

INTRODUCTION TO GAMMA PROCESSING

TECHNICAL TIP #01

What is gamma radiation?

High-energy photons are emitted from an isotope source (e.g., Cobalt 60). These photons can create ionization (electron disruptions) throughout a product.

What are the effects of gamma radiation?

High-energy gamma radiation produces electron disruptions (ionization) in any material that it encounters. In living cells, these disruptions result in damage to the DNA and other cellular structures. These photon-induced changes at the molecular level may cause the death of the organism or render the organism incapable of reproduction. This effect is useful in killing bacteria, insects, or other living contaminants which may exist in, or on, a product.

What is gamma radiation used for?

Common applications for gamma processing (treatment) include the sterilizing (killing of bacteria) of medical devices, microbial reduction of foods, cosmetics and their packaging, and the de-infestation of agricultural products. A list of commonly treated products is available in a separate Technical Tip.

Are there items that gamma radiation cannot be used for?

Gamma radiation is not widely used for aqueous drug products and pharmaceuticals with a proteinaceous component, because it can degrade such products. Also, food with a high fat content may not be good candidates.

What is a typical gamma processing cycle?

The entire process from receipt to release is documented per the established Quality System requirements. Product arrives on truck and is unloaded into the processing facility. Product is loaded in carrier/tote per established configuration, dosimeters are placed, and the product is exposed to the radiation field. Monitoring dosimeters are analyzed while product is quarantined.

All documentation and processing history records are reviewed and, if acceptable and the Customer specifications are met, the product is released and shipped for use or further distribution. The entire process can take from a few hours to several days depending on the volume of product being processed.

The two common irradiator types are continuous and batch. Continuous units function with an automated conveyance system moving product through a "maze" (which prevents photons from exiting the shield), past a gamma source, and back out on a continuous basis. A batch unit works by loading a set number of totes or carriers and positioning the totes in the irradiation chamber. The cobalt is then raised from its shielded storage position (normally underwater) to an exposure position, and the product is irradiated for a specified period of time. The source is then returned to its shielded position and the product totes are moved out of the chamber as a "batch."

What are the safety issues with gamma processing?

There are safety issues associated with the process; therefore, processing plants are strictly regulated by either a state or federal nuclear regulatory body. Redundant (or layered) safety systems exist to protect workers and the general public. All irradiator operators undergo rigorous safety training. Treated product does **not** become radioactive and there is no negative environmental impact resulting from this use of Cobalt 60.

Is there other regulatory oversight?

In addition to state or federal NRC supervision (due to the possession of isotope), the marketing and manufacture of medical devices is regulated by the FDA. The treatment of foodstuffs is also under the jurisdiction of the USDA (for minimum dose and handling practices) and the FDA (for maximum dose limits). Therefore, processing must be performed with appropriate validation and quality assurance controls and documents to assure effective gamma processing.

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