Dose Establishment for Radiation Sterilization Process

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The Ionizing radiation sterilization process widely used around the world is based on exposing products to radiation until they receive the minimum dose to achieve the desired degree of Sterility Assurance Level (SAL). Relevant information about the product's bioburden and SAL needs to be considered in the Minimum Sterilization Dose Validation (ISO 11.137-2). Methodologies that are based on the bioburden standard resistance or the specific bioburden of a product can be applied. Common minimum doses (DMin) range from 10 to 25 kGy.

As important as establishing the minimum dose, the intended use of the product and its essential performance characteristics need to be carefully assessed in order to define the Maximum Dose (Dmax) allowed to the product and its packaging system. Product compatibility tests need to be carried out and documented.

Finally, the evaluation of the dose distribution (DUR) in the product through the execution of a Performance Qualification (PQ) dose mapping will allow the process to be evaluated and validated.

This presentation covers methodologies for validating the minimum sterilization dose in a product, as well as aspects related to the definition of the maximum dose, compatibility tests and relevant aspects for validating the irradiation process in Gamma and Ebeam technologies, with examples of common process ranges.