TECHTIP

CONSIDERATIONS WHEN ESTABLISHING A MAXIMUM STERILIZATION DOSE FOR RADIATION PROCESSING

Per ISO 11137, products sterilized by X-ray, gamma, and E-beam irradiation require a documented and validated dose range. A dose range is composed of:

1. A minimum dose based on the microbiologic considerations (type and quantity of organisms and their resistance) to substantiate a sterile claim on a product.
2. A maximum dose based on the product tolerance and performance specifications required. This means the product is not only sterile, but functions as intended and is safe for use.

The importance of a maximum dose

A dose range cannot be delivered with only one number (e.g., 25 kGy). It must always have a range (e.g., 25-40 kGy) and is qualified based on product specific testing as a maximum for product functionality. The maximum dose is not the same for all products, even products with the same minimum dose, purpose, or appearance from different manufacturing processes.

Once a dose range is established, any delivered dose in that range is accepted and the product will perform and function effectively and as intended. For example, if a product has a dose range of 25-40 kGy and the irradiator delivers 39.999… kGy, this is acceptable and the product will meet requirements and not only perform as intended but maintain a sterile claim.

Material considerations for determining maximum dose

When considering different materials for maximum dose testing, it is important to note that documented literature references using the same base polymer within a product is not a substitute for testing. Many resin manufacturers can produce the same base polymer for different purposes; they are not just a base polymer, they have other ingredients added to allow products to work adequately for their intended purpose. This may include, but is not limited to, substances that make the material easier to mold, tolerate heat for melting, free radical scavengers, antioxidants, colorants and copolymer blends to obtain preferred properties. Other material and design considerations are outlined:

1. Manufacturers of similar resin names are not identical. It cannot be assumed a manufacturer can change from one part number to another from the same manufacturer or an alternative manufacturer.
2. A pure base polymer is not used to manufacture product. Instead, a resin designed for a *purpose with ingredients added* is used to manufacture product to tolerate the molding process. They may be engineered for color and clarity, and may be blended with multiple base polymers to achieve desired physical properties.
3. The design of a product can impact results. Sharp bends, thick-to-thin transitions, conditions of storage, and how parts are connected can impact effects of a terminal sterilization process. Testing small samples of material cannot evaluate these effects and these variables should be considered as early in the product design phase as possible.

Maximum dose testing considerations

Long-term testing, such as aging for packaging testing and biocompatibility, are done at the maximum dose, not sterilization dose range. These tests use large numbers of product units and take significant time to ensure the product will function and perform as intended up to the product expiry date (e.g., five years) when receiving the maximum dose allowed.

Products must be tested in their final form, not just the raw materials or indirectly through literature references and documented to demonstrate the way dose can affect a material. Evaluating form, fit, and function are important and assure a safe and effective product. Other testing considerations are outlined below:

1. Knowing the dose a product can tolerate may allow for additional processing, for example, if reprocessing is desired or dose augmentation is needed due to a dose audit failure.
2. Maximum doses are linked to product claims. Products can look similar, but claim they are used for different purposes or in different environments.
3. Maximum doses need to be high enough over the established minimum dose needed to sterilize to allow for a dose range that is physically possible to deliver. The dose range can impact if the product can be processed at all, as a very narrow dose range may not be achievable.

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4. The irradiator type and facility location where a a product is processed may impact the efficiency of the processing.

5. Scheduling, turn times, and transportation costs should be considered in determining a location that is capable of delivering the validated dose range. Testing may be trial and error. Starting points may be refined by:

    a. Checking with resin supplier info, recommendations, or experiences

    b. Investigating if the selected type of materials are expected to tolerate irradiation

    c. Knowledge of similar products

    d. Experience of design engineers

6. Dose effects are cumulative. Eventually, even a tolerant material will experience undesirable changes if the total dose delivered is too high. Dose cannot be removed, nor its effects corrected once delivered.

Regulatory considerations

Products sterilized by X-ray, gamma, and E-beam irradiation require a documented maximum dose per ANSI/AAMI/ISO standards (e.g., section 8.1 of ISO 11137-1 "*the maximum acceptable dose for product shall be established. When treated with the maximum acceptable dose, product shall meet its specified functional requirements throughout its defined lifetime.*") and should be considered as early in the product design process as possible.

Conclusions

When manufacturing a product making a sterile claim, setting a maximum dose is required to establish a dose range. A wide dose range allows for an easier and more efficient process. Testing and material considerations are important in ensuring that the form, fit, and function of a product are not compromised. Maximum dose testing and documentation are required to establish a dose range. There are no substitutes to testing and setting the maximum dose is always specific to product requirements, ensuring the product functions and performs as intended throughout the product life cycle.

References:

1. AAMI TIR 17, Compatibility of Materials Subject to Sterilization

2. ANSI/AAMI/ISO 11137, Sterilization of Health Care Products Radiation, Part 1-3

3. ANSI AAMI ISO 11737, Sterilization of Health Care Products Microbiological Methods, Part 1-2

4. Roxby, P., Michel, H., Céline Huart, & Dorey, S. (2024). Effect of Gamma and X-ray Irradiation on Polymers Commonly Used in Healthcare Products. Biomedical Instrumentation & Technology, 58(1), 7–17. https://doi.org/10.2345/0899-8205-58.1.7

5. Hemmerich, K. J. (2000, February 1). Polymer Materials Selection for Radiation-Sterilized Products. www.mddionline.com. https://www.mddionline.com/materials/polymer-materials-selection-for-radiation-sterilized-products

6. ASTM Test Methods

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