SfSAP
society for sterility assurance professionals

Pathways to develop expertise in different sterilization modalities by acquiring knowledge, skills, and experiences.

LEARNING FRAMEWORKS AND OUTCOMES

HEALTHCARE PRODUCTS RADIATION STERILIZATION

Version 1 26.3

Healthcare Products Radiation Sterilization Learning Framework

DOCUMENT NUMBER: RHLF001
Revision: 1

MODULE	KNOW What are the topics in this module that I need to know and understand?	APPLY How does an expert use (apply) this knowledge?	EXECUTE What experiences should I have where I can apply this knowledge? (Learn by doing; developing a repertoire of experiences)	DEMONSTRATE How can I demonstrate to an incumbent expert that I have the relevant knowledge and skills?	Competence	
Maximum acceptable dose: ISO 11137 Parts 1, 2 and 3, TS13004, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax, acc) for a product						Acknowledge Competence
Dose Establishment: VDMAX 15 & 25 / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST67						
Performance Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.						
Operational Qualification Requirements: ISO 11137 Part 1, 3, 4 and ISO/ASTM 52303.						
Dose Audit & Dose Augmentation, and routine maintenance/Requalification: ISO 11137 Parts 1 and 2, part 4						
Dosimetry and terminology: ISO/ASTM 52628, E3083						
Dosimetry System Calibration: ISO/ASTM 51261, ISO/ASTM 51707						
Irradiation (technology specific) and terminology: ANSI Category II, III and IV standards. ASTM Gamma, ebeam, Xray documents. IAEA Safety Series 8						
Reading and Handling dosimeters: ISO/ASTM 52628 Used in conjunction with the relevant ISO/ASTM standard that pertains to the dosimetry system being used: ISO/ASTM 51275 (for radiochromic film) ISO/ASTM 51607 (Alanine-EPR Dosimetry System) ISO/ASTM 51650 (Cellulose Triacetate Dosimetry System) ISO/ASTM 51276 (for PMMA) ISO/ASTM 52701 on Influence Quantities ISO/ASTM 51707 on Uncertainties may be adequate in addition to 52628.						
Product Family Adoption: AAMI TIR 35						

Healthcare Products Radiation Sterilization Learning Outcomes

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This document is to use in conjunction the **Medical Device Radiation Sterilization Learning Framework** to define expected learning out come from each of the modules within the curriculum.

For continual development in each of the modules **Further Continual Development learning outcomes** have been suggested.

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Maximum acceptable dose: ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 17, Panel Guide on the establishment of the maximum acceptable dose (Dmax,acc) for a product

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Requirements for determining the maximum acceptable dose including determining sample size, delivering dose(s) to the samples, and use throughout product shelf life after exposure • Requirements for assessing qualification of packaging materials ref ISO 11607 and the medical devices		

Note: there are no fixed standards for how to assess maximum acceptable dose for a device. All the above documents give at guidance on the approaches that might be followed. The precise regimen will depend on the device, its intended use, and the materials used.

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Dose Establishment: VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand the rationale behind each method • Understand the limitations, advantages and disadvantages of each method • How to make the best method selection for your product • How to perform each method including understanding how verification and sterilization doses are calculated • Interpretation of data • How the results translate to routine processing parameters **Further Continual Development learning** • Understand dose distribution limitations on irradiation geometry, and time limitation on dose rates and fractionated doses for media which can support growth • Determine dose targets for different methods in at least ISO 11137 part 2 and ISO TS 13004 • Interpret results (pass/fail) for methods 1 and VDmax; interpret results for methods 2A and 2B Continued on next page		

Healthcare Products Radiation Sterilization Learning Outcomes

Module - CONTINUED

Dose Establishment:
VDMAX / Method 1/ Method 2 ISO 11137 Parts 1 and 2, TS13004, AAMI TIR 40, AAMI TIR 35, AAMI ST 67

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Interpret when bioburden results will guide the user away from VDmax towards Methods 1 or 2 (i.e. interpret probability of survival at very low or very high bioburden) • Understand the requirements for dose establishment based on standard distribution of resistances for bioburden numbers in Method 1, actual bioburden resistance for Method 2, VDmax and substantiation of a selected dose for VDmaxSD. • Requirements to use TIR40 to perform a reduced incremental dosing for Method 2 • Requirements for TIR35 to perform a product adoption or reduced sample sizes for dose audits and dose verifications		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Performance Qualification Requirements: ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understanding the requirements of performance qualification for a product • Interpretation of the standard requirements • Translating that interpretation into your specific process requirements • Understand orientation or configuration on the impact of product fill • Understand the elements that need to be covered during PQ • How to select representative products/processing categories • Importance of traceability • Importance and impact of uncertainty • How to create the mapping grid for your container and process • Consideration of centre plane mapping • How to determine the type, number and spacing of dosimeters • Analysis of results and comparison to previous data Continued on next page		

Healthcare Products Radiation Sterilization Learning Outcomes

Module - CONTINUED

Performance Qualification Requirements:
ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
Further Continual Development learning • Understand how different materials and distributions of materials are likely to affect local dose distributions in materials: Voids, boundaries • Understand different dosimeter systems and their advantages / disadvantages in terms of obtaining a measurement of dose to water on or in a product • Maintaining traceability in dose measurements on real product devices • Interpretation of dose map results, identification of minimum and maximum doses and their statistical or other relationships to monitored quantities including routine monitor dose • Derivation of routine processing conditions and target routine monitor dose values • Interpretation of process capability, and actions taken when the process does not work, i.e. when Dmax(target) < Dmin(target) • Ongoing assessments, such as of cumulative minor changes to products: When is a new PQ required • Processing category		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Operational Qualification Requirements: ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understanding the requirements for operational qualification of an e-beam, x-ray and gamma irradiator • Interpretation of the standard requirements • Translating that interpretation into your specific process requirements • Determine the extremes of density for your process • Understand carrier fill and selection of dunnage • Understand the elements that need to be covered during OQ • Assessment and application of ancillary studies such as transitioning and process interruption • Importance of traceability • Importance and impact of uncertainty • How to create the mapping grid for your container and process • How to determine the type, number and spacing of dosimeters • Analysis of results and comparison to previous data • Equivalency Continued on next page		

Healthcare Products Radiation Sterilization Learning Outcomes

Module - CONTINUED

Operational Qualification Requirements:
ISO 11137 Part 1, 3, and 4, ISO/ASTM 51608, 51649, 51702, 52628 and 52303.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
Further Continual Development learning • (For electron) Beam width; spot size; depth-dose measurements (for energy); trip effects • (For gamma) Dwell times; source transit time effects • Understand likely dose distributions in loads comprising different density materials in different types of irradiators (e-beam / gamma / X-ray / Low Energy electrons) • Construction of dosimeter placement map (or grid) based on that understanding • Interpretation of the results in terms of routine processing capabilities, and components of uncertainty and variability		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Dose Audit & Dose Augmentation, and routine maintenance/Requalification: ISO 11137 Parts 1 and 2, part 4

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• How to follow the comprehensive steps detailed in ISO 11137-2 • Understand the relationship and potential limitation of the original Dose Establishment method • Frequency of Sterilization Dose Audits based on Dose Establishment method and bioburden level • Reaction to failure and how to manage the outcomes of these studies • Impact of radiation resistant organisms • Importance of trend analysis and annual review. • Understand the requirements for conducting dose audits, • Understand the requirements for conducting dose augmentation. • Understand the requirements for investigation and risk assessments **Further Continual Development Learning** • Interpretation of bioburden fluctuations • Interpretation of pass/fail on dose audit • Actions that might be considered…		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Dosimetry and terminology: ISO/ASTM 52628, 52701, 51707 and ASTM E3083

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand the different dosimeter types and working ranges • Understand terminology Dose, Kilogray, Mega Rads, Dmin, Dmax , Afmin, AFmax Dref, (AFmin)corr, (AFmax)corr etc. • Understand how to read and interpret the dosimetry data. • Understand influence quantities of the dosimetry systems **Further Continual Development Learning** • Choice of dosimeters • Physical or chemical effects used as dosimeter response / indication • Dose to water against dose to other materials • Traceability • Impact of Influence quantities on process outcome		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Dosimetry System Calibration: ISO/ASTM 51261

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Options and selection of an appropriate dosimetry system • Understand the options and selection of the calibration approach • How to perform the calibration and create the calibration curve • How to calculate the uncertainty budget • Data analysis, interpretation of data and reaction • Understand and perform system checks, verification of the calibration curve **Further Continual Development Learning** • Expected range to be calibrated; dose points chosen; measurements per dose point • Limits imposed by physical or chemical effects • Effect of influence quantities • Correction factors, or components of uncertainty budget? • In-plant or laboratory; calibration verification • Measured response as a function of known dose, and invert • Choices of mathematical fitting functions • Degrees of freedom • Weighted or unweighted fits • Acceptance criteria		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Irradiation (technology specific) and terminology: ANSI Category II, III and IV standards. ISO/ASTM 51608, 51649, 51702 and 51818. IAEA Safety Series 8.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand the principles with regards to technology specific radiation processing • Understand the terminology eg Photons, Electrons, Beta, Gamma etc, with regards to technology specific radiation processing **Further Continual Development Learning** • Differences between different types of irradiator • Shielding and safety; ozone and other gases; induced activity • Temperature effects: Radiation-induced temperature rises and heat transfers • Dose rates, fractionation		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Reading and Handling dosimeters: ISO/ASTM 52628 ISO/ASTM 51275 (for radiochromic film) ISO/ASTM 51276 (for PMMA) ISO/ASTM 51607 (Alanine-EPR Dosimetry System) ISO/ASTM 51650 (Cellulose Triacetate Dosimetry System) may be adequate in addition to 52628.

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Understand the requirements regarding selecting the type of dosimeters • Understand the correct use of the type of dosimeters. • Understand process and options • Importance of dosimetry placement – location and frequency • Traceability • Re-read process and rationale to support it. • Uncertainty allowance/correction • Storage of dosimeters – potential impact of temperature, humidity, light etc		

Healthcare Products Radiation Sterilization Learning Outcomes

Module
Product Family Adoption: AAMI TIR 35

Learning Outcome (what person should be able to do with the knowledge and skills)	Outcome met? Y/N	Comment
• Interpretation of the standard requirements • Translating that interpretation into your specific product array • Assessment considerations • Understand the rationale behind family definition • Understand the requirements for establishing product families		