United States Environmental Protection Agency

Reducing Ethylene Oxide Use

Healthcare facilities and commercial sterilization facilities often use ethylene oxide (EtO) to sterilize moisture and heat-sensitive medical instruments. This fact sheet provides background information on the hazards of EtO and describes environmentally preferable alternatives.

EtO Hazards

EtO is listed as a hazardous air pollutant in the 1990 Clean Air Act Amendments. In December 2016 the U.S. Environmental Protection Agency (EPA) updated its EtO inhalation cancer risk estimate. The prior estimate was based on experimental animal results, while the 2016 estimate relies more on human study data. Formerly categorized as a probable carcinogen, the 2016 update concluded that EtO is carcinogenic to humans, in agreement with the International Agency for Research on Cancer (2012). Human studies show that sufficient exposure to EtO may result in lymphoid cancer and breast cancer in females.

Depending on exposure assumptions, the updated EtO inhalation cancer risk estimate is about 30-60 times higher than prior values. This means EPA now believes EtO is considerably more potent than previously thought for inducing human cancer. Evidence considered in the 2016 update indicates that children under 16 years of age have greater susceptibility to EtO's inhalation cancer risk[1]. The updated EtO cancer potency information supports the need to reduce EtO air emissions.

In addition to the cancer risk, EtO poses several other health hazards:

- Inhaling EtO at higher concentrations can cause nausea, vomiting, and neurological disorders.
- In solution, EtO can severely irritate and burn the skin, eyes and lungs.
- EtO may damage the central nervous system, liver, and kidneys, or cause cataracts.

EtO is also extremely reactive and flammable, increasing the risk of chemical accidents that could injure hospital employees and patients. Even static electricity can cause EtO to ignite; therefore, employees using it should be well-trained and aware of its potential dangers. While EtO is reactive, it is sufficiently persistent in the atmosphere that EtO emissions causes community exposure; its half-life in air ranges from 69 to 149 days[2].

Sterilization Alternatives

EtO use and emissions can be reduced through alternative sterilization approaches, some of which are described here:

Heat:

- *Steam sterilizers* or autoclaves are the most common heat treatments. Steam sterilizes medical equipment quickly – it can take between 15 to 60 minutes for batch processing, while EtO sterilization can take in excess of 12 hours. Steam also can corrode metal equipment and damage heat-sensitive materials. It is best suited for clinics or hospitals that need a quick turnaround on their medical devices.

[1] https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025

[2] https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf

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Chemical:

- *Nitrogen Dioxide (NO2)* has several advantages compared with EtO. NO2 sterilizes at room temperatures whereas EtO needs temperatures of up to 55-65 degrees C to work properly. NO2 does not condense or penetrate as deeply to sterilize, significantly cutting down on aeration time. NO2 is not highly flammable, volatile or a carcinogen, and does not have a reference concentration for inhalation exposure. NO2 contributes to Ozone formation and is regulated under the National Ambien Air Quality Standards (NAAQS). NO2 is incompatible with cellulose-based materials like paper or cardboard, a factor that would impact contract sterilizers more than hospital sterilizers. NO2 requires a different type of sterilization chamber than EtO, making a simple conversion cost prohibitive.

- *Ozone (O3)* is similar enough to EtO that EtO sterilizers can be converted for use with O3. However, O3 damages many common medical equipment materials like metals, rubber and some plastics. O3 is a main contributor to "smog" formation and also is subject to the NAAQS. Breathing O3 causes respiratory issues ranging from coughing and shortness of breath to inducing asthma attacks and permanent lung damage.

- *Vapor-Phase Hydrogen Peroxide (VPHP)* sterilizes more quickly than EtO, however it is also incompatible with iron, some plastics and cellulose-based materials. VPHP is a human health risk if not handled properly, but has lower exposure risk than EtO. The typical VPHP control device is the catalytic converter that breaks down hydrogen peroxide into water and oxygen.

- *Peracetic Acid,* like the other chemical alternatives, offers a faster turnaround than EtO due to reduced aeration time. Similar to VPHP, the end byproducts are nontoxic (water, oxygen and vinegar), but there is a potential health risk from exposure during operation. Peracetic Acid is less viable than VPHP since it often requires full immersion of the medical equipment and must be used within 2 hours after immersion to remain sterile.

Radiation:

- *Gamma-Ray Radiation* uses Cobalt-60 to emit particles that penetrate through many materials except for some polyvinyl plastics. Although equipment is irradiated, the gamma rays do not carry enough energy to leave the equipment radioactive. Gamma-ray radiation would be cost prohibitive if out-sourced since specialists are required to use the potentially harmful radioactive material. Gamma rays provide a quick turn-around for medical equipment use and are a popular choice for single-use products, since multiple doses can sometimes discolor or even damage some plastic materials.

- *Electron-Beam Radiation* has similar attributes to Gamma-ray Radiation, but also important differences:
    - E-beam Radiation operates on electricity rather than Cobalt-60, which cannot be turned off.
    - E-Beam Radiation can sterilize on a continuous basis instead of in batches.
    - Since E-Beam Radiation uses electricity as an energy source, operators can control radiation exposure with E-Beams allowing for higher doses, quicker turnaround, and increased safety compared with Gamma-rays. Despite the dose control, E-Beam Radiation cannot penetrate high-density materials like Gamma-rays can.