Technical Information Report

AAMI TIR16: 2017

Microbiological aspects of ethylene oxide sterilization

AAMI
Advancing Safety in Health Technology

AAMI Technical Information Report

AAMI TIR16:2017
(Revision of AAMI TIR16:2013)

Microbiological aspects of ethylene oxide sterilization

Approved 17 November 2017 by
Association for the Advancement of Medical Instrumentation

Abstract: Addresses various microbiological aspects of the development and validation of an ethylene oxide sterilization process. Does not address the various factors that can have an effect on the bioburden of the product and on the sterilization process. Provides additional guidance to ANSI/AAMI/ISO 11135:2014 for medical device manufacturers, including those that use contract sterilization facilities or contract sterilization operations.

Keywords: sterilization, microbiological aspects, validation, ethylene oxide, bioburden, performance qualification

AAMI Technical Information Report

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

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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.

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Committee representation

Association for the Advancement of Medical Instrumentation

Industrial Ethylene Oxide Sterilization Working Group

This technical information report (TIR) was developed by the Association for the Advancement of Medical Instrumentation (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.

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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.

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 listed below:

— AAMI TIR14:2009, *Contract sterilization using ethylene oxide*

— AAMI TIR15:2009, *Physical aspects of ethylene oxide sterilization*

— AAMI TIR28:2009/(R)2013, *Product adoption and process equivalence for ethylene oxide sterilization*

— AAMI TIR39:2009, *Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices*

— 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*

The original TIR16, 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, *Sterilization of health care products—Ethylene oxide—Part 2: Guidance on the application of ISO 11135-1*, which was based to a great extent on the earlier AAMI technical information reports. ANSI/AAMI/ISO 11135-1:2007 and ISO/TIR 11135-2:2008 were revised into a single document: ISO 11135:2014.

This TIR provides guidance related to the microbiological aspects of EO sterilization that is typically not covered in depth, or at all, in the existing guidance documents for EO sterilization. It is designed to provide information that will assist in design, qualification, and routine processing of EO sterilization processes. This TIR condenses pertinent information that may be available in a variety of sources in one location and is based on practices that have been found to be used successfully within the United States. This TIR contains guidelines that are not intended to be absolute or to apply in all circumstances. One should use judgment 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 not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the TIR. "Can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulations. 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 Fairfax Drive, Suite 301, Arlington, VA 22203.

NOTE This foreword does not contain provisions of AAMI TIR16:2017, *Microbiological aspects of ethylene oxide sterilization*, but it does provide important information about the development and intended use of the document.

Microbiological aspects of ethylene oxide sterilization

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

1 Scope

This technical information report (TIR) addresses various microbiological aspects of the development and validation of an ethylene oxide (EO) sterilization process. It does not cover the various factors that can have an effect on the bioburden of the product and on the sterilization process. This TIR provides additional guidance to ANSI/AAMI/ISO 11135:2014 for medical device manufacturers, including those that use contract sterilization facilities or contract sterilization operations.

Although the information presented was developed for application to medical devices, the content of this guideline may also be applied to other relevant products or materials.

Products that have been used in a healthcare setting and are being presented for resterilization in accordance with the manufacturer's instructions (see ANSI/AAMI/ISO 17664) are a special case. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination in spite of the application of a cleaning process. Hence, it is important to pay particular attention to the validation and control of the cleaning and disinfection processes used during reprocessing. Healthcare facilities are encouraged to review AAMI ST35, TIR30, and TIR34 for additional information on handling reusable or non-sterile devices requiring sterilization processing.

2 Terms and definitions

For the purposes of this TIR, the terms and definitions in ANSI/AAMI/ISO 11135: 2014 and the following apply.

2.1 compromised tissue: Skin or mucous membrane that has been intentionally or accidentally opened, exposed, or breached

2.2 inoculated carrier: Supporting material on or in which a defined number of test organisms has been deposited

3 Process and equipment characterization

3.1 Sterilization equipment

Guidelines for equipment selection can be found in AAMI TIR15 and EN 1422. Careful selection of the sterilizing equipment and development of the facility design will enable a manufacturer to process a product safely and effectively.

3.2 Process characterization—Physical parameters

3.2.1 Introduction

The variables that have a significant effect on the lethality of an ethylene oxide (EO) sterilization process are EO concentration, temperature, EO exposure time, and often relative humidity (RH). These variables are interrelated and a change in one can often be compensated for by a change in another. Other aspects that might affect lethality are the actual depth and rate of evacuations during the sterilant-removal phases as evacuations can be affected by chamber temperature, humidity, sterilant levels, vacuum pump performance, and/or product load configuration.