

PACKAGING CONSIDERATIONS FOR GAMMA PROCESSING

TECHNICAL TIP #29

Changes to product packaging that impact outer dimensions, weight, or product orientation, require that revisions be made to the processing specifications and handling instructions on file with a contact sterilization provider. This TechTip focuses on what Customers need to know before initiating changes to product packaging, in order to ensure that the efficiency and effectiveness of the gamma process is maintained.

ANSI/AAMI/ISO 11137-1: 2006, Sterilization of healthcare products – Radiation – Part 1, states that all changes in product, its package, or the presentation of product for sterilization shall be assessed for its effect on the appropriateness of the sterilization process. While the referenced standard addresses healthcare products, the same conditions must be assessed for all products processed in a gamma irradiator, regardless of product type or use. Communicating proposed package changes to the sterilization provider in advance will help ensure an accurate processing and performance qualification plan is established, and changes are implemented in a cost effective manner.

Package Volume, Package Density, Carrier/tote Loading Specifications

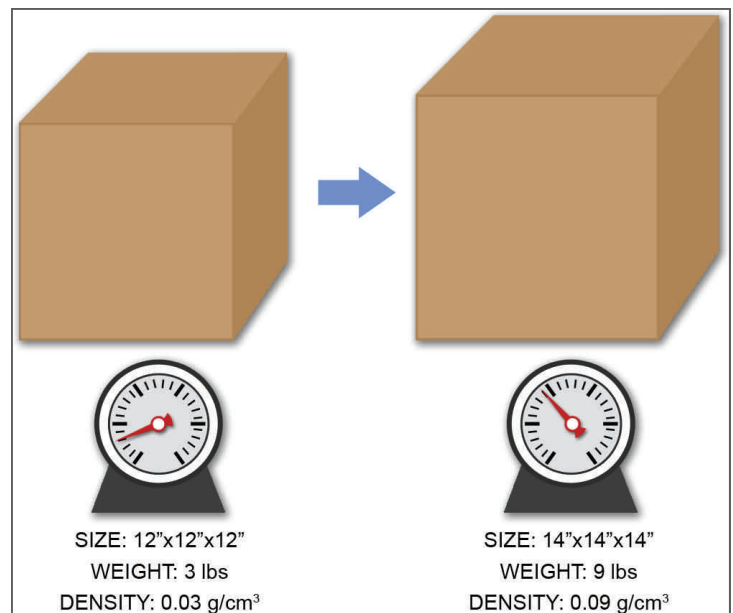
Most commercial gamma irradiators utilize a carrier/tote with fixed internal dimensions to transport product through the irradiation process. The specific carrier/tote internal dimensions should be obtained from the respective processing facility, and must be considered prior to making changes to the package. This will ensure that the loading configuration or number of packages/units per carrier is not adversely affected by a change.

When a package is initially received at a processing facility, it is weighed and measured, and a carrier/tote loading specification is developed. This loading specification becomes a critical component of the Performance Qualification (PQ), and provides routine handling instructions for future processing of the respective product. Any changes to the package dimensions or weight that will result in a change in volume or density may invalidate the original loading specification and adversely impact the performance qualification (see figure 1). With prior notification of a pending package change, the sterilization provider will assist with the necessary assessment by evaluating the impact of the change on the current loading specification and performance qualification. Verification of weights and measures are completed upon the next receipt of the package, loading specifications are revised, and an appropriate PQ plan is established.

Validated Process – Performance Qualifications (PQ)

Routine product processing is performed in a validated system in order to ensure reliability and reproducibility of the process. Performance qualifications (PQ), referred to as dose mappings, are performed to identify the location and magnitude of the minimum and maximum delivered radiation dose, as well as the relationship between the two. Product packaging factors that may impact the PQ process include package volume (outer package dimensions), package density (density = package weight / volume) and the package configuration (carrier/tote loading specification) within the irradiator. Changes to any of these factors that differ from the original PQ must be assessed to ensure processing specifications are achieved.

Figure 1: Example of change in packaging volume and weight.



Processing Specifications

Once the package loading configuration, package density and PQ dose mapping is completed, the results become part of the product routine processing specification or work instructions. These work instructions will be utilized by the sterilization provider to process future deliveries of the same product/package.

Changes to package size or weight may require revisions to the following:

- Package loading configuration to include the physical number of packages within an irradiation carrier/tote
- Dosimeter monitoring locations as determined by the PQ
- Processing cycle time to ensure dose specifications are achieved

Why notify your sterilization provider in advance?

Changes to product packaging that impact outer dimensions, weight, or product orientation have a direct impact on the irradiation process and performance qualification. In order to deliver the required radiation dose, the sterilization provider must calculate an exposure or cycle time for the products being processed. The determination of the required cycle time is based upon the qualified product packaging dimensions that have been established and documented in the current processing specifications. Therefore, changes in the qualified parameters that have not been assessed prior could result in processing anomalies or delays.

References

ANSI/AAMI/ISO 11137-1: 2006. Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

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