TECHNICAL TIP

MONITORING OF DELIVERED DOSE USING REFERENCE DOSIMETRY

Introduction

Monitoring of the minimum delivered dose position for healthcare products is required per industry standards (i.e. ANSI/AAMI/ISO 11137). For most healthcare products, orientation of the product within the shipping cartons does not significantly affect dose magnitude and dose distribution as long as they remain consistent from the time the product dose map occurred. Routine monitoring positions are determined through qualification runs and other dose mapping studies performed with dosimeters on the outside of the product packaging. However, high density and shielded products present unique challenges in meeting the requirement to monitor the minimum delivered dose. In order to ensure that the minimum delivered dose is being monitored in these high density products (such as bulk powders or liquids) or products with areas of localized shielding (such as those processed with dry ice, ice packs or lead shielding), reference dose mapping studies are performed.

Reference Dose Mapping Considerations

Products that have localized areas of high density can create additional shielding, thereby reducing the minimum dose delivered to certain location. As a result, the minimum delivered dose may be in an area of the product which would require placement of a dosimeter inside the product packaging. Placement of dosimeters in the center of these products is not always possible or practical due to Customer requirements (during the placement or retrieval process, product sterility or the product itself may be compromised). In addition, processing products with dry ice represents a challenge in the quantifying of delivered dose based on dosimeter response. Dosimeter response at dry-ice temperatures is an unknown that the industry is currently working to quantify.

Reference Dose Mapping Studies

In these studies, the minimum and maximum delivered dose locations are determined by placing dosimeters throughout a surrogate product at ambient temperature. The surrogate product mimics the distribution of gamma rays through the actual product that will be processed on a routine basis. In addition to the dosimeters placed throughout the product, a reference dosimeter location is chosen and placed on the outside of the product being processed. The reference position is a fixed location and is chosen based on reproducibility of dose from each irradiation run. Once the minimum and maximum delivered dose positions are determined, a ratio between the dose delivered to these positions and the reference position is calculated. These reference ratios can then be used to calculate the dose required to the reference position in order to ensure the correct minimum dose is delivered to the product without exceeding the maximum required dose.

Routine Irradiation of Reference Dose Mapped Product

During routine processing, the dosimeter is placed at the same external reference position as was determined during the reference dose mapping study. Product packaging configuration and loading configuration within the carrier must be the same as what was dose mapped. After irradiation, the dose delivered to the product can be calculated based on the dose delivered to the reference dosimeter(s) and the reference ratios established during the reference dose mapping study.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
Web: www.steris-ast.com // Email: ast_info@steris.com
(EMEAA) +44 (0) 8456 88 99 70
(Americas) 877.783.7479

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REFERENCES

1. ANSI/AAMI/ISO 11137-3:2006 “Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects”
2. AAMI TIR 29:2012 “Guide for process characterization and control in radiation sterilization of medical devices”
3. Technical Tip #32 “Reference Dosimetry for Frozen Healthcare Products”

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