Technical Information Report

AAMI TIR15: 2016

Physical aspects of ethylene oxide sterilization

AAMI
Advancing Safety in Healthcare Technology

AAMI Technical Information Report

AAMI TIR15:2016
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Physical aspects of ethylene oxide sterilization

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AAMI

Abstract: This technical information report (TIR) provides additional guidance to augment the ANSI/AAMI/ISO 11135 series. Topics covered in this TIR are sterilization equipment, considerations for preconditioning, calculations for relative humidity, calculations of ethylene oxide concentration, and flammability.

Keywords: sterilization equipment, ethylene oxide, relative humidity, flammability, preconditioning

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

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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

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.

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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:

- AAMI TIR14:2009, *Contract sterilization using ethylene oxide*;
- AAMI TIR16:2009, *Microbiological aspects of ethylene oxide sterilization*;
- AAMI TIR28:2009, *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.*

The original TIR15, along with other AAMI TIRs, provided additional guidance to the 1994 edition of the industrial ethylene oxide sterilization standard ANSI/AAMI/ISO 11135, which was revised in 2007 and 2014 under a new designation, ANSI/AAMI/ISO 11135:2014, *Sterilization of health care products—Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices*. In 2008 and 2014, the International Organization for Standardization (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 TIRs. Correspondingly, the AAMI Industrial Ethylene Oxide Sterilization Working Group is updating its TIRs to take into account changes to the 11135 standard and to avoid redundancy with ANSI/AAMI/ISO 11135:2014.

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 is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the technical information report. "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 Dr., Suite 301, Arlington, VA 22203-8263.

NOTE—This foreword does not contain provisions of AAMI TIR15:2016, *Physical aspects of ethylene oxide sterilization*, but it does provide important information about the development and intended use of the document.

Physical aspects of ethylene oxide sterilization

NOTE—This technical information report (TIR) is not a standard and the material contained herein is not normative in nature. In a few instances, the committee has used the term “shall” based on its knowledge of requirements contained in relevant standards, regulatory requirements, or both.

1 Scope

This AAMI TIR provides additional guidance to augment ANSI/AAMI/ISO 11135:2014. This TIR addresses some of the physical aspects of ethylene oxide (EO) sterilization and provides guidance on sterilization equipment, considerations for preconditioning, how to calculate relative humidity, EO concentration and flammability, as well as guidance on the use of statistics for process equivalence.

2 Definitions

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

2.1
dew point
temperature at which the saturation water vapor pressure is equal to the partial pressure of the water vapor in the atmosphere

NOTE Any cooling of the atmosphere below the dew point would produce water condensation.

2.2
humidity
A measure of the water vapor present in a gas. It is usually measured as absolute humidity, relative humidity, or dew point temperature.

2.3
preconditioning area
chamber or room under defined temperature and humidity conditions for the purpose of conditioning the product prior to entering the gas exposure phase of the process.

2.4
relative humidity (RH)
Ratio of water vapor partial pressure actually present to water vapor pressure required for saturation at a given temperature.

$$\%RH = \frac{\text{actual vapor pressure}}{\text{saturation vapor pressure}} \times 100$$

2.5
chamber humidification
phase of the sterilization process whereby moisture is added to the chamber to replace any environmental moisture potentially lost in the vacuum stages for air removal or inert gas dilution.

2.6
steam purity
measurement of the amount of solid, liquid, or vaporous contamination in the steam.

Note 1 to entry: Normally, steam purity is reported as the solids content. The steam purity needed for an EO sterilization system is defined by the equipment user and needs to be suitable for its intended use.