

## **Summary - Gamma Radiation Sterilization**

Critical Process Parameters for gamma radiation sterilization include:

- Exposure time,
- Timer setting (batch mode processing),
- Conveyor speed (continuous mode processing),
- Dose measurement.

Gamma Radiation Commissioning and/or Qualification should include, and not be limited to, documentation of the following:

- Verification that the gamma irradiator is installed according to design criteria;
- Identification of irradiator location within the facility and flow of materials through the facility;
- Description of the construction and operation of the irradiator, including the conveyor system and timer;
- Description of the irradiation carriers, including materials of construction and dimensions;
- Identification of I/Es used to control, monitor, and record critical process parameters;

Establishment of a Sterilization Dose Using AAMI Method 1 for a Single Production Batch includes the following steps:

- a. Determine the average indigenous bioburden of the API, drug product, medical device, or non-product item using ten (10) randomly collected samples;
- b. Determine the verification dose for a Sterility Assurance Level (SAL) of  $10^{-2}$  from an AAMI table using the average bioburden
- c. Verify that the verification dose does not exceed the established maximum sterilization dose limit;

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