

Technical Information Report

AAMI TIR28: 2016/(R)2024

Product adoption and process equivalence
for ethylene oxide sterilization

Product adoption and process equivalence for ethylene oxide sterilization

Approved 18 November 2016 and reaffirmed 11 September 2020 and 26 March 2024 by
AAMI

Abstract: This technical information report provides guidance for the adoption of new or modified products into an existing validated sterilization process and for the determination of equivalence of a sterilization process as conducted with different equipment. Guidance is intended to augment the ANSI/AAMI/ISO 11135 series in the areas of product adoption and process equivalence.

Keywords: sterilization, ethylene oxide, product adoption, process equivalence, product family

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

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

Published by

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

© 2017 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. 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 978-1-57020-654-2

Contents

Page

Glossary of equivalent standards	iv
Committee representation	v
Foreword	vii
1 Scope	1
2 Terms and definitions	1
3 Product adoption	2
3.1 Establishment of an EO product family	2
3.2 Establishment of EO processing category	3
3.3 Evaluation for product adoption	3
3.3.1 Determination of adverse effects	3
3.3.2 Determination of product design effects	3
3.3.3 Determination of product material and characteristics effects	3
3.3.4 Determination of sterile barrier system effects	4
3.3.5 Determination of load configuration effects	4
3.4 Conclusions of product adoption evaluation	4
3.4.1 Comparative resistance study	4
3.4.2 Temperature and humidity distribution study	5
3.4.3 Residual study	5
3.5 Maintenance of EO product adoption	5
3.6 Documentation	5
4 Process equivalence	6
4.1 General	6
4.2 Requirements of process equivalence	6
4.3 Determination of process equivalence	6
4.3.1 Process analysis and evaluation	6
4.3.2 Microbiological evaluation	8
4.3.3 Results evaluation	8
4.4 Process requalification and maintenance of equivalence	8
4.5 Documentation	8
Annex A Guide for evaluation of a product for adoption into an EO product family or EO processing category	10
Bibliography	12

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Industrial Ethylene Oxide Sterilization Working Group

This technical information report (TIR) was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Working Group approval of the TIR does not necessarily imply that all committee members voted for its approval.

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

Cochairs: Jonathan Bull, Johnson & Johnson
Jeffrey Martin, Sterilization and Quality System Consulting

Members: Erin Armstrong, B Braun Medical
Edward Arscott, NAMSA
David Ballard, Dynatec Scientific Labs
Stacy Bohl, Boston Scientific Corporation
Anne F. Booth, MS, Booth Scientific
Carolyn Braithwaite-Nelson, Spectranetics
Jonathan Bull, Johnson & Johnson
Tim Carlson, BD Medical
Sarah Chamberlain, Accuratus Labs Solutions
Dennis Christensen, BS, Sterilization Validation & Consulting
Gary N. Cranston, Consulting & Technical Services/PCS
Elaine Daniell, Bard Medical Division
Douglas D. Davie, Sterilization Validation Services
Darci Diage, Direct Flow Medical
David Dion, Cardinal Health
Mary Ann Drosnock, MS, Healthmark Industries
Paul Fioriti, PF Quality Consulting
William F. FitzGerald, PE, FitzGerald & Associates Ltd.
Dan B. Floyd, RM, Dupont Protection Solutions
Lisa Foster, Adiuvo QS & SA Consulting
Matthew Freeman, Terumo BCT
Zory R. Glaser, PhD MPH CSPDM, Johns Hopkins University
Michael Groendyk, Arthrex
Douglas Harbrecht, Sterility Assurance
Arthur C. Harris, Cook
Deborah A. Havlik, Hospira, a Pfizer Company
Jason Hedrick, Medtronic
Clark W. Houghtling, Cosmed Group
Krista Howard, WL Gore & Associates
Naipur Jain, Intuitive Surgical
Carolyn L. Kinsley, LexaMed
Karen A. Kowalczyk, Centurion Sterilization Services
Christine Loshbaugh, Edwards LifeSciences
Mollie Love, Smiths Medical
Jeffrey Martin, Sterilization and Quality System Consulting
Albert May, Andersen Products Inc.
Patrick McCormick, PhD, Bausch & Lomb
David Ford McGoldrick, BS, Abbott Vascular Devices
Russell D. Mills, GE Healthcare
Gerry A. O'Dell, MS, Gerry O'Dell Consulting
Dave Parente, ECOLAB Healthcare
Michelle Peterson, Stryker Instruments
Andrew Porteous, Baxter Healthcare
Nancy Rakiewicz, IUVO BioScience
Keith Reiner, Terumo Cardiovascular Systems
Beth Ridgeway, Mesa Laboratories
Manuel Saavedra Jr., Halyard Health
Harry Shaffer, Sterilization Consulting Services