Changing Radiation Modalities or Sites in Radiation Processing: Issues and Guidance

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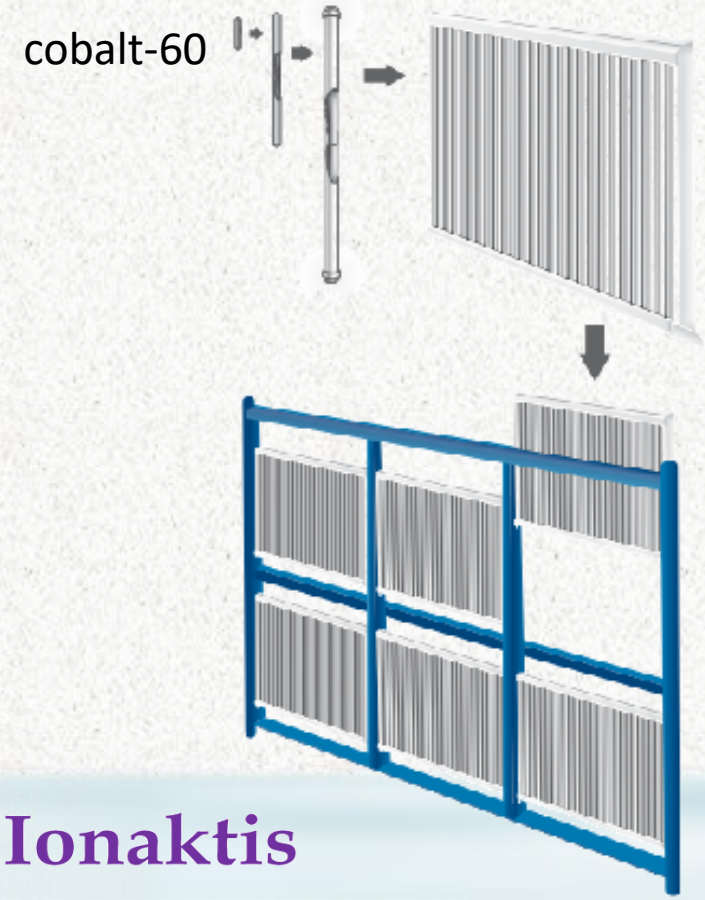
Contents of Presentation

- Different radiation types may create differences in effects for some irradiated products
- Potential differences must be assessed in moving products from one irradiator to another
- A guidance document for doing so was published in 2022 for radiation sterilization of health care products

BACKGROUND INFORMATION

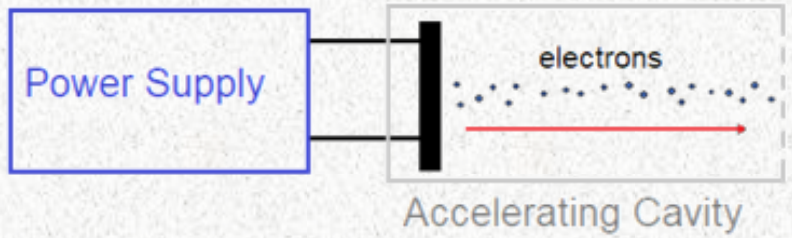
Ionizing Radiation Used in Sterilization

Gamma radiation from nuclear reaction

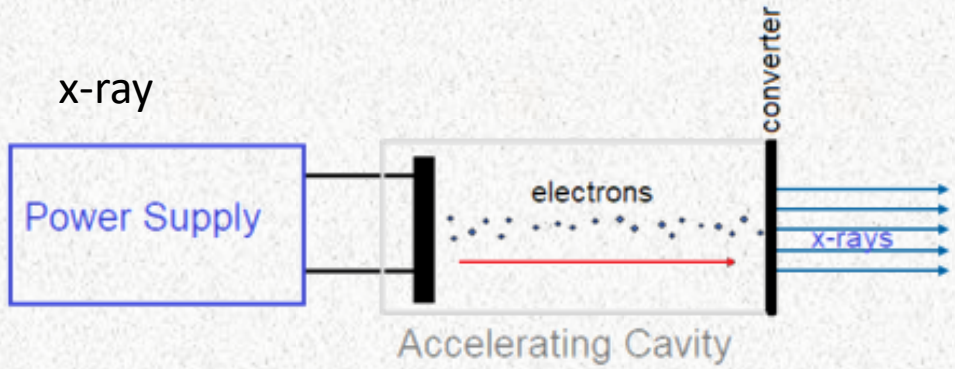


Machine-produced accelerated electrons

e-beam



x-ray



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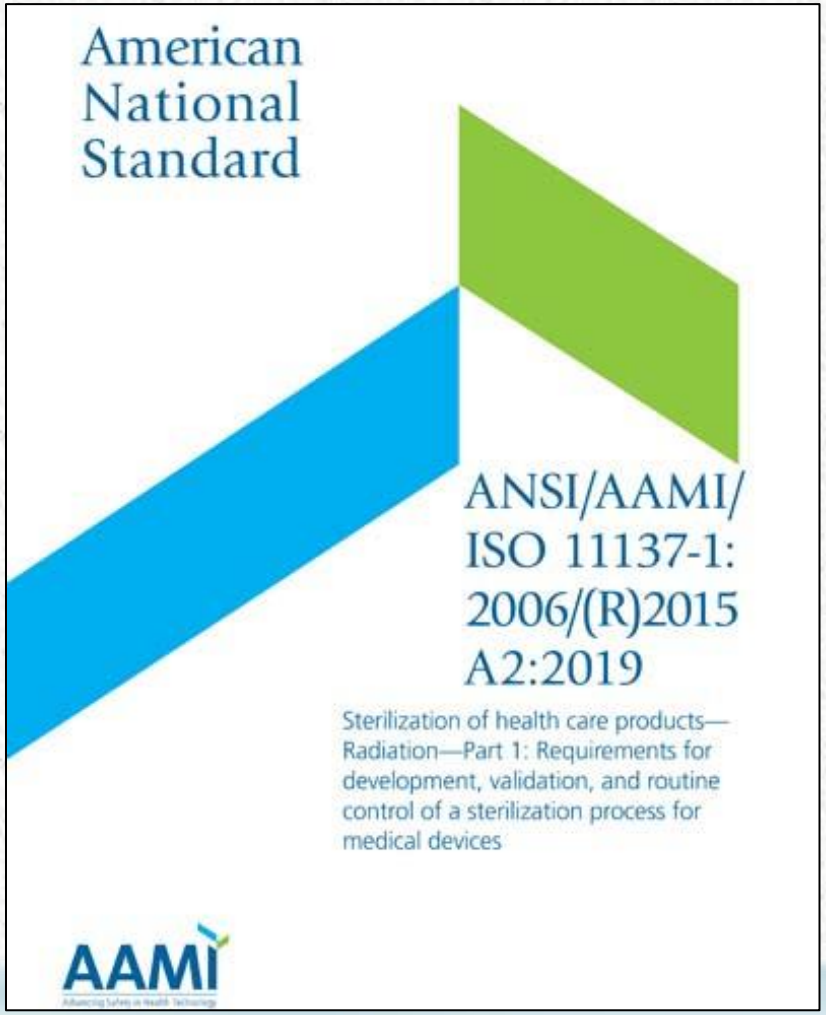
BACKGROUND INFORMATION

Association for Advancement of Medical Instrumentation (AAMI)

- Publisher of
  - Radiation sterilization standard ISO-11137 (multiple parts)
  - Technical Information Reports (TIRs) for guidance and interpretation of standards



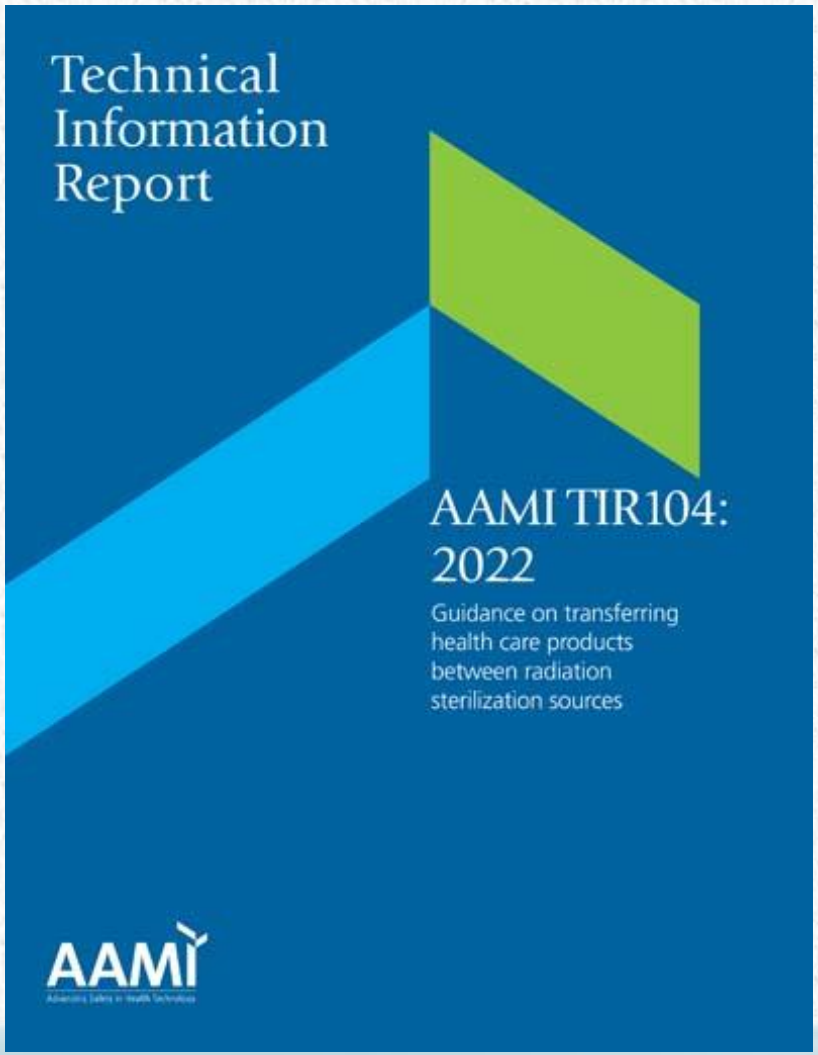
BACKGROUND INFORMATION

Terminology

Sterility Assurance Level (SAL)	Related to the probability of single viable microorganism occurring after sterilization
Sterility Dose	Dose necessary to achieve SAL
Verification Dose	Dose below sterility dose used for process verification
Maximum Acceptable Dose	Highest dose that results in acceptable degree of radiation degradation

TIR-104: Guidance on transferring health care products between radiation sterilization sources

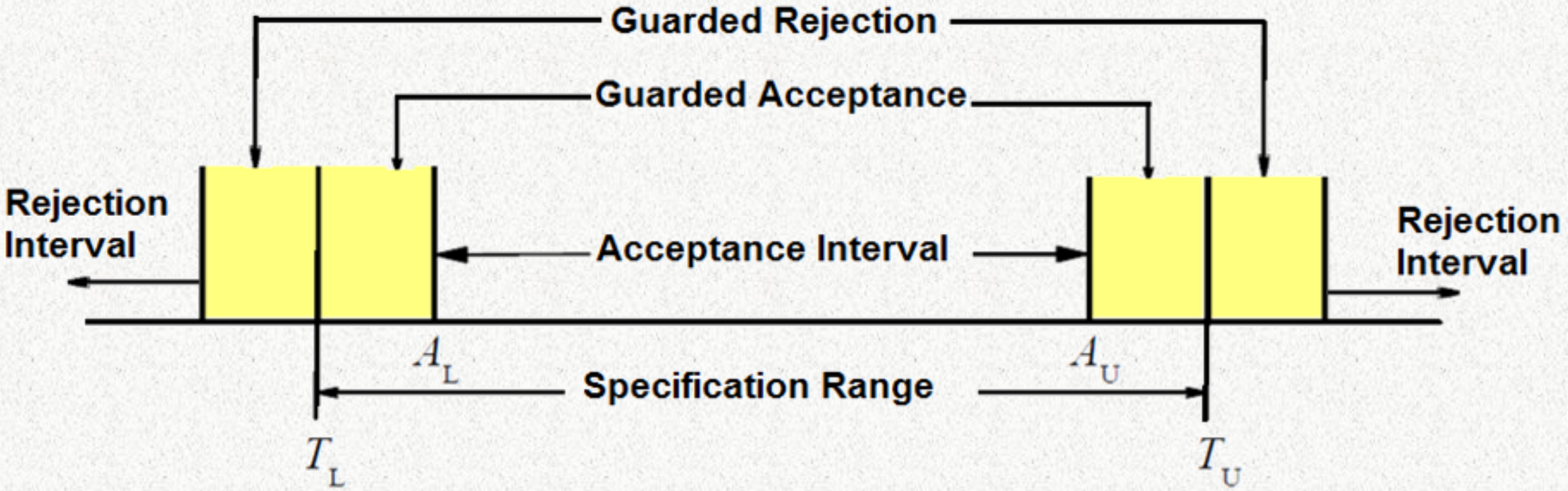
- Guidelines for products transferred between radiation sites
  - assessment of change;
  - evaluation of differences between radiation sources;
  - assessment of sterilization and verification dose; and
  - assessment of maximum acceptable dose



Assessment of Change

Fundamental question:

Does product fit the acceptance interval at the new irradiator?



Adapted from JCGM 106:2012 Evaluation of measurement data – The role of measurement uncertainty in conformity assessment

Step 1: Evaluate Process Capability

Is it possible to irradiate the product at the new irradiator?

- Is the box too big or too small?
- Will the product fit into the schedule?

  mostly relevant to gamma
- Does the achievable maximum-to-minimum dose ratio match current product specifications?
- How difficult will it be to transport the product to the irradiator?

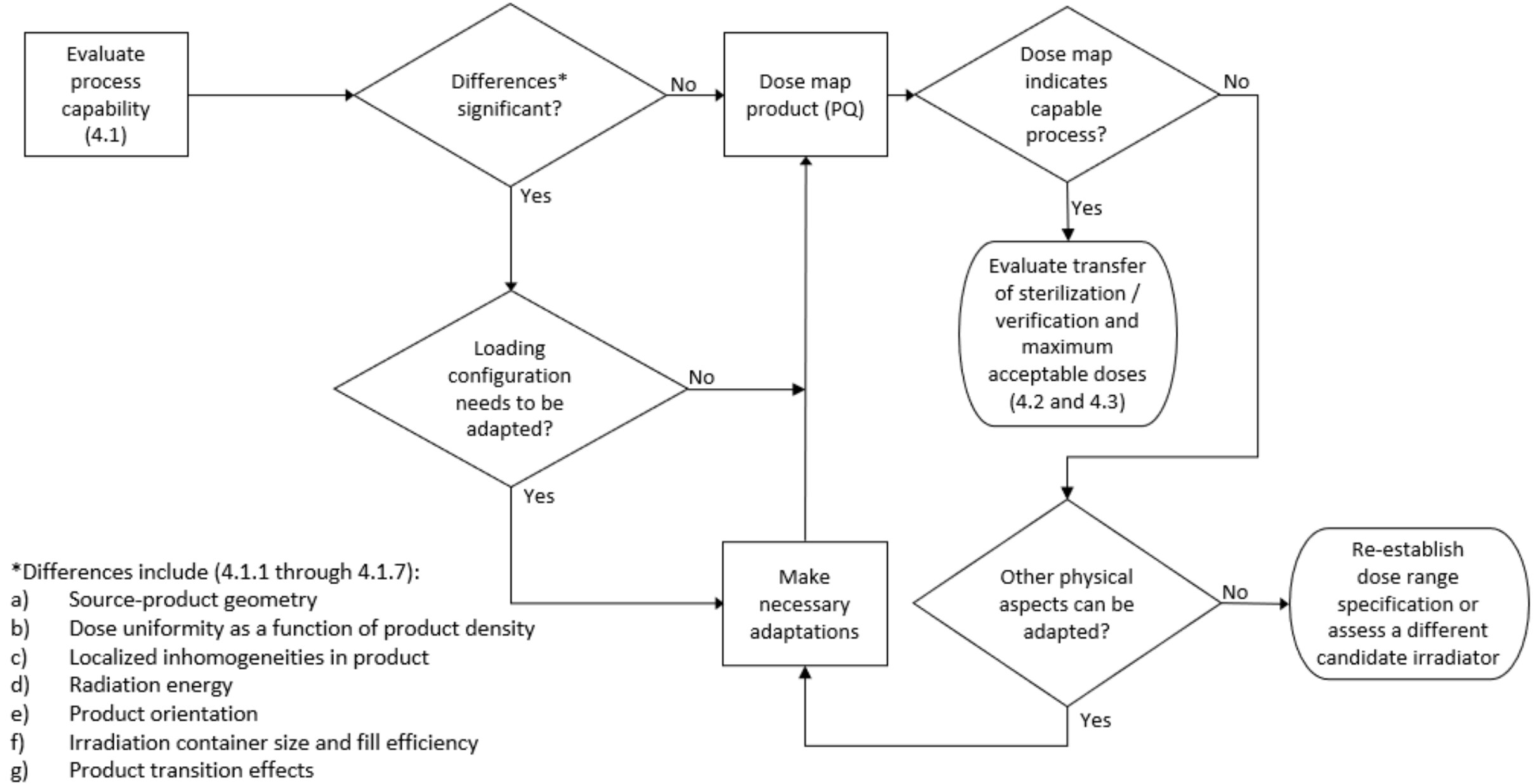
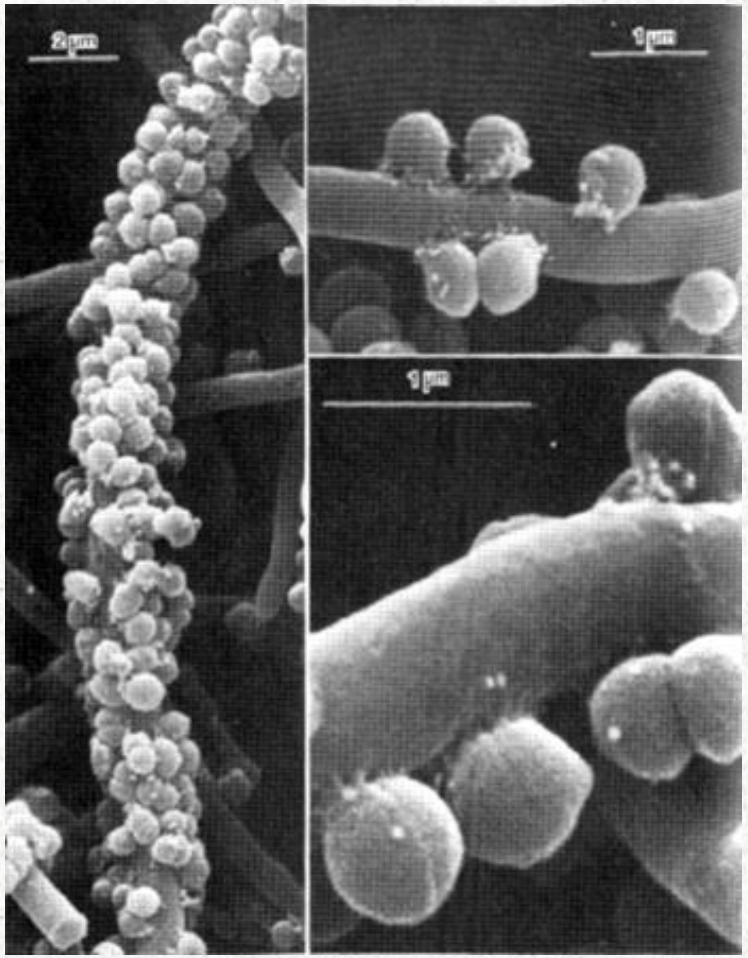


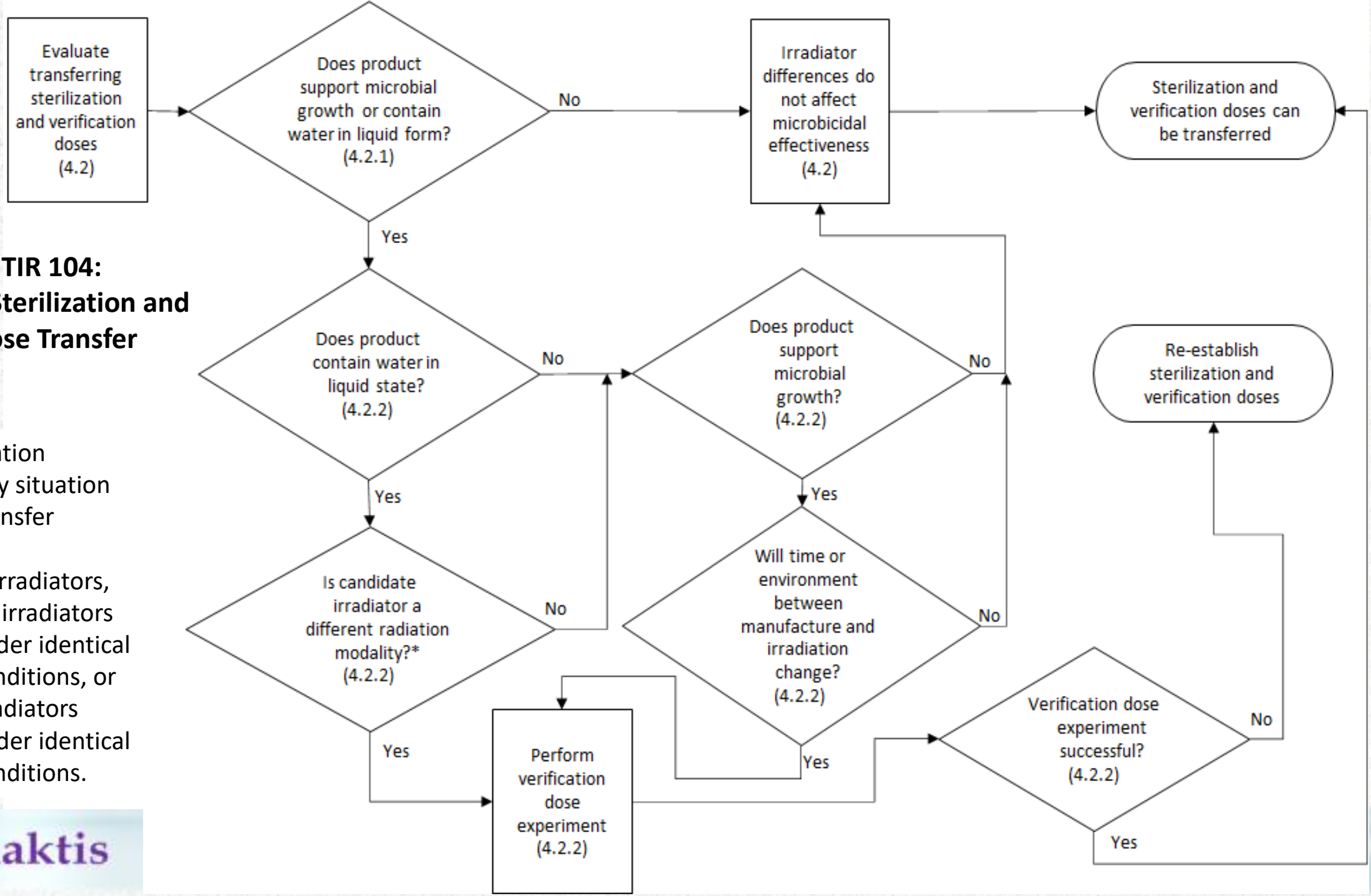
Figure 1 AAMI TIR 104: Evaluation of Process Capability

Step 2: Evaluate Transfer of Sterilization and Verification Doses



- Sterilization dose is based on bioburden of specific product
  - Characterization of microbiological content is first part
  - Various methods are used to establish and verify required dose to achieve SAL

Figure 2 AAMI TIR 104: Evaluation of Sterilization and Verification Dose Transfer



"Different radiation modality" is any situation that is not a transfer between:

- two gamma irradiators,
- two electron irradiators operating under identical operating conditions, or
- two X-ray irradiators operating under identical operating conditions.

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Step 3: Evaluate Transfer of Maximum Acceptable Dose

- Irradiation causes chemical and/or physical changes that may be detrimental to the product
  - Polymer
  - Glass or ceramic
  - Metal
- Different types of radiation can cause different effects or a different degree of same effect

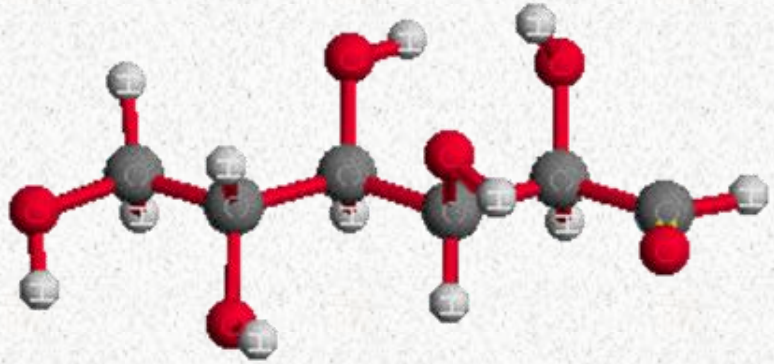
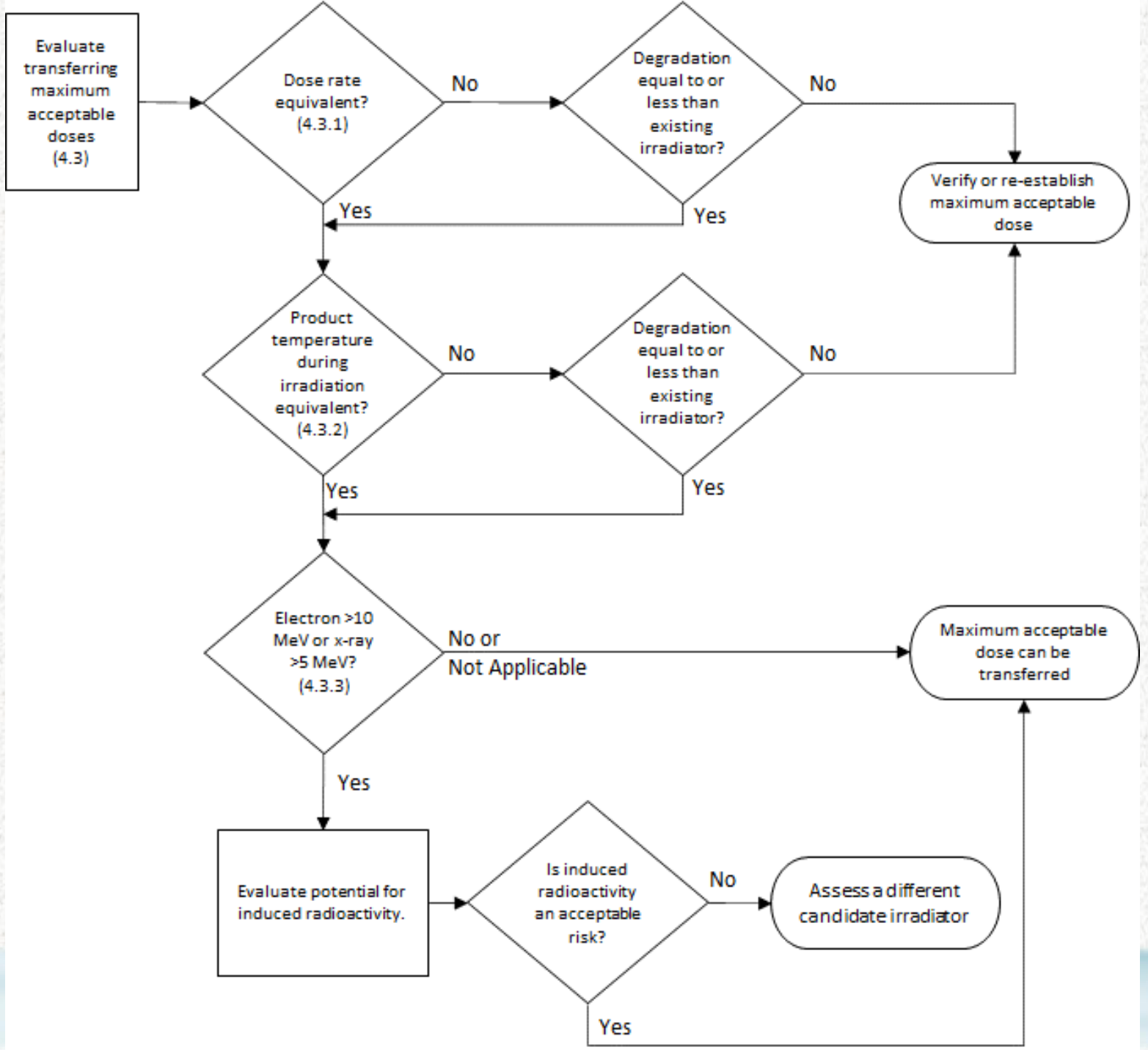


Figure 3 AAMI TIR 104: Evaluation of Maximum Acceptable Dose Transfer



Ongoing Programs

- Published reports (Fermi Lab, IAEA): significant impediments in data and education for transition from cobalt-60 and ethylene oxide (at or very near capacity throughout industry) to e-beam and/or x-ray
- Ongoing collaborative studies with national laboratories, equipment manufacturers, irradiator operators, and academia are addressing data gaps

Ongoing Programs

- Some assumptions in ISO-11137-1 regarding microbicidal efficacy (e.g., presence of water) are being evaluated during revision of the standard
- Ongoing studies and product evaluations are in process for assessing induced radioactivity with higher energy e-beam and x-ray

So, Now What?

- A guidance document exists for evaluating healthcare product transfer between radiation sterilization modalities and sites
- Guidelines do not address every eventuality

  (i.e., unexpected things can happen sometimes)
- Nothing has specifically addressed similar concerns for nonmedical applications
- As any researcher with a grant would say, “Further studies are warranted.”