



TECHNICAL TIP

IRRADIATION GLOSSARY OF TERMS

AAMI:

Association for the Advancement of Medical Instrumentation. Publish guidelines used for sterilization. For irradiation, sterilization documents 11137 and TIR 33 are most commonly referenced for dose setting. Additional documents on microbiological testing, materials, etc. related to the device industry are also available.

Absorbed Dose:

Quantity of energy delivered per unit mass of matter. The unit of absorbed dose is the Gray (Gy). See Kilogray also.

Accelerated Aging:

Storage of product at elevated temperature and or other intensified conditions (such as humidity) in order to simulate real time ageing in a shorter period of time.

ANSI:

American National Standards Institute

Augmentation:

Action taken to increase the sterilization dose based on the results obtained from a dose audit. Occurs when a dose audit has failed at the original verification dose.

Bacteriostasis and Fungistasis (B/F):

Test performed with selected microorganisms to demonstrate the presence of substances that inhibit the multiplication of microorganisms. This is done prior to a sterility test to assure that the readings of the sterility test are true. For example, if the product has an inhibitory effect on bacterial growth, you might get a false sense of security as to the sterility of the product.

Bioburden:

Population of viable organisms on a product. This value is used to determine correct verification and sterilization dose. This represents the contamination that the product received in the

process of being manufactured. Samples tested for bioburden are un-irradiated samples from the complete manufacturing process in final format and packaging.

Cobalt 60:

Radioactive isotope of Cobalt 59, produced for commercial applications by neutron bombardment. Cobalt 59 (27 protons and 32 neutrons) is the stable natural isotope. Cobalt 60 when produced absorbs one additional neutron (27 protons and 33 neutrons). The half life of Cobalt 60 is 5.26 years; the gamma rays produced as it decays have 1.17 MeV and 1.44 MeV of emitted energy. These high energy photons can penetrate deeply into a product, which makes them effective at sterilization.

Colony Forming Unit (cfu):

Visible growth of microorganisms arising from a single cell or multiple cells.

Curie:

Radionuclide unit of measure. 1 Curie= 3.7×10^{10} disintegrations per second (1 Becquerel = 1 dps).

D10 Value (decimal reduction value):

Dose in kGy required to achieve inactivation of 90% of a population of the test organisms under stated exposure conditions.

Dose Uniformity Ratio:

The ratio of the maximum dose divided by the minimum dose.

Dosimeter:

Device or system having a reproducible, measurable response to radiation which can be used to measure the absorbed dose to a product. Common types include Harwell Red Perspex, alanine pellets, ceric cerous or FWT film.

FOR MORE INFORMATION

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Dosimetry:

Measurement of absorbed dose by the use of dosimeters

Gamma Ray:

Short wavelength, high energy electromagnetic radiation (photons) emitted from a radioactive material in the process of nuclear transition. For commercial applications, this is commonly Cobalt 60.

Half Life:

Time required for a radioactive isotope to decay to half of its original Curie content.

Irradiator:

Assembly of equipment that allows safe and reliable sterilization processing which includes a radiation source, conveyer, carriers or totes, safety devices and shielding, etc.

a. *Batch irradiator:* Irradiator in which containers are introduced or removed while the radioactive source is in the storage position.

b. *Continuous irradiator:* Irradiator which can be loaded and unloaded with product while the source is in the processing position.

Kilogray:

Unit of absorbed dose. 1 Gray (Gy) equals 1 Joule of energy per Kilogram of product (1 Gray= 100 rads. 1 kilogray is 1000 Joules per Kilogram. This is the mean energy imparted to a unit of matter divided by the mass of that matter. The kGy is the international unit of absorbed dose. Older literature may use a term called Megarad. 1 Megarad equals 10 kGy.

Real Time Aging:

Storage of product at ambient conditions in order to evaluate the function over time.

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