

ETHYLENE OXIDE (ETO)

Overview

Ethylene Oxide (EtO) is a commonly used biocide both in the healthcare and food industry. It is a universally applicable sterilizer used for a wide variety of sterilization purposes. EtO is the sterilizer included under the "hospital sterilizer" category specified in the Environmental Protection Agency's (EPA) Clean Air Act section 112(c) regulating toxic air pollutants.

EtO is identified by the National Toxicology Program as a known human carcinogen and has several other acute and chronic health effects. EtO is also extremely reactive and flammable, increasing the risk of chemical accidents that could injure hospital employees and patients. Efforts to reduce EtO emissions have been voluntary up until the EPA released emission standards in 2007.

Health care workers such as technicians, nurses, and physicians as well as patients in hospitals and clinics are at the highest risk for exposure to Ethylene Oxide. Use of EtO requires special handling procedures and is regulated in order to minimize emissions and reduce occupational exposure. Safer alternatives for sterilization are beginning to replace EtO sterilization as technology improves.

Environmental Impact/Opportunity

According to the EtO National Emission Standards Proposal, the EPA estimates in that there are approximately 1,600 to 1,900 hospitals nationwide that conduct ethylene oxide sterilization. Nationally, the U.S. ethylene oxide usage was estimated to be 192 Mg/yr (212 tpy) in 2000 and 122 Mg/yr (135 tpy) in 2005. Approximately half of the ethylene oxide is being used by hospitals in controlled sterilizers with air pollution control devices (APCDs) that nearly eliminate EtO emissions and the other half is used in uncontrolled sterilizers. Uncontrolled sterilizer use in hospitals resulted in about 40 Mg/yr (44 tpy) of ethylene oxide being emitted in 2005.

According to the EPA's final ruling on EtO National Emission Standards, hospitals with uncontrolled sterilizers are now required to implement a management practice to sterilize full loads of items having a common aeration time. An exception to full loads is allowed only under medically necessary circumstances determined by healthcare

experts. This management practice is estimated to reduce the 40 Mg/yr emitted from uncontrolled sterilizers by 2 to 9 Mg/yr per year based on a range of assumptions for the extent to which hospital sterilizers are presently not being run with full loads. Emissions from controlled hospital sterilizers are negligible; the estimated ethylene oxide emissions from hospitals average less than 300 pounds per year. The cost-effectiveness of applying APCDs is over \$200,000 per ton of ethylene oxide reduced, excluding any potential monitoring, recordkeeping, and reporting costs, which the EPA determined is excessive for control of these emissions.

Approximately 630 hospitals do not currently have add-on APCDs for EtO and will be expected to implement the management practice. Hazardous EtO exposure should be significantly lowered and cancer incidence from EtO exposure is expected to be reduced. The EPA expects minimal effects on other air quality or non-air quality environmental impacts and will be negligible energy or economic impacts.

Best Practices

OPERATIONAL CHANGES

Uncontrolled Hospitals (Operating with No APCD)- Implement a Management practice to sterilize full loads of items having a common aeration time, except where emergency circumstances dictate the use of less than full loads to protect human health. Operation at full loads reduces operating costs by reducing the consumption of ethylene oxide, minimizing wear and tear on machines, and reducing associated labor costs. Sterilization records are required for EtO sterilization cycles that include date and time of each cycle, whether the cycle was full or not, and if not run full, a note from the hospital staff the reason it was medically necessary.

Controlled Hospitals (Operating with an add-on APCD)- Hospitals with controlled sterilizers are required to operate the APCD during all sterilization processes and follow APCD manufacturer recommended procedures. Hospitals with APCDs are also required to ensure that they are operating the sterilizers in accordance with state or local regulations. A system to document the annual usage of EtO usage and number of sterilization cycles per year is recommended.

MATERIAL SUBSTITUTIONS

Alternatives to EtO Sterilization- Possible alternative methods of sterilization are becoming more and more available through advancements in technology, but many lack

the wide material compatibility of EtO. Some possibilities include steam, gamma and electron-beam radiation, Vapor-Phase Hydrogen Peroxide (VPHP), plasma, microwave radiation, ozone oxidation, peracetic acid, ultra-efficient EtO sterilizers and Ortho-phthalaldehyde (OPA).

Products that are currently available:

- * Sporox™ Sterilizing & Disinfection Solution, Sultan Chemists, (7.5% hydrogen peroxide).
- * Sterrad Sterilization Systems, Johnson & Johnson, (hydrogen peroxide plasma).
- * STERIS 20™ Sterilant, STERIS Corporation, (0.2% peracetic acid).
- * Acecide™ High Level Disinfectant and Sterilant, Minntech Corp., (8.3% hydrogen peroxide 7.0% peracetic acid).
- * EndoSpor™ Plus Sterilizing and Disinfecting Solution, Cottrell Limited , (7.35% hydrogen peroxide 0.23% peracetic acid).
- * Peract™ 20 Liquid Sterilant/Disinfectant, Minntech Corp., (1.0% hydrogen peroxide, 0.08% peracetic acid).
- * Sterilox Liquid High Level Disinfectant System, Sterilox, Technologies, Inc., (hypochlorite and hypochlorous acid).
- * Cidex OPA Concentrate, Advanced Sterilization Products, (5.75% ortho-phthalaldehyde).
- * Cidex OPA Solution, Advanced Sterilization Products, (0.55% ortho-phthalaldehyde).
- * EOGas™ system, Anderson Products, Inc., (100 percent EtO gas cartridges and plastic sterilization bags).

Policies/Regulations/Standards

The Environmental Protection Agency (EPA) issued National Emission Standards for Hospital Ethylene Oxide Sterilizers that went into effect on December 28, 2007. All hospitals were to comply by December 29, 2008. A Hospital Sterilizers Summary Brochure for hospital facilities lists compliance requirements and regional EPA offices that can aid in meeting the new EtO regulations.

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