Ethylene Oxide "Gas" Sterilization

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

AT A GLANCE

Ethylene Oxide "Gas" Sterilization from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

ON THIS PAGE

Overview

ETO is a colorless gas that is flammable and explosive. The four essential parameters (operational ranges) are: gas concentration (450 to 1200 mg/l); temperature (37 to 63°C); relative humidity (40 to 80%)(water molecules carry ETO to reactive sites); and exposure time (1 to 6 hours). These influence the effectiveness of ETO sterilization.[814, 857, 858] Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

The use of ETO evolved when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices; however, favorable properties (Table 6) account for its continued widespread use.[872] Two ETO gas mixtures are available to replace ETO-chlorofluorocarbon (CFC) mixtures for large capacity, tank-supplied sterilizers. The ETO-carbon dioxide (CO_2)mixture consists of 8.5% ETO and 91.5% CO_2. This mixture is less expensive than ETO-hydrochlorofluorocarbons (HCFC), but a disadvantage is the need for pressure vessels rated for steam sterilization, because higher pressures (28-psi gauge) are required. The other mixture, which is a drop-in CFC replacement, is ETO mixed with HCFC. HCFCs are approximately 50-fold less damaging to the earth's ozone layer than are CFCs. The EPA will begin regulation of HCFC in the year 2015 and will terminate production in the year 2030. Two companies provide ETO-HCFC mixtures as drop-in replacement for CFC-12; one mixture consists of 8.6% ETO and 91.4% HCFC, and the other mixture is composed of 10% ETO and 90% HCFC.[872] An alternative to the pressurized mixed gas ETO systems is 100% ETO. The 100% ETO sterilizers using unit-dose cartridges eliminate the need for external tanks.

The main disadvantages associated with ETO are the lengthy cycle time, the cost, and its potential hazards to patients and staff; the main advantage is that it can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the medical devices (Table 6). Acute exposure to ETO may result in irritation (e.g., to skin, eyes, gastrointestinal or respiratory tracts) and central nervous system depression.[859-862] Chronic inhalation has been linked to the formation of cataracts, cognitive impairment, neurologic dysfunction, and disabling polyneuropathies.[860, 861, 863-866]Occupational exposure in healthcare facilities has been linked to hematologic changes [867] and an increased risk of spontaneous abortions and various cancers[318, 868-870]. ETO should be considered a known human carcinogen.[871]

The basic ETO sterilization cycle consists of five stages (i.e., preconditioning and humidification, gas introduction, exposure, evacuation, and air washes) and takes approximately 2 1/2 hrs excluding aeration time. Mechanical aeration for 8 to 12 hours at 50 to 60°C allows desorption of the toxic ETO residual contained in exposed absorbent materials. Most modern ETO sterilizers combine sterilization and aeration in the same chamber as a continuous process. These ETO models minimize potential ETO exposure during door opening and load transfer to the aerator. Ambient room aeration also will achieve desorption of the toxic ETO but requires 7 days at 20°C. There are no federal regulations for ETO sterilizer emission; however, many states have promulgated emission-control regulations.[814]

ETO is absorbed by many materials. For this reason, following sterilization the item must undergo aeration to remove residual ETO. Guidelines have been promulgated regarding allowable ETO limits for devices that depend on how the device is used, how often, and how long in order to

pose a minimal risk to patients in normal product use.[814]

ETO toxicity has been established in a variety of animals. Exposure to ETO can cause eye pain, sore throat, di
Exposure can also cause dizziness, nausea, headache, convulsions, blisters and vomiting and coughing.[873] In
studies, ETO has been demonstrated to be carcinogenic. ETO has been linked to spontaneous abortion, genetic damage, nerve damage, peripheral paralysis, muscle weakness, and impaired thinking and memory.[873] Occupational exposure in healthcare facilities has been linked to an increased risk of spontaneous abortions and various cancers.[318] Injuries (e.g., tissue burns) to patients have been associated with ETO residues in implants used in surgical procedures.[874] Residual ETO in capillary flow dialysis membranes has been shown to be neurotoxic in vitro.[875] OSHA has established a PEL of 1 ppm airborne ETO in the workplace, expressed as a TWA for an 8-hour work shift in a 40-hour work week. The "action level" for ETO is 0.5 ppm, expressed as an 8-hour TWA, and the short-term excursion limit is 5 ppm, expressed as a 15-minute TWA[814]. For details of the requirements in OSHA's ETO standard for occupational exposures, see Title 29 of the Code of Federal Regulations (CFR) Part 1910.1047.[873] Several personnel monitoring methods (e.g., charcoal tubes and passive sampling devices) are in use.[814] OSHA has established a PEL of 5 ppm for ethylene chlorohydrin (a toxic by-product of ETO) in the workplace.[876] Additional information regarding use of ETO in health care facilities is available from NIOSH.

Mode of Action

The microbicidal activity of ETO is considered to be the result of alkylation of protein, DNA, and RNA. Alkylation, or the replacement of a hydrogen atom with an alkyl group, within cells prevents normal cellular metabolism and replication.[877]

Microbicidal Activity

The excellent microbicidal activity of ETO has been demonstrated in several studies [469, 721, 722, 856, 878, 879] and summarized in published reports.[877] ETO inactivates all microorganisms although bacterial spores (especially *B. atrophaeus*) are more resistant than other microorganisms. For this reason *B. atrophaeus* is the recommended biological indicator.

Like all sterilization processes, the effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts, and organic materials.[469, 721, 722, 855, 856, 879] For example, although ETO is not used commonly for reprocessing endoscopes,[28] several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels [855]or lumen test units [469, 721, 879] and residual ETO levels averaging 66.2 ppm even after the standard degassing time.[456] Failure of ETO also has been observed when dental handpieces were contaminated with *Streptococcus mutans* and exposed to ETO.[880] It is recommended that dental handpieces be steam sterilized.

Uses

ETO is used in healthcare facilities to sterilize critical items (and sometimes semicritical items) that are moisture or heat sensitive and cannot be sterilized by steam sterilization.

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NOVEMBER 28, 2023

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