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*AAMI Consensus Report*

# Guidance on radiation sterilization

validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing

*AAMI CR513:2024*

# Guidance on radiation sterilization validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing

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**AAMI**

**Abstract:** This consensus report provides guidance on simplified approaches for validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing sterilized by radiation.

**Keywords:** radiation sterilization, validation, routine control, single-use systems, pharmaceutical manufacturing, biopharmaceutical manufacturing

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# Guidance on radiation sterilization validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing

## 1 Purpose

Current practices for radiation sterilization validation and routine control of single-use systems often result in using products and test methods that can be overly conservative and burdensome. This document provides alternative, scientifically valid approaches that simplify and improve validation and routine control of sterilization for these products. As some of the approaches described are uncommon applications of information in the standards, it is important to include a person or persons knowledgeable in sterilization microbiology and radiation science to ensure they are being applied appropriately. Although this document is written in the context of SUS, the concepts are applicable to any health care product.

### 1.1 Scope

This consensus report provides guidance on simplified approaches for validation and routine control of single-use systems used for pharmaceutical and biopharmaceutical manufacturing sterilized by radiation.

## 2 References and resources

ISO/FDIS 11137-1:2024, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ANSI/AAMI/ISO 11137-2: 2013/(R)2019 & Amd1, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ANSI/AAMI/ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

AAMI/ISO TIR11137-4, *Sterilization of health care products — Radiation — Part 4: Guidance on process control*

ISO 13004:2022 Sterilization of health care products-Radiation-substantiation of selected sterilization doses-Method $VD_{max}SD$

ISO/TS 19930:2017 *Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of $10^{-6}$*

AAMI TIR104, *Guidance on transferring health care products between radiation sterilization sources*

ISO/ASTM 52628, *Standard practice for dosimetry in radiation processing*

ISO/ASTM 52303, *Guide for absorbed-dose mapping in radiation processing facilities*

ANSI/AAMI/ISO 11737-1 & Amd 1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ANSI/AAMI/ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*