



## TECHNICAL TIP

### OVERVIEW OF A GAMMA IRRADIATION VALIDATION

Prior to beginning routine gamma irradiation, a product with a sterile claim needs to complete a validation process to ensure the Sterility Assurance Level claimed is met. ANSI/AAMI/ISO 11137-2006 provides guidance for completing such a validation through three parts that are included under the general title Sterilization of health care productions - Radiation:

- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- Part 2: Establishing the sterilization dose
- Part 3: Guidance on dosimetric aspects

This TechTip will provide a step-by-step overview of a gamma irradiation validation process that complies with the standards established in ANSI/AAMI/ISO 11137-2006.

#### Product Design Stage

When designing products to be treated for sterilization consideration should be given to the material challenges of the process on the product and packaging. The Gamma Irradiation process can modify polymers, add an ozone odor to the package contents, or cause some discoloring; depending on the applied radiation level (dose) and material choices. These effects should be considered while designing the product to be sterilized.<sup>1</sup>

Another consideration is that a series of product cartons will be loaded into an aluminum container (called a tote or carrier) which will convey the product around the radiation source. Standardizing product carton sizes and densities in an effective manner will offer the most economical return on the irradiation process.<sup>2</sup>

#### Bioburden Determination

The typical Gamma Sterilization Validation process is unique in that the manufacturer uses the natural microbial load present on the product and sealed packaging to determine the processing parameters. Generally, statistically representative

samples of the product will be submitted to a microbiology laboratory to quantize the population in Colony Forming Units (CFU's) through a *Bioburden Determination*.<sup>3</sup>

#### Verification and Material Testing Dose Determination

Based on the bioburden results, reference tables in ANSI/AAMI/ISO 11137 will provide guidance on the required radiation dose to apply to the product in KiloGrays (kGy) to achieve a specified Sterility Assurance Level (SAL). The referenced SAL dose is termed the "Verification Dose".

Multiple methods are available for determining sterility within ANSI/AAMI/ISO 11137 based on the level of sterility assurance, selected processing dose, and the number of samples which can be used for testing.<sup>4</sup>

It is also recommended that a "high dose material test" be performed by irradiating the product at least 1.6-2.0 times the expected minimum sterilization dose (or 40 to 50 kGy if the minimum dose is unknown) to evaluate the attributes of the product after processing.

#### Verification and Material Testing Experiments

The ANSI/AAMI/ISO 11137 Verification Dose is generally very low and is required to be within +/- 10% of the Verification Dose reference values. This type of irradiation is very difficult to achieve in a large processing irradiator and typically requires a small research irradiator to achieve the ANSI/AAMI/ISO requirements. The research irradiator will apply the required Verification Dose by monitoring the imparted dose by placing quantitative measuring devices on the product package called dosimeters. If Material Testing is also desired, it can also be submitted at this time for irradiation.

#### Sterility Testing

Once the Verification Dose has been applied, the product samples will be routed back to the microbiology laboratory to perform a *Sterility Test*. The sterility test will confirm

### FOR MORE INFORMATION

STERIS Applied Sterilization Technologies

Web: [www.steris-ast.com](http://www.steris-ast.com) // Email: [ast\\_info@steris.com](mailto:ast_info@steris.com)

(EMEA) +44 (0) 8456 88 99 70

(Americas) 877.783.7479





## TECHNICAL TIP

### OVERVIEW OF A GAMMA IRRADIATION VALIDATION

whether all viable microbes present on the product sample achieved lethality to deem the process successful.

#### Sterilization Dose Determination

With a passing result on the Verification Dose, ANSI/AAMI/ISO 11137 will be reviewed again, and a Sterilization Dose (or the minimum dose) will be determined to achieve a SAL based on the product type.

#### Dose Range Determination

During routine irradiation the product volume and density will increase as it is processed in a larger carrier or tote, thus a dose “window or range” needs to be established for a large irradiator to process product efficiently. The chosen Sterilization Dose range will be the minimum dose needed to achieve the sterility claim and a dose level value below the dose applied during the Material Test as the maximum end of the range, or generally a minimum of at least 1.6 times the Sterilization Dose. A dose level value below the dose applied during the Material Test is recommended as the maximum end of the range, or generally a minimum of at least 1.6-2.0 times the Sterilization Dose.

#### Routine Processing Facility Determination

Once the Sterilization Dose Range is established a STERIS Isomedix Services account manager will determine the best *Processing Facility* to routinely process marketable product and introduce the manufacturer to the facility.<sup>2</sup>

#### Routine Sterilization Customer Set-Up

The processing facility will ask that Processing Specifications and new Customer set-up documentation are completed to provide the means to identify all incoming products and the required dose range to achieve the sterility claim.

#### Dose Mapping and Routine Dosimeter Placement Determination

Once the product is received by the processing facility,

measurements of the product carton and density will be made. The facility will establish if like product density and volume has been processed and will perform a *Dose Mapping* on the product, if required. Dose mapping is performed by determining the most efficient means of placing product in a carrier or tote and placing numerous dosimeters throughout the product load to establish the minimum and maximum areas of imparted dose. Once these areas have been determined, routine dosimeter placement will be limited to the minimum and maximum dose zones in a select sampling of routine processing totes or carriers.

#### Routine Processing

Once the processing specifications are established, routine processing irradiations will be identified by the product code, as received at the facility, and the irradiation process will commence without further requirements from the Customer. Although it is recommended that if any product changes (size or density), or priority turn time requirements occur; the Customer contact the processing facility for communicating the unique requirements.

#### Dose Audits

As the initial sterilization dose determination was based on the natural bioburden of the product and packaging, the ANSI/AAMI/ISO 11137 standard recognizes that the microbial population (quantity or type) can change with seasonal or periodic manufacturing changes, thus the standard requires a bioburden determination and Dose Audit at the Verification Dose level to confirm that the minimum sterilization dose is still valid. These irradiations would be performed at the research irradiator at the same tight constraints of the verification dose (+/- 10%) in addition to performing a Sterility Test to validate effectiveness.<sup>3</sup>

### FOR MORE INFORMATION

STERIS Applied Sterilization Technologies

Web: [www.steris-ast.com](http://www.steris-ast.com) // Email: [ast\\_info@steris.com](mailto:ast_info@steris.com)

(EMEA) +44 (0) 8456 88 99 70

(Americas) 877.783.7479





## TECHNICAL TIP

# OVERVIEW OF A GAMMA IRRADIATION VALIDATION

## REFERENCES

---

1. See STERIS Applied Sterilization Technologies Tips #02, #04, and #09 at [www.steris-ast.com](http://www.steris-ast.com) for more information
2. Consult the STERIS Applied Sterilization Technologies Sales staff at 877.783.7479 for assistance
3. See ANSI/AAMI/ISO 11137-2006 or 11737 for more information
4. Consult the STERIS Applied Sterilization Technologies Radiation TechTeam at 847.247.4782 for assistance

## FOR MORE INFORMATION

---

STERIS Applied Sterilization Technologies  
Web: [www.steris-ast.com](http://www.steris-ast.com) // Email: [ast\\_info@steris.com](mailto:ast_info@steris.com)  
(EMEA) +44 (0) 8456 88 99 70  
(Americas) 877.783.7479

