Material Evaluation

Prior to using Gamma or Electron Beam Radiation for the sterilization of healthcare products, it is essential to determine the effect radiation will have on the materials used in the product, its components and packaging.

Because each polymer reacts differently to ionizing radiation, it is important to verify that the maximum dose likely to be administered during the sterilization process will not adversely affect the quality, safety or performance of the product throughout its shelf life. The device manufacturer is ultimately responsible for ensuring that the final product meets its labeling claims.

Experimental samples of the product should be irradiated to at least the highest dose to be encountered during routine processing. For example, a product that is to receive a sterilizing dosage of 25 to 40 kiloGray (kGy) should be tested by irradiating samples to at least 40 kGy. A preferred, more conservative approach is to irradiate samples at twice the anticipated maximum dose.

Since various device applications call for certain performance properties or functional characteristics, it is important to test each device in an appropriate manner. Physical and functional methods for evaluating plastic materials can be found in the ANSI/AAMI/ISO 11137-1994 document. It is important to note that standards call for the development of a test program that will address “variations in the manufacturing processes, tolerances, radiation doses, radiation source, raw materials and storage conditions.”

Tests that more closely approximate the actual mechanical application of the product may also be performed by the product engineering or research staff.

Evaluation and test results are to be maintained in the product’s device history file, serving as physical confirmation that all product claims and specifications have been met.

If product testing indicates a potentially adverse effect from high levels of radiation, a maximum permissible dose should be established by the manufacturer and emphasized in the processing instructions provided to the contract sterilizer.
**Sterilization Dose Selection**

The process of selecting a sterilization dose is intended to establish the minimum permissible dose necessary to provide the required or desired sterility assurance level (SAL), meaning the “probability of a viable microorganism being present on a product unit after sterilization.” This requirement is dependent upon the intended use of the product. For example, a product, which is to be used in the body’s fluid path, is considered a Class III device. Under this classification, the product must receive a sterilization dose high enough to ensure that the probability of an organism surviving the dosage is no greater than one in one million units tested (10^-6).

The chances of one organism surviving after irradiation decreases logarithmically with increasing dosages. However, it is important to consider microbial population characteristics that define a product’s pre-sterilization bioburden (“population of viable microorganisms on a product”). Relevant characteristics include the magnitude of the population and the resistance of the population to radiation.

**Product Dose Mapping**

A dose mapping study is to be performed in order to identify minimum and maximum dose zones within the product load using a predetermined loading pattern. This verifies the minimum sterilization dose is achieved while material integrity is maintained by staying within the maximum allowable dosage. In addition, the dose mapping study establishes the reproducibility of the sterilization process and is used in the selection of the dose monitoring locations for routine processing.

**Certification**

Information that is gathered or produced during the validation process is to be documented and reviewed for acceptability by a designated individual or group and maintained in the product’s device history file.

**Sterilization Dose Audit**

In accordance with ANSI/AAMI/ISO 11137-1994, an audit must be performed to determine the continued validity of the sterilization dose any time there is a change in the manufacturing process that could significantly affect level or nature of the bioburden. In the absence of any change, a sterilization dose audit is to be performed every three months.

**Summary**

In order to conduct and maintain a successful validation process, it is important that the manufacturer, contract sterilizer and testing laboratory work cooperatively. Detailed results of each phase of the validation process are to be kept in the manufacturer’s device history file. This standardization procedure will optimize the sterilization process, maintain material integrity and allow similar results to be produced in the future.

**References**