Medical Device Sterilization Workshop 2023: Past, Present, and Future

Report of Contributions

https://indico.fnal.gov/e/medicaldevice2023

Contribution ID: **1** Type: **not specified**

Keynote - Nick Butler, NNSA

Wednesday, 20 September 2023 08:15 (45 minutes)

Nick Butler, the Deputy Director of the National Nuclear Security Administration's Office of Radiological Security (ORS), provides an overview of the office's mission to enhance U.S. and global security by preventing high-activity radioactive materials from being used in acts of terrorism. As part of this mission, ORS promotes the use of non-radioisotopic alternative technologies through research, outreach, education, and complete device replacements in order to reduce global reliance on high-risk radioisotopes in medical, research, and industrial applications. Within the realm of medical device sterilization, ORS supports academia and industry partners by funding research, including through the key collaborative effort of "Team Nablo." ORS supports and communicates advancements in technology and listens to industry needs and concerns through outreach activities such as the inaugural ORS Industry Day and annual Fermi Medical Device Sterilization Workshops.

Contribution ID: **2** Type: **not specified**

Medium-energy, Low-power Needs - Ilia Geltser, Terumo BCT

Wednesday, 20 September 2023 09:00 (40 minutes)

Contribution ID: **3** Type: **not specified**

Packaging & Sterilization - Kiip, Srun & Blom

Wednesday, 20 September 2023 09:40 (40 minutes)

It is known that radiation sterilization can result in degradation of certain materials, and of particular concern is molecular changes to the polymers. Because of this, aging studies are typically required for most medical devices and their packaging. However, even though most packaging materials have been well characterized and studied, and there are no known cases where packaging has failed due to shelf life concerns, most medical device companies spend significant time and resources to perform aging studies on their product and packaging. It is known that the presence of antioxidants in a polymer formulation inhibits the degradation that can occur after exposure to radiation. Instead of focusing solely on performing aging studies on every device and packaging combination, we are proposing an alternative approach where device manufacturers could characterize and test their materials for the presence of anti-oxidants as a predictor of material degradation over time. In addition to discussing the science behind this topic, we will also be discussing how we plan to use effective means of collaboration to achieve our goals.

Contribution ID: **4** Type: **not specified**

International Regulatory Panel - ANVISA, FDA, Health Canada, and TÜV-SÜD

Wednesday, 20 September 2023 10:40 (40 minutes)

including: ANVISA, FDA, Health Canada, and TÜV-SÜD

Contribution ID: **5** Type: **not specified**

The evolution of a standard - AAMI TIR104 and beyond, Emily Craven, Boston Scientific

Wednesday, 20 September 2023 11:20 (55 minutes)

This presentation looks at the drivers behind the creation of industry guidance on the transfer of health care products between radiation sterilization sources. Some information existed within ISO 11137-1 but it was unclear and incomplete. In the process of writing TIR104, the AAMI radiation sterilization working group collaborated to clarify a process to follow when assessing the transfer of doses. An overview of this framework will be presented. The resulting document and data that was published in support of this new guidance has significantly influenced the next revision of ISO 11137-1. We will examine the path forward once ISO 11137-1:2023 is published and which next steps will be of greatest benefit to our industry.

Contribution ID: **6** Type: **not specified**

Morning Wrap-up & Close of Virtual Session

Wednesday, 20 September 2023 12:15 (5 minutes)

Contribution ID: **7** Type: **not specified**

Discussion - TIR 104 - Mark Pasmore, Mara Senescu, Baxter

Wednesday, 20 September 2023 13:30 (1 hour)

Contribution ID: **8** Type: **not specified**

Discussion - FDA Panel

Wednesday, 20 September 2023 14:30 (1 hour)

Contribution ID: **9** Type: **not specified**

Discussion - Risk Evaluations in Implementing X-ray for Single-Use Systems Sterilization, Samuel Dorey, Sartorius

Wednesday, 20 September 2023 16:00 (1 hour)

The single-use disposable technologies for biopharmaceutical manufacturing combine single-use holistic processes and facility strategy to overcome scale limitations and enable cost-efficient manufacturing to support the growing demand for many biologics. This industry is facing challenges with irradiation sterilization capacity resulting in assessing X-rays as a suitable and equivalent alternative to gamma. Comparative studies between the effects of different types of radiation and their health impact on the materials/products studied arise. The Bioprocess Systems Alliance (BPSA) published a consensus risk-based qualification approach including materials, physical, functional, chemical, and biological investigation to assess the impact of X-ray vs gamma. The Team Nablo project also proposed a holistic research approach covering several disciplines. To achieve its goals, the team has integrated technological, academic, and industrial research. The BioPhorum X-ray workstream will also publish Guidance for risk evaluation of X-ray irradiation of single-use systems. This will be providing a robust, consistent, and repeatable methodology to assess the inclusion of X-ray irradiation of previously gamma irradiated-treated single-use products. We then propose an insight in the different risk evaluations available currently to simplify the adoption of X-ray for the sterilization purpose.

Contribution ID: **10** Type: **not specified**

Close of Day 1

Wednesday, 20 September 2023 17:00 (30 minutes)

Contribution ID: **11** Type: **not specified**

Welcome

Thursday, 21 September 2023 08:00 (10 minutes)

Contribution ID: **12** Type: **not specified**

Microbiological Resistance / Population C, Martell Winters, Nelson Labs

Thursday, 21 September 2023 08:10 (40 minutes)

Population C, also called the Standard Distribution of Resistances (SDR), has been the microbiological benchmark for radiation sterilization since the early 1980s. The development of the SDR should be understood by industry and it provides insights into how the SDR, and associated dosing tables, can be used when investigating sterilization dose establishment or dose audit failures and aberrant bioburden data. Also, analysis of the SDR reveals a potential Achilles heel which is currently being discussed in the industry and is prompting additional guidance that is being proposed in the review of ISO 11137-1.

Contribution ID: **13** Type: **not specified**

Training - Beyond Read and Learn, Vu LeKate (Abbott), Kim Patton (PRI)

Thursday, 21 September 2023 08:50 (40 minutes)

Contribution ID: **14** Type: **not specified**

Training Resources - John Williams, Medtronic

Thursday, 21 September 2023 09:30 (20 minutes)

Contribution ID: **15** Type: **not specified**

Engaging with the FDA - Radiation Master File Pilot

Thursday, 21 September 2023 10:50 (30 minutes)

Engaging with FDA: Radiation Master File Pilot, Submission Review, Responses, & Misconceptions

This session will build on last year's FDA mock Q-Submission session and cover several topics related to engaging with FDA.

1) The first topic will be an overview of FDA's Radiation Sterilization Master File Pilot Program. This program was initiated in April 2023 to pilot a novel way for FDA to support sterilization changes to PMA approved devices such as changing from gamma or ethylene oxide sterilization to x-ray or e-beam sterilization.

2) Next, there will be a panel discussion of some common questions and things to consider when submitting a premarket submission to FDA for a sterilization change to a medical device. The panel discussion will continue for the last set of topics in the session:

3) responding to FDA requests for information during submission review and some common questions and misconceptions about this part of the premarket review process.

Contribution ID: **16** Type: **not specified**

Engaging with the FDA - Responses & Misconceptions

Thursday, 21 September 2023 11:50 (30 minutes)

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Contribution ID: **17** Type: **not specified**

Discussion - Collaborating w/Kilmer/AAMI - FDA Collaborative Communities

Thursday, 21 September 2023 13:30 (1 hour)

Contribution ID: **18** Type: **not specified**

Networking

Thursday, 21 September 2023 14:30 (1 hour)

Contribution ID: **19** Type: **not specified**

Networking

Thursday, 21 September 2023 16:00 (30 minutes)

Contribution ID: **20** Type: **not specified**

Close of Workshop

Thursday, 21 September 2023 16:30 (10 minutes)

Contribution ID: **21** Type: **not specified**

Morning Wrap-up & Close of Virtual Session

Thursday, 21 September 2023 12:20 (10 minutes)

Contribution ID: **22** Type: **not specified**

Engaging wiht the FDA - Submission Review

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Engaging with FDA: Radiation Master File Pilot, Submission Review, Responses, & Misconceptions

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Contribution ID: **23** Type: **not specified**

Finding the optimal sterilization configuration using simulations - Funk & Badali, Triple Ring

Thursday, 21 September 2023 09:50 (40 minutes)

The dose delivered during radiation sterilization is highly dependent on many factors, such as the orientation of the device relative to the beam, how the devices are arranged in the shipping box, and how devices are positioned within their packaging. Experimentally exploring this trade space to find the best sterilization configuration is a very expensive and time consuming process since it requires relying on trial-and-error measurements and rules-of-thumb. In this presentation, we use simulations to demonstrate that the dose delivered to even a very simple medical device can be strongly influenced by the factors listed above. Simulations offer a powerful way to optimize the sterilization configuration in silico, in order to improve the efficiency of the sterilization validation process.

Contribution ID: **24** Type: **not specified**

No-host Social - Two-Brothers Roundhouse

Wednesday, 20 September 2023 17:30 (3 hours)

Contribution ID: **25** Type: **not specified**

Welcome - Bonnie Fleming, Deputy Director for Science and Technology, FNAL

Wednesday, 20 September 2023 08:05 (10 minutes)