

Welcome to Today's FDA/CDRH Webinar

*Thank you for your patience while additional time is
provided for participants to join the call.*

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FDA Innovation Challenges: Identify Sterilization Alternatives and Reduce Ethylene Oxide Emissions

Chris Dugard

Scientific Reviewer
Office of Surgical and Infection Control Devices

Steve Elliott

Scientific Reviewer
Office of Surgical and Infection Control Devices

Center for Devices and Radiological Health

Agenda

- Overview of Ethylene Oxide Sterilization
- The FDA's Efforts to Address Issue
- Overview of the Innovation Challenges
- Tips for Potential Applicants
- Resources
- Questions

Overview of Ethylene Oxide Sterilization

- Sterilization is a process intended to render devices free of viable microorganisms.
- Medical devices are sterilized to prevent patient exposure to pathogenic microorganisms.
- Processes to sterilize medical devices include:
 - Thermal: Moist heat (steam), dry heat
 - Chemical: Ethylene oxide gas, vaporized hydrogen peroxide, chlorine dioxide gas
 - Irradiation: Gamma, x-ray, electron beam
- Sterilized medical devices are critical to our health care system and patient safety.

Overview of Ethylene Oxide Sterilization

Ethylene oxide (EtO)

- Common sterilant for medical devices
 - Is used to sterilize ~50% of medical devices provided sterile (sterilized by manufacturer or contract sterilizer).
 - Can penetrate multiple layers of packaging.
 - Compatible with a broad range of device materials.
- Involves exposure of product to EtO gas under vacuum in a sealed chamber with defined temperature and humidity conditions.

Overview of Ethylene Oxide Sterilization

- Process Challenges:
 - Multiple variables (critical parameters) to address
 - Long turnaround times
 - Highly flammable and explosive
 - Carcinogen
 - Emission of ethylene oxide (EtO) gas resulting from sterilization is an identified concern:
 - The Environmental Protection Agency identifies ethylene oxide as a hazardous air pollutant.
 - To date, we are aware of one industry EtO sterilization facility that has been closed on the basis of ethylene oxide emissions.
 - There are concerns associated with manufacturing and processing of devices historically sterilized with EtO.

Medical Device Public Health Impact

- Unavailability of EtO as an industrial sterilant for medical devices is a concern
 - The effectiveness of the technology for broad spectrum antimicrobial sterilization is well established
 - The high throughput/low cost of this technology allows for large sterilization capacity which guarantees the supply chain of medical devices sterilized using the technology is preserved
 - EtO is the only acceptable sterilization method for a large number of delicate, complex, and sophisticated medical devices manufactured with sensitive materials and removal of EtO as an option could lead to device shortages



Examples of FDA's Efforts to Address the Issue

- The FDA is actively working with sterilization experts, medical device manufacturers, and other government agencies to:
 - Advance medical device sterilization using EtO
 - Prevent potential for medical device shortages due to a lack of alternatives to EtO
- **Advisory Committee:** The FDA plans to hold an advisory committee on November 6-7, 2019 to obtain panel recommendations regarding challenges and opportunities for ethylene oxide reduction and the use of alternative strategies to inform the FDA's decision-making.

Overview of the Innovation Challenges

Challenge Goals:

Challenge 1: Identify New Sterilization Methods and Technologies

Identify safe and effective sterilization methods or technologies for medical devices that do not rely on ethylene oxide

Challenge 2: Reduce ethylene oxide emissions

Develop strategies or technologies to reduce emissions to as close to zero as possible from the ethylene oxide sterilization process.

Overview of the Innovation Challenges

Eligibility

- Any safe and effective alternative methods or technologies to ethylene oxide sterilization for medical devices.
- Any innovative strategies or procedures in any stage of the ethylene oxide sterilization process that are demonstrated to reduce ethylene oxide emissions to near zero.

Challenge 1

Examples that would be considered within the challenge scope:

- Methods that can sterilize a wide range of polymeric materials without changing the chemical and physical properties of the polymers by degrading them (e.g., through oxidization, chain scission, or other unfavorable reactions) or by generating unacceptable levels of toxic by-products such as leachables
- Materials or medical devices that are typically sterilized by Ethylene Oxide that can be shown to be sterilized using other modalities
- Methods that can or have potential to sterilize bulk volumes/large loads of products
- Methods that employ the use of technologies and infrastructure that is readily accessible or can be rapidly deployed to medical device manufacturers and sterilization providers in the US

Challenge 2

Examples that would be considered within this challenge scope:

- Methods that do not negatively impact throughput of current Ethylene Oxide sterilization processes
- Methods that employ the use of technologies and infrastructure that is readily accessible or can be rapidly deployed to medical device manufacturers and Ethylene Oxide sterilization providers in the US
- Strategies to control or reduce bioburden prior to sterilization
- Incorporation of processes that use lower levels of Ethylene Oxide while assuring that requisite sterility assurance/sterilization is attained
- Capture of Ethylene Oxide emissions and transformation to harmless byproducts
- Detection, measurement, tracking, and containment of Ethylene Oxide emissions or byproducts to minimize or prevent dissemination into the sterilization facility and environment
- Allowing for the safe use of Ethylene Oxide while minimizing exposure to sterilization workers or nearby communities

Overview of the Innovation Challenges

Who can apply?

- Sterilization companies
- Medical Device companies or distributors
- Technology manufacturers (including Start-up companies or labs)
- Academic and research institutions
- Health care facilities
- Professional societies
- Foundations and other non-profits
- Other

Overview of the Innovation Challenges

Submissions for either challenge should describe:

- The development plan for the method or technology
- The development team
- The scientific basis and/or preliminary data to support the proposed method or technology
- Anticipated benefit of the technology or method
- Impact of the method or technology on public health
- Compatibility of the method or technology with medical device materials
- Capability of the method or technology to ensure scalability and high throughput for safe and effective sterilization of large volumes of devices

Incentives

- Potential public health benefit
- Frequent interactions with FDA during development phase
- Accelerated development and review of technology
- FDA recognition

Overview of the Innovation Challenges

Challenge Timeline:

- Challenge begins: July 15, 2019
- Submission period: July 15, 2019-October 15, 2019
- Submit applications to:
CDRH-Innovation-Sterilization@fda.hhs.gov
- Judging period: October 16, 2019 – November 16, 2019

We intend to announce applications selected for the challenge in December 2019.



Application Format/Tips for Potential Applicants

- Applications should be no longer than 20 pages (including cover page and executive summary)
- Should include a cover page with
 - Company name, address, and primary contact with name, phone number, and e-mail
 - Name of the alternative sterilization method or technology
 - FDA regulatory history, if appropriate
 - Name of the challenge you are addressing
- Executive summary (limit to 1 page)
 - Summary of the method or technology
 - Significance of the problem it will solve
 - Summary of the proposed development plan
- You may submit more than one application if you have more than one eligible device or concept
- There is no official application form. The application format is outlined on the challenge web pages.

Overview of the Innovation Challenges

If Your Application is Selected:

- Expect confirmation from FDA and instructions on next steps.
- Potential for web presentations to evaluate finalists.

Resources

- Ethylene Oxide Sterilization page
<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices>
- Challenge 1 page:
<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies>
- Challenge 2 page:
<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions>
- FDA Voices:
<https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/preventing-medical-device-shortages-ensuring-safe-and-effective-sterilization-manufacturing>

Questions?

About the Innovation Challenge:

CDRH-Innovation-Sterilization@fda.hhs.gov

About Medical Device Regulation:

Division of Industry and Consumer Education

DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be
available at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: Specialty Technical Topics;

Subheading: Sterility