EPA United States Environmental Protection Agency

Ethylene Oxide Commercial Sterilizers: Clean Air Act National Emission Standards for Hazardous Air Pollutants (NESHAP)

Emissions Calculations and Exposure Modeling

Presentation for State, Local, and Tribal Air Agencies

May 12, 2022

Background

- US EPA has identified elevated cancer risks for communities near some commercial sterilizers that use ethylene oxide (EtO).
- EPA will soon be proposing revisions to the Clean Air Act section 112 air emission standards for commercial sterilizers that use EtO.
- In the near-term, we would like to work with you, our co-regulators, to:
  - Reduce emissions at facilities and exposure to communities; and
  - Communicate with affected communities.
- At the May 5th webinar, we provided:
  - Background on EtO and why it is a concern;
  - Approaches for addressing EtO emissions and exposure;
  - Information on the commercial sterilizer rule; and
  - Plans for outreach to communities.
- More technical discussion today -- describe the emissions estimates for facilities and the dispersion and exposure modeling.

Commercial Sterilizers Associated with Elevated Risk Due to EtO

Region	Facility Name	Location
1	PCS	Taunton, MA
2	Cosmed	Franklin, NJ
--	EtO Sterilization Plant #2*	Linden, NJ
--	~~Steris Isomedix~~	~~South Plainfield, NJ~~
--	Customed	Fajardo, PR
--	Edwards*	Añasco, PR
--	Medtronic	Villalba, PR
--	Steri-Tech*	Salinas, PR
3	Elite Spice	Hanover, MD
--	Elite Spice	Jessup, MD
--	Fuchs North America	Hampstead, MD
--	Trinity Sterile	Salisbury, MD
--	B Braun Medical	Allentown, PA
--	Cosmed*	Erie, PA
--	ACS	Zelienople, PA
--	Sterilization Services of VA*	Richmond, VA

Region	Facility Name	Location
4	International Sterilization Lab	Groveland, FL
--	Centurion	Salisbury, NC
--	DeRoyal	New Tazewll, TN
--	Sterilization Services of TN*	Memphis, TN
6	~~Baxter*~~	~~Mountain Home, AR~~
--	Sterigenics**	Santa Teresa, NM
--	LEMCO Ardmore	Ardmore, OK
--	Midwest*	Laredo, TX
--	Steritec	Athens, TX
7	Midwest*	Jackson, MO
--	Becton Dickinson	Columbus, NE
8	Terumo*	Lakewood, CO
--	Becton Dickinson	Sandy, UT
9	~~ACS*~~	~~Chandler, AZ~~
--	Stryker	Phoenix, AZ

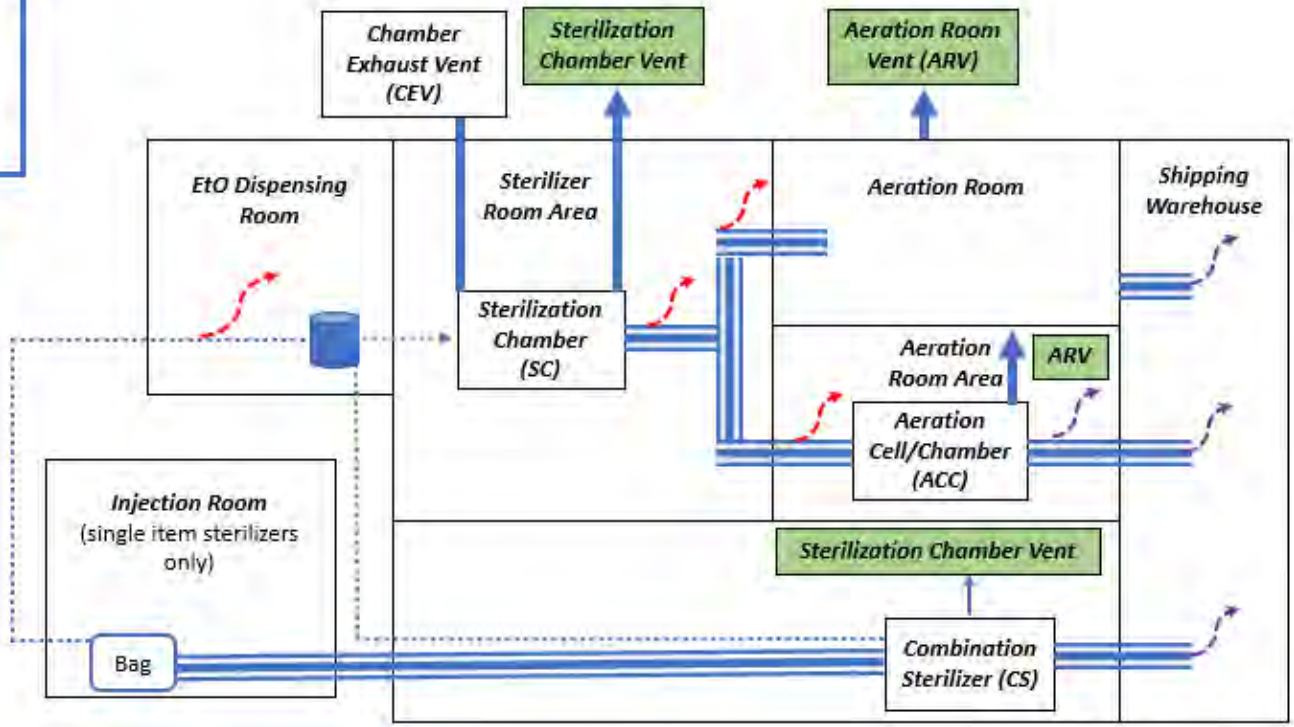
* Facility is also located in a census tract identified in the March 2022 AirToxScreen results (based on 2017 emissions data) as having elevated EtO cancer risks.

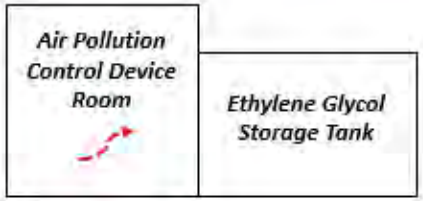
** This facility no longer has elevated risk; however, in the 2018 NATA, it was identified as having elevated risk. As part of the Office of the Inspector General (OIG) management alert, EPA has committed to outreach to the community near this facility. Additional information is available at: https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/inspector-general-follow-ethylene-oxide-0

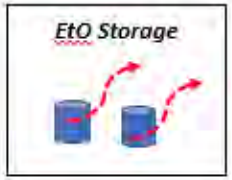
Overview

- EtO Sterilization Process and Emission Points
- Emissions Calculations
- Source Parameters and Locations
- Exposure Modeling

EtO Commercial Sterilization Source Category







Notes:
1.There is another step called "preconditioning," but it is not included here because it does not use EtO.
2. Operators will typically use either SCs or CSs, not both.
3. Operators will typically use either ARs or ACCs, not both.
4. Some SCs don't have CEVs, and in those situations, the emissions that would normally be released from the CEV are instead released as fugitive emissions.
5. Wastewater emissions are only an issue if a once-through, liquid ring pump is used. Based on data gathered from the December 2019 questionnaire, most facilities using recirculating, liquid ring pumps.

Stack Emission Sources

- Sterilization Chamber Vent
  - Products are first loaded into a sterilization chamber and dosed with EtO. After a lengthy dwell period, the chamber undergoes several gas washes to reduce the concentration of EtO within the product.
  - Emissions are routed through the sterilization chamber vent.
  - On average, about 93% of EtO used at a facility is routed to this point.
  - Emissions from facilities using less than 1 ton/year of EtO are currently unregulated.
- Aeration Room Vent
  - After sterilization is completed, the product is transferred to an aeration room, where EtO continues to be off gassed. On average, about 4% of EtO used at a facility is routed to this point.

Stack Emission Sources

- Chamber Exhaust Vent
  - Typically, when the sterilization chamber door is opened to transfer the product, a chamber exhaust vent (CEV), also called a “back vent,” is activated at the rear of the chamber, so that workers are not exposed to EtO when moving material.
  - Some facilities either do not have a CEV or they conduct sterilization and aeration within the same chamber (i.e., a “combination sterilizer”).
  - On average, about 1% of EtO used at a facility is routed to this point.
  - In 2001, standards for this emission point were removed due to safety concerns.

Fugitive Emission Sources

Room Air Emissions

- Indoor EtO Storage
  - EtO is typically stored in large drums or cylinders that have the potential to leak.
- EtO Dispensing
  - EtO storage containers are connected to the sterilizer chamber via piping and lines that feed or charge EtO into the chamber. Leaks and losses of EtO can occur during transfer from a non-cartridge storage container to a sterilizer chamber.
- Vacuum Pump Operation
  - This equipment is used to remove air from the chamber before sterilization begins and to evacuate the sterilant gas after the sterilization cycle is complete.
- Pre-Aeration Handling of Sterilized Material
  - At facilities where sterilization and aeration occur in separate vessels, room air emissions can occur when transferring sterilized product from the sterilizer chamber to an aeration vessel.
- Post-Aeration Handling of Sterilized Material (Shipping/Warehouse)
  - This is the largest source to control; it is often treated separately from other room air emissions.
- Non-oxidizer Air Pollution Control Device (APCD)
  - When EPA conducted the 2021 information collection request (ICR), we noticed elevated EtO concentrations in rooms where these control devices were stored.

Emissions Calculations

Emission Process Group (EPG)	Industry Average Percentage of EtO Use (2019 and 2021 data)
Aeration Room Vent (AV)	4%
Chamber Exhaust Vent (CE)	1%
Indoor EtO Storage	CBI
EtO Dispensing (HC)	0.1%
Vacuum Pump Operation (VP)	0.1%
Pre-Aeration Handling Sterilized Material (PR)	0.2%
Post-Aeration Handling Sterilized Material (PO)	0.2%
Non-oxidizer APCD Area (NO)	0.04%

Fugitive emissions factor: 0.64%

It is assumed that 1% of EtO use leaves the facility still in the product. The percent of EtO use going to the Sterilization Chamber vent (SC) is the balance

Emissions Calculations

- Room air data can be plugged into the equation below (derived from the ideal gas law) to get the amount of EtO being emitted from each area:

$$\frac{44 \times A \times C \times h \times n}{0.73 \times 10^6} \times \left(\frac{t \div 4}{T_S + 459.69} + \frac{t \div 4}{T_W + 459.69} + \frac{t \div 2}{T_I + 459.69}\right)$$

  - A = room floor area, ft^2
  - C = EtO concentration, ppm
  - h = room height, ft
  - n = # of air changes per hour
  - t = annual operating hours
  - T = temperature, Fahrenheit
  - 44 is the molecular weight of EtO
  - 0.73 is the ideal gas constant for these units (ft^3, R, atm, and lb·mol)
  - 459.69 is used to convert the temperatures to Rankine; the ideal gas law works on absolute temperature scales
  - If we assume all other inputs are constant, the only variable that will impact the amount of EtO being emitted is the temperature, which is reflected in the equation

Example Calculation: Centurion North Carolina

Room air data shown here are from 2019, so emissions and percentages will be calculated relative to 2019 operating hours (8,760) and EtO use (40,727.2 lb)

	EtO storage/Sterilizer Room	QC area/back warehouse (and half hall)	Front warehouse (and half hall)
Emission process group	HC, VP, PR	PO	PO
Room floor area (A, sqft)	1,260	14,600	50,850
Room height (h, ft)	12.9	20.1	14.3
# Air changes per hour (n)	15.5	1.9	2.0
Summer temp (Ts, F)	105.0	98.0	98.0
Winter temp (Tw, F)	105.0	68.0	68.0
Spring/fall temp (Ti, F)	105.0	73.0	73.0
EtO concentration (C, ppm)	0.1209	0.0921	0.0599
Annual EtO emissions (lb)	28.5	50.5	85.2
Percentage of EtO use	0.07%	0.13%	0.21%

Example Calculation: Centurion North Carolina

EPG	Stack or fugitive?	% EtO use going to this EPG (a)	Control Device Removal efficiency	Emissions (pounds per year)
SC	Stack	93.59%	99.991%[b]	3.4
AR	Stack	4%	99.995%[c]	0.08
CE	Stack	1%	99.995%[c]	0.02
HC	Uncontrolled vent	0.018%	0%	7.3
VP	Uncontrolled vent	0.018%	0%	7.3
PR	Uncontrolled vent	0.035%	0%	14.6
PO	Fugitive	0.34%	0%	135.7

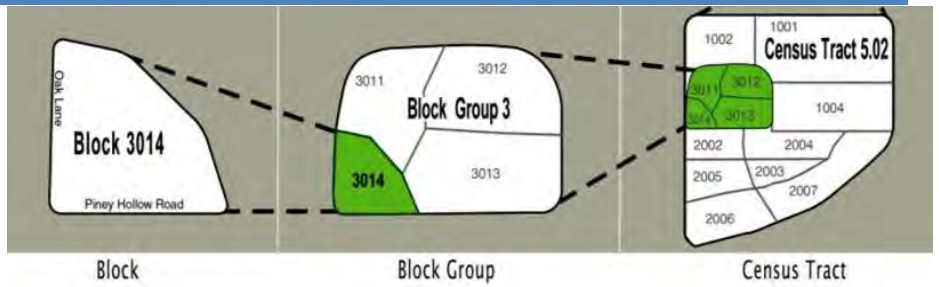
(a) – When calculating emissions for a particular year, the emission factor calculated from reported data is used and applied to the year-specific EtO throughput to calculate emissions for the process group.
(b) – From 6/11/15 state permit application
(c) – From 6/27/19 state inspection, which references 2013 performance test

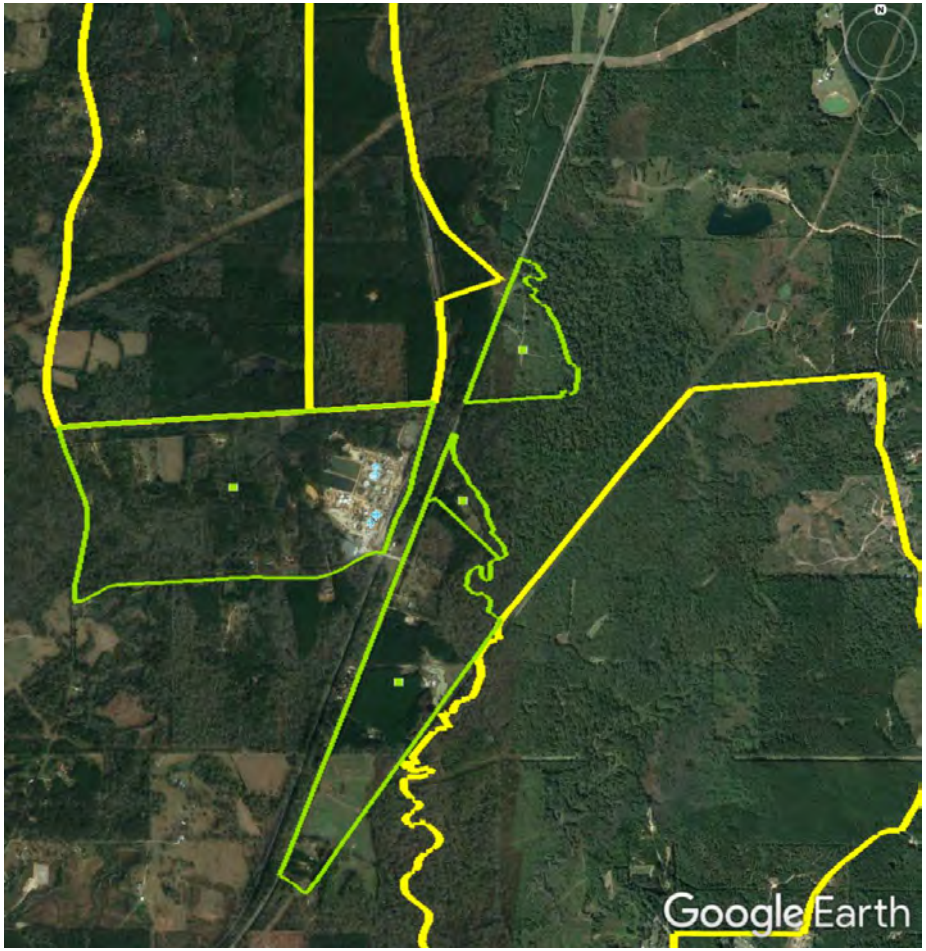
Exposure Modeling

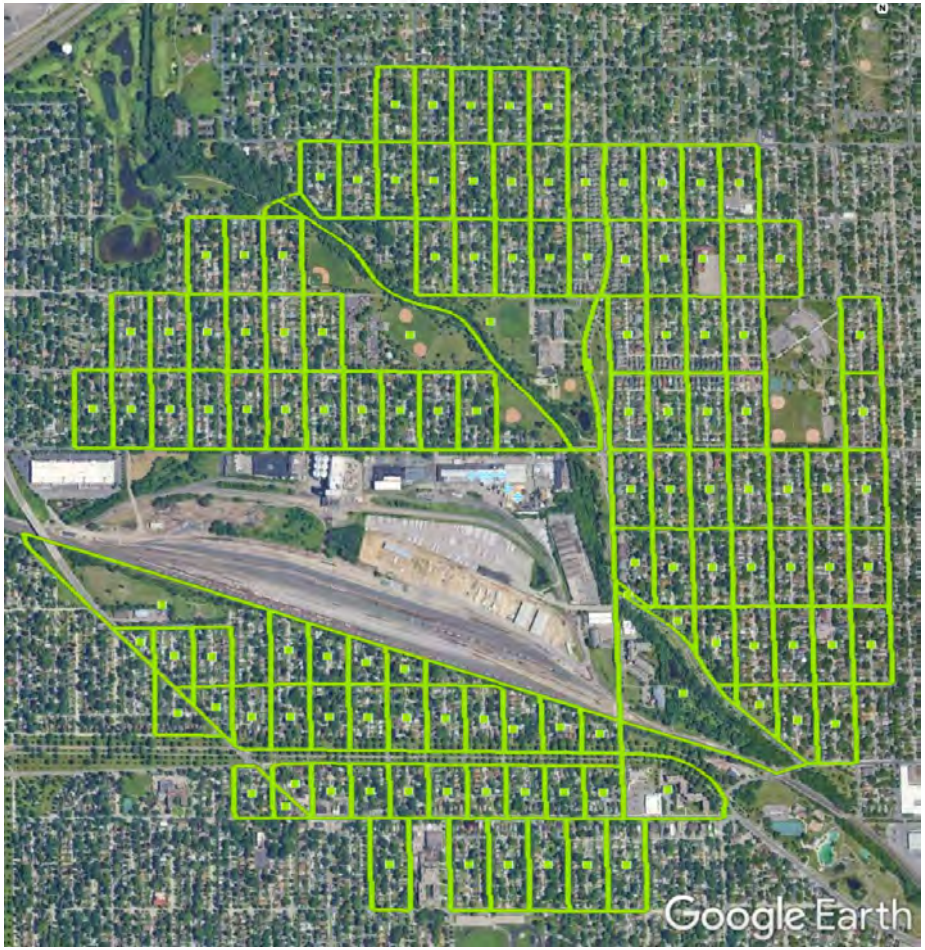
- For modeling lifetime exposure to ethylene oxide emissions from commercial sterilization facilities, EPA used version 4 of the Human Exposure Model (HEM)*
- HEM is an Inhalation Exposure Modeling System
  - Used to assess risks from multiple air toxic emissions
    - Regulatory uses – Risk and Technology Review analyses
    - Non-regulatory uses – special projects
- HEM uses the AERMOD dispersion model to estimate pollutant concentrations
- HEM uses health reference values and Census data to estimate individual risks and population risks

* Information about HEM is available at: https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem

Risks Assessed at Census Blocks





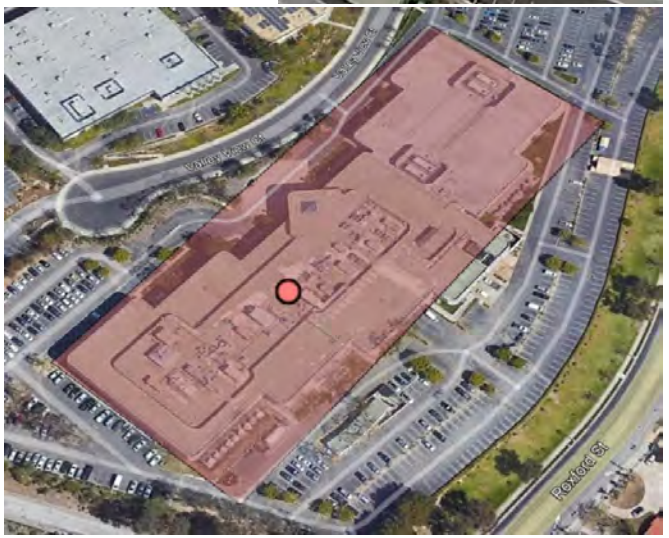


Census Block/Receptor Check

- Receptors used in the risk assessment modeling are based on 2010 census block centroids
- Prior to modeling, receptors around each facility are visually checked
  - Based on that visual check, receptors can be:
    - Added: user receptors
    - Moved: centroid not representative of where people live
    - Removed: no one living in the census block

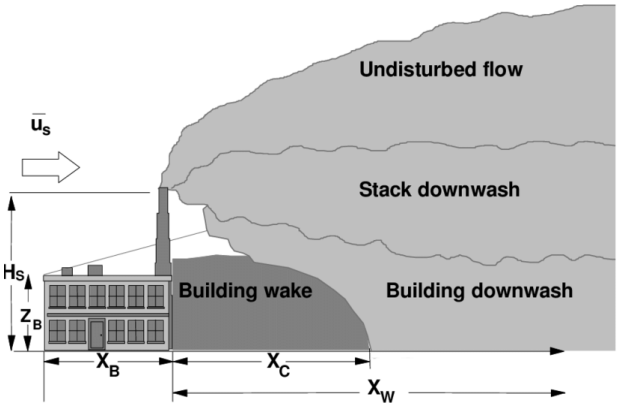
Source Parameters and Locations

- ICR responses and data provided by State, Local, and Tribal agencies are used, when available.
  - Stack parameters: height, diameter, temperature, exit velocity, exit flow
  - Fugitives: roof vents, air handling exhaust
- When information is not available, default/industry average values are used.
  - Stacks: average stack parameters, midpoint of the facility
  - Fugitives: footprint of the building



Building Downwash

- Downwash accounts for how the flow over and around buildings impacts emissions from nearby stacks
- Model plant analysis for EtO sterilizers determined it was important for facilities within 200 meters of a receptor
- Used for 26 total facilities
  - 21 within 200 meters of a receptor
  - 5 additional facilities included that were taller than model plant
- Building dimensions based on ICR data



HEM4's Facility Output Risk Map