Technical Information Report

AAMI TIR14: 2016

Contract sterilization using ethylene oxide

AAMI
Advancing Safety in Healthcare Technology

AAMI Technical Information Report

AAMI TIR14:2016
(Revision of AAMI TIR14:2009)

Contract sterilization using ethylene oxide

Approved 5 June 2016 by
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report provides additional guidance to augment the ANSI/AAMI/IS0 11135 series both for medical manufacturers that use contract sterilization facilities and for contract sterilization operations. It addresses how ANSI/AAMI/ISO 11135:2014 applies to ethylene oxide sterilization operations for devices marketed in the United States. Ethylene oxide sterilization guidance for health care facilities is not specifically covered.

Keywords: documentation, sterilization, medical device, manufacturing, ethylene oxide, contract sterilization, validation program, product sampling

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1-57020-613-9

Contents

Page

Glossary of equivalent standards iv

Committee representation v

Foreword vii

1 Scope 1

2 Definitions 1

3 Selection of sterilization facility 1

4 Written agreement between product manufacturer and contract sterilizer 2

5 Validation program 4

5.1 General 4
5.2 Responsibilities 4
5.3 EO product families and EO processing groups 4

6 Handling of BIs, PCDs, and product samples 4

7 Sterilization processing documentation 5

7.1 Validation documentation 5
7.2 Routine processing documentation 6

8 Controls for routine processing 7

8.1 Product load configuration 7
8.2 Shipment and receipt of product for processing 7
8.3 Process control 7
8.4 Process documentation review 7
8.5 Indicators and test samples 8
8.6 Change controls and process deviations 8
8.7 Resterilization 8
8.8 Shipment of product following processing 8

Bibliography 9

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

AAMI Industrial Ethylene Oxide Sterilization Working Group

This Technical Information Report was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group. Committee 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
Anne F. Booth, MS, Booth Scientific
Carolyn Braithwaite-Nelson, Spectranetics
Jonathan Bull, Johnson & Johnson
Tim Carlson, BD Medical
Sarah Chamberlain, Accuratus Labs Services
Gary N. Cranston, Consulting & Technical Services/PCS
Elaine Daniell, Bard Medical Division
Douglas D. Davie, Sterilization Validation Services
Darci Diage, Direct Flow Medical
Mary Ann Drosnock, MS, Healthmark Industries
Paul Fioriti, PF Quality Consulting
William F. FitzGerald, PE, FitzGerald & Associates Ltd.
Dan B. Floyd, RM, Nelson Laboratories Inc.
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 Worldwide
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
Ted May, Andersen Products Inc.
Patrick McCormick, PhD, Bausch & Lomb
David Ford McGoldrick, BS, Abbott Laboratories
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
Liza Salerno, Accuratas Labs Services
Harry Shaffer, Sterilization Consulting Services
Arnold Shechtman, BS, Validation Challenges Consulting
David Silor, Zimmer

Bill South, Isomedix Services
Michael G. Sprague, Ethide Laboratories
Sopheak Srun, MPH SM(NRCM), Quality Tech Services
Fenil Sutaria, Medline Industries
Mara Tafoya, WuXi AppTec
Radhakrishna S. Tirumalai, US Pharmacopeial Convention
Steven E. Turtil, FDA/CDRH
Craig A. Wallace, 3M Healthcare
P. Richard Warburton, ChemDAQ Inc.
Richard L. Weisman, Fresenius Medical Care Renal Therapies Group
Beverly Whitaker, CQA RAB MBA, Indigo Consulting Group
Stacy Bohl Wiehle, Boston Scientific
Dennis L . Wildes, St. Jude Medical
William T. Young, Sterigenics International

Alternates

August Baur, Centurion Sterilization Services
Erika Kitagawa Bawor, Arthrex Manufacturing
MarJean Boyter, Fresenius Medical Care
Robert Bradley, CBET, Mesa Laboratories
Robert Bradley, Mesa Laboratories
Trabue D. Bryans, BryCor
Greg Bush, Alcon Research
Claudia Camp, Stryker Instruments
Greg Crego, IUVO BioScience
Jessica Desmond, Accuratus Labs Services
Dave Dion, Cardinal Health
David Dominguez, Carefusion
Brian Drumheller, Bard Medical Division
Venice Eldred, Medline Industries
Steven Elliott, FDA/CDRH
Diane Faivre-Swiat, Cardinal Health
Naomi Gamm, St. Jude Medical
Scott Giraud, Medtronic Cardiac Surgical Products
William K. Gordon, Steris Isomedix Services
David M. Hilliker, ChemDaq
Brent Huberty, Boston Scientific
Nicole Jackson, Ecolab
Satu King, Spectranetics
Chris Kobus, GE Healthcare
Ezra Koski, A, Terumo BCT
James P. Kulla, BS MS, LexaMed
Wesley Lantz, Zimmer
John Lindley, Andersen Products Inc.
Paul L. Littley, BSE, Nelson Laboratories
Mauricio Martinez, Smiths Medical
Nicole M. McLees, 3M Critical & Chronic Care Solutions
Joseph Mello, Ethide Laboratories
Laurie Nawrocki, NAMSA
Koyejo Obadina, Abbott Vascular
Ken Paddock, Baxter Healthcare
Michael A. Padilla, BSME, SteriPro Labs
Tyrone S. Rouse, Halyard Health
Jade Schiesser, Quality Tech Services
Michael Shoene, Bausch & Lomb
Kristen Thompson, Stryker Instruments
Brian Wallace, Intuitive Surgical
Jill Warren, WuXi AppTec
Scott Weiss, Ethicon
Daryl Woodman, Andersen Products
Casimir John Wos, PhD, FitzGerald & Associates

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

Foreword

This document is part of a series of technical information reports (TIRs) intended for use in conjunction with ANSI/AAMI/ISO 11135:2014. The other reports in the series are:

- AAMI TIR15:2009, Physical aspects of industrial ethylene oxide;
- AAMI TIR16:2009/(R) 2013, Microbiological aspects of ethylene oxide sterilization;
- AAMI TIR28:2009/(R) 2013, Product adoption and process equivalence for ethylene oxide sterilization;
- AAMI TIR56: 2013, Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices; and
- AAMI TIR74:2016, Change summary for ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

The 2016 edition of AAMI TIR14, *Contract sterilization using ethylene oxide* which supersedes AAMI TIR14:2009.

The original TIR14, along with other AAMI TIRs, provided additional guidance to the 1994 edition of the industrial EO sterilization standard 11135, which was revised in 2007 under a new designation, ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. In 2008, ISO published its own guidance document for the 11135 standard, ISO/TR 11135-2:2008, which was based to a great extent on the earlier AAMI technical information reports. Correspondingly, the AAMI Industrial EO sterilization working group updated its TIRs to take into account changes to the 11135 standard as well as to avoid redundancy with ANSI/AAMI/ISO TIR11135-2:2008.

The medical device industry is using contract sterilization operations at an increasing rate. The resulting rise in the percentage of medical devices that are sterilized under contract calls for additional guidance to support this trend. A direct impact of using contract sterilization facilities is the downsizing of the sterilization support and technical knowledge within the medical manufacturer's resources. Experience indicates that contract sterilization procedures require enhanced communications between the manufacturer and the contract sterilizer to ensure a well-controlled sterilization process. As the contract sterilization industry continues to grow, it is increasingly evident that responsibility for sterility is shared by the medical manufacturer and the contract sterilization facility. Furthermore, it is essential that the division of responsibilities be clearly defined and understood by both parties.

This technical information report (TIR) contains guidelines that are not intended to be absolute or to apply in all circumstances. Judgment should be used in applying the information in this TIR.

As used within the context of this document, "should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation. See also the NOTE on Page 1.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of AAMI TIR14: 2016, *Contract sterilization using ethylene oxide*, but it does provide important information about the development and intended use of the document.

Contract sterilization using ethylene oxide

NOTE—This technical information report is not a standard and the material contained herein is not normative in nature. The committee has in a few places used the term "shall" based on their knowledge of requirements contained in relevant standards and/or regulatory requirements.

1 Scope

This AAMI TIR provides guidance that augments ANSI/AAMI/ISO 11135:2014, both for medical manufacturers that use contract sterilization facilities and for contract sterilization operations. This TIR addresses how ANSI/AAMI/ISO 11135:2014 applies to contract ethylene oxide (EO) sterilization operations for devices marketed in the United States.

EO contract sterilization guidance for health care providers is not specifically covered in this TIR.

2 Definitions

For the purposes of this TIR, the terms and definitions in ANSI/AAMI/ISO 11135:2014 (see Bibliography item [20]), and the following apply:

2.1
method suitability test
test performed with selected microorganisms to demonstrate the presence or absence of substances that inhibit their multiplication

2.2
contract sterilizer
facility that offers to provide a contractual service intended to sterilize medical devices that are manufactured by another establishment

NOTE—The definition can include any facility that sterilizes products manufactured by another establishment that is within the same corporation. This establishment may sterilize its own devices as well as provide contractual services.

2.3
manufacturer
establishment, including any repacker or relabeler, that manufactures, fabricates, assembles, or processes a finished device

NOTE—According to the FDA (21 CFR 820.3(l)), a finished device is any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

2.4
verification
evaluation that is performed to ensure current operation or applicability for use of a system

3 Selection of sterilization facility

3.1 When a manufacturer has selected to use a contract sterilizer, a number of factors require assessment to identify a contract sterilizer that best suits its needs.

These factors include the following:

a) proximity of the facility to the manufacturer, transportation routes and the product distribution center or end user;

b) sizes and available capacity of chambers in relation to the expected volume of manufactured material;

c) processing capability of the facility with respect to preconditioning (if used), sterilization, and aeration (if used);