Sterigenics®
A Sotera Health company

Sterigenics

NATIONAL ACADEMY OF SCIENCES RADIATION COMMITTEE

OCTOBER 2020

Questions by Committee - Sterigenics

1. Please provide an overview of your company and its market.
2. Please provide an overview of your company's products that utilize radiation sources or alternative technologies and their applications.
3. What are some pros and cons in performance of the source versus alternative technologies for the different applications?
   a. What efforts, if any, are currently in progress to solve equivalency issues?
4. What trends has your company seen over the past 10-15 years in terms of demand for radiation sources versus alternative technologies in developed versus developing countries?
   a. What are, in your view, the factors that led to those trends?
5. What are your views about the future of radiation sources and alternative technologies over the next 10 years?
6. Please provide any information on new/emerging non-source technologies that your company is developing and may be deployed over the next 10 years.
7. Please provide any additional information or advice that you think is relevant to this committee's work.

Key Messages for Committee

- Sterigenics is a sterilization services provider for medical devices and pharmaceutical products. We utilize the sterilization modality as chosen by the customer to meet their specific needs.
- Co-60 gamma irradiation and its alternatives have been in use several decades to sterilize medical products and treat various food products.
- Significant improvements have been implemented at Co-60 facilities to address security threats and be more efficient with usage of Co-60.
- Sterigenics continuously reviews technology improvements or alternative technologies to meet our customers' sterilization needs.
- Co-60 gamma irradiation is critical to public health -- currently used to sterilize 40% of medical devices in NA, including those used for the COVID pandemic.

Sotera Health Overview

- Sterigenics is one of three divisions of Sotera Health which operate with one common mission, Safeguarding Global Health®.
- Sterigenics is a leading global provider of comprehensive sterilization solutions.

Sotera Health

Safeguarding Global Health®

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Comprehensive Sterilization Services

- Provider of mission-critical and government mandated sterilization services
  - » 48 facilities in 13 countries
- Offers all major sterilization technologies: Gamma Irradiation (“Gamma”), Ethylene Oxide (“EO”) & Electron Beam (“E-Beam”)
- End markets include Medical Devices, Pharma, and Food
- 2,800+ customers in 52 countries including virtually all leading medical device OEMs, served via multi-year contracts

Safeguarding Global Health – with every product we sterilize.

Nelson Labs
A Sotera Health company

Expert Lab Testing and Advisory Services

- Provider of microbiology and biopharma testing services
  - » State-of-the-art facilities across 13 global lab locations
- Offers 800+ tests across the product lifecycle, from initial product validation to ongoing quality control and extractables and leachables testing
- End markets include Medical Devices, Pharma and Tissue
- 3,500+ active customers including leading medical device and pharma manufacturers

Safeguarding Global Health – with every test we complete.

Nordion
A Sotera Health company

Gamma Technologies

- Global leader in Cobalt-60 (“Co-60”) supply
  - » Co-60 is the key input for Gamma sterilization
- Long-term Co-60 supply contracts with nuclear reactors at multiple reactor sites
- 40 active customers including contract sterilizers and medical device manufacturers, served via multi-year agreements

Safeguarding Global Health – with every critical isotope we supply.

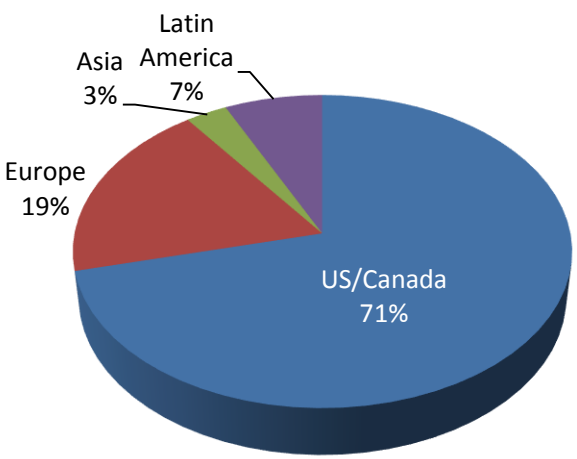
Overview of Sterigenics and its Markets

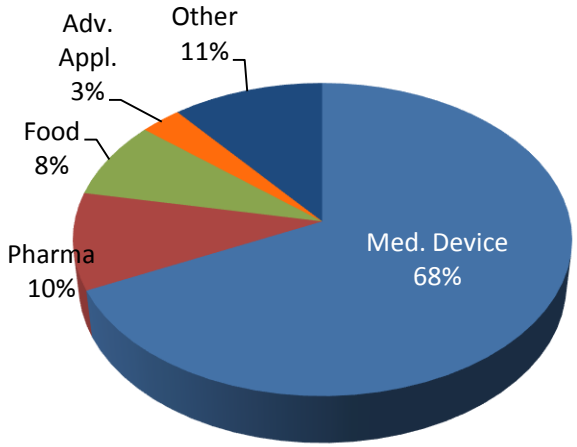
Sterigenics provides outsourced sterilization and decontamination services to safeguard patients, consumers, and our customers' brand

23 Facilities **17 Facilities** **8 Facilities**

Through 48 facilities in 13 countries we offer cycle design, process validation, sterilization, decontamination, materials modification, and phytosanitary applications

The service we provide makes the products of our customers safe for their intended use, and in many cases is required by local regulatory bodies





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1. Based on FY 2018 Sales

Overview of products that utilize radiation sources or alt. technologies

- The U.S. medical device market is valued at $156 billion annually and is growing 5-7% *
- Per the FDA, >40 billion sterilized medical devices are sold annually in the U.S.
- Single use, medical device sterilization uses the following technologies:
  - Cobalt-60 Gamma: ~ 40% of volume processed in North America
  - Ethylene Oxide (EO): ~ 50% of volume processed in North America
  - E-Beam (accelerator based): ~ 10% of volume processed in North America
  - X-Ray (accelerator based): ~ <1% of volume processed in North America
- Products sterilized using gamma radiation include syringes, surgical drapes and gowns, gloves, staplers, wound dressings, implants (including stents, pacemakers and orthopedic devices).

MORE THAN 16 Billion

devices sold in the U.S. every year are sterilized with cobalt-60 gamma radiation

~40%

of medical products that require sterilization in North America are sterilized using cobalt-60 gamma radiation

* Source: iia Briefing Report, "Uses and Applications of Radiation Processing in 2020"

Pros and cons in performance of cobalt versus alt. technologies

Modality	EO	Gamma	E-Beam	X-Ray
Typical Products	• Radiation-sensitive products (including surgical kits, tubing sets, tracheostomy equipment, catheters)	• Syringes • Surgical drape & gowns • Gloves • Staplers • Wound dressings • Implants (including stents, pacemakers, orthopedic devices) • Food products	• Medical devices that require limited penetration • Labware • Clean Room Supplies • Tissues • Food products	• Potentially similar to Gamma • Limited current acceptance
Market Breakdown	~ 50%	~ 40%	~10%	<1%
Pros	• Ability to penetrate pallets of finished products • Good option for radiation-sensitive products	• Quick processing times • Good penetration of finished products	• Quickest processing times • Good for material modification	• Potentially quick processing times • Good penetration of finished products
Cons	• Longer processing times • EO residuals • Use of a hazardous gas	• Cannot treat radiation-sensitive products • Use of Co-60, a radioactive material	• Cannot treat radiation-sensitive products • Limited product penetration	• Cannot treat radiation-sensitive products • Current availability • Limited acceptance • Energy inefficiencies

What efforts, if any, are in progress to solve equivalency issues?

- EO sterilization is typically the only process available for commercial sterilization of radiation-sensitive medical device products.
- The current FDA Approval Process is lengthy and challenging:
  - Device manufacturers select sterilization based on modality, materials, density, complexity and packaging.
  - Technology validation costs vary widely by technology and product.
  - Validation and regulatory approvals are complex and can take significant time and costs.
  - Switching can result in significant business and patient risk.
- Limited knowledge is available about comparative impacts of the three radiation technologies (Co-60 Gamma, E-beam and X-ray).
- There are few x-ray sterilization facilities for medical products and currently only limited medical products approved for x-ray sterilization.

Trends (past 10-15 years) for demand of gamma versus alt. technologies?

- Co-60 radiation technology and commercial alternatives have been around for decades.
- Current market split of technologies has remained relatively constant.
- Recent growth in e-beam driven in particular by non-medical applications or less-regulated products.
- Co-60 gamma radiation remains the customer-preferred methodology for regulated medical devices.
- Sterigenics uses the technology chosen by the customer to meet customer product needs.
- Trend within the industry to develop alternative uses for low-activity Co-60 pencils.

What are, in your view, the factors that led to those trends?

- Focus on patient safety and the resulting regulatory approval process limits the ability to switch sterilization technologies for medical devices and pharmaceutical products.
  - The industry is evaluating ways to expedite this approval process and find ways to validate alternative technologies.

- Recent tightness in the cobalt supply has led the industry to optimize the use of cobalt for more highly-regulated medical products.

Views on future of gamma and new/emerging/alt. technology in next 10 yrs?

Co-60 irradiation will continue to be used for medical devices for the foreseeable future, but the following steps may increase the use of alternative technologies:

- Evaluate use of e-beam and x-ray to complement Co-60 gamma irradiation
- Generate more data about differences in material impacts related to different radiation modalities
- Review utilization of low-activity Co-60 pencils in current or new production irradiators to extend the useful life of Co-60
- Evaluate x-ray technology improvements
- Evaluate use of alternative gas technologies, such as nitrogen dioxide (NO2), vaporized hydrogen peroxide, vaporized peracetic acid, and/or chlorine dioxide

Additional info. or advice that you think is relevant to this committee's work

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