existing Controls -- Emission Controls

- **Small volumes vented directly to atmosphere**
  - **Maximum 176 grams EO per cycle/day, typical 100 grams EO**
- **Abator option is available at 99.9% efficiency**
  - **Maximum 0.18 grams EO per cycle/day, typical 0.10 grams EO**
- **Requirements vary by state and local regions**
- **Only run one cycle per day per sterilizer**
- **Must run in full chamber (unless abated)**





## Existing Controls Emission Controls (cont'd)



## Existing Controls -- Emission Controls (cont'd)

- **Maximum Chamber Size = 8 cubic feet**
- **Maximum Application Rate = 789 mg/L**
- **Maximum Emission Rate = 176 g/day/sterilizer (without controls)**
- **Maximum Emission Rate = 0.18 g/day/sterilizer (with Abator at 99.9% efficiency)**
- **Copper Vent Line or Release Height = no limit and protect from freezing**
- **Copper Vent Line Diameter =  $\frac{3}{4}$  - 1 inch with 180° downward bend**
- **Copper Vent Line Distance = >25 feet from any buildings**



# Existing Controls -- Emission Controls

## EPA Hospital Final Rule



- **Adopt a management practice**
  - **Hospitals without an air pollution control device must sterilize full loads except under medically necessary circumstances**
    - Record date and time of each cycle
    - Note any cycles that were not a full load
    - Hospitals are NOT required to purchase an air pollution control device
  - **The use of an air pollution control device (abator) is an acceptable alternative**

- **Ref:**  
<http://www.epa.gov/fedrgstr/EPA-AIR/2007/December/Day-28/a25233.pdf>

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 63**

**[EPA-HQ-OAR-2005-0171; FRL-8512-1]**

**RIN 2060-AM14**

**National Emission Standards for Hospital Ethylene Oxide Sterilizers**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

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**SUMMARY:** EPA is issuing national emissions standards for new and existing hospital sterilizers that emit hazardous air pollutants and are area sources within the meaning of Clean Air Act section 112(a)(2). The final rule is based on EPA's determination as to what constitutes the generally available control technology or management practices for the hospital sterilizer area source category.

This action is being finalized as part of EPA's obligation to regulate area sources listed for regulation pursuant to Clean Air Act section 112(c)(3).

**DATES:** The final rule is effective on December 28, 2007.

# Summary

- **EO sterilization is still the gold standard in hospitals**
  - Public safety and patient care
- **EO sterilization is adequately controlled in hospitals**
  - Recommended practices, training, education, certification, re-certification (FDA, AAMI, OSHA, manufacturers)
  - Facility layout and work practices (AAMI, OSHA, manufacturers)
  - Engineering controls (AAMI, manufacturers)
  - Process controls (EPA, FDA, AAMI, manufacturers)
  - Personal monitoring (OSHA)
  - Available area monitors
- **EO sterilization emissions are adequately controlled in hospitals**
  - Small single dose amounts in hospital settings (approximately 1% EO used for sterilization in U.S.)
  - Emission is once per day per sterilizer (EPA -- full loads and aeration)

## **PWP for EO**

- **General Comments**
- **Usage Information**
- **Regulatory Requirements**
- **Anticipated Data Needs**
- **Water Quality Data**
- **Additional Information Request**

## PWP -- Usage Information

- **Usage information may no longer be accurate**
  - **Approximately 98% of the total pounds of EO sold for pesticidal purposes are used for sterilization of medical devices by contract sterilizers and medical device manufacturers**
  - **The use of spice treatment and the number of hospitals performing in-house sterilization has declined since the 2008 RED, and will continue to decline substantially**
    - **Approximately 1% of the total pounds of EO used for pesticidal purposes will be used in hospitals or other medical facilities**
    - **Approximately 1% of the total pounds of EO sold for pesticidal purposes are used for fumigation of herbs and spices**
- **EOSA is reviewing industry data and has requested the opportunity to provide current reliable usage information**

## Usage Information

- **Typical usage is by large contract sterilization companies, medical device manufacturers, or spice processors**
  - All comply with EPA's NESHAP and have OSHA restrictions
  - EO usage is different than the typical agricultural field pesticide use as the process is performed in vacuum chambers
- **The Exposure Analysis Plan used the AERSCREEN model results in Appendix F of the PWP**
  - Utilizes EO release assumptions from Appendix E
    - Grossly overestimates the EO used in the typical EO process
    - Does not account for the required emission controls
- **The basis for the assumptions detailed in Appendix E is unclear**
  - Does not reflect current usage or release scenarios from the typical EO sterilization process

# Regulatory Requirements

- **FDA has established several requirements for this sterilization process**
  - **It regulates EO residual levels in the medical device products that contact the patient**
  - **FDA requirements and the ISO 10993 Standard were modified in 2008 such that allowable EO residual levels in the product were reduced**
  - **Current requirements have contributed to reduced EO exposures in facilities as well as treated products**
- **OSHA 29 C.F.R. § 1910.1047 regulates EO usage**
  - **Established a 1.0 ppm TWA requirement of an 8-hr period for all workers in the EO sterilization process**
- **All EO sterilization companies must comply**

## Anticipated Data Needs

- **Acute Inhalation Toxicity Study**
- **Chronic Toxicity/Carcinogenicity Study (ECH)**
- **Inhalation Exposure Study for Applicators**
- **Product Use Information**
- **Post-Application Inhalation Exposure Study**
- **Monitoring Data on Fumigated Commodities**
- **Ambient Air Monitoring Study**
- **Avian Acute Inhalation Toxicity Study**
- **Honeybee Acute Vapor Exposure Toxicity Study**
- **Vegetative Vigor, Gas Chamber Exposure Study**

## Acute Inhalation Toxicity

- **Study intended to provide quantitative data on acute effect that would be used for separate acute inhalation risk assessments for EO**
  - **The PWP identifies the availability of adequate subchronic data (PWP Table 8, page 18)**
  - **These data should be deemed sufficient to support any short-term inhalation risk**



# Inhalation Exposure Study for Applicators

- **Applies to all use sites**
- **2008 occupational risk assessments**
  - **Contract sterilization**
    - Based on data for 21 facilities submitted by EOSA
  - **Hospitals and medical devices**
    - Based on information derived from the IMIS database
  - **Fumigation of herbs and spices**
    - Based on exposure study for two workers submitted by ASTA data for 21 facilities
- **Approach**
  - **Contract sterilization and medical facilities**
    - EPA can utilize OSHA data and observational monitoring data to update its risk assessment
  - **Fumigation of herbs and spices**
    - Given small proportion of total use (approximately 1%), such usage does not warrant imposition of a new exposure study

## Ambient Air Monitoring Study

- **Proposing requirement for ambient air monitoring for “communities in proximity to treated facilities”**
- **The PWP grossly overestimates the emissions of EO from industrial facilities**
- **The PWP contains no rationale for this purported data need**
  - **EPA indicates it does not expect significant post-application residential exposure from off-gassing of EO from sterilized items**
  - **That computer modeling will be sufficient to confirm that there are no inhalation risks for residents located near fumigation or sterilization facilities that emit EO**
- **If there is not any significant risk for those residents who live near specific facilities that emit EO, there is no basis for concern about EO exposures in nearby communities**

## Fumigated Commodities

- **EOSA requests clarification of what is considered a fumigated commodity**
  - **FDA regulates the residual levels in sterilized pharmaceutical and medical device products**
  - **There are existing tolerances for EO and ECH**
  
- **What is the objective for requiring additional monitoring data?**
  - **EPA already possesses monitoring data concerning the use on spices**
  - **If required, it should be sufficient either to measure exposure of the affected workers or to monitor off-gassing in areas where those workers may be present**

## Ecotoxicity Studies and Ecological Data

- **The PWP identifies anticipated data needs regarding ecotoxicity data for several endpoints**
  - **Avian acute inhalation**
  - **Honeybee acute vapor exposure**
  - **Vegetative vigor**
- **Such studies should not be needed once the EO emission data assumptions are corrected**

## Water Quality Data

- **EPA invites submission of water quality data**
  - **There are no water emissions from the typical EO sterilization or fumigation process**
  - **There does not appear to be a need for additional water quality data associated with EO sterilization and fumigation processes**

## **Additional Information**

- **Label Information**
- **Use or Potential Use Distribution**
- **Use History**
- **Usage/Use Information for Non-agricultural Uses**
- **Typical Application Interval**
- **State or Local Use Restrictions**
- **Ecological Incidents Not Already Reported to EPA**
- **Monitoring Data**
- **Availability of Scrubber Technology for EO**

# Confirmation of Label Information

## ■ Application sites

- **EO may be used only to sterilize medical or laboratory items, pharmaceutical, and aseptic packaging; or**
- **To reduce microbial load on cosmetics, whole and ground spices, or other seasoning materials; and**
- **Use of EO is only approved for industrial and hospital use**

## ■ Formulations

- **23 active Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registrations for products containing EO as the active ingredient (AI)**
  - **8 products contain 100% EO**
  - **15 products contain EO in percentages ranging from 8.5% to 98.06%**
    - **All products are blended with inert ingredients, not other AIs**

## **Confirmation of Label Information (cont'd)**

- **Geographic limitations on use**
  - **Products containing EO are registered in all 50 states and Puerto Rico and EPA-registered products are shipped to other countries**



## Confirmation of Label Information (cont'd)

- **Application methods and equipment**
  - EO may only be used in vacuum or gas-tight chambers
- **Maximum application rates**
  - The concentration of EO is determined by the process used to validate the sterilization cycle in accordance with FDA requirements
  - Method for treatment of spices and other seasoning materials is described on the label and specified a maximum EO concentration of 500 mg/L
- **Frequency of application, application intervals, and maximum number of applications**
  - EO treatment facilities typically operate seven days per week
  - Application intervals and the number of applications vary from site to site depending on the products to be treated
  - FDA requirements control the maximum number of treatments for medical device sterilization

## Use or Potential Use Distribution and History

- **Products containing EO are used at more than 80 contract sterilization facilities, medical device manufacturing facilities, and spice treatment facilities**
  - **Facilities currently exist in 31 states and Puerto Rico**
- **EO has been used for sterilization and fumigation purposes for decades**

## Usage/Use Information for Non-Agricultural Uses

- **Approximately 98% of the total pounds of EO sold for pesticidal purposes are used for the sterilization of medical devices by contract sterilizers and medical device manufacturers**
- **Use of EO to reduce microbial load on cosmetics, artifacts, archival materials, and library objects is increasingly rare**
  - **Estimate that such uses comprise a fraction of a percent of the total annual pesticidal use**

## Other Additional Information

- **Typical application interval**
  - There are no “typical” application intervals for medical device sterilization
  - Splice treatment parameters are specified on the label
- **State and local use restrictions**
  - New Jersey lists EO as a state Restricted Use Pesticide
- **Ecological incidents not already reported to EPA**
  - None involving EO that we are aware of
- **Monitoring data**
  - Facilities using products containing EO required to operate in compliance with OSHA EO Standard monitoring requirements
- **Availability of scrubber technology for EO**
  - Many sterilization companies use acid scrubbers, catalytic oxidizers, absorbent systems, or a combination to meet NESHAP requirements

## Summary of Key Points

- **EOSA believes the assumptions made concerning emissions do not reflect current usage and the perceived dangers due to those emissions are not reflective of the current situation**
- **Data is being compiled on use distribution and these data will be provided to EPA by ARC Specialty Products as confidential business information (CBI)**

## Summary of Key Points (cont'd)

- **Invitation to visit a sterilization facility**
- **EO sterilization plays a critical role in maintaining public health and we must get it right**
- **EOSA is committed to the registration review process and the products**
- **EOSA requests an opportunity to meet with EPA to discuss the PWP and anticipated data needs prior to the preparation of the Final Work Plan**

# Thank You

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Ethylene Oxide Meeting – January 29, 2014 1:00 pm – Potomac Yards South

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Ethylene Oxide Meeting - January 29, 2014 1:00 pm - Potomac Yards South

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