Technical Information Report

AAMI TIR16: 2023

Microbiological aspects of ethylene oxide sterilization

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Microbiological aspects of ethylene oxide sterilization

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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

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This technical information report was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

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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 listed below:

— AAMI TIR14, *Contract sterilization using ethylene oxide*.

— AAMI TIR15, *Physical aspects of ethylene oxide sterilization*.

— AAMI TIR28, *Product adoption and process equivalence for ethylene oxide sterilization*.

— AAMI TIR56, *Guidance for the development, validation and routine control of an ethylene oxide sterilization process utilizing flexible bag systems for the sterilization of medical devices*.

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— “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of AAMI TIR16:2023, *Microbiological aspects of ethylene oxide sterilization*, but it does provide important information about the development and intended use of the document.

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Introduction

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 and is designed to provide information that will assist in design and qualification for BI or parametric release processes. Parametric release is desired for routine processing, but this TIR also includes guidance on the use of PCDs for routine processing when BI release is used. This TIR condenses pertinent information that may be available from a variety of sources into 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.

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 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.

NOTE 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 17664-1 and 17664-2) 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 (if used) processes used during reprocessing. Healthcare facilities are encouraged to review ANSI/AAMI ST79, ANSI/AAMI ST98, and AAMI TIR34 for additional information on handling reusable or non-sterile devices requiring sterilization processing at the healthcare facility.

2 Normative references

No normative references were used in the development of this TIR. References referred to in the text are listed in the Bibliography.

3 Terms and definitions

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

3.1
***D* value**
***D*10 value**
time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganisms
[SOURCE: ISO 11139:2018, 3.75]

3.2
EO dwell
period for which the process parameters are maintained within their specified tolerances
Note to entry: It is the period of time between the end of sterilant injection (or nitrogen injection if following the sterilant injection) and the beginning of EO removal (See Figure 1).

3.3
exposure phase
cycle stage between the introduction of the sterilizing or disinfecting agent into the chamber and when the agent is removed
[SOURCE: ISO 11139:2018, 3.111]