TIR – 104 Case Study

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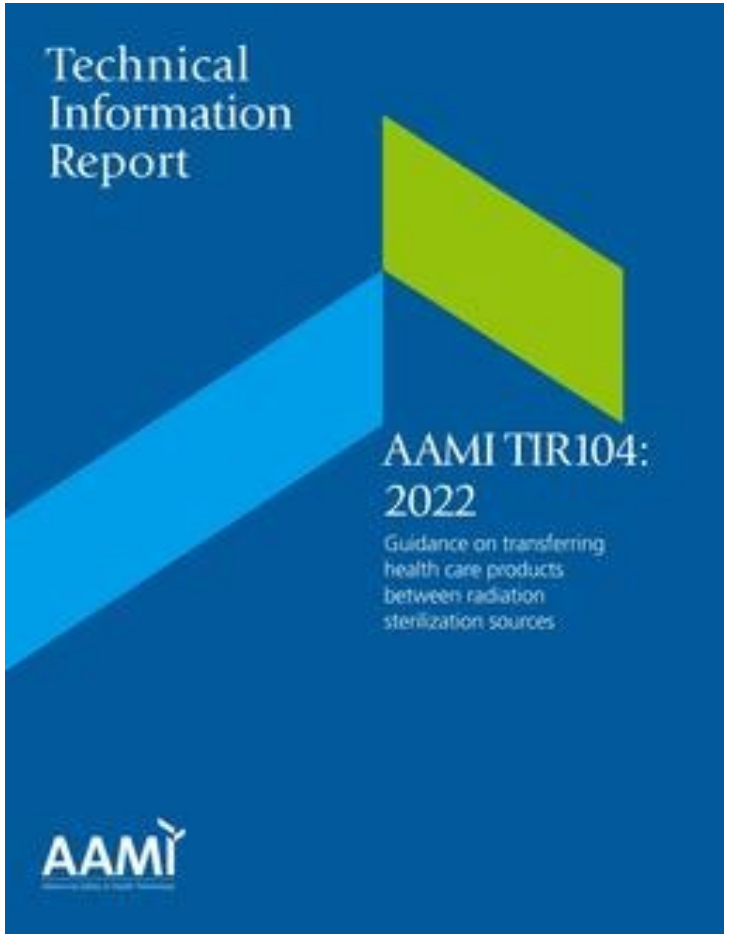
Agenda

- What is TIR – 104
- Transfer Workflow Outline in TIR – 104
- Case Study Overview
- Case Study Work Through of TIR – 104
  - Evaluate Irradiator Dose Delivery Characteristics
  - PQ Dose Mapping
  - Evaluate Sterilization Dose Transfer
  - Max Dose Transfer
  - Summary
- Questions

What is TIR - 104

- AAMI TIR 104:2022
- Guidance document for managing the transfer of a health care products sterilized by ionizing radiation from one radiation modality to another or from one irradiator to another
- Latest version released in 2022 after a substantial revisions and updates
- Designed outcomes following TIR – 104
  - Can a product be processed at the candidate irradiator
  - Rational for transferring or reestablishing verification dose
  - Rational for transferring or reestablishing maximum dose



Transfer Workflow Outlined in TIR - 104

Evaluation of Process Capability

Evaluate Irradiator Dose Delivery Characteristics

- Source Product Geometry
- DUR as a function of density
- Homogeneities in product
- Radiation source energy
- Product Orientation
- Irradiation container size and fill efficiency
- Product transition effects

PQ Dose Mapping

- Following dose delivery characteristics assessment conduct dose mapping to confirm process capabilities

Evaluation of Transferring Sterilization and Verification Doses

Evaluate Irradiator Dose Delivery Characteristics

- Determine if product contains water or supports microbial growth
- Develop rationale for sterilization dose transfer or reestablishment

Max Dose Transfer

- Energy – related induced radioactivity
- Product temperature and other secondary exposures
- Dose rate

Documentation Requirements

Documents That Should Be Included in Transfer Report

- Product Identification or description
- Type of doses being transferred
- Irradiator description
- Description of effect on microbial efficacy of dose delivered
- Description of material / product changes caused by transfer
- Test results / data packet
- Conclusion and rationale for accepting / declining transfer

Case Study Overview

Proposal:

The transfer of a product that is currently sterilized in a 4 MCi Cobalt 60 chamber to a 10 MeV Electron Beam following TIR – 104 guidance

Product Overview

Dimensions (cm)

54.5 L x 31.7 W x 19.2 H

Weight (kg)

4.5

Contains water or supports microbial growth

No

Materials

PP, HDPE, Silicon Oil

Sterilization Overview

Current Modality

Source	Gamma
Energy	1.17 & 1.33 MeV
Power	4 MCi

Proposed Transfer

Source	Electron Beam
Energy	10 MeV
Power	15 kW
Dose Rate	3kGy / Sec

Evaluate Irradiator Dose Delivery Characteristics

Characteristics to Evaluate:

- Source Product Geometry
- DUR as a function of density
- Homogeneities in product
- Radiation source energy
- Product Orientation
- Irradiation container size and fill efficiency
- Product transition effects

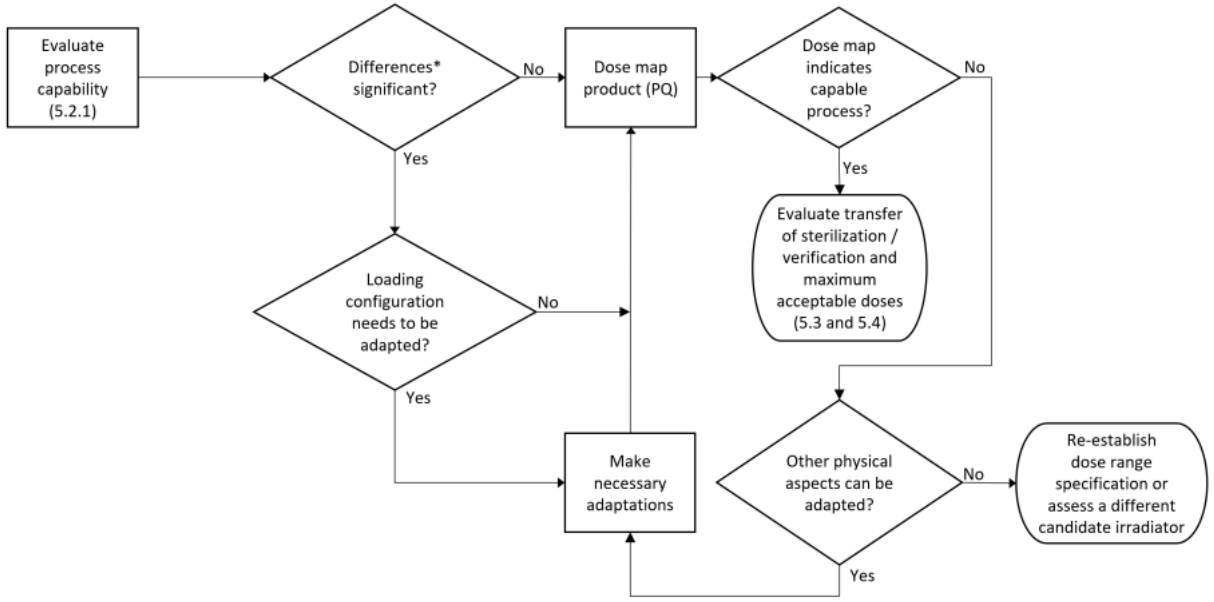


Figure 1 – Flow Chart for evaluation of process capabilities in transferring products between irradiators, AAMI TIR – 104:2022

Evaluate Irradiator Dose Delivery Characteristics

Source of Product Geometry:

Comparison - Gamma facility utilizes hanging carrier configurations, electron Beam facility utilizes conveyor tote material handling system. (Differences Significant)

TIR Recommendation – Due to a change in the geometrical arrangement between the radiation source and the irradiated product that is caused by transferring the product from a conveyor to a tote system a dose map should be preformed to inkstand the effects on the DUR of the product

DUR as a function of density:

Comparison – Gamma sterilization has a much higher penetration capability and can process high density products when compared to Electron Beam. (Differences Significant)

TIR Recommendation – Due to a change in the source of radiation from Gamma to eBeam previous OQ or PQ data will not be sufficient for determining if acceptable DUR can be achieved and a dose map is required

Additional Recommendation – We use aerial density calculations to aid in failure risk reduction and determine if Electron Beam sterilization can be ruled out as a feasible options early in testing

Homogeneities in product:

Comparison – Gamma sterilization has a much higher penetration capability and its DUR produced is less effected by density variations within a product when compared to Electron Beam (Differences Significant)

TIR Recommendation – Due to a reduced ability to produced a uniform dose in products with non-homogenous densities a more sensitive dose map is required to rule out attenuation or shadowing when transferring to Electron Beam

Product Orientation:

Comparison – Gamma sterilization and Electron Beam have different material handling system and could result in a change in the orientation of the product to the beam. (Differences Significant)

TIR Recommendation – Due to a change in the products orientation to the source when transferring to Electron Beam a dose map is required to ensure an acceptable DUR

Additional recommendation – Dose Mapping studies are preformed with Electron Beam investigating every possible orientation that fits within the material handling system to allow for operational optimization or changes if needed

Evaluate Irradiator Dose Delivery Characteristics

Irradiation container size and fill efficiency:

Comparison – Electron Beam carries that will be used are different in volume from the Gamma carriers and can be partially filled. (Differences Significant)
TIR Recommendation – Dose maps are required at the different container fill levels to understand any potential changes in the DUR that might occur

Product Transition Effects

Comparison – Electron Beam will not have transition effects that need to be evaluated
TIR Recommendation – No testing required

Radiation source energy:

Comparison – Gamma energy 1.17 and 1.33 MeV, Electron Beam energy 10 MeV. Also will be transferring from photon to electron particles. (Differences Significant)
TIR Recommendation – Due to a significant change in the energies and particle type a dose map is required

Evaluate Irradiator Dose Delivery Characteristics and PQ Dose Mapping

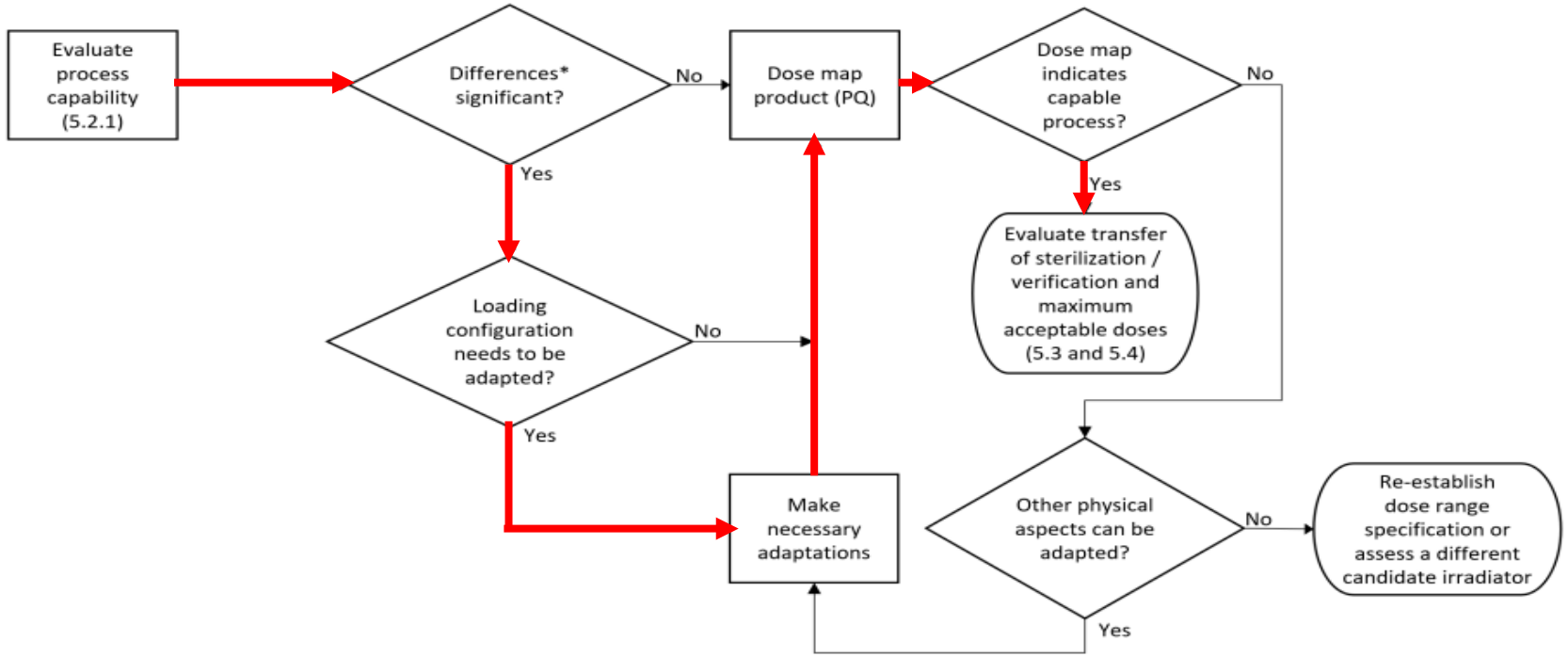


Figure 1 – Flow Chart for evaluation of process capabilities in transferring products between irradiators, AAMI TIR – 104:2022

Evaluate Sterilization Dose Transfer

Characteristics to Evaluate:

- Dose product contain water or support microbial growth
  - No
  - If the product did contain water or support microbial growth, then a verification dose experiment would be required since we are transferring a product from Gamma to Electron Beam
- Are we changing modalities
  - Yes
  - Peer reviewed literature exist showing that the D10 values are consistent across all radiation modalities when

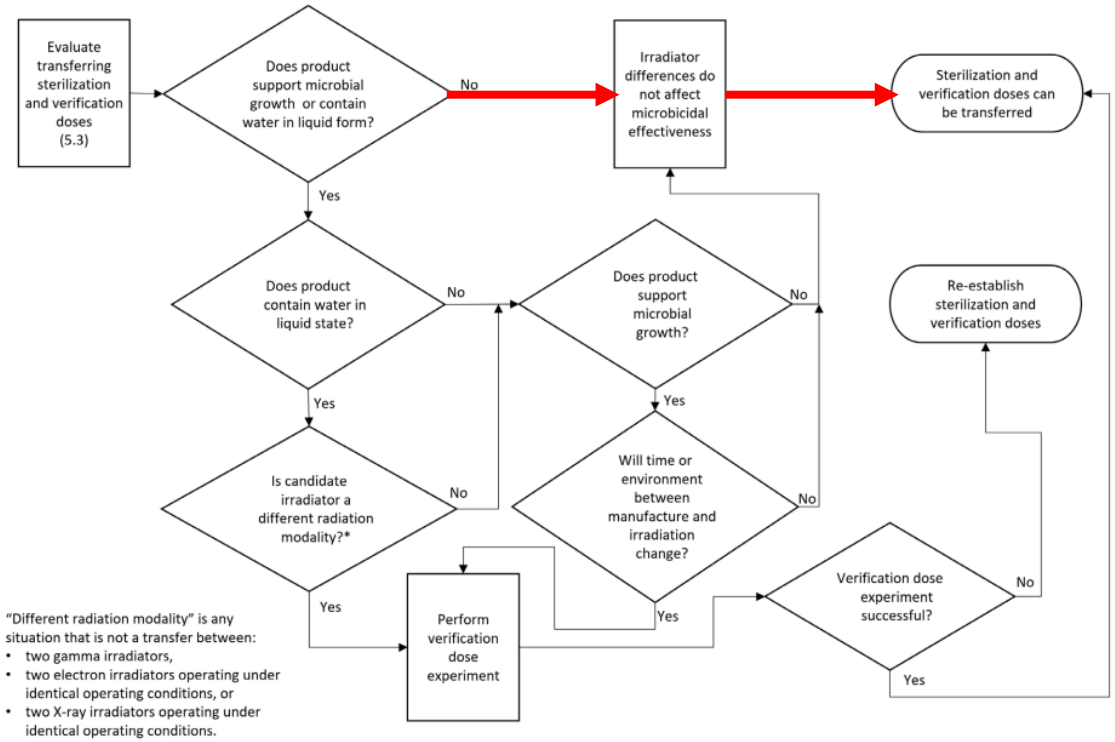


Figure 2 – Flow Chart for evaluation of transferring sterilization verification doses when transferring products between irradiators, AAMI TIR – 104:2022

Evaluate Max Dose Transfer

Characteristics to Evaluate:

- Dose Rate
  - Equivalent dose rates
    - No, electron beam 1000+ greater
  - Testing was required to determine if degradation was less than or equal to gamma
- Temperature
  - Temperature exposure changes between modalities
    - Yes
  - Electron Beam exposes products to elevated temperature for shorter durations but delivers temperature change instantly
  - Testing was required to determine if degradation was equal to or less that gamma
- Induced Radioactivity
  - Is Electron Beam energy above 10 MeV
    - No
  - No additional testing required

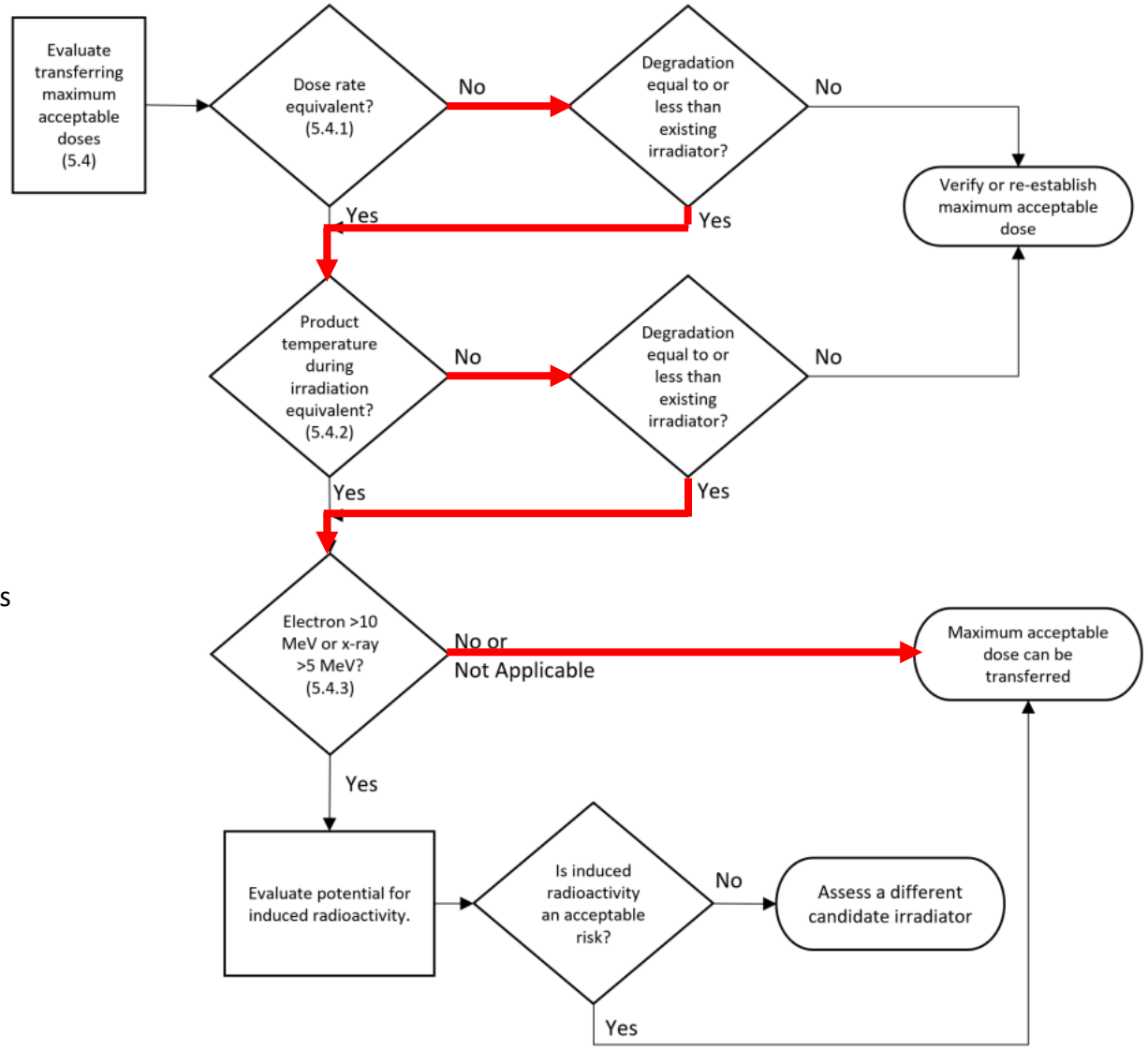


Figure 3 – Flow Chart for evaluation of transferring maximum acceptable dose in transferring product between irradiators, AAMI TIR – 104:2022

Questions?

Input your questions for speakers at any time via the Q&A function at the bottom of your screen: