



24-Hour Summary

General Hospital and Personal Use Devices Panel

Advisory Committee Meeting

November 6-7, 2019

Introduction:

On November 6 and 7, 2019, the General Hospital and Personal Use Devices Panel of the Medical Device Advisory Committee met to discuss the topic of industrial ethylene oxide (EtO) sterilization of medical devices and its role in maintaining public health. Ethylene oxide (EtO) sterilization is compatible with a broad range of medical devices and medical device materials and therefore is widely used by medical device manufacturers and contract sterilizers worldwide. During industrial EtO sterilization, large numbers of unsterile medical devices can be sterilized by exposure to EtO gas in a single sterilization chamber at controlled pressure, temperature, and humidity. Roughly half of all sterile medical devices used in the United States (U.S.) are sterilized with EtO in this manner.

On November 6, 2019, opening remarks were given by the United States Food and Drug Administration, Environmental Protection Agency and the Centers for Disease Control and Prevention's Agency for Toxic Substances and Disease Registry and by the Medicines and Healthcare Products Regulatory Agency of the United Kingdom. As part of their opening remarks, FDA and EPA discussed their respective roles. Specifically, that EPA regulates the emission of EtO from industrial sterilization facilities while FDA regulates the performance of EtO industrial sterilization processes for medical device sterilization. Following the opening remarks, FDA staff gave presentations on the Agency's oversight of medical devices and their sterility, and summarized FDA's role monitoring and addressing medical device shortages due to reduced supply of certain ethylene oxide sterilized medical devices.

Following the FDA presentations, invited speakers presented information to the panel on the impact of contract sterilization on medical device supply chains, reducing EtO emissions for medical device sterilization, and alternative modalities for industrial sterilization with existing industrial infrastructure.

During the open public hearing portion of the panel meeting, the advisory committee heard about the impact of the loss of EtO sterilization on the supply of medical devices and the impact of the environmental release of EtO on communities surrounding EtO industrial sterilization facilities.

On November 7, 2019, the General Hospital and Personal Use Devices Panel of the Medical Device Advisory Committee continued to discuss the topic of industrial ethylene oxide (EtO) sterilization of medical devices. FDA presented a summary of the topics discussed on the first day

and recommendations from the panel. Following the overview of the first day, invited speakers presented information to the panel regarding sterilization modalities for which the current industrial capacity may be limited or not well known to the FDA.

On the second-half-of-the-day (November 7, 2019), the meeting transitioned to discuss the topic of technological design advancements and effective reprocessing of duodenoscopes that will enhance the safety of these devices. FDA is concerned that current practices for reprocessing duodenoscopes are not sufficient to avoid infections associated with ERCP.

General Issues Discussed:

On the first day (November 6, 2019) of panel deliberation, the panel discussed that, if EtO sterilization is reduced, eliminated or replaced to a different sterilization modality, there are options that can mitigate the impact of medical devices shortages. The panel's consensus was that FDA should prioritize stakeholder communication and work to facilitate validation of sterilization processes.

The panel discussed how FDA can help mitigate device shortages due to reduced device sterilization capabilities. The panel's consensus reemphasized the need for stakeholder communication and collaboration to help manage shortages, including working collaboratively with other government entities, on the federal and state level. The panel also recommended that it may be appropriate to enhance FDA's ability to respond to device shortages by incorporating processes currently used with drug shortages that would necessitate additional authorities for FDA.

The panel deliberated on the possibility of changing EtO sterilization cycles or sterilization loads to reduce EtO use while maintaining effective sterilization. The panel's consensus was that there were potential methods that appeared viable, but no single method would address all issues and that manufacturers and contract sterilizers should pursue all applicable methods for reducing EtO use.

The panel considered various methods to validate EtO sterilization cycles in hopes of reducing EtO-use while still maintaining an effective sterilization process. The panel recommended that FDA encourage the use of alternatives to the overkill validation method which are included in the consensus standards for EtO sterilization processes.

The panel discussed the sterilization of some medical devices to a less rigorous sterility assurance level (SAL) (e.g. 10^{-5} , 10^{-4} , etc. instead of 10^{-6}) be considered as part of the approach to reduce sterilant use. The panel's consensus was that consistent with current standards, FDA should consider moving to a risk-based assessment of the SAL for some sterilized medical devices.

The panel discussed existing large-scale industrial sterilization modalities as a possibility that can take over a portion of the EtO sterilization. The panel deliberations identified that none of the currently available large-scale industrial modalities have the capacity or material compatibility necessary to take over a significant fraction of the medical devices currently sterilized via EtO. At the same time, the panel saw merit in actively pursuing exploration of the alternative modalities that could potentially provide some relief to the ecosystem, recognizing that the capacity for EtO sterilization is significantly constrained at

present. The panel recommended that manufacturers review which sterilization modalities may be compatible with their devices and where possible validate alternate methods. The panel also recommended that FDA continue to collaborate with industrial stakeholders to facilitate industrial efforts to develop alternatives to EtO sterilization as well as utilization of optimized EtO processes that use less EtO and emit less EtO into the environment in the near term.

On the second day (November 7, 2019) of panel deliberation on the topic of EtO sterilization of medical devices, the panel discussed the potential for sterilization modalities currently with limited or unknown industrial capacity to serve as an alternative to EtO. The panel discussed a possible timeline for implementing these modalities and the impact they may have on current medical device manufacturing practices, as well as FDA's role as a facilitator for utilization of these modalities.

In addition, the panel discussed how FDA may work with all stakeholders to facilitate the adoption of strategies to reduce or replace industrial EtO sterilization as well as the types of medical devices that may be amenable to being sterilized with modalities other than EtO. This discussion included considerations for device materials and geometry.

On the second-half-of-the-day the panel discussed data currently available in the Medical Device Reports (MDR) and postmarket surveillance studies, as well as the challenges with implementing new reprocessing methods and adoption of new technologies. The panel was asked to comment on FDA's previous actions and whether the trajectory that FDA had taken to reduce the risk of infections continued to be appropriate. The consensus of the panel was that training of reprocessing personnel was of utmost importance. The panel recognized that such training falls outside of FDA's purview; nonetheless, FDA was encouraged to collaborate with manufacturers, accrediting organizations, and other stakeholders to promote correct reprocessing of duodenoscopes in healthcare settings. Some panel members commented that the magnitude of the problem did not raise concerns, and that FDA mandates on strategies to reduce the risk of infection for duodenoscopes would not be helpful. The panel recommended that FDA carefully consider next steps and make deliberate decisions.

The panel discussed FDA's proposal to standardize duodenoscope durability testing. The panel's consensus was that standardized durability testing was appropriate, because damage to the duodenoscopes was not often recognized by healthcare personnel. The panel noted that the details of the durability testing should be further discussed and refined with industry.

The panel discussed the potential of new designs to reduce duodenoscope contamination rates and the urgency with which the transition should be made. The panel's consensus was that there is a potential that the new designs could reduce contamination, but there is insufficient data to demonstrate that reduction. The panel commented that additional modifications to the device design and reprocessing instructions, education, and practices could be made.

The panel was asked to comment on the appropriate balance between obtaining data premarket versus postmarket for devices that are intended to reduce the risk of infection from duodenoscopes. The panel noted that there is a need to demonstrate effectiveness of designs intended to reduce the risk of contamination prior to those devices being available for use, however the challenges associated with generating such data prior to marketing were also noted.

The panel discussed the adequacy/margin of safety for high level disinfection, as well as the challenges and benefits of sterilization for routine for duodenoscope reprocessing. The panel's consensus was that cleaning is the most important step in duodenoscope reprocessing. The panel noted that in properly cleaned duodenoscopes, high level disinfection is appropriate, however panel members acknowledged that reports indicate that duodenoscopes are not properly cleaned. The panel also discussed the challenges of implementing sterilization of duodenoscopes, such as potential decreased patient access to ERCPs and increased costs.

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