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2022 Medical Device Sterilization Workshop

Medical Device Sterilization: From Possibilities to Practice

Summary Report

Fermi National Accelerator Laboratory

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1 Baxter International
2 Fermi National Accelerator Laboratory
3 Abbott
4 Medtronic

About Fermi National Accelerator Laboratory

Fermilab is a U.S. Department of Energy laboratory managed by Fermi Research Alliance, LLC under contract DE-AC02-07CH11359. The Laboratory is located outside Chicago at Kirk Road and Pine Street, Batavia, Illinois, 60510-5011. For information about Fermilab and its pioneering science and technology programs, see www.fnal.gov .

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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 22-23, 2022, the Organizing Committee of the Medical Device Sterilization Workshop convened a virtual meeting for stakeholders exploring accelerator-based sterilization alternatives. The workshop, titled "Medical Device Sterilization: From Possibilities to Practice," remained virtual. Registration this year was 345 of which 252 attended from 22 countries. Sixty percent were first-time attendees. Day 1 of the workshop focused on Switching Modalities, Day 2 described Approaches to qualifications and regulatory interactions and Day 3 explored Modeling and Obtaining irradiators.

The highlight of this year's workshop was a mock meeting with the US Food and Drug Administration (FDA). The FDA makes available certain meetings, called Q-subs, that allow industry to ask questions on regulatory issues before formal submissions for approval. However, much of the industry is unfamiliar with these meetings. The workshop hosted a mock meeting where a fictional company engaged in a pre-submission meeting regarding a fictional product. The mock meeting showed productive and un-productive ways of asking questions so that the company could get the most from their time with the FDA.

Participants at the workshop represented the entire supply chain for sterilization of medical devices, from medical device manufacturers, service providers, accelerator manufacturers, regulatory agencies, standard setting organizations, software companies, etc. Sterilization capacity for medical devices continues to be very tight due to limitations in cobalt-60 supply and concerns about ethylene oxide, the two most common methods for sterilizing medical devices. This makes the expansion into accelerator-sourced radiation more urgent along with safety and security concerns regarding cobalt-60. This series of workshops strives to help facilitate that expansion by increasing the communication between the players and facilitating the transfer of knowledge.

Fermilab has been working with the National Nuclear Security Administration (NNSA) to facilitate and promote accelerator-based radiation sources to reduce the dependence on radioactive isotopes, such as cobalt-60, and reduce the security risks that those materials pose. In addition to supporting the NNSA's mission for reducing our reliance on radioactive sources, this collaboration also helps develop a market for compact superconducting accelerators, one of IARC's major technology development activities.

These workshops are organized in partnership with individuals from Baxter International, Medtronic, and Abbott. Direct communication with industry about their needs means IARC can focus on developing an accelerator that will provide a more efficient and reliable source of electron beams and X-rays for the medical device sterilization of the future.

DAY 1

8:30 A.M. Welcome from Roger Snyder, DOE

The workshop was opened by a welcome from Roger Snyder who is the manager of the Department of Energy's site office at Fermilab. Fermilab is part of the DOE's national laboratory system. Mr. Snyder spoke of DOE's efforts to support alternatives to radioactive materials and to foster communication regarding alternatives.

8:45 A.M. Keynote: Aftin Ross, FDA— Medical Device Sterilization: Increasing Understanding and Outreach Between FDA and Stakeholders

The keynote presentation was given by Aftin Ross who highlighted the various mechanisms that are available to manufacturers to communicate with the FDA to make the regulatory process easier. She spoke of the various types of meetings that manufacturers can have with the FDA prior to submission. These meetings, or Q-subs, can be either informal meetings or can result in written feedback on processes or submissions that manufacturers are considering. She also spoke of recent FDA actions included the EtO Innovation Challenge and the EtO Master File Program. She also spoke of Collaborative Communities that the industry can create in order to work together on common objectives for the benefit of all.

9:30 A.M. James McCoy, BD – TIR-104 Case Study

James McCoy provided a case study on the use of the recently released TIR-104 from AAMI. This report provides guidance on transferring products from one radiation modality to another or between irradiators. The process includes evaluating dose delivery characteristics, PQ dose mapping, sterilization dose transfer and maximum dose transfer.

10:15 A.M. Mark Bogs, ICU Medical – Sterilization Conversions

Mark Bogs presented some case studies that he had been involved with. They included EtO to gamma conversions, gamma to e-beam conversions, and EtO to e-beam conversions. He presented key considerations to address in these decisions including the materials that are in use.

10:45 A.M. Panel Discussion, Driving a "One Voice" Bioprocess Approach to Qualify X-ray as an Equivalent Alternative to Gamma

The final event of the first day was a short presentation followed by a panel discussion with the Bio-process industry. This industry produces single use systems that are used in the manufacture of pharmaceuticals and vaccines. They have been engaged in a coordinated effort to add x-ray to their portfolio of sterilization methods. They have developed a risk-based approach that they have presented to the FDA in order to get regulator alignment. The discussion also considered whether changes from gamma to e-beam or x-ray should be termed a change in "modality" or "radiation source". The panel consisted of James Hathcock, Pall Corporation; Ping Wang, Janssen Pharmaceutical; Ken Wong, Sanofi; Tom Oliver, BioMarin; Timo Neuman, Merch-Millipore; and Matt Hammond, Amgen.

12:55 P.M. Q&A

DAY 2

8:40 A.M. Eric Crawley, A Practical Approach to Establishing a 2x Process for Radiation Sterilized Product

Eric Crawley of Abbott started day 2 by talking about how to adjust dose targets for irradiation so that a second irradiation may be possible if necessary. A modest tightening of dose limits in an irradiation process can leave room for a second irradiation. Rearraigning packaging or orientation for the second irradiation may narrow the dose distribution so that the maximum dose will not be exceeded.

9:30 A.M. Mock Pre-sub Meeting

Next was a mock pre-submission meeting with the FDA. Five persons from the FDA made up their side of the panel. Four industry representatives posed a number of questions regarding the validation strategy of a product from Frankenstein Industries. This was an implantable Class III device within a family of 100 different configurations. Some questions were posed in a way that enabled the FDA representatives to give good feedback. Other questions were purposely asked in a manner that didn't allow the FDA reps to say much. One member of the industry team kept track of time to make sure all questions were asked. The FDA representatives were Ryan Ortega, Clarence Murray III, Chris Dugard, Sreekanth Gutala, and Stephen Anisko. The Mock company representatives were Debbie Cotton, Patrick Anibaldi, Kristen Bozelli, and Mark Pasmore.

10:35 A.M. Panel Review of Mock Pre-sub

After the mock meeting, a panel session was held with the same people to review how the meeting went. The type of questions asked were discussed for appropriateness and how they did or did not enable to FDA reps to provide feedback. Various strategies were discussed.

12:25 P.M. Q&A

DAY 3

8:30 A.M. Welcome and Survey Results

On the first day of the workshop, a survey provided to the attendees asking about their understanding and use of modeling/simulation to evaluate dose of irradiated products. The results of this survey were then supplied to the three modeling presenters and a summary shared during the attendees on Day 3. The complete results are included in Appendix A. A summary is given here.

Familiarity with modeling was fairly evenly distributed among the respondents, between no knowledge and ready to purchase such software. Many felt it was valuable to know the dose distribution early in the device development cycle. There was moderate concern for radiation sensitive components. Respondents were uncertain whether they would use such software in-house or would contract it out.

Ranking the desired characteristics of such software gave the following results 1) Cost, 2, tie) Ease of Use, 2, tie) Accuracy, 4) Precision, 5) Simulation Speed, 6) Spatial resolution of the dose map, and 7) Security of the model.

Ranking the tasks that such software would be used for resulted in 1) Improving design for sterilization, 2) Improving packaging design, 3) Improving dose mapping, 4) De-risking product development, 5) Accelerating identification of orientation of the product to the radiation source. This second ranking did not have a very large spread so the five tasks had similar importance.

A series of questions were asked on willingness to pay for certain elements of functionality. While not formatted as such the results did lend themselves to ranking. 1) identifying the location of min & max dose, 2) ensuring that difficult locations received sufficient dose, 3) guiding placement of dosimeters, 4) choosing optimal orientation of the device w.r.t. the beam, 5) choosing the appropriate sterilization modality, 6) assessing suitability of devices with electronics or radiation sensitive components.

8:40 A.M. Samuel Dorey, Sartorious - Evaluation of Monte Carlo Simulation in Radiation Processing

The first presentation of the day discussed TRAD's simulation program RayXpert. Samuel Dorey of Sartorius showed how RayXpert was used to model the dose to a single use system and compared the simulations to actual dose maps.

9:10 A.M. Daniel Badali, Triple Ring – Design for Sterilization

Next was TripleRing presented by Daniel Badali. He presented their software Dose Insight and how they use it in their "Design for X" strategy. The development of their code has been partially funded by the FDA. The presentation include comparisons of dose between their simulations and measurements.

10:30 A.M. Leo Fifield & Randy Schwartz – Team Nablo Latest Development – Polymer Effects Testing and PUFFin Software Package

Team Nablo is a collaboration of US national laboratories and universities, sterilization providers, and medical device manufacturers. It is examining the performance of a number of materials and common medical devices after irradiation from gamma rays from cobalt-60, x-rays, and electron beams. It does so to fill gaps in the

understanding of this performance data to assist manufacturers in expanding their sterilization options to include accelerator-based sources of radiation. This was the fourth presentation by the collaboration presenting their continued efforts in this area.

11:00 A.M. Irradiator Panel

The workshop concluded with a panel discussion which hosted representatives of contract sterilizers and accelerator manufacturers. Some of the questions that were asked were: What are the plans for meeting customer demand and medical device growth? Has there been interest in custom vs standard accelerator systems, and have you seen demand differences between in-house and contract sterilization? Preferences between e-beam and x-ray? Is conversion efficiency of X-ray of concern? What is the plan for growing competency with field service and engineering support as the accelerator businesses and technology grows? Has anyone had experience or started training and getting alignment with the framework provided by the SfSAP?

One theme that ran through a few of the questions and responses was given the demand for accelerator systems it is difficult for providing customized systems that might be used for in-house applications.

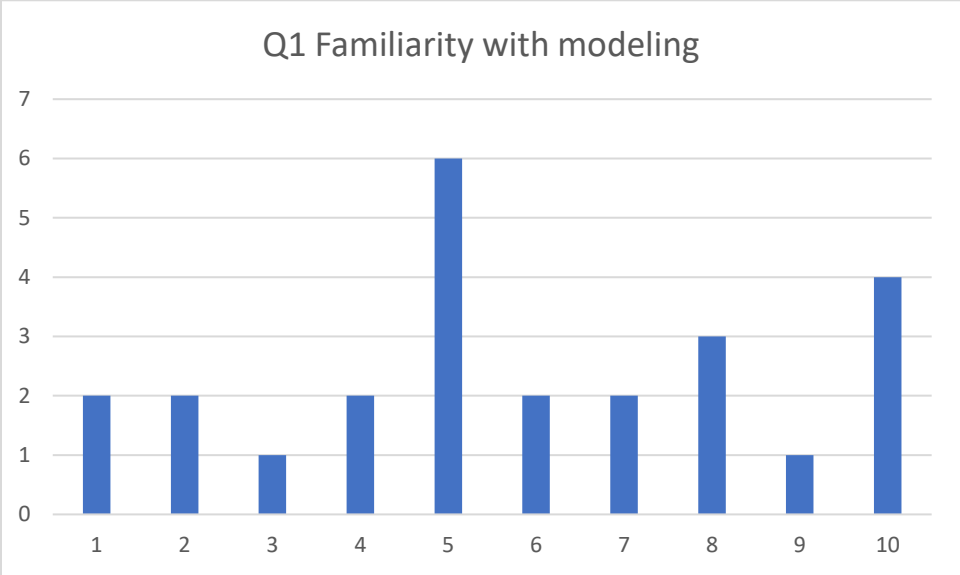
12:00 P.M. Closing

SURVEY RESULTS

On day one of the workshop, a survey was posed to the attendees. It asked a number of questions regarding familiarity with and desired features for modeling and simulation software. There were 26 responses.

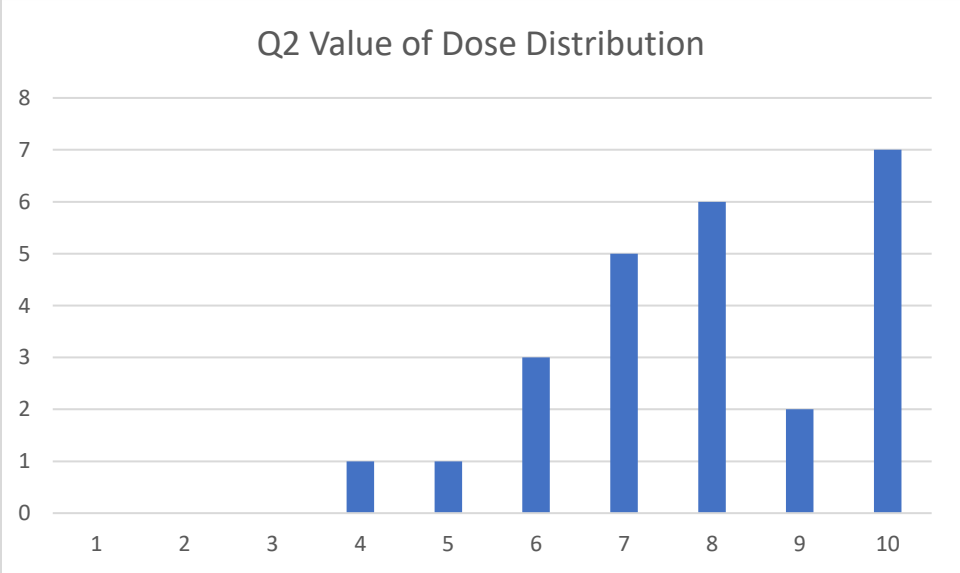
Question 1: *How familiar are you with modeling or simulation of the radiation dose to medical devices?*

1 - never heard of it ---------- 10 - when can I buy one?

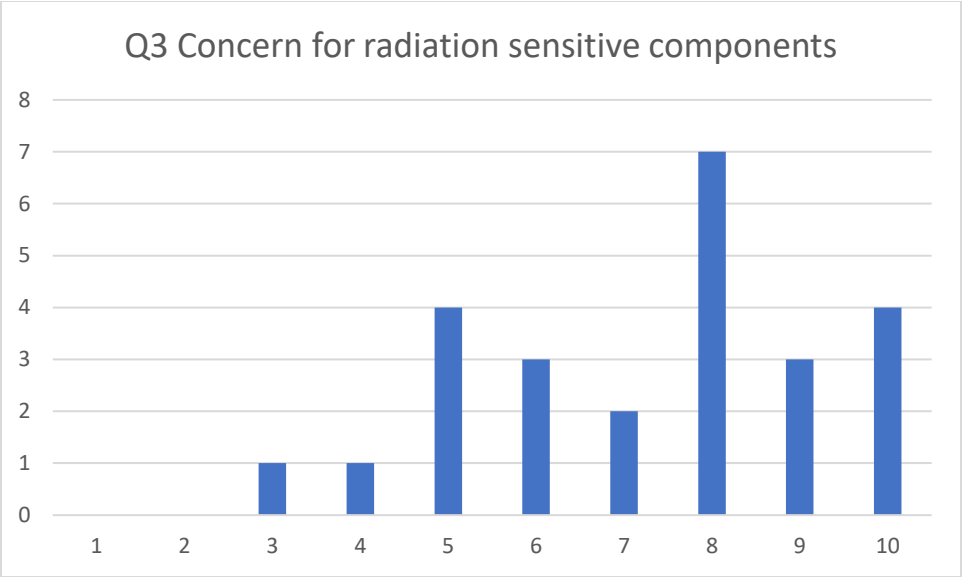


Questions 2-4 were to be answered on a scale of 1-10.

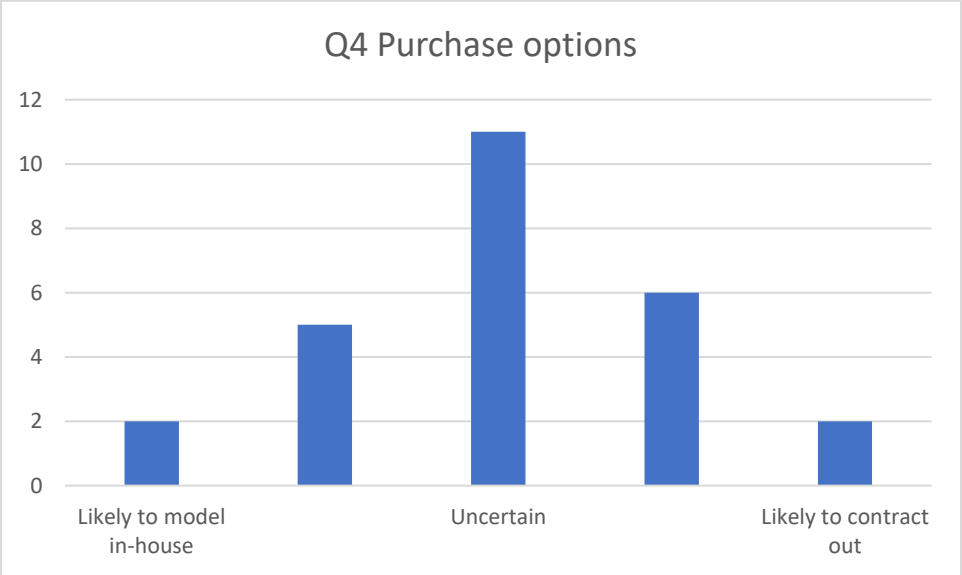
Question 2: *How valuable is it to know dose distribution delivered during radiation sterilization as early as a CAD model exists?*



Question 3: *How concerned are you about radiation-sensitive components in your device (e.g., electronics, drugs, etc.)?*

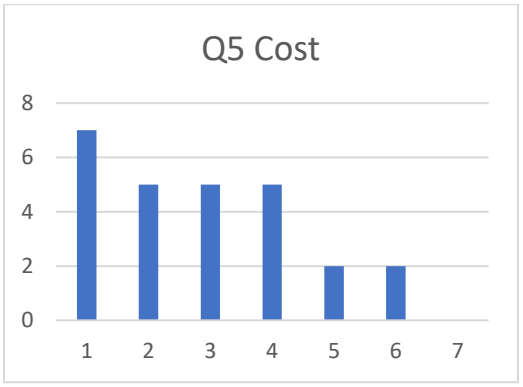


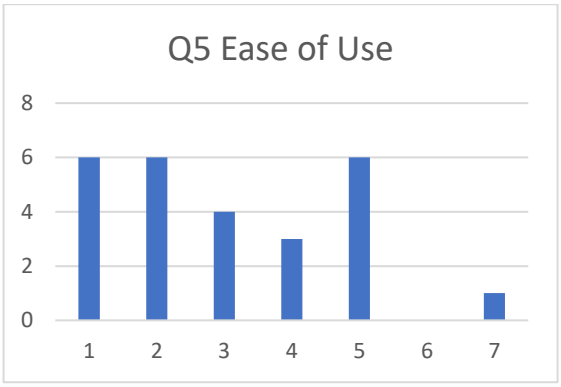
Question 4: *How likely are you to purchase a simulation package and run the model in-house versus contracting with a third-party simulation firm to perform the modeling?*

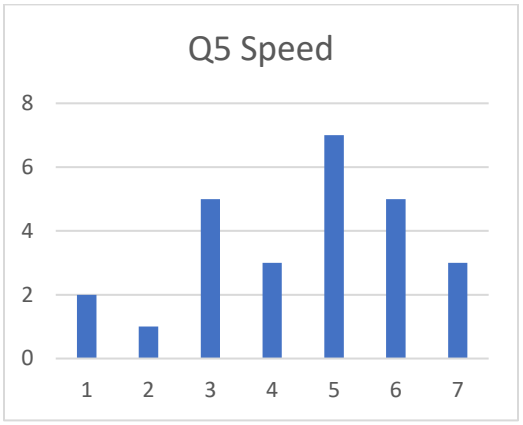


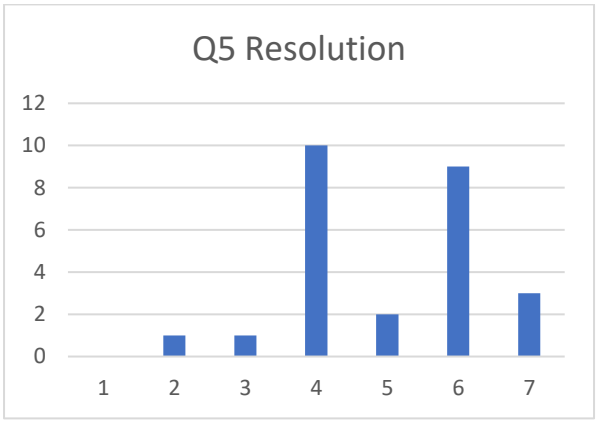
Questions 5 and 6 asked respondents to rank characteristics they would like to see in a modeling/simulation package and tasks they would want to use the package for.

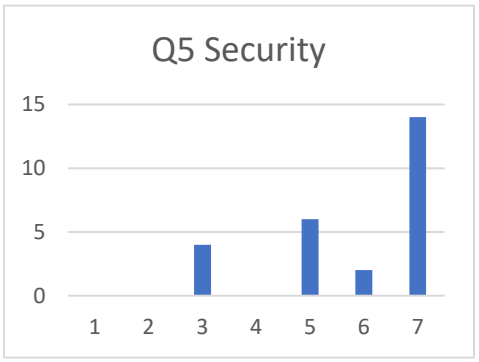
Question 5: *Rank the following characteristics of sterilization simulation tool in the order of relative importance to you?*

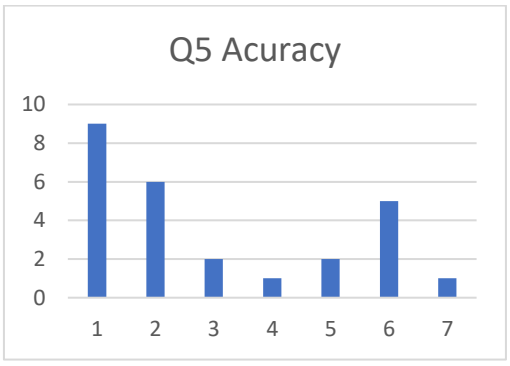


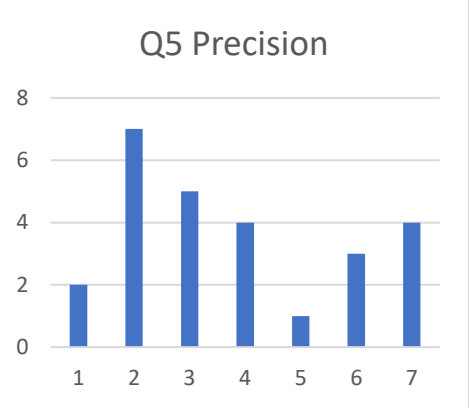






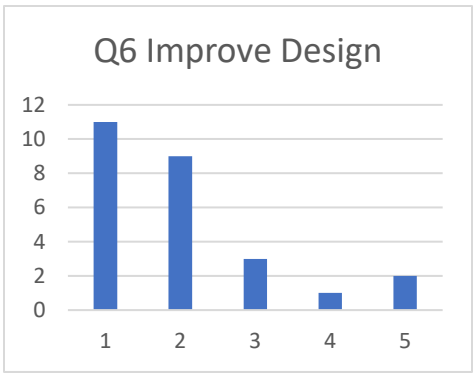


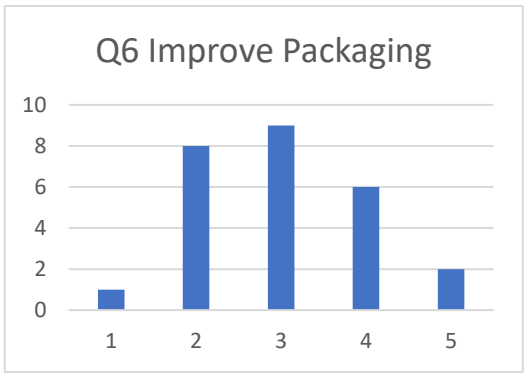


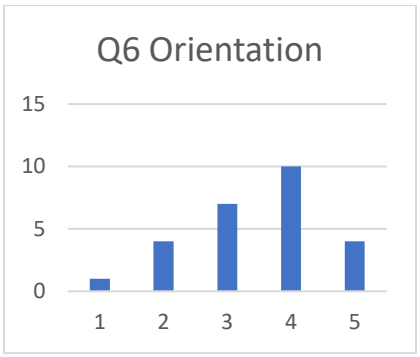


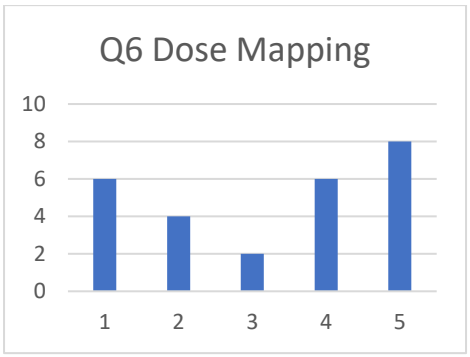
	Weighted Average	Weighted Std Dev	Characteristic
1	2.8	2.43	Cost
2	3.0	2.49	Accuracy of the calculated dose to actual dose
2	3.0	2.74	Ease of Use
4	3.8	1.84	Precision in the calculated dose values
5	4.5	2.06	Simulation speed (i.e., time to a simulated dose map)
6	5.0	4.22	Spatial resolution of the simulated dose map
7	5.8	6.19	Security of CAD model

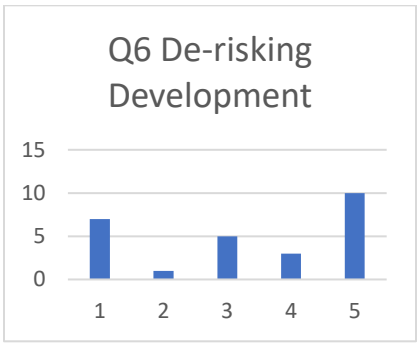
Question 6: Rank the following tasks for modeling software in order of importance:









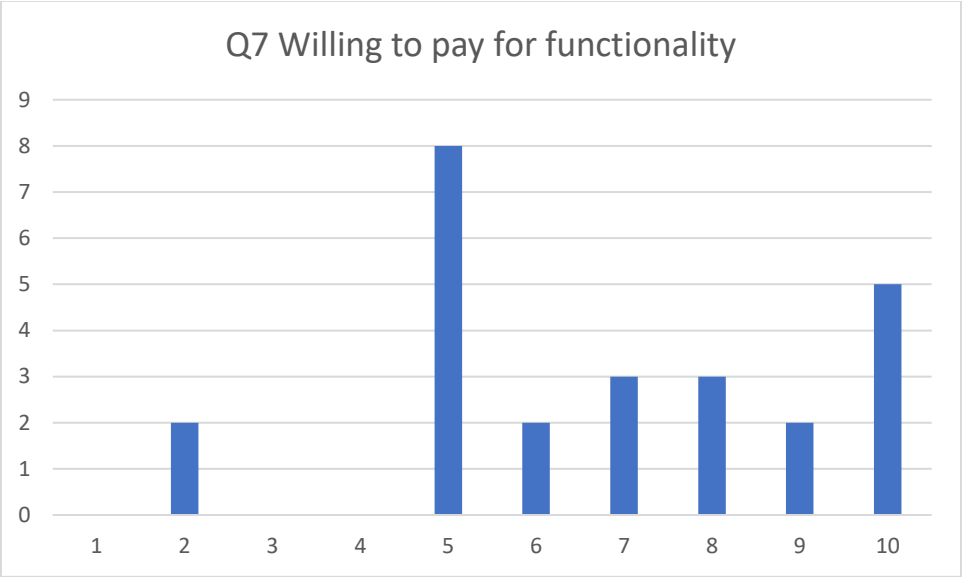


	Weighted Average	Weighted Std Dev	Characteristic
1	2.0	4.31	Improving design for sterilization
2	3.0	4.51	Improving packaging design for sterilization
3	3.2	3.97	Improving dose mapping
4	3.3	5.07	De-risking the product development process for radiation sterilization
5	3.5	4.65	Accelerating identification of orientation to the radiation source

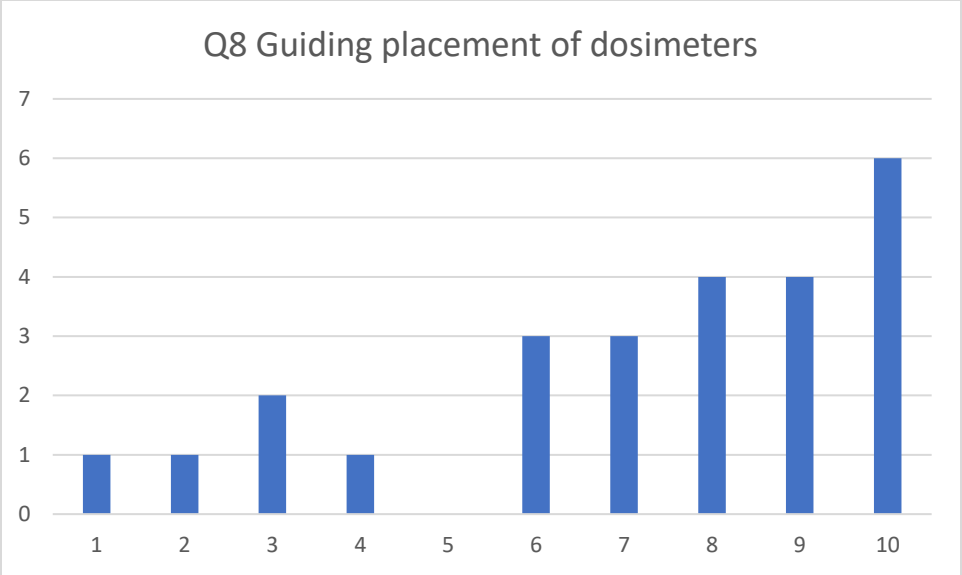
The following questions were asked individually on a scale of 1-10. However, it did appear that the results allowed them to be ranked. The rankings follow the individual results. Note that because the questions asked about the likelihood to pay, the numerical values of the rankings are reversed from the previous rankings.

How willing would you be to pay for the functionality in a radiation sterilization simulation package to perform the following tasks: (Questions 7 – 12)

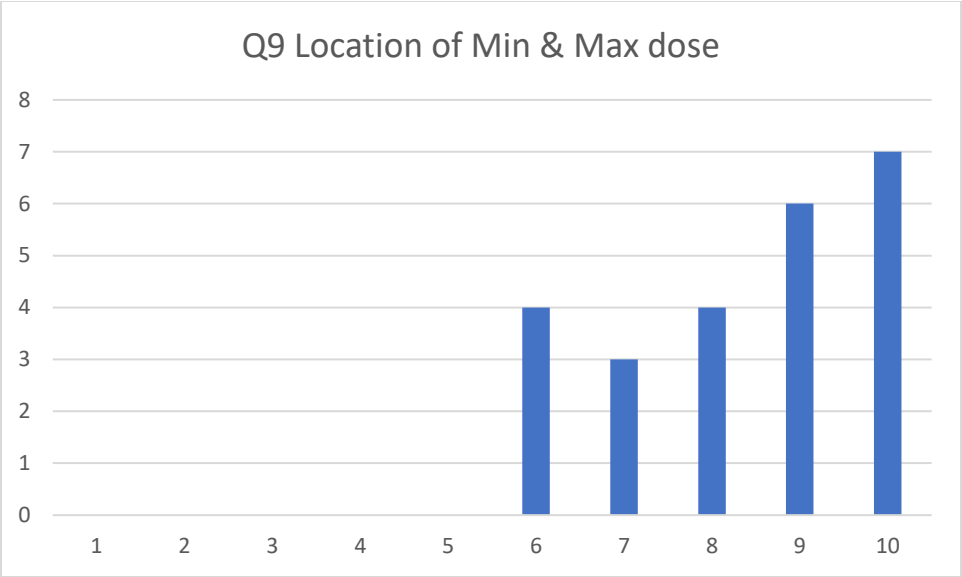
Question 7: *Choosing an appropriate sterilization modality (e-beam, X-ray, or gamma)*



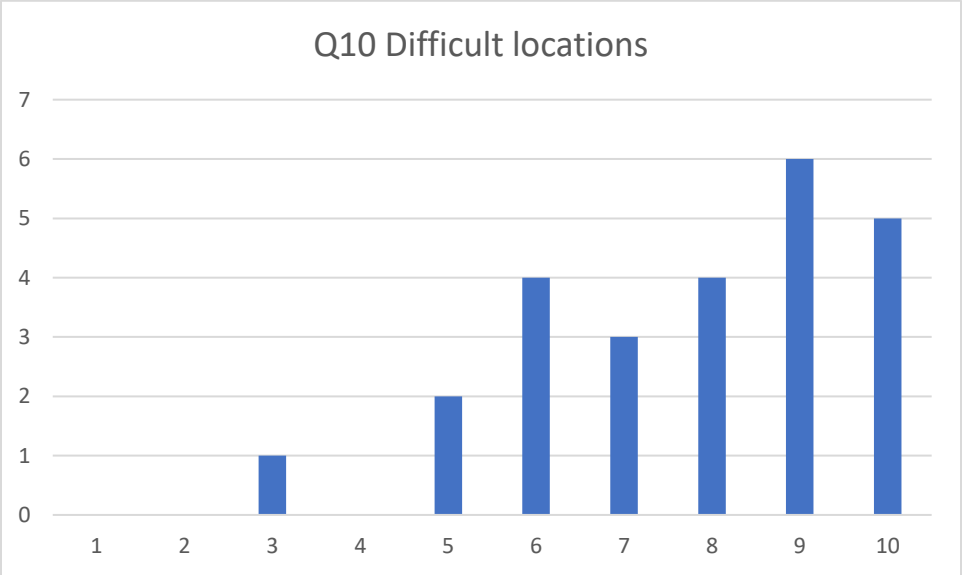
Question 8: *Guiding the placement of dosimeters*



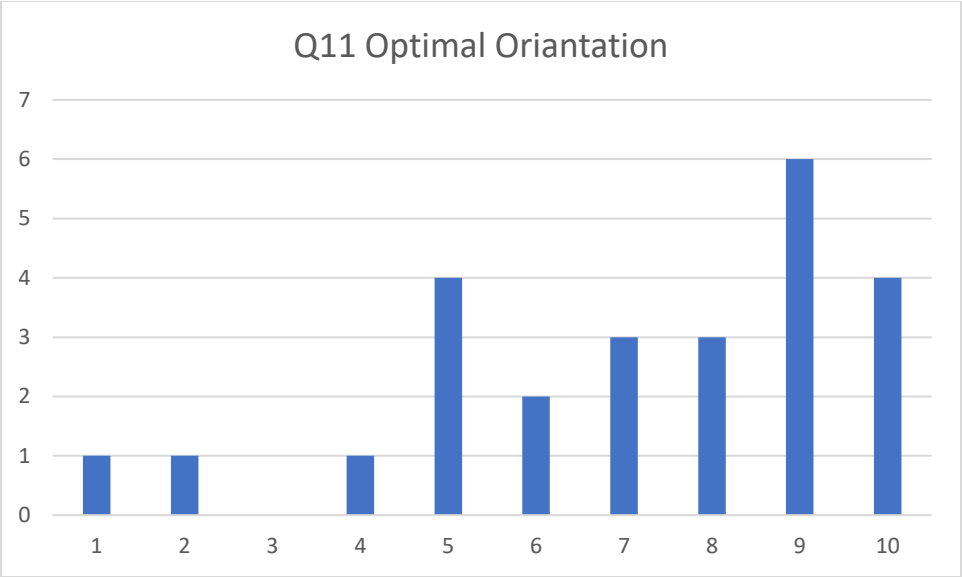
Question 9: *Identifying the location and magnitude of the minimum and maximum dose*



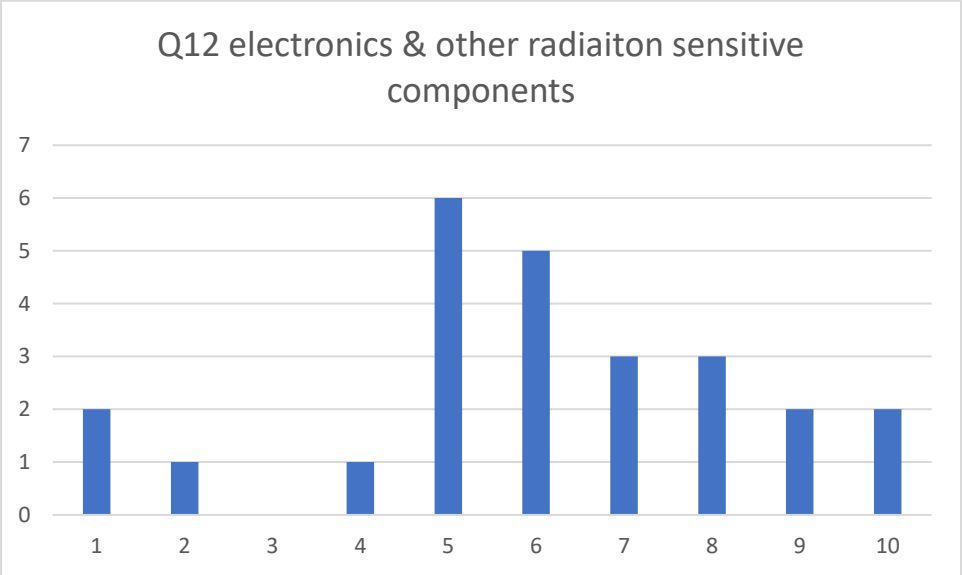
Question 10: *Ensuring that difficult or impossible to access areas receive sufficient dose, e.g., dose to the inside of a needle.*



Question 11: *Choosing the optimal orientation of the device with respect to the beam*



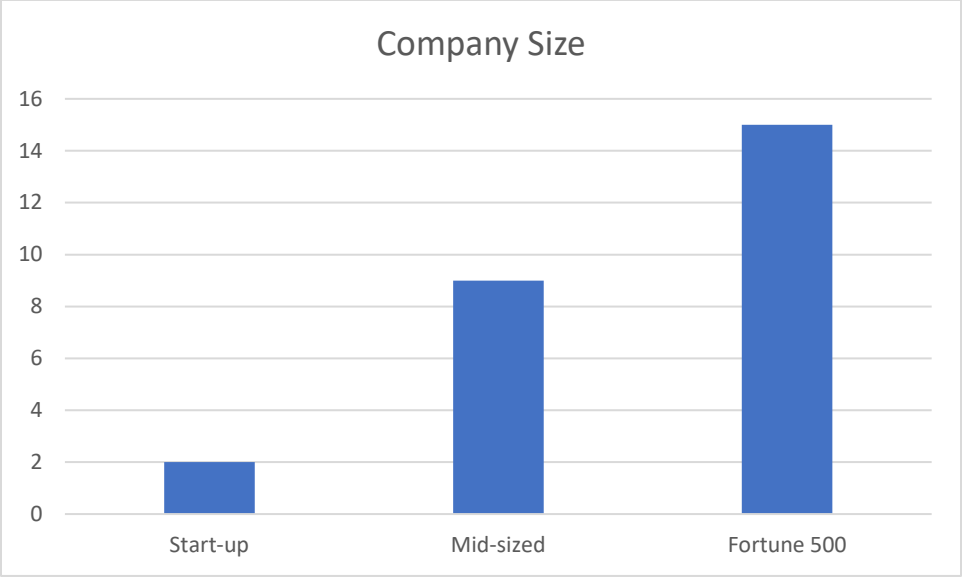
Question 12: *Assessing suitability of radiation sterilization for devices with integrated electronics or other radiation-sensitive components*



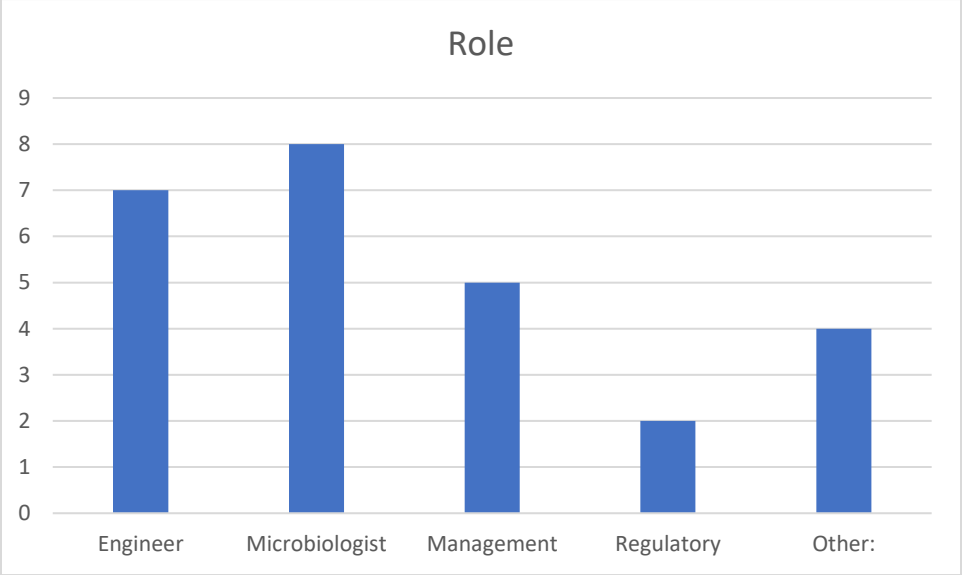
	Weighted Average	Weighted Std Dev	Characteristic
1	8.4	5.95	Identifying the location and magnitude of the minimum and maximum dose
2	7.8	5.13	Ensuring that difficult or impossible to access areas receive sufficient dose, e.g., dose to the inside of a needle.
2	7.2	4.78	Guiding the placement of dosimeters
4	7.1	4.67	Choosing the optimal orientation of the device with respect to the beam
5	6.8	4.72	Choosing an appropriate sterilization modality (e-beam, X-ray, or gamma)
6	6.0	4.04	Assessing suitability of radiation sterilization for devices with integrated electronics or other radiation-sensitive components

The survey concluded with a few demographic questions.

Question 13: *How large is your company?*



Question 14: *What is your role?*



Other: Sterility Assurance, Business Development, Sterilization Manager, Admin-testing.

Question 15: *What would you most want to see out of a modeling software? (or any other comments to make to software developers)*

- Data integrity & GxP Compliance
- The modeling configuration to identify the range of the verification dose and the end product for products that may not be able to handle with an SAL-6.
- Possibility to create a geometry of a product and the constituting material onto which perform a simulation. Performance of dose distribution. A way to perform a sweep such as simulating for various angles/directions for a given product geometry (to find out the best treatment configuration)

- Dose estimates within a device
- evidence that modeling results are representative of what will actually occur when performing dose map with dosimeters
- easy visualizations of likely locations of min and max locations on a device

LIST OF REGISTRANTS

Adams	Dave	Baxter Healthcare
Agarwal	Vartika	Baxter
Ager	Kate	Convatec
allen	curtis	Accelerad Technologies, Inc.
Anibaldi	Patrick	Abbott
Anisko	Stephen	FDA
Arcaraz	Estibaliz	MicroPort CRM
Arts	Isabelle	Baxter
Asbun	Carmen	HHS BARDA ASPR
Badali	Daniel	Triple Ring Technologies
Baker	Peter	Quantum EBX
Barajas	Jose Hugo	BD
Bartoletti	Vincent	Terumo BCT
Blomberg	Max	Meissner Filtration Products
Boentges	Paul	BD
Bollensen	Maria	Colder Products Company
Boneschansker	Jun	Thermo Fisher
Bowen	Joshua	West Pharmaceutical Services
Boyle	Megan	Medtronic
Bozzelli	Kristen	Baxter Healthcare
Bresciani	Giorgia	Copan Italia
Brightwell	Angela	Medtronic
Brodbeck	Bill	STERIS
Brydon	Nicholas	NextBeam
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Chopra	Preeti	Stryker
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Cook	Jeff	Baxter
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Croonenborghs	Bart	Sterigenics
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Diallo	Makhtar	Cytiva
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LeGarda	Mark	Cytiva
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Longhorn	Daniel	Abbott Diabetes Care
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Silverman-Wise	Nan	DOE/NNSA/ORS
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Thompson	Tim	Arthrex
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Tinker	Jared	Mitsubishi Chemical Group
Toufexis	Filippos	TibaRay, Inc.
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Wang	Ping	Jassen R&D
Weimer	Marc	BD
Weitzmann	Carl	Sanofi
Whitaker	Brian	L3Harris
Williams	John	Medtronic
Wojtczak	Daniel	Baxter
Wolinski	Joseph	Baxter Healthcare
Wong	Ken	Sanofi
Wong	Teck Min	Medtronic Inc
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