



November 11, 2014

Mr. Aaron Yeow, M.P.H.
Designated Federal Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Comments to the Chemical Assessment Advisory Committee (CAAC) for the Integrated Risk Information System (IRIS) Evaluation of the Inhalation Carcinogenicity of the Ethylene Oxide

Dear Mr. Yeow,

3M Health Care is a manufacturer of ethylene oxide (EO) sterilization equipment and accessories used to reprocess medical instruments in hospitals as well as provider of EO-sterilized medical supplies. We would like to submit the following comments regarding the U.S. Environmental Protection Agency's IRIS Evaluation of the Inhalation Carcinogenicity of the Ethylene Oxide.

The Importance of Ethylene Oxide to Medical Instrument Sterilization

Ethylene oxide has been used for over fifty years as the primary method for sterilization of heat and moisture sensitive medical instruments. It is the most efficient sterilant for these medical devices because of its ability to penetrate complex geometries such as lumened devices. It is also gentler on device materials compared to oxidative sterilants such as hydrogen peroxide, helping to extend device life and reduce the need for repairs.[1,2] The combination of the penetration ability and superior materials compatibility makes EO critical for sterilization of intricate devices while assuring the most cost-effective sterilant in the health care setting. Recent incidences with medical device reprocessing reveal risks associated with improperly sterilizing medical instruments.[3] With the increased focus on reducing health care associated infections and lower overall health care costs, EO is an important option that needs to be available to health care facilities.

Adequate Controls are in Place

Guidelines exist that provide a framework for the safe use of EO in sterilization activities. The following standards are in place:

- ANSI/AAMI ST:41 - *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.*

- ANSI/AAMI/ISO: 11135, *Sterilization of health care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices.*
- AAMI/ISO 10993-7 - *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residues.*
- ANSI/AAMI ST24 - *Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities.*

These guidelines include recommendations for facility design, installation, maintenance, staff qualifications and training personnel, processing recommendations, quality control and environmental condition monitoring. A combination of equipment controls and facility controls exist to minimize user and patient exposure to EO while allowing the benefits of sterility assurance through EO use.

In addition, since 1985 the US Occupational Safety and Health Administration (OSHA) has reduced the exposure limit for EO (29 CFR 1910.1047) [4] and increased controls required by law for employers utilizing EO. In OSHA's 2005 review of the state of EO use in the years after the regulation, it was concluded that no further changes were warranted.[5]

We appreciate the opportunity to add to the Agency discussion on the use of EO in medical device sterilization. Should you have any questions related to these comments, I can be contacted at the information provided below.

Sincerely,

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References

1. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
2. Schneider, M.S. New Technologies for Disinfection and Sterilization. Published in Disinfection, Sterilization and Antisepsis from: Principles, Practices, Challenges, and New Research, edited by William Rutala. Published by the Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, 2003. www.apic.org
3. VA Office of Inspector General. Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities, June 16, 2009
4. U.S. Occupational Safety and Health Administration. Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047)
5. https://www.osha.gov/dea/lookback/ethylene_oxide_lookback.html