AN OVERVIEW

The radiation sterilization standards document, *ANSI/AAMI/ISO 11137-1, Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*, incorporates methodologies of both ISO (International Standards Organization) and ANSI (American National Standards Institute). Further, it confirms agreement between the international standards for medical device sterilization and the guidelines for Gamma and Electron Beam Radiation previously followed by U.S. device manufacturers.

The purpose of the validation process is to make certain products are rendered free of viable microorganisms, and thus, are "sterile." The standards ensure certain predetermined criteria that validate sterilization are met prior to the production of a sterile healthcare product.

These criteria include:

- ❑ Evaluation of materials to be used in the product and its packaging
- ❑ Determination of the product's radiation stability
- ❑ Sterilization dose selection
- ❑ Product dose mapping
- ❑ Certification of the process
- ❑ Verification of the sterilization dose

Documentation, which is to be maintained throughout, demonstrates the viability and reproducibility of the sterilization process.

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Guidelines for Validation Radiation Sterilization

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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 life.

The device manufacturer is ultimately responsible for ensuring that the final product meets its labeling claims.

Product representative of that to be manufactured routinely 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 dose of 25 to 40 kiloGray (kGy) should be tested by irradiating samples to at least 40 kGy. A common 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. ISO 11137 does require the performance of studies of the effects of radiation on product.

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.

Potentially adverse effects from high levels of radiation should be mitigated by the manufacturer establishing a maximum permissible dose.

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."[2] 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"[2]). 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 at a frequency not less than annually.

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

1 AAMI TIR29, Guide for process characterization and control in radiation sterilization of medical devices.

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

3 Genova, Hollis, Crowell and Schady, "A Procedure for Validating the Sterility of an Individual Gamma Radiation Sterilized Production Batch," Journal of Parenteral Science and Technology, Volume 41, No.1, pp. 33-36, Jan 1987.

4 Gaughran and Morrissey, "Sterilization of Medical Products," Volume 2, ISBN-0-919868-14-2, pp. 35-39, 1980.