Technical Information Report

AAMI TIR14: 2016/(R)2024

Contract sterilization using ethylene oxide

AAMI

Advancing Safety in Health Technology

AAMI Technical Information Report

AAMI TIR14:2016/(R)2024
(Revision of AAMI TIR14:2009)

Contract sterilization using ethylene oxide

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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

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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.

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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

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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.

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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.

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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, 901 N. Glebe Road, Suite300, Arlington, VA 22203.

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.

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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);