TECHTIP

TRANSFER OF IONIZING RADIATION TECHNOLOGIES FOR MEDICAL DEVICES BASED ON GUIDANCE IN ISO 11137-1, ISO 13004, AND AAMI TIR 104

Transferring radiation sources can include either a change in facility location using the same technology or a technology transfer (such as gamma to E-beam or X-ray). This TechTip will address transfer types and areas of consideration. Considerations should also be given to specific product requirements and registrations, as the information provided is based primarily on guidance in ISO 11137 and may not cover all the requirements and registrations specific to a manufactured product.

Considerations when transferring radiation technologies and/or processing locations

Dose rate

Exposure time should be considered when making a radiation technology transfer and a comparison of dose rate per ionizing radiation technology is outline below:

- Gamma irradiation delivers kGy per hour (considered slow/gradual)
- E-beam irradiation delivers kGy per second (considered fast/rapid)
- X-ray irradiation delivers kGy per hour (considered intermediate, but significantly faster than gamma irradiation due to accelerator technology)

Temperature effects

Temperature effects should be considered when making a radiation technology transfer. Many product materials have more specific heat requirements (such as those of polymeric material properties) and may retain more heat than other materials used. Since dose rates change, ISO 11137-1 suggests that consideration be given to the effect, if any, of temperature change in processing (ISO 111371 A8.4.1.) and a comparison of dose rate per ionizing radiation technologies is outline below:

- Gamma irradiation temperature is dependent on Cobalt activity. The typical maximum temperature range is 45 to 50°C
- E-beam irradiation temperature is dependent on power of machine. The typical maximum temperature is 50°C
- X-ray irradiation temperature is dependent on power and design of machine. The typical maximum temperature range is 35 to 40°C

Location of processing

Time and environment between manufacturing and sterilization facility location should be considered when transferring location of processing. This change could affect the microbial growth on or in a product.

When a product is capable of supporting microbial growth between manufacturing and sterilization, additional microbial growth should be considered, and variables promoting growth during shipment should be identified and kept in control.

If the time between manufacturing and sterilization changes when the processing location changes, a verification dose can be used to demonstrate that the verification dose may be transferred to the new location and does not alter the microbial effectiveness of the manufactured product (AAMI TIR 104 Clause 5.3.1 and Figure 2 and 5.3.3).

Minimum dose required and validated for manufactured product

Per 11137-2 or ISO 13004*, the minimum dose is set based on bioburden, not on sterilization technology (gamma, E-beam, or X-ray) used to deliver dose. Bioburden is related to verification dose and minimum sterilization dose used. Gamma, electron beam, and X-ray irradiation are all considered ionizing radiation technologies and do not have three separate dose tables for each technology. If the product and manufacturer are not changing, the minimum dose required will not change, nor will the microbiological effectiveness of dose change.

The following referenced publications arrive to the same conclusion that the sterilization dose is not dependent of the radiation sources:

- Radiation Sterilization: Dose Is Dose. Joyce M. Hansen, Niki Fidopiastis, Trabue Bryans, Michelle Luebke and Terri Rymer AAMI: Industrial Sterilization: Process Optimization and Modality Changes – 2020
- Microbicidal effectiveness of X-rays used for sterilization purposes Tallentire, A. and Miller, A. (2015) Radiation Physics and Chemistry, 107, pp. 128–130 doi: 10.1016/j.radphyschem.2014.09.012
- A comparison of the microbicidal effectiveness of gamma rays and high and low energy electrons radiations Alan Tallentire, Arne Miller, Jacob Helt-Hansen Radiation Physics and Chemistry 79 (2010) 701-704

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*This is also discussed in ISO 11137-1 and its annexes, as well as AAMI TIR 104.

To document the microbial effectiveness of the sterilization dose for a product, it is advised that a dose audit at the current verification dose is completed.

Maximum allowable dose

The maximum allowable dose investigates the effect of maximum allowable dose on product performance, considering the worst case. In general, a dose rate that is faster than the validated rate will have less impact on materials (ISO 11137-1, Clause A.8.4.1), especially as it relates to oxidation effects. Faster dose rates will result in less time in the ionizing field. ISO 11137-1 Clause 8.4.1 requires documentation to assess that the differences in radiation conditions do not affect the validity of the established maximum acceptable dose.

ISO 11137-1 states the maximum dose and temperature should be considered, and the worst-case dose could also be expected to be the worst-case temperature effect. To assure that impact of dose and temperature is considered, maximum dose testing is required. Since a product, already validated in gamma will have data on a given maximum dose, it is advisable to consider comparisons in the alternate technology that is proposed, at the same maximum dose. Databases and publications of materials may not provide evidence of all specific functional requirements of manufactured product. The absence of data may require more extensive re- establishment of the maximum allowable dose in alternate radiation technologies.

If the change in technology is a move from a photon-based process (gamma or X-ray) to a charged electron-based process (E-beam), the adequacy of the current maximum dose should be discussed with the processing facility. The change in technology may require testing a slightly higher maximum dose or a change in product presentation to the beam vs. the previous photon-based system.

Comparison of existing data and a risk assessment of critical criteria should be used to design a test plan for maximum dose technology change. A testing plan should be documented with acceptance criteria before testing is initiated.

Product performance qualification (PQ) mapping

Any change in irradiator, even if the same technology, must complete an assessment of dose distribution to assure the product, as it will be processed, can meet the dose range requested (demonstrate that the process is capable of delivering the dose range requested). This is achieved by dose mapping, regardless of technology chosen.

Activation testing

Currently, ISO 11137-1 (Clause 5.1.2) requires that E-beam systems over energy levels of 10 Mev and X-ray systems over energy levels of 5 MeV assess the potential for induced radioactivity. E-beam systems generally operate at 10 MeV or less and X-ray systems typically operate at 7 MeV. Publications, such as Gregorie, etc., provide assessments of many metallic and non-metallic elements. These documents may not cover all the materials in an individual product, and some may require more evaluation including a test for activation. Activation is tested on products that have received the maximum allowable dose. Once tested, if the product materials do not change and results give activation levels in allowable limits, the test is not repeated.

Note* gamma average energy is only 1.25 Mev, which is not capable of activation, and is not tested for activation.

Conclusions

Minimum requirements for transfer of technology include:

1. Document the effectiveness of minimum sterilization dose. This can be achieved through a dose audit
2. Document acceptability of existing maximum allowable dose or re-establish with alternate technology selected. Risk assessment of criteria of acceptance can be used to design a test plan
3. Complete an assessment of activation if E-beam over 10 MeV is used or X-ray over 5 MeV is used. Published literature will assist in this, but most testing needed should be judged based on products materials

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4. Complete a PQ map in the facility where product will be processed with the irradiator used is required. This is true of any irradiator change with any of the technologies discussed

5. Consider any regulatory requirements for the product and effects on or changes needed to product registrations

References

1. ANSI/AAMI/ISO 11137-1, Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

2. ANSI/AAMI/ISO 13004, Sterilization of health care products – radiation – Substantiation of selected sterilization dose: Method VDmaxSD.

3. ANSI/AAMI TIR 104, Guidance on transferring health care products between radiation sterilization sources.

4. AAMI Industrial Sterilization 2021, Herve Michel, Thomas Kroc, Brian J. McEvoy, Deepak Patil, Pierre Reppert and Mark Smith, Potential Induced Radioactivity in Materials Processed with X-ray Energy Above 5 MeV, pp. 17-26.

5. Gregoire, O., et al. Radiological safety of medical device sterilized with X-rays at 7.5 MeV, Radiation Physics and Chemistry, 2003;67(2): pp.149-167.

6. Tallentire, A and Miller, A., Microbicidal Effectiveness of X-rays Used for Sterilization Purposes, Radiation Physics and Chemistry, 2015; 107, pp.128-130.

7. Hansen, Joyce, Niki Fidopiastis, Trabue Bryans, Michelle Luebke and Terri Rymer, Radiation Sterilization: Dose is Dose, AAMI Industrial Sterilization 2020: pp.45-52.

8. McEvoy, Brian J., et al. X-ray: An Effective Photon, AAMI Industrial Sterilization, 2020, pp. 23-30.

9. Beerlage, Christiane, et al. Change in Radiation Sterilization Process from Gamma to X-ray, AAMI Industrial Sterilization,2021, pp. 78-84.

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