TECHNICAL TIP

CUMULATIVE RADIATION DOSING

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.

When ionizing radiation passes through a material, its energy is deposited into the material. The energy deposited into material can be done so in order to accumulate a cumulative amount of energy, or dose. Radiation dose is cumulative and the effect of absorbed dose on the destruction of micro-organisms is cumulative. Therefore, product can be irradiated several times in order to accumulate a specific dose.

Products that are capable of supporting microbial growth may be able to support cumulative dosing. An assessment of the impact on the process interrupt between cumulative doses for these types of products should be performed by the product manufacturer.

Generally, unless the product can support growth based on some nutritive quality or component, process interruption should not be problematic. During radiation processing, when the delivered dose falls short of the products specified dose range the product can be augmented, or “topped off”, to achieve the requested dose range as radiation dose is cumulative.

Without specific knowledge of the product, in general, products that do not have high moisture content are not nutritive for bacteria and therefore their dose can be augmented by the cumulative dosing. Again, an assessment for these types of products should be performed by the product manufacturer.

REFERENCES:

1. AAMI TIR 29:2012. Guide for process control in radiation sterilization of medical devices (Sections 8.6.1.6.4 and 8.6.1.6.5)

2. AAMI 11137-1:2006, Appendix A10.10

3. Fairand, Barry P., “Radiation Sterilization for Health Care Products, X-Ray, Gamma, and Electron Beam”, p.103. (2002).

FOR MORE INFORMATION

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