EOSA The Ethylene Oxide Sterilization Association, Inc.
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April 30, 2015

Via E-Mail

Ms. Natasha Facey
Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 66, Rm 1552
Silver Spring, Maryland 20993-0002

Re: Comments Regarding the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting (Docket Number FDA-2015-N-0722)

Dear Ms. Facey:

The Ethylene Oxide Sterilization Association, Inc. (EOSA) appreciates the opportunity to submit these comments for consideration by the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (Advisory Committee). EOSA is a non-profit organization whose members include medical device manufacturers, sterilization consultants, laboratories, contract sterilizers, raw materials suppliers, and equipment manufacturers with a common interest in promoting the safe use of ethylene oxide (EO).

As users of EO, the investigation of transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals is critically important to EOSA members. EOSA, thus, has a significant interest in this important matter.

Benefits of EO Sterilization

Since its discovery as an effective sterilant, EO has played a critical role in antimicrobial sterilization to protect public health, and is essential to a functioning U.S. healthcare system. Decades later, it is now used to sterilize more than 20 billion medical devices each year in the U.S. alone. This represents more than 50 percent of all medical devices that are sterilized annually. The use of EO sterilization provides unparalleled benefits to society by its use throughout the medical community. Numerous medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. EO sterilization is critical in the safe delivery of sterile devices and medical care.

The relatively low temperatures at which the EO sterilization occurs provides the medical community significant advantages when sterilizing devices and products. Many critical

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healthcare products, such as duodenoscopes, are complex and sophisticated devices. For the majority of these healthcare products, EO sterilization is the most effective and efficient sterilization technology. The gentle yet thorough nature of EO allows for the sterilization of healthcare products and devices that would otherwise be destroyed and rendered unusable by radiation, moist heat, dry heat, other chemicals, and other alternative sterilization methods.

High-Level Disinfection and Sterilization

The most common biocidal practice used for duodenoscopes and flexible endoscopes is high-level disinfection (HLD) using a liquid chemical disinfecting agent. Terminal sterilization, however, is validated and even recommended for many types of endoscopes. Faster device reprocessing time is the primary reason HLD is a more common method than terminal sterilization, even though there is a trade-off in the margin of safety. HLD and sterilization are two types of decontamination that reduce overall levels of microbial contamination. Both decontamination methods are commonly employed by hospitals for reusable devices such as endoscopes.

Since HLD can be performed relatively quickly, it is often employed in hospitals for complex equipment or for equipment that might be used multiple times within a day. For HLD, the minimum requirement is to have a 10^{-3} reduction in bioburden so that no more than one in 1,000 products processed are non-sterile. For sterilization, however, the minimum requirement is a 10^{-6} reduction in the bioburden, meaning that no more than one in 1,000,000 products are non-sterile. Therefore, the sterilization process yields a much greater safety factor than HLD, leading to improved healthcare delivery to the patient. EO is often used by hospitals or contract sterilizers for such sterilization. In fact, many endoscope manufacturers have suggested EO sterilization for endoscopes re-used within hospitals.

A more careful comparison of HLD versus sterilization will support the premise that sterilization of duodenoscopes can provide a greater margin of safety and should be considered. There is support in the scientific literature for use of EO sterilization to increase the margin of safety in duodenoscope reprocessing. EO sterilization was used as part of the resolution of recent outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) associated with the use of duodenoscopes.[1,2,3] Foliente, R.L., *et al.*, was able to demonstrate that EO sterilization

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1 Smith, Z.L., Oh, S.Y., Saeian, K., Edmiston, Jr., C.E., Khan, A.H., Massey, B.T., Dua, K.S. 2015. *Transmission of Carbapenemresistant Enterobacteriaceae During ERCP: Time to Revisit the Current Reprocessing Guidelines*. Gastrointestinal Endoscopy 81(4):1041-1045.

2 McCool, S. 2014. *High Level Disinfection Failure in Gastrointestinal Scopes with Elevator Channels -- Is It Time to Switch to Ethylene Oxide (ETO) Sterilization?* Abstract. ID Week. Oct. 7-11, 2014. San Diego, CA.

was able to eliminate all organisms from duodenoscopes in simulated use testing, while several methods of HLD were not.[4]

Worker Exposure and Safety

The EO sterilization industry is committed to worker safety and closely monitors this issue. Workplace safety and practices continuously improve as EO sterilization equipment and processes advance with the introduction of advanced technology. In addition, sterilization processes are designed to provide a safe working environment. Many of these modern practices, designed for worker safety, have been approved by the U.S. Food and Drug Administration (FDA) for use in the health care industry, including those used for endoscopes.[5]

The Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) have developed consensus-based standards, which are recognized by FDA.[6] By following these standards, hospitals and other facilities are better equipped to ensure the safe and effective use of EO sterilization in healthcare facilities and minimize any EO exposure to both workers and patients.

Patient Health Impacts

The use of less effective processing methods can have significant adverse public health consequences. A change in sterilization technology could introduce the real risks of increased morbidity and mortality. For some healthcare products, proper microbial reduction

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3 Epstein, L., Hunter, J., Arwady, M., Tsai, V., Stein, L., Gribogiannis, M., Frias, M., Guh, A., Laufer, A., Black, S., Pacilli, M., Moulton-Meissner, H., Rasheed, J.K., Avillan, J.J., Kitchel, B., Limbago, B.M., MacCannell, D., Lonsway, D., Noble-Wang, J., Conway, J., Conover, C., Vernon, M., Kallen, A.J. 2014. *NewDelhi Metallo-ß-Lactamase -- Producing Carbapenem-Resistant Escherichia Coli Associated with Exposure to Duodenoscopes*. JAMA. 312(14):1447-1455.

4 Foliente, R.L., Kovacs, B.J., Aprecio, R.M., Bains, H.J., Kettering, J.D., Chen, Y.K. 2001. *Efficacy of High-Level Disinfectants for Reprocessing GI Endoscope in Simulated-Use Testing*. Gastrointestinal Endoscopy. 53(4).

5 Danielson, N.E. 1998. *Ethylene Oxide Use in Hospitals: A Manual for Health Care Personnel*. Third Edition, American Society of Healthcare Central Service Professionals of the American Hospital Association; Chicago, IL.

6 ANSI/AAMI ST41:2008(R)2012. *Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness.*

levels may not be achieved other than through the use of EO sterilization. It is critical for endoscopes that are reused that they be processed in a safe and effective manner, especially when they are used in surgical procedures on patients with compromised defense systems.

EO residual levels are tested and are qualified to meet all regulatory limits before they can be cleared to use, thus assuring patient safety.[7,8] A number of best practices for achieving this are currently available and practiced within the EO sterilization industry.

Best Practices and Guidelines for Reprocessing Duodenoscopes and Endoscopes at User Facilities to Minimize the Transmission of Infection

Many reusable endoscopes are currently approved by FDA. It is critical for facilities that are processing these devices to work with the product manufacturer(s) and sterilization service provider to ensure that all current standards and procedures are being followed. This applies to both preparation for sterilization, and the sterilization procedure itself. Furthermore, several manufacturers have and can provide processing instructions for this use.

EOSA urges the Advisory Committee to review this information, as well as the comments submitted by 3M, as it develops recommendations to assist FDA in minimizing patient exposure to infectious agents that may result from reprocessed duodenoscopes and endoscopes. If you have any questions, or would like to request additional information, please do not hesitate to contact me at 410-255-2773 or jvandevort@bc-cm.com.

Respectfully submitted,

Jake Vandevort
Manager
The Ethylene Oxide Sterilization Association, Inc.

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7 ANSI/AAMI ST24:1999/(R)2013. *Automatic, General-Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities.*

8 ANSI/AAMI/ISO 10993-7:2008. *Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization Residuals.*