STERILITY ASSURANCE LEVELS (SALS): IRRADIATION

STERIS
Applied Sterilization Technologies

TECHNICAL TIP #19

This TechTip provides information on the selection of an appropriate Sterility Assurance Level (SAL) for medical devices. Many factors go into this selection, but since the choice of SAL is directly related to sterilization dose, this decision is critical to making a sterile claim on any product and one must consider the impact on the product design (materials selection, customer needs and desires, functionality, etc).

A sterile medical device is one that is free of viable microorganisms. For a sterile medical device this can be achieved through:

- A terminal sterilization process
- Sterilization of components, followed by sterile filtration and aseptic filling into a sterilized container
- A combination of chemical/physical sterilization and aseptic processing

The sterility of any product is defined by the probability of a viable microorganism on the product after it has been sterilized. This probability is referred to as a sterility assurance level (SAL). An SAL is normally expressed as 10^{-n} with historically, a 10^{-3} or a 10^{-6} value being used most frequently for sterilization. The SAL expression 10^{-n} is a quantitative value to assure sterility. When applying this quantitative value, one has a greater assurance of sterility with a lower SAL. For example, a 10^{-6} SAL is lower than a 10^{-3} SAL and therefore provides a greater assurance of sterility. While the probability can never be reduced to zero (100% assurance level) and still have product for use, it can be and is expected to be reduced to very low numbers.

An SAL of 10^{-6} is frequently used for the terminal sterilization of medical devices (probability of 1 in 1,000,000 of finding a non sterile unit). An SAL of 10^{-3} has also been used for some medical devices depending on their intended use or their ability to withstand a terminal sterilization process which provides a 10^{-6} SAL. The choice of a sterilization process and SAL should be addressed early in the development of the product and process design requirements in conformance with a quality system. An appropriate validation method is selected in order to demonstrate that the sterilization process will routinely deliver the chosen SAL (e.g., ANSI/AAMI/ISO 11137:2006 for irradiation). The substantiation of this sterile claim over time is through the dose audit process (dose setting and audits are discussed in further detail in other TechTips).

For the sterilization of all medical devices the most rigorous SAL should be selected and used based upon the ability of the product to function after it undergoes the sterilization process. If a product can not withstand a 10^{-6} SAL, the 10^{-5} and 10^{-4} SAL should be investigated prior to choosing a 10^{-3} SAL. A determination must also be made that meets the regulatory requirements for the specific device before proceeding. AAMI ST67 gives the following criteria for selection.

A 10^{-6} SAL, or an SAL providing greater assurance of sterility (i.e. 10^{-6}, 10^{-7}, etc.) is used for:

- Products intended to come into contact with breached skin or compromised tissue
- Invasive products that enter normally sterile tissue
- Products with claims of sterile fluid pathways
- Surgically implanted devices

A 10^{-3} SAL, or an SAL providing greater assurance of sterility (i.e. 10^{-4}, 10^{-5}, etc.) is used for:

- Products not intended to come into contact with breached skin or compromised tissue
- Topical products that contact intact skin or mucous membranes
- Product distributed and sold within EU (European Union). This is to comply with the European Medical Device Directive

When a product requires a 10^{-6}, but it is incapable of withstanding the sterilization process, the selection of an SAL other than 10^{-6} may be necessary. A different SAL can be applied when **all** of the following apply:

- The product cannot be designed to allow a sterilization process that achieves an SAL of 10^{-6} without adversely affecting its function and safety
- The product offers unique or superior benefits for patient diagnosis, treatment, or care
- No alternative product is available that can be sterilized with a process that achieves a 10^{-6} SAL

Examples of terminally sterilized products and the selected sterility assurance level

Sterility assurance levels for terminally sterilized products*

10^{-3} SAL	**10^{-6} SAL** (or SAL providing greater assurance of sterility, e.g., 10^{-7}, 10^{-8})

1. Products not intended to come into contact with breached skin or compromised tissue, such as:
• Collection or transfer devices:
  • Blood collection tubes for in vitro diagnostic tests
  • Culture media devices
  • Serological pipettes
  • Specimen containers
• Topical devices:
  • ECG electrodes
  • Drainage bags
  • Grounding pads
  • Surgical drapes and gowns
• Mucosal containing devices:
  • Tongue depressors
  • Examination gloves
  • Urinary catheters
2. Products that cannot withstand a 10^{-6} SAL process:
• Porcine heart valves
• Wound dressings of a biological nature
	1. Products intended to come into contact with breached skin or compromised tissue, such as:
	• Wound dressings
	• Cardiac catheters
	  • Cauterizing devices
	  • Scalpels and other surgical instruments
	  • Surgeon's gloves
	  • Syringes
	  • Hypodermic needles
	  • Parenteral solutions
	  • Peritoneal dialysis solutions
	• Prefilled syringes
	• Laparotomy sponges
	• Incise drapes
	2. Invasive products that enter normally sterile tissue
	3. Products with claims of sterile fluid pathways:
	• Fluid pathways of IV sets
	• Fluid pathways of syringes
	• Blood collection containers or bags
	4. Surgically implanted devices:
	• Reconstructive devices (e.g., hip, knee, elbow)
	• Implantable device (e.g., pacemaker)
	• Trauma devices (e.g., nails, screws, plates, pins, wires)
	• Sutures
	• Intraocular lenses
	5. Components used in aseptic processing
	6. Products distributed and sold within EU

* Depending on its intended use and material composition, the same product may be listed in both columns and require different SALs

References:

ANSI/AAMI ST67:2003. Sterilization of health care products – Requirements for products labeled "STERILE"

ANSI/AAMI/ISO 11137: 2006. Sterilization of health care products

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