TECHNICAL TIP

ACTIVATION ASSESSMENT (X-RAY AND ELECTRON BEAM)

Background

Radioactive material of natural origin is abundant and varies widely in both type and amount. The energy from these materials, plus that of cosmic or cosmogenic origin, is called background radiation. Artificial radioactivity is the result of human operation where it was not previously present.

Assessment of induced radioactivity in radiation-sterilized healthcare products is utilized to determine whether such activity is present at a level higher than background. This assessment is considered from the perspective of employees within the medical device manufacturing supply chain and patient end-users:

- External exposure from sources outside a person's body may be of concern for those who handle the product and/or packaging in the manufacturing supply chain (irradiation facility, distribution warehouse, or transportation of materials), and for healthcare workers (physicians and nurses) who handle the product.
- Internal exposure from sources inside a person's body may be of concern for patients who have an irradiated product placed or implanted in their body.

When to conduct an activation assessment

ISO 11137 requires an evaluation of potential activation of materials irradiated under the following conditions:

- X-ray irradiation exceeding 5 MeV in energy
- Electron beam irradiation exceeding 10 MeV in energy

Where does STERIS conduct activation assessments?

Activation testing is completed at the STERIS Applied Sterilization Technologies (AST) Radiation Technology Centers (RTC) in:

- Libertyville, Illinois, USA
- Däniken, Switzerland

How is an activation assessment conducted?

An activation assessment should be conducted when planning maximum dose testing for a product that will be treated with energy greater than 5 MeV with X-ray or 10 MeV with E-beam.

When conducting maximum dose testing, additional samples will be required and will be irradiated at 10-20% above the product maximum dose testing. These samples will be tested in a detector that can measure extremely low levels of radiation to determine if any activation level can be found within the samples.

Interpretation of Results

If the product shows an activity level greater than the detection limit of the system, it is considered "activated" and an assessment is completed.

The assessment identifies the isotope and determines whether the activity level is greater than the threshold for which the isotope is considered "radioactive".

- If the assessment concludes that the activity level is less than the isotope's radioactivity threshold, no additional action is required.
- If the assessment concludes that the activity level is greater than the isotope's radioactivity threshold, the sample is declared as non-radiatioactive and no additional action is required.

In most cases where activation is detected, the activity level is well below the exempt level to consider to product sample to be a radioactive hazard. In addition, activation levels typically decay within minutes.

FOR MORE INFORMATION

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* Section 5.1.2 of ANSI/AAMI/ISO 11137-1 states that "the potential for induced radioactivity in product shall be assessed." View our AMMI BI&T article *Potential Induced Radioactivity in Materials Processed with X-ray Energy Above 5 MeV* on how compliance with this requirement may be achieved using qualified test methods. Materials of consideration are conceptually discussed, and results of testing conducted on products processed with a 7.5-MeV X-ray irradiation process are provided. As X-ray becomes more widely used in healthcare sterilization, having standard assessment protocols for activation coupled with a shared database of material test results will benefit manufacturers seeking to utilize this innovative technology.

REFERENCES

1. Hervé Michel, Thomas Kroc, Brian J. McEvoy, Deepak Patil, Pierre Reppert, and Mark A. Smith. Potential Induced Radioactivity in Materials Processed with X-ray Energy Above 5 MeV. *Biomed Instrum Technol.* 2021 Mar 1;55(s3):17-26. doi: 10.2345/0899-8205-55.s3.17. PMID: 34153999.

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