

Technical Information Report

AAMI/ISO TIR21387: 2023

Sterilization of health
care products—Guidance
on the requirements
for the validation and
routine processing of
ethylene oxide sterilization
processes using parametric
release

Sterilization of health care products—Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release

Approved 30 June 2023 by
AAMI

Registered 27 August 2023 by
American National Standards Institute, Inc.

Abstract: Provides guidance on the requirements of ISO 11135 that apply when parametric release is used to release the product after exposure to the sterilization process. Provides a path for transition of existing cycles, as well as a path for the development and implementation of a parametric release specification for a new cycle. Highlights the importance and interrelationship of other process factors, i.e. load configuration and equipment performance, which influence reproducibility of an ethylene oxide (EO) sterilization process.

Keywords: ethylene oxide, sterilization, parametric release, validation

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

© 2023 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact the Copyright Clearance Center.

Printed in the United States of America

ISBN 978-1-57020-872-0

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. A TIR must be acted on and the action formally approved usually every three years.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Contents

Page

Committee representation.....	v
Background of AAMI adoption of ISO/TS 21387:2020.....	viii
Foreword.....	ix
Introduction	x
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Quality management systems	2
5 Sterilization agent characterization	2
6 Process and equipment characterization.....	2
7 Product definition.....	4
8 Process definition	5
9 Validation.....	5
10 Routine monitoring and control	10
11 Product release from sterilization.....	10
12 Maintaining process effectiveness.....	11
13 ISO 11135:2014, Annex A.....	12
14 ISO 11135:2014, Annex B	12
Annex A (informative) Establishing specifications for parametric release based on routine processing data.....	14
Bibliography.....	17

Committee representation

Association for the Advancement of Medical Instrumentation

Industrial Ethylene Oxide Sterilization Working Group

The adoption of ISO/TS 21387 as an AAMI Technical Information Report was initiated by the AAMI Industrial Ethylene Oxide Sterilization Working Group. AAMI ST-WG01 provides input to the AAMI Sterilization Standards Committee, which is the responsible group for providing the U.S. input to the relevant group in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Industrial Ethylene Oxide Sterilization Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI Industrial Ethylene Oxide Sterilization Working Group** had the following members:

Cochairs: Ken Gordon
Nicole McLees

Members: Erin Armstrong, B Braun of America Inc
Edward Arscott, NAMSA
Jennifer R. Asleson, Quality, Microbiology & Sterilization Services LLC
David Ballard, Dynatec Scientific Labs Inc
Dean James Bird, Olympus America Inc
Tim Bollnow, Intuitive Surgical Inc
Nicholas Brydon, NextBeam [Nick Brydon Consulting LLC]
Brandon Buxton, WL Gore & Associates Inc
Glenn W. Calvert, West Pharmaceutical Services, Inc.
Kenneth Campbell, Kenneth Campbell Person
Elaine Daniell, EDan-SA LLC
Douglas D. Davie, Sterilization Validation Services
Michael Douthit, Minus 6 Sterilization Consulting
Zachary Dukerich, Arthrex Inc
Dan B. Floyd, DuPont Tyvek Medical and Pharmaceutical Protection
John Fraser, Becton Dickinson & Company
Jacob Gibbons, Genentech Inc
Dr. Zory R. Glaser, Johns Hopkins University-School of Public Health
Ken Gordon, STERIS Corporation | Healthcare
Magnus Graham, BSI Healthcare
Amy Gravley, DEKRA Certification
Rob Grizzle, Rob Grizzle Person
Erick Gustin, Stryker
Chris Haas, Getinge USA
Douglas F. Harbrecht, Sterility Assurance LLC
Leonard Harris, Eurofins Medical Device Testing
Deborah A. Havlik, DA Havlik Consulting
Jason Hedrick, Medtronic Inc Campus
Sean Andre Hodges, Sean Hodges Consulting
Mollie J. Holter, MicroBio Consulting LLC
Clark W. Houghtling, Cosmed Group Inc
Nichole Jackson, Ecolab
Manuel Saavedra Jr., Avanos Medical
Ezra Koski, Terumo BCT
Karen A. Kowalczyk, Medline Industries Inc
Wesley (Wes) Lantz, Zimmer Biomet
Paul Littley, Integra LifeSciences Corporation
Emily Lorcheim, ClorDiSys Solutions, Inc
Christine Loshbaugh, Edwards Lifesciences
Albert (Ted) E. May, Andersen Products Inc
Mauricio Martinez Sr, Smiths Medical

Patrick J. McCormick, Bausch & Lomb Inc
 David Ford McGoldrick, Abbott Laboratories
 Jami McLaren, Boston Scientific Corporation
 Susan Messier, Ethide Laboratories
 Susumu Nozawa, Siemens Healthineers
 Gerry A. O'Dell, Gerry O'Dell Consulting
 Jeff One, AbbVie
 Tarika Onishi, DexCom Inc
 Mike Padilla, Sotera Health LLC
 David Parente, Sterwell LLC
 Kimberly Patton, Performance Review Institute MedAccred
 Andrew Porteous, Baxter Healthcare Corporation
 John Prattico, IUVO BioScience
 Nicole Robichaud, Mesa Laboratories Biological Indicator Division- Bozeman Facility
 Beau Rollins, Convatec
 Tyrone S. Rouse, Owens & Minor
 Matt Russelburg, Healthmark Industries Company Inc
 Vicki Sage, University of Rochester Medical Center
 Gracia Schroeder, 3M Health Care
 Harry L. Shaffer, Sterilization Consulting Services
 Sopheak Srun, Quality Tech Services LLC
 Jeffrey Martin, Sterilization and Quality System Consulting LLC
 Diane Faivre-Swiat, Cardinal Health
 Radhakrishna S. Tirumalai, US Pharmacopeia Convention Inc
 Andre Tuggles, Johnson & Johnson
 Donald P. Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
 Steven E. Turtill, FDA/CDRH
 Peter Veselovsky, Mevex Corporation
 Wendy Wangsgard, ICU Medical Inc
 Richard L. Weisman, Fresenius Medical Care
 Beverly G. Whitaker, Indigo Consulting Group LLC
 Cathy Leckwart, WuXi AppTec Inc
 Frank Yanocha, Cordis US Corp
 Jarl Yeager, Powder River Medical Resources
 Roberto Zumbado, Philips

Alternates: Fabiano Andreazza, Becton Dickinson & Company
 Kenneth Aston II, Intuitive Surgical Inc
 Darryl Babcock, Integra LifeSciences Corporation
 Amanda Bertalotto, Amanda Bertalotto (Individual)
 David J. Brodersen, Getinge USA
 Trabue Daley Bryans, BryKor LLC
 Nicole Burns, Ecolab
 Casey Butcher, Fresenius Medical Care
 Bradley John Catalone, Healthmark Industries Company Inc
 Carrie Clark, STERIS Corporation | Healthcare
 Bethany Daniell, EDan-SA LLC
 Venice Eldred, Medline Industries Inc
 Shawn Engberg, MD Furniture & Supply
 Daniel Fowler, WuXi AppTec Inc
 Naomi Gamm, Abbott Laboratories
 Chad Geiger, DexCom Inc
 Michael Groendyk, West Pharmaceutical Services, Inc.
 Jeffrey Karp, AbbVie
 Satu King, Philips
 Sarath Koruprolu, Ethide Laboratories
 Courtney Lang, Sotera Health LLC
 Leisel Masson, BSI Healthcare
 Shaun McGinley, Zimmer Biomet
 Nicole McLees, Boston Scientific Corporation

Rosa Vale Mercado, Johnson & Johnson
Lauren Miller, Medtronic Inc Campus
Hiren Mistry, FDA/CDRH
Ken Paddock, Baxter Healthcare Corporation
Jeffrey Peltier, Cardinal Health
Janelle Pence, WL Gore & Associates Inc
Michelle Peterson, Stryker
Jimmy Reyes, Alcon Laboratories Inc
Michael J. Schoene, Bausch & Lomb Inc
Erika Skluzacek, Arthrex Inc
Mark D. Sundt, DuPont Tyvek Medical and Pharmaceutical Protection
Molly S. Swanson, Quality Tech Services LLC
Ileana M. Toro-Guzman, Avanos Medical
Wayne Usher, 3M Health Care
Stephanie Volk, Convatec
Jill A. Warren, Siemens Healthineers
Scott Weiss, Alcon Laboratories Inc
Daryl Woodman, Andersen Products Inc

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.
