

Sterilization Alternatives

Gamma Radiation

For over fifty years, Gamma Radiation has been highly regarded as a safe, cost-competitive methodology for the sterilization of healthcare products, components and packaging. Today, spurred in large measure by its compatibility with single-use, disposable medical devices, Gamma Radiation is being used by an ever-increasing percentage of the healthcare industry. As a result, Gamma Radiation, which once accounted for only 5% of the sterilization market, has grown to nearly 50%.

Simplicity and reliability, along with budget-sparing cost-effectiveness, are the driving factors behind the industry's conversion to Gamma Radiation.

A major contribution to the orderly control of Gamma processing was made by the members of a select committee from the Association for the Advancement of Medical Instrumentation (AAMI). Their American National Standard, ANSI/AAMI/ISO 11137-1994, *Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization*, has become the working document for the industry and its regulations.

The AAMI's approach to dose-setting methodology has proven practical in meeting industry requirements of product release without post-sterilization testing or quarantine.

The Nature of Gamma Radiation

A form of pure energy that is generally characterized by its deep penetration and low dose rates, Gamma Radiation effectively kills microorganisms throughout the product and its packaging with very little temperature effect.

Benefits of Gamma Radiation include:

- precise dosing
- rapid processing
- uniform dose distribution
- system flexibility
- dosimetric release—the immediate availability of product after processing.

Penetrating Sterilization, Even with High-Density Products

Gamma Radiation is a penetrating sterilant. No area of the product, its components, or packaging is left with uncertain sterility after treatment. Even high-density products, such as pre-filled syringes, can be readily processed and used with confidence.

Package Efficiency and Integrity

Packaging remains intact with Gamma processing. Since there is no requirement for pressure or vacuum, seals are not stressed. In addition, Gamma Radiation eliminates the need for permeable packaging materials.

Packaging and raw material suppliers have recognized the shift to radiation and are continuing to develop products specifically formulated for radiation stability. Tough, impermeable packaging materials provide a strong, long-term sterile barrier.

Substantial Decrease in Organism Survival

Gamma Radiation kills microorganisms by attacking the DNA molecule. Both direct and indirect mechanisms are instrumental in the disruption of the DNA bond, which results in the prevention of cellular division and, consequently, the propagation of life.

Although sterility is a relative term, it represents the likelihood or odds of a microorganism surviving the sterilization process. Gamma processing is a highly reliable procedure, due primarily to its simplicity. Because time is the only variable requiring control, the possibility of deviation is reduced to an absolute minimum.

Dosimetric Release = Immediate Product Release

Gamma Radiation provides for the immediate release of product using a procedure known as “dosimetric release.”

Dosimetric release is based solely on the dosage of radiation delivered to the product. This measurement, usually identified in kiloGrays (kGy), is obtained through the use of “dosimeters” which are placed on product containers during processing. Upon completion of the Gamma process, the dosimeters are removed from the product containers and read, using a specialized instrument, to verify the minimum and maximum dosages of radiation received by the product. Once the delivered dose is verified, the products are released for shipment.

Dosimetric release is accepted by the Food and Drug Administration (FDA) due to the inherent reliability of the Gamma Radiation process and is outlined, in detail, in the standards document ANSI/AAMI/ISO 11137-1994.

No Residuals, No Radioactivity

Gamma rays, emitted from Cobalt-60, are pure energy, similar in many ways to microwaves and X-rays. Gamma rays delivered during radiation sterilization destroy chemical bonds by interacting with the electrons of the atomic constituents. Although Gamma rays are highly effective in killing microorganisms, they do not create residues, nor do they have sufficient energy to impart radioactivity.

Cost Effective

Gamma processing provides fast, flexible and highly cost-effective sterilization. Cost savings can be largely attributed to the elimination of sterility tests associated with biological indicators, or BIs, (due to the FDA’s acceptance of dosimetric release), as well as the elimination of inventory quarantine and the potential for re-processing.

	Gamma Radiation	Electron Beam (E-beam)	Ethylene Oxide (EO)
Process Methodology	Continuous or batch	Continuous	Batch
Product Release	Dosimetric release (immediate, no post-sterilization testing is required).	Dosimetric release (immediate, no post-sterilization testing required).	Historically, BIs were required to verify sterility assurance level (SAL). Today, state-of-the-art Parametric Release enables significantly faster product release.
Penetration	Complete penetration	Complete penetration, dependent upon material thickness.	Complete penetration with the use of gas-permeable packaging.
Material Compatibility	Most materials are satisfactory. Considered somewhat incompatible with PVC, PTFE and Acetal.	Most materials are satisfactory.	Nearly all materials are compatible.
Residuals	None	None	Ethylene Chlorohydrin, requiring an aeration period following processing. With advanced CyclEOne technology, separate aeration is not required.

References

- American National Standard, ANSI/AAMI/ISO 11137-1994, *Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization*, 1994.
- American National Standard, ANSI/AAMI ST32-1991, *Guidelines for Gamma Radiation Sterilization*, 1991.
- Scholla, M.H. and Wells, M.E. “Tracking Trends in Industrial Sterilization.” *Medical Device and Diagnostic Industry*, September 1997, pp. 92-95.