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2020 Medical Device Sterilization Workshop

Medical Device Sterilization: Continuing the Conversation

Summary Report

Fermi National Accelerator Laboratory

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1 Baxter International

2 Fermi National Accelerator Laboratory

3 Medtronic

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About Fermi National Accelerator Laboratory

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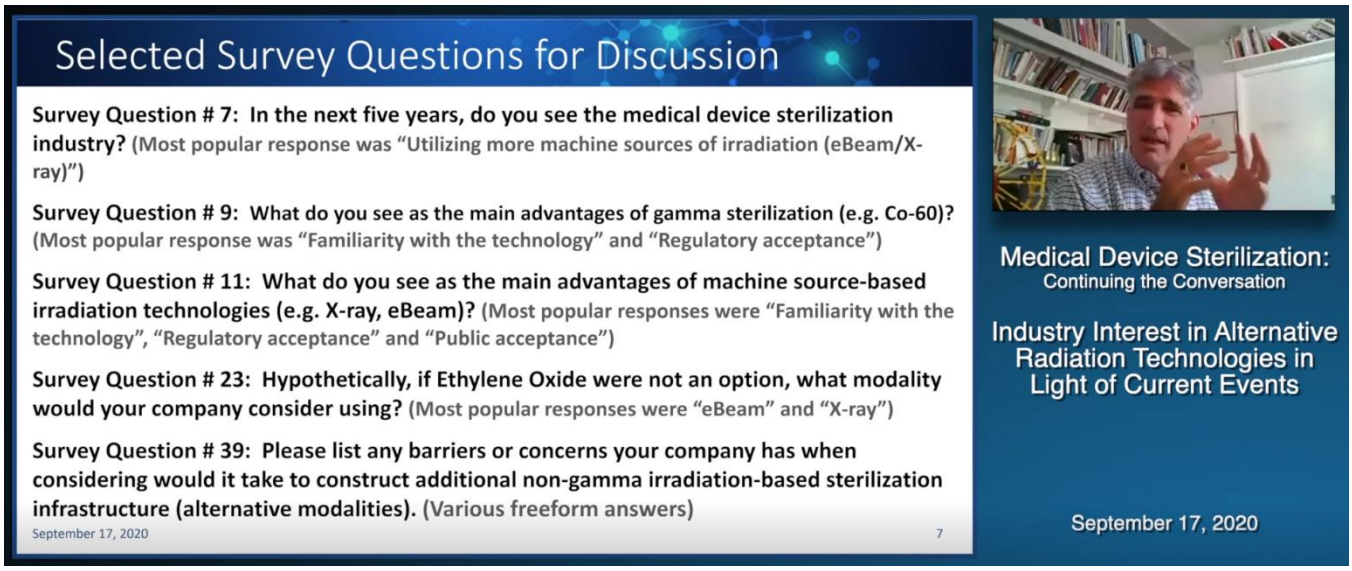

The Q&A section of the webinar resulted in vivid discussion among the panelists, which included Byron Lambert of Abbott Laboratories, the keynote speaker for the 2019 workshop.

Abbreviations and Acronyms

510k	A premarket submission to the FDA for a device that is substantially equivalent to an existing device
AAMI	Association for the Advancement of Medical Instrumentation
ASTM	Formerly the American Society for Testing and Materials; it is an international standards organization.
DOE	U.S. Department of Energy
DUR	Dose Uniformity Ratio
E-beam	Electron beam
EO	Ethylene oxide
FDA	Food and Drug Administration
IFU	Instructions for Use
ISO11137-1	International Organization for Standardization standard, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. Note: gamma, e-beam and x-ray radiation sterilization are in scope.
ISO11137-3	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control. Note: gamma, e-beam and x-ray radiation sterilization are in scope.
MDIC	Medical Device Innovation Consortium
NNSA	National Nuclear Security Administration
PDA	The Parenteral Drug Association
PMA	premarket approval to the FDA for a new medical device
PNNL	Pacific Northwest National Laboratory
The Panel	The Panel on Gamma and Electron Irradiation (https://www.irradiationpanel.org/)
R&D	Research and development
TIR	Technical Information Report; designation for an AAMI guidance document
AAMI TIR104	Guidance on transferring health care products between radiation sterilization sites or modalities; early draft
Method VD_{max}	An ISO/EN/AAMI method for establishing radiation sterilization dose using the dose substantiation methodology.
X-ray	High-energy electromagnetic radiation

Workshop Background and Overview

On September 17, 2020, the Organizing Committee of the Medical Device Sterilization Workshop hosted a virtual meeting for stakeholders exploring accelerator-based sterilization alternatives.

Technical advancements are making accelerator-based sources of radiation viable candidates for sterilization of medical devices. Electron beams and x-rays are becoming more cost-competitive and new facilities are being built to provide needed capacity and redundancy. As the industry becomes more receptive to these modalities, there is a need for information and data to enable prospective users to evaluate these options for their products. The workshops offered in 2019[1] and now in 2020 strive to foster conversation between device manufacturers, equipment and service providers on needs, capabilities, and knowledge.

Security and environmental concerns with the two major sterilization modalities — gamma rays from cobalt-60 and ethylene oxide gas — have led to new interest in accelerator-based radiation sources, both electron beams and X-rays, for sterilizing medical devices. A "we've always done it this way" mentality and a limited number of accelerator-based facilities have slowed the adoption of new technologies. However, things are changing. The desire to learn more about these alternative technologies is growing, and there have been recent announcements of new facilities offering accelerator-based radiation for sterilization.

The meeting provided an update on developments in material characterization and guidance over the past year. The Organizing Committee provided three presentations:

- A reprise of the physics fundamentals of radiation sterilization: how to understand what is actually happening that results in sterilization.
- An update from Team Nablo: new data on material compatibility of polymers, used in medical devices, in all three radiation modalities— gamma, e-beam, and x-ray.
- An update on various standards and guidance documents to provide the industry with additional knowledge on how to meet the performance and regulatory requirements for implementing and changing modalities.

There were multiple Q&A sessions throughout the event.

- One-hundred-thirty people registered, almost doubling the 70 registrants involved in the inaugural 2019 Medical Device Sterilization Workshop.
- More than two-thirds of this year's registrants are new participants in the work, having not attended the previous event.
    - Among these new attendees were individuals from the bioprocessing industry, which makes products for the manufacture of pharmaceuticals and vaccines.

9:45 A.M. Free-form Q&A

An open session of Q&A was provided before the formal start of the workshop to answer questions submitted by attending during registration. Any questions regarding presentation related topics covered in the workshop are answered in those areas.

[1] Kroc, Thomas, Margolis, Jeffrey, and Sauers, Aaron. Fri . "2019 Midwest Medical Device Sterilization Workshop: Summary Report". United States. https://www.osti.gov/servlets/purl/1574826.

10:00 A.M. Introduction and Welcome Mark Pasmore, Baxter International [2]

The workshop was opened by Mark Pasmore of Baxter International. He introduced the organizing committee members and reviewed the schedule of the workshop.

10:10 A.M. Physics of Radiation Sterilization - the Basics That You Need to Know to Consider Your Sterilization Options Thomas Kroc, Fermilab [3]

This presentation was a reprise of one given at the 2019 workshop.[4] It provides an overview of exactly how radiation sterilizes. The focus was on how electrons are the agents of interest. How they are produced by photons – x-rays or gammas. The basis for the regulatory energy limits for electron beams and x-rays. As well as the practical aspects that determine dose rate and the irradiation of materials.

10:40 A.M.Q&A Session

Question:	Klystron vs Magnetron: what's the difference?
Answer:	Klystrons and Magnetrons refer to the power sources for the radiofrequency (RF) power for the accelerator system that produces the electrons or x-rays. This is sort of analogous of whether you have a reciprocating piston or rotary engine in your car.

Question:	Why is X-Ray limited to 7.5 MeV? While E-beam can go up to 10 MeV?
Answer:	10 MeV for electrons ensures that there is essentially no activation of what is being irradiated. 7.5 MeV ensures that the X-ray producing target does not become radioactive.

Question:	I understand that sterilization in Ebeam is acceptable at energies higher than 10 MeV, the regulations require that a radioactive survey is conducted as part of the process qualification. Can you go into more detail on this process?
Answer:	Yes, the regulations do allow for the possibility to go higher in energy. Doing so would require an analysis of the elements that make up the materials being irradiated; taking into account activation threshold energies, the abundance of each isotope, and the cross section for activation. After the analysis, actual tests would probably be needed to verify the analyses. The analysis and data would then need to be submitted to regulatory agencies to assure them that there would be no reason for concern.

[2] **https://vms.fnal.gov/asset/detail?recid=1963570**

[3] **https://vms.fnal.gov/asset/detail?recid=1963567**

[4] Kroc, Thomas K, et al. Accelerator-Driven Medical Sterilizationto Replace Co-60 Sources, http://inspirehep.net/record/1624371/files/fermilab-pub-17-314-di.pdf

Question:	Medical devices can contain limited quantities of Tungsten (generally used to provide radio-opacity to components so that they can be imaged using X-Ray during patient procedure). Would that be 'activated' during X-Ray sterilization?
Answer:	There are three isotopes of tungsten that have activation energies between 7 and 7.5 MeV. In the Bremsstrahlung target, where the x-rays are produced, the electrons first generate photons (the x-rays) and then for activation to occur, those photons have to be above the threshold energy and then cause a photon-neutron or photon-proton reaction. The probability of each these steps is low and when multiplied together, the result is very low. So, this is, most likely, only important for the Bremsstrahlung target where this is continually occurring over a long period of time. For the once-through instance of irradiating a product, the amount of activation would be extremely low. A validation test could conceivably be necessary to assure regulators that any activation was below allowable limits.

Question:	Is there any company or organization providing training for x-ray dosimetry?
Answer:	A couple of institutions were mentioned by other participants. ▪ Aérial in France, https://www.aerial-crt.com/en/ ▪ Risø High Dose Reference Laboratory, https://www.nutech.dtu.dk/english/products-and-services/industrial-dosimetry/hdrl

Question:	Any limitation of Ebeam/X-ray for product containing metal (film) or containing water?
Answer:	There is no fundamental reason to argue for or against these materials or modality. The only caveat would be the possibility of activation of the metal, which has been discussed above.

Question:	The dose rate in gamma is variable based on other products also being irradiated. How does the dose rate change for x-ray?
Answer:	In a gamma irradiation chamber, the photons (gamma rays) are emitted from a distributed source, a plane of cobalt pencils. As the product moves through its path in the chamber, the gamma rays come from many different angles and for much of the time have passed through other packages that are in front of or alongside of the package in question. With x-ray, there is a line source of radiation that is mostly perpendicular to the surface of the package. Typically, only a single layer or pallet is in front of the beam.

Question:	If a medical device has already been sterilized using EBeam...is it worth it to move to Xrays? What could be the advantages?
Answer:	There isn't a fundamental difference. Generating the electrons is much more energy efficient than generating x-rays. There might be capacity or throughput reasons to switch.

Question:	What about heating?
Answer:	If you ignore dissipative effects, the temperature rise is dependent on the dose absorbed and the specific heat of the material. A gray (Gy) is a joule per kilogram. As an example, 25 kGy will produce a 6 C rise in water, 13 C in polyethylene, and 28 C in PVC. However, there are dissipative effects. Longer irradiation times will give those dissipative effects more time to reduce the temperature rise. The geometry and surroundings will also affect the temperature. On the other hand, the ambient temperature is generally higher in a gamma irradiation chamber (due to inefficient use of the gamma rays) than in an x-ray or e-beam irradiation chamber.

Question:	From a regulatory perspective is it sufficient to prove that there is no activation of e.g. metals once or is it necessary to do it frequently
Answer:	Obviously, the regulators get the final say. But, if the dose (probably Dmax) is the same and the composition of the materials being irradiated doesn't change, then there would be no reason to suspect a change in activation.

Question:	What if a tote is used vs a tray, and do you lose efficiency with Xray using a tote?
Answer:	I'll include electrons in this answer also. ▪ A 10 MeV electron beam will lose 1.6 MeV passing through 1/8" of aluminum. ▪ A 10 MeV electron beam will lose 0.8 MeV passing through 1/16" of aluminum. ▪ A 7.5 MeV x-ray will lose 2% of its intensity passing through 1/8" of aluminum. ▪ A 7.5 MeV x-ray will lose 1% of its intensity passing through 1/16" of aluminum. So, for x-ray, this is not much of an issue and it would be up to the designer of the facility to balance convenience and throughput against loss of efficiency. For e-beam this would have much greater impact as the energy loss represents a significant loss of range (about 15%).

10:50 A.M. Update from Team Nablo - Measurements of Effects on Polymers for All Three Radiation Modalities Mark Murphy, Pacific Northwest National Lab [5]

Team Nablo is a group of stakeholders that are collaborating under the direction of Pacific Northwest National Lab and is investigating the performance of various materials in all three radiation sterilization modalities. They showed the results of a number of tested products and materials. While there were dependencies on dose, there was little or no dependence on modality.

11:20 A.M.Q&A Session

Question:	Have the polymer properties been tested such as molecular weight, cross-linking degree etc in addition to the functional testing?
Answer:	The testing thus far has included: • Hardness • Tensile • Mass change • Yellowness index Future tests could possibly include: • Gel permeation chromatography (GPC)/size-exclusion chromatography (SEC) for molecular weight determination • Gel content for determination of extent of cross-linking • Differential scanning calorimetry/dynamic mechanical analysis for determination of phase transitions and crystalline content • Fourier transform infrared spectroscopy (FTIR) for chemical bonding analysis

Question:	Really nice overview. Thank you. Has PNNL looked into any differences in extractables & leachables, or biocompatibility assessments (USP <88> or ISO 10993) of these materials post x-ray as compared to post-gamma (50 kGy)? In Biotech plastic materials, we see these as some of the key focus areas for the risk assessment.
Answer:	Team Nablo is currently looking into a potential collaboration to test extractables, leachables, and biocompatibility for some specific products.

Question:	Does Nablo Team have a website?
Answer:	No. However, the Polymer Effects Library being developed will likely have a page on Team Nablo.

[5] https://vms.fnal.gov/asset/detail?recid=1963568

Question: Do we have a rationale or hypothesis why the performance (of some of the polymer materials) changed?

Answer: Energy imparted to plastic materials and devices through radiation processing can lead to formation of reactive radicals in the polymer molecular chains. These can result in oxidation of the polymer, cross-linking of the polymer chains and chain scission (breaking chains into pieces).

Since physical and mechanical properties of plastics are dependent constituent polymer chemistry, these chemical processes can lead to changes in physical and mechanical performance of the irradiated plastics. Antioxidants are often added to polymer formulations in plastics to quench reactive radicals and mitigate polymer chain damage.

Differences in induced changes observed in materials processed using different radiation modalities may be due to differences in the rates and nature of chemical reactions associated with specific processing conditions such as dose rates, local heating, and ambient environments.

Question: Can you explain why the yellowing is so much worse for ebeam than in the other methods?

Answer: The PVC tubing in the e-beam photo had a higher dose level than the X-ray and Gamma photos, but at least for PVC there still appears to be slightly more coloring/darkening for a given kGy when e-beam is used. Of course, high doses of radiation cause yellowing/browning of polymers. Oxidation impacts the outer layers of products. In X-ray and gamma both irradiation and oxidation are occurring. In e-beam irradiation is occurring, while very little (if any) oxidation is occurring since the irradiation duration is so short compared to gamma and X-ray.

Another point to stress is that coloration is affected differently in different plastics. It is obvious the PVC is affected differently in e-beam; however, PC is affected in X-ray. If you look at the photos of the Stryker Mixer product, the base and lid of the mixer is a PC, however the e-beam did not affect it comparatively… whereas the X-ray (and to some extent the gamma) did turn it greyer. So, oxidative effects can differ for different polymers, and can be seen visually.

Three other things to emphasize:

1. there is often no correlation between color and mechanical properties,
2. A change in visible color can occur with a very low density (~ 0.001% of bulk number density) of color-center creation, and

3. polymer coloring can diminish some over time, especially if exposed to bright light (photo-bleaching) or heat (thermal annealing).

Question: Are there any hypotheses for why PC saw more yellowing with X-Ray and PVC saw more yellowing with E-beam?

Answer: Yes, photos indicate PC is effected/colored more by e-beam, and PC is affected/colored more in X-ray. If you look at the photos of the Stryker Mixer product, the base and lid of the mixer is a PC, however the e-beam did not affect it comparatively… whereas the X-ray (and to some extent the gamma) did turn it greyer. So, surface oxidative effects can differ for different polymers, and can be seen visually; and there is more oxidation during X-ray and gamma irradiation since the associated durations in irradiation cell are much longer (dose rates are much lower).

Comment from Cody Wilson, IBA:

As Thomas indicated, the primary advantages of x-ray relative to e-beam are logistical ones. X-ray offers more flexibility in the arrangement of products to be treated, eliminating the depalletizing and repalletizing portion of the process and potentially simplifying the conveyor system. Additionally, the dose uniformity ratio should be considered and in some cases may be improved with x-ray.

Question: For the dose rate study – are you expecting to see material differences at the different dose rates?

Answer: Processing at different dose rates to a common dose may involve substantive differences in times during which the plastic materials are actively experiencing oxidation or degradation mechanisms. These exposure time differences may be reflected in observable mechanical, physical or other properties. The ISO 11137-1:2006 radiation sterilization standard communicates the expectation that the higher dose rates of e-beam or x-ray sterilization would result in favorable material effects relative to the lower dose rate gamma sterilization.

Team Nablo, through a partnership between PNNL, BD, IBA and Aerial, is currently pursuing a study to directly determine dose rate effects on select material properties.

Question: There was a request from a representative from the NNSA on needs for future materials to be investigated:

	Materials of interest: silicones, PP, PVDF, PES, nylon (to some extent), PC, LDPE, HDPE, TPE (materials that have already been evaluated for biotech use post-gamma).
Answer:	Of the materials listed, Team Nablo has compared some of the effects of radiation modalities on polypropylene (PP), low density polyethylene (LDPE) and polyolefin elastomer (POE) (a thermoplastic elastomer (TPE). The team looks forward to the opportunity to investigate the other polymers of interest listed.

Question:	Is there a difference between nitrogen atmosphere vs. air on the effects to materials?
Answer:	It is understood that a nitrogen atmosphere during radiation will prevent induced radicals from reacting with oxygen in the atmosphere resulting in degradative oxidation. If oxidation is a major sterilization degradation mechanism for the material in question, then a difference in resulting effects of the processing would be expected.

Question:	There was a question about future goals. Hi Mark – I'd love to ask a question about the project goals – can you add a goal to "Educate community - about the foundational hypothesis that physics (dose rate) and regulatory (ISO 11137) frameworks indicate that a conversion from gamma to e-beam/X-ray will likely be successful." (and Team Nablo data is a great confirmatory example of this hypothesis)
Answer:	Byron Lambert (with input from Team Nablo) is currently working on a short paper for potential publication in an industry Newsletter (AAMI?).

11:30 A.M. Progress in Providing Guidance for the Industry - AAMI, ASTM, and Others John Williams, Medtronic [6]

It was apparent in the 2019 workshop that there is a great need for guidance on how to evaluate and perform a change in sterilization modality. This presentation was prepared to highlight the various efforts that are underway to provide that guidance.

11:50 A.M. Q&A Session

[6] https://vms.fnal.gov/asset/detail?recid=1963571

Question:	Is the goal of ASTM E61 to copy paste the ISO or to go deeper in the description and in the understanding of all radiation processes?
Answer:	No, not at all, the purpose of the ASTM documents are to complement the ISO documents. The ISO documents tell you what you need to do; the ASTM documents tell you how. For example, the ISO 11137-1 document requires that dose mapping is performed as part of Performance Qualification. ISO/ASTM 52303 Absorbed Dose Mapping in Radiation Processing Facilities describes in great detail how to perform a dose map.

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 [7]

Sandia is conducting a study to compare the economics of gamma, e-beam and X-ray sterilization. The workshop committee assisted Sandia in distributing a survey of all stakeholders in device sterilization, and the preliminary results were discussed by leading members of the field. The members of the round-table discussion were Byron Lambert of Abbott Vascular, Suresh Pillai of Texas A&M University and the National Center for Electron Beam Research, Paul Wynne of the International Irradiation Association, and Rod Parker of Stryker Instruments. Jodi Lieberman of Sandia and Joe Adduci of Argonne National laboratory led the discussion.

Roundtable

- The industry sees a likely increase in machine sources of irradiation (including E-beam and X-ray), but does not feel Co-60 will disappear as a major player in the sterilization space. Additionally, market growth is expected to outpace demand in the short term.
- The industry highlighted a wide range of advantages for machine-based sources, including public acceptance, regulatory acceptance, familiarity with the technology, and ease of operation. The main advantages of cobalt were familiarity and regulatory acceptance.
- Many respondents indicated that a lack of EO in the marketplace would lead to the consideration of alternative technologies over gamma (though both were included as likely considerations).

Co-60 Study (Findings so far)

- The marketplace for cobalt-60 panoramic irradiators is complex. Aggregation of panoramic irradiation is challenging to do in a way that meaningfully highlights industry nuance or provides broad cost comparisons across market sectors.
- While there is an appreciation of X-ray and E-beam technology within the irradiation field, and both modalities are growing in use, market and regulatory barriers limit transitions to these modalities on a wide scale, particularly in the case of X-ray.
- Demand for sterilization services (both in the medical and food sectors) is likely to increase, and it is likely that Co-60 will remain a major part of the sterilization marketplace for the near future.

[7] https://vms.fnal.gov/asset/detail?recid=1963569

12:30 P.M. Acknowledgments and Next Steps

Mark Pasmore formally closed the workshop. We plan to offer another workshop in 2021 with the date to be determined later.

12:35 P.M. Free-form Q&A

A final opportunity was provided for any un-asked questions. Again, any questions regarding topics covered in the workshop are answered in those areas.

List of Registrants

First Name	Last Name	Affiliation
Aaron	Sauers	Fermi National Accelerator Laboratory
Aaron	Starkey	Iotron Industries
Abbas	Nasreddine	Aerial
Adam	Whaites	3M+KCl
Alain	Strasser	Aerial
Alandrea	Cox	Medtronic
Alison	Bailey	Convatec
Amit	Bhatt	Merck & Co.
Anand	Tahiliani	Baxter
Andreas	Ostrowicki	BGS Beta-Gamma-Service GmbH
Andrew	Dalesandro	FNAL
Andrew	Porteous	Baxter Healthcare Corp.
Aymeric	Longin	BBH Technology
Barry	Sanders	Thermo Fisher Scientific
Beau	Rollins	ConvaTec
Bob	Stringham	ICU Medical
Byron	Lambert	Abbott Labs
Candice	Nagel	IBA
Charles	Cogdill	Medtronic
Charles	Golub	Saint-Gobain
Christophe	Malice	IBA
Christopher	Justi	self
Ciara	Mac Sweeney	Baxter
Cody	Wilson	IBA
Daniel	Wojtczak	Baxter
Davi	Waltz	Rosatom Latin America
Debbie	Cotton	Baxter Healthcare
Deborah	Havlik	DAHavlik Consulting, LLC
Deepak	Namdev	Baxter
Deepak	Patil	STERIS AST
Denise	Cleghorn	Boston Scientific Corp
Dessy	Frederic	IBA
Dupuy	Nathalie	Aix Marseille Université
Emily	Craven	Boston Scientific

Eric	Beers	Mevex
Eric	Burgett	Accelerated SterileTechnologies
Eric	Nakagawa	Steri-Tek
Eric	Peryer	Baxter Healthcare Corporation
Fernando	Luna	Avantti Medi Clear MBP SAPI DE CV
Florent	Kuntz	Aerial
Fransua N	Muniz Valentin	Stryker
Gustavo H	Costa Varca	E-BEAM Services, Inc.
Harrison	Mavric	IAEA
Hilario	Negron	Baxter
Isabelle	Arts	Baxter
Isabelle	Gay	Sartorius
James	Hathcock	Pall Biotech
James	Ludlow	Saint-Gobain
Jami	Mclaren	Boston Scientific
Jeff	Sauter	Steri-Tek
Jeffrey	Peltier	Cardinal Health
Jeremy	Brison	Ion Beam Applications - IBA (Belgium)
Jodi	Lieberman	Sandia National Laboratories
John	Williams	Medtronic
Jordan	Fujioka	Steri-Tek
Josef	Mittendorfer	High Tech Consulting
Joseph	Wolinski	Baxter Healthcare
Juan	Prieto	Baxter
Julie	Hirata	Baxter Healthcare
Kanchan P	Adhikari	NAMS,Bir Hospital
Katie	Campbell	Saint-Gobain
Kelly	Mr.	3M
Ken	Baker	NewAge Industries Inc.
Ken	Paddock	Baxter Healthcare
Kevin	Ott	Bio-Process Systems Alliance
Kyle	Naumann	Iotron Industries
Kyrstan	Polaski	STERIS
Lance	Garrison	National Nuclear Security Administration
Larry	Nichols	Steri-Tek
Laura	Wahlen	Baxter
Leo	Fifield	Pacific Northwest National Laboratory
Lina	Nguyen	Saint-Gobain Corporation
Lodewika	Van Der Merwe	Iotron Industries Inc.
Lucia	Polakova	Convatec
Macario	Moreno	AvanttiMediClear
Manish	Bagre	Raja Ramanna Centre for advanced Technology
Mara	Senescu	Baxter Healthcare
Maria	Garmendia-Haro	Avantti Medi Clear

Maria	Ruiz	3M
Mariela	Picado	Baxter, Costa Rica
Mark	Murphy	Battelle-Pacific Northwest National Lab
Mark	Simpson	Iotron Industries
Matthew	Keskula	Argonne National Laboratory
Mauricio	Suarez	Fermilab
Michael	Itamura	Sandia National Laboratories
Michael	Tucker	Watson Marlow
Michelle (Shelly)	Luebke	Baxter Healthcare
Mike	Geelhoed	Fermilab
Mike	Rust	3M
Mike	Sadowski	Baxter
Monica	Cardona	MilliporeSigma (Merck LifeSciences)
Neville	Niessen	Baxter Health Care
Nick	Troise	PendoTECH
Nicole	Mclees	3M
Nilanjal	Misra	Bhabha atomic research centre
Nina	Perier	Sartorius/aix marseille university
Olivier	Rosseler	Saint-Gobain
Palash	Das	Baxter
Paul	Wynne	iia
Peter	Laurence	Nutek Bravo
Philippe	Dethier	Mevex
Rachel	Pytel	Saint-Gobain
Rafael	Rodriguez	Cytiva
Rahul	Singh	Baxter Healthcare Corp.
Ram	Dhuley	FNAL
Richard	Wiens	Nordion
Rishabh	Jain	Boston Scientific
Rodney	Parker	Stryker
Ruan	Souza	Rosatom Latin America
Rupesh	Gawade	Baxter
Samuel	Dorey	Sartorius
Sandra	Cushnan	WuXi Biologics
Sarah	Herold	Boston Scientific
Sean	Lynch	NewAge Industries
Slavica	Grdanovska	Fermilab
Stephanie	Volk	ConvaTec
Stephany	Unruh	Fermilab
Stephen	Liu	Saint Gobain
Susana Marina	De Leon Rosario	ConvaTec
Suzanne	Butler	Medtronic
Thomas	Bunch	Thermo Fisher Scientific

Thomas	Kroc	FNAL
Tim	Carlson	Becton Dickinson
Timo	Neumann	Millipore
Valeriia	Starovoitova	IAEA
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William	Jeschke	Baxter Healthcare
Yenny	Ocampo	Baxter
Ying	Zhang	3M
Yves	Henon	Industrial Irradiation Association
Zachary	Deziel	Idaho State