The Future of Ethylene Oxide

Background:
For years, rumors have circulated about the gas Ethylene Oxide (EO) and its use as a low-temperature, medical device sterilant. It has been speculated that EO sterilization systems are harmful for people and the environment, and that EO is being banned from use in medical facilities. These rumors are not true. When used correctly, EO is safe for both the user and the patient, and it provides an efficacious method of low-temperature sterilization.

Key Learnings:
• The use of 100% EO as a sterilant has not been banned in either the hospital or industrial setting.
• Properly installed and operated according to manufacturer’s instructions, EO sterilizers are safe for use by healthcare workers.
• EO is a highly efficacious sterilant with no instrument restrictions.

Frequently Asked Questions:
1. Has sterilization with Ethylene Oxide been banned from use?
No. EO has not been banned.
• The production of chlorofluorocarbons (CFCs), which were mixed with EO to reduce the flammability, was phased out by the end of 1995. Therefore, the use of EO/CFC gas mixtures was banned. Other EO gas mixtures (for example: Ethylene oxide/hydrochlorofluorocarbon (EO/HCFC) and Ethylene oxide/carbon dioxide (EO/CO₂) ) are still sold but are considerably more expensive than 100% EO.
• In fact, use of EO as a sterilant is on the rise, growing over 4% per year. Specifically, EO sterilization of medical devices has increased steadily since the mid-1990s. Over 56% of all medical devices are currently sterilized by EO, while gamma radiation accounts for nearly 41%.
• More than 7,000 100% EO sterilizers are in use today, in over 70 countries throughout the world.
Frequently Asked Questions:

2. Is Ethylene Oxide safe to use for healthcare workers?

Yes. When properly installed and operated according to manufacturer’s instructions, using 100% EO sterilizers, such as the 3M™ Steri-Vac™ System, is safe.

- Use of EO is well regulated by OSHA and the EPA. Because of its established history as a sterilant, OSHA and EPA regulations and AAMI recommendations provide guidance on the safe use of ethylene oxide, protecting both the worker and the environment.

- Safety features of Steri-Vac EO sterilizers allow your facility to comply with OSHA permissible exposure limits, including the operator excursion limit of 5 part per million (ppm).

- Steri-Vac EO sterilizers are equipped with multiple safety checks. Specifically, these sterilizers perform a self-diagnostic system check before the beginning of each cycle. They operate under negative chamber pressure throughout the cycle. In the event of a leak, air is drawn into the chamber, rather than EO escaping into the work area, eliminating potential operator exposure. As well, EO cartridges contain the exact amount for each load and are punctured only when the proper vacuum has been drawn inside the sterilizer chamber.

- Steri-Vac EO sterilizers begin in-chamber aeration immediately following the sterilization cycle. If desired, an optional locked aeration cycle, whereby the sterilizer door remains locked until load is fully aerated, can be selected. Abators convert EO into carbon dioxide, water, and heat, which are harmless substances, prior to emission to the atmosphere. An abator can be installed in jurisdictions that restrict atmospheric emissions of ethylene oxide.

3. How does the safety of Ethylene Oxide compare with Hydrogen Peroxide?

All chemicals used in low-temperature sterilization processes are toxic – after all, their function is to kill/inactivate microorganisms. Like other chemicals, these sterilants pose a threat to workers if they are exposed to greater than recommended levels.

- The National Fire Protection Association (NFPA) rates substances on a numbers of hazards using a scale of 0-4 with 4 being the highest risk. As a Health Hazard, NFPA rates both Hydrogen Peroxide ($\text{H}_2\text{O}_2$) and EO as “3” (Extremely hazardous). \(^{4,5}\)

- The Occupational Safety and Health Administration (OSHA) has established a 1 part per million (ppm) 8-hr time weighted average Permissible Exposure Limit (PEL) for hydrogen peroxide ($\text{H}_2\text{O}_2$), the same as for ethylene oxide. Area monitors are available to protect workers from accidental exposure to both ethylene oxide and hydrogen peroxide. Ethylene oxide users must follow the requirements of OSHA’s occupational exposure standard for ethylene oxide (29 CFR 1910.1047).
• NIOSH’s Immediately Dangerous to Life or Health (IDLH) toxicity level is set at 75 ppm for \( \text{H}_2\text{O}_2 \) and 800 ppm for EO.\(^6\) In the hospital sterilization application, concentrated hydrogen peroxide solution poses a risk to healthcare workers as it is a severe irritant/corrosive to the skin and eyes, and inhalation of mist or vapors may be severely irritating to the nose, throat and lungs.\(^4\) Ethylene oxide can cause severe skin and eye irritation and is a cancer and reproductive hazard. \(^7\)

• Vaporized \( \text{H}_2\text{O}_2 \) is a newer sterilization technology using a toxic chemical. Hence, there are not yet any regulations to mandate safety standards for healthcare workers using the system.

4. Does the use of Ethylene Oxide require environmental maintenance fees?

Yes. Most states require environmental maintenance fees for all forms of sterilization.

• There are some states within the US – namely Wisconsin, New Jersey, California, New York, Texas and Washington – that require an additional minimal installation ($2000) fee and annual licensing fees.

• EO has not been banned in any of these states.

5. Ethylene Oxide is highly penetrating; how does it compare to other technologies?

EO is a penetrating sterilant rather than a surface or contact sterilant. This ability to penetrate, along with its materials compatibility, provide significant benefits in efficacy without packaging or device material restrictions.

• EO kills microorganisms using an alkylation process which affects the proteins of an organism to provide effective kill. As an alkylating rather than an oxidative sterilant, materials compatibility is not a concern for the device materials or packaging. The ability of EO to penetrate into complex devices and long lumens without breaking down make it an excellent low temperature sterilant. The trade-off, of course, is that devices must be adequately aerated to remove residual ethylene oxide prior to patient use.

• Hydrogen Peroxide and Ozone sterilants both kill microorganisms by an oxidative process; they will only sterilize surfaces reached, and can have a harsh effect on materials. Hence, these technologies have lumen, materials, and packaging restrictions.
Summary:

To clarify, the use of EO has not been banned. When used correctly, EO is safe for both the user and the patient. The safety of EO is comparable with that of other low-temperature chemical sterilants. At the same time, EO has no lumen restrictions, has a long history of compatibility with medical devices, and is highly efficacious.

For more information, call the 3M Help Line: 1-800-228-3957

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1 Letter from the US EPA dated August 11, 1992. (As background, this comes from the 1988 US ratification of the Montreal Protocol: “The Montreal Protocol, the result of nearly 15 years of political and public concern over the impact of CFCs on the ozone layer, outlines specific measures and timetables for reducing production and consumption of CFCs and halons”)

2 ARC Specialty Products 2004 Market Study

3 3M Health Care 2007

4 Advanced Sterilization Products MSDS 09461-0-001 Issue Date 8/11/2005

5 NFPA 560, Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation, 2007 Edition

6 NIOSH Pocket Guide to Chemical Hazards, NIOSH Publication No. 2005-149

7 3M Steri-Gas Brand Cartridges MSDS Issue Date 7/23/2004