factsheet

Radiation Sterilization of Medical Devices

In the 1950's the replacement of re-usable devices by single-use devices was made possible by the availability of affordable polymers. As these new materials could not withstand the high temperatures of traditional heat sterilization, it was necessary to use a 'cold' processes. Gamma irradiation using a Cobalt-60 source provided the required penetration and characteristics and became a leading sterilisation modality. Today electron beam and X-ray technologies offer alternatives but to date these technologies are not widely used to sterilise medical devices.

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Drapes, gowns, surgical gloves, scalpels and prosthetic implants are among the medical devices commonly sterilized by radiation sterilization.

Sterility Assurance

Over the years, the concept of sterility evolved from absence of any viable microorganism, an absolute condition, to the probabilistic notion of Sterility Assurance Level (SAL), i.e. the presence of one surviving microorganism in a population of items. Indeed the inactivation of a population of microorganisms follows an exponential pattern and there is always a finite probability of a microorganism surviving sterilization, regardless of the extent of processing applied. An SAL of 10^{-6} indicates a probability of one item being contaminated in one million. This is still the most widely used value though some devices could certainly be sterilized at less drastic SAL values without added risk for the patient. As medical devices have become more complex it has become difficult to achieve a SAL of 10^{-6} without damaging the device. In such situations a reduced SAL would enable complex devices that include biological components to be more effectively sterilized.

Calculating Dose

An essential element in the design of a radiation sterilization process is the determination of the minimum dose necessary to obtain the required SAL. The Association for the Advancement of Medical Instrumentation (AAMI) developed a variety of methods for this purpose and to periodically ensure that this dose remains effective (dose audits). As the tolerance of polymers to irradiation varies, it is also necessary to determine the maximum dose that can be used without affecting the quality or functional properties of the device, considering that irradiation is not delivered homogeneously but leads to gradients of doses within the treated product.

When a radiation sterilization process has been properly validated, the release of sterilized items in routine is essentially based on the verification of the doses that were delivered. It is not necessary to test treated samples for sterility or to use biological indicators to assess efficacy.

As of June 2017, the main references for radiation sterilization are the following standards:

- **ISO 11137-1:2006**
  Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

- **ISO 11137-2:2013**
  Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

- **ISO 11137-3:2017**
  Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects