Medical Device Sterilization Workshop; Continuing the Conversation

September 17, 2020

Attendees must register in advance at https://indico.fnal.gov/e/continuingtheconversation

All agenda items in Central Daylight Time

9:40 A.M.	Meeting Opens
9:45 A.M.	Free-form Q&A
10:00 A.M.	Introduction and Welcome *Mark Pasmore, Baxter International*
10:10 A.M.	Physics of Radiation Sterilization - the Basics That You Need to Know to Consider Your Sterilization Options *Thomas Kroc, Fermilab*
10:40 A.M.	Q&A Session
10:50 A.M.	Update from Team Nablo - Measurements of Effects on Polymers for All Three Radiation Modalities *Mark Murphy, Pacific Northwest National Lab*
11:20 A.M.	Q&A Session
11:30 A.M.	Progress in Providing Guidance for the Industry - AAMI, ASTM, and Others *John Williams, Medtronic*
11:50 A.M.	Q&A Session
12:00 P.M.	Industry Interest in Alternative Radiation Technologies in Light of Current Events – Discussion of the Pre-Conference Survey *Jodi Lieberman, Sandia National Laboratories & Joe Adduci, Argonne National Laboratory*
12:30 P.M.	Acknowledgments and Next Steps
12:35 P.M.	Free-form Q&A
1:00 P.M.	Meeting Close

Biographies

Joseph Adduci, Argonne National Laboratory: Joe Adducci serves as the "Manager of Infrastructure and Intelligence Fusion" within the Strategic Security Sciences Division at Argonne National Laboratory. Joe is the laboratory manager for Argonne's efforts related to the National Nuclear Security Agency's Office of Radiological Security (ORS). Argonne's efforts for ORS focus on work related to radiological situational awareness, inventory scoping and alternatives to radiological sources in medical and industry settings. He is an adjunct professor of geospatial science at the College of DuPage and Wheaton College, Joe has been teaching for over 18 years and has taught over 80 semester classes in GIS, remote sensing and geospatial intelligence.

Debbie Cotton, Baxter Healthcare: Debbie Cotton is the Sterilization Category manager in Purchasing for Baxter. Prior to this role, Debbie spent 43 years in Sterility Assurance at Baxter, most notably as the radiation Subject Matter Expert, providing support to manufacturing sites, Product Development teams, Sustaining Products organization and Regulatory Affairs. In the Purchasing Organization, Debbie is responsible for managing supplier relationships, negotiating service agreements, developing the corporate strategy with respect to sterilization and balancing volume requirements with available capacity. Debbie has significant experience with medical devices, specializing in radiation sterilization as well as experience in ethylene oxide and moist heat. Debbie received her B.S. degree in Microbiology from the University of Illinois, Champaign-Urbana

Thomas K. Kroc, Fermilab: Thomas Kroc has been at Fermilab for over 37 years. Initially trained as an experimental high energy physicist, he moved on to accelerator physics. For 20 years he was part of the team providing cancer treatment through Fermilab's Neutron Therapy Facility. He was head of that facility for the final five years of its operation, ending in 2013. He then took his accelerator and medical application experience to Fermilab's Illinois Accelerator Research Center (IARC), looking to apply Fermilab's technology to various applications. In 2017, he was the primary author of "Accelerator-driven Medical Sterilization to Replace Co-60 Sources," which was conducted at the request of the National Nuclear Security Administration. Since then Thomas and IARC have continued to be involved in promoting and facilitating the application of accelerator-based sources of ionizing radiation for many applications, including sterilization.

Jodi Lieberman, Sandia National Laboratories: Jodi B. Lieberman is a project lead at Sandia National Laboratories, where she focuses on projects to reduce the risk of nuclear and radiological terrorism. She has accumulated nearly 27 years of professional experience working in various aspects of the WMD, nuclear and radiological fields. Prior to joining Sandia, Ms. Lieberman served as a senior advisor at Argonne National Laboratory where she worked on activities that focused on nuclear non-proliferation and reducing the risk of radiological terrorism. While there, she successfully developed and deployed two training courses for first responders focusing on crisis communications and radiation basics for NNSA. Ms. Lieberman previously held positions at the US Nuclear Regulatory Commission and the US Departments of State and Energy, where she focused on arms control and nuclear nonproliferation, nuclear and radiological security, the IAEA, nuclear safeguards and safety, and bilateral nuclear cooperation. During her seven years as a senior government relations specialist at the American Physical Society, Ms. Lieberman worked with Congress to ensure adequate funding for Federally funded scientific research. In particular, she represented the scientific community in efforts to reauthorize the Federal helium reserve, one of only two pieces of legislation passed by Congress during that term. Failure to do so would have jeopardized the conduct of whole areas of physics research, the viability of Magnetic Resonance Imaging (MRI) for medical treatment and high-tech industries that rely on helium for critical aspects of their production. While at APS, she also supported efforts to encourage the NRC to include proliferation potential as an element of its licensing review for construction and operation of laser enrichment technology in the US.

In additional to professional positions she has held, from 2015 – 2018, Ms. Lieberman produced a daily nuclear news summary published by the Bulletin of Atomic Scientists, a resource distributed to and accessed by a sizable number of professionals, the academic community, and government organizations, both domestically and worldwide.

She has also held staff positions in the House of Representatives and the Senate, serving as Professional Staff on the Senate Homeland Security Committee where she worked on issues associated with chemical, biological, nuclear and radiological threats, and as an international relations fellow in the offices of Senator Robert Menendez and Congressman Joseph Crowley. Ms. Lieberman has published and spoken on a range of nuclear and radiological issues, including implementation of 123 agreements and the inclusion of the so-called "Gold Standard" in them, the South African nuclear weapons program, and nuclear power in Eastern Europe. She holds a master's degree in international relations from Columbia University.

Mark Murphy, Pacific Northwest National Laboratory: Mark Murphy has worked as a research scientist and manager at Pacific Northwest National Laboratory for over 30 years. He has expertise in a broad range of radiation dosimetry, radiation field metrology, and experimental design for irradiation studies. This dosimetry and radiation metrology work has covered a wide range of applications, including nuclear worker protection, radiation effects on materials and electronics, radiation therapy, radiation biology, and radiation processing. Mark currently is the lead PI for the NNSA/ORS Team Nablo project.

Mark Pasmore, Baxter Healthcare: Mark Pasmore is a Senior Manager supporting Renal and Acute business units of Baxter Healthcare. His responsibilities include Sterility Assurance as well as the in-use microbial control of Baxter Renal products. Mark started his career has a Research Professor and Lab Manager at Montana State University in the Department of Chemical Engineering and Center for Biofilm Engineering. He has also held positions as a Senior Engineer at STERIS Corporation and Vice President of Research and Development at TSO3. He is a member of the AAMI Renal Disease committee and the Parenteral Drug Association. He has multiple peer reviewed publications and involvement in producing technical report documents on biofilms, ultra pure dialysate, and disinfection. He has expertise in biofilms, microbial control, and vaporized hydrogen peroxide sterilization.

John A. Williams, Medtronic, Inc.: John A. Williams is the Sterility Assurance Director at Medtronic, Inc. and is responsible for supporting terminal sterilization across their Cardiac Rhythm and Heart Failure business. John also leads the Sterility Assurance Council for the Cardiac and Vascular Group of Medtronic. Prior to working for Medtronic, he was a Quality Director at Baxter Healthcare Corporation. John has 25 years of experience in the use of radiation for industrial applications, primarily for the sterilization of medical devices. He serves as the Vice Chairman of ASTM Committee E61 on Radiation Processing: Dosimetry and Applications and is the US Overall Advisor to ISO/TC85 WG3 on Radiation Dosimetry. John is also an active member of AAMI and PDA.