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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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## Task Group representation

**Association for the Advancement of Medical Instrumentation**

**AAMI Radiation Sterilization Working Group**

This AAMI Consensus Report (CR) was developed by a task group under the auspices of the AAMI Radiation Sterilization Working Group.

The **AAMI Radiation Sterilization Working Group** had the following members:

*Cochairs:*
Niki Fidopiastis
Kimberly Patton

*Members:*
Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
Jody Birks, Eagle Medical Inc
Tim Bollnow, Intuitive Surgical Inc
Eric Bomba, Cook Medical - Bloomington
Trabue Bryans, BryKor LLC
Nicholas Brydon, NextBeam LLC
Nicole Burns, Ecolab
Linnette Cachares, Arthrex Inc
Denise Cleghorn, Boston Scientific Corporation
Lisa Cook, B Braun of America Inc
Elaine Daniell, EDan-SA LLC
Douglas Davie, Sterilization Validation Services (SVS)
Jeffrey DelGaudio, Cordis US Corp
Michael Douthit, Minus 6 Sterilization Consulting
Niki Fidopiastis, Medtronic Inc Campus
Michael Flanagan, Zimmer Biomet
Jacob Gibbons, Genentech Inc
Amy Gravley, DEKRA Certification
Michael Graybill, Solventum (fka 3M Health Care)
Jen Gygi, Canyon Labs
Chris Haas, Getinge USA
Douglas Harbrecht, Sterility Assurance LLC
Deborah Havlik, DA Havlik Consulting
Mollie Holter, MicroBio Consulting LLC
Betty Howard, STERIS Corporation | Healthcare
Jeffrey Karp, AbbVie
Ezra Koski, Terumo BCT
Mark Krocko, Mevex Corporation
Paulo Laranjeira, FDA/CDRH
Cathy Leckwart, WuXi AppTec Inc
Vu Lekate, Abbott Laboratories
John Logar, Johnson & Johnson
Randy Mack, Pfizer Parenteral Center of Excellence
Jeffrey Marti, Sterilization and Quality System Consulting LLC
Leisel Masson, BSI Healthcare
Patrick McCormick, Bausch & Lomb Inc
Nicole McLees, Olympus America Inc
Edmarie Mendez Laguna, Becton Dickinson & Company
Susan Messier, Ethide Laboratories
Marina Milenkovic, Edwards Lifesciences
Larry Nichols, Steri-Tek
Susumu Nozawa, Siemens Healthineers
Gerry O'Dell, O'Dell & Hodge Consulting
Kevin O'Hara, Sotera Health LLC
David Parente, Sterwell LLC
Kimberly Patton, Performance Review Institute MedAccred

Michelle Pierce, NAMSA
Rudy Pina, Dynatec Scientific Labs Inc
Tyrone Rouse, Owens & Minor
Jody Rupert, WL Gore & Associates Inc
Manuel Saavedra, AirLife
Mara Senescu, Baxter Healthcare Corporation
Harry Shaffer, Sterilization Consulting Services
Paul Sordellini, Integra LifeSciences Corporation
Molly Swanson, Quality Tech Services LLC
David Tran, Stryker
Christofer Vance, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Stephanie Volk, Convatec
Wendy Wangsgard, ICU Medical Inc
Richard Weisman, Fresenius Medical Care
Scott Weiss, Alcon Laboratories Inc
Beverly Whitaker, Indigo Consulting Group LLC
James Whitcomb, LexaMed Ltd
Jarl Yeager, Powder River Medical Resources
Roberto Zumbado, Philips

*Alternates:*

Joshua Bowen, West Pharmaceutical Services, Inc.
David Brodersen, Getinge USA
Emily Craven, Boston Scientific Corporation
Bethany Daniell, EDan-SA LLC
Martin Dawson, BSI Healthcare
Christophe Deneux, Becton Dickinson & Company
Zachary Dukerich, Arthrex Inc
Gordon Ely, LexaMed Ltd
Shari Formica, Medtronic Inc Campus
Sreekanth Gutala, FDA/CDRH
Dustin Hilkey, Cook Medical - Bloomington
Trang Hoang, Edwards Lifesciences
Samantha Hodge, O'Dell & Hodge Consulting
Gemma Husmillo, AbbVie
Nichole Jackson, Ecolab
Tara Jacobson, Abbott Laboratories
Satu King, Philips
Sarath Koruprolu, Ethide Laboratories
Wendy Mach, Canyon Labs
Mauricio Martinez, ICU Medical Inc
Thomas McElroy, IUVO BioScience
Jacqueline Parada, Integra LifeSciences Corporation
Kyrstan Polaski, STERIS Corporation | Healthcare
Nicole Robichaud, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Hudson Santos, WuXi AppTec Inc
Michael Schoene, Bausch & Lomb Inc
Krista Schulte, Quality Tech Services LLC
Kristen Spigiel, Stryker
Abigail Stein, Zimmer Biomet
Justin Tettenborn, Fresenius Medical Care
Ileana Toro-Lozada, Avanos Medical
Julie Tuinstra, NAMSA
Wayne Usher, Solventum (fka 3M Health Care)
Peter Veselovsky, Mevex Corporation
Jill Warren, Siemens Healthineers
Martell Winters, Sotera Health LLC
Dan Wojtczak, Baxter Healthcare Corporation
Frank Yanocha, Cordis US Corp

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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*

 