Technical Information Report

AAMI TIR56: 2013/(R)2016

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

AAMI
Advancing Safety in Healthcare Technology

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

Approved 27 December 2013 and reaffirmed 18 October 2016 by
AAMI

Abstract: This AAMI Technical Information Report (TIR) provides information to be considered during the development, validation, and routine control of EO sterilization processes that are performed using gas diffusion within individually sealed flexible sterilization bags.

Keywords: sterilization, flexible bag systems, diffusion, EO, ethylene oxide

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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.

Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-519-4

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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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Association for the Advancement of Medical Instrumentation

Industrial EO Sterilization Working Group

This Technical Information Report (TIR) was developed by the AAMI Industrial EO 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 document does not constitute endorsement by the federal government or any of its agencies.

Foreword

The processes, methods, and equipment described in this TIR vary significantly from those described in ANSI/AAMI/ISO 11135-1:2007. These differences include but are not limited to the following:

- The body of information provided in ANSI/AAMI/ISO 11135-1:2007 is complemented by supporting documentation found in ANSI/AAMI/ISO 11135-2:2008, as well as a number of related AAMI TIR documents, significant parts of which may not apply to methods and materials that are the subject of this TIR.
- The 11135 series includes 100 % verification of chamber installation and the associated performance qualification (physical and microbiological) of fixed equipment; the methods described in this document rely upon the validation of an integrated, flexible bag/chamber design and a high degree of quality assurance during the manufacturing process of the flexible bag/chamber (and other accessories).
- Methods included in this document identify processes based solely on gas injection by weight, variable, or diminishing (i.e., decreasing by diffusion through the flexible bag) ethylene oxide (EO) concentrations in the atmosphere external to the package but internal to the “flexible bag sterilization systems” per the design of the method.
- Approaches to validation, routine monitoring, and control of cycles may differ significantly from those indicated in 11135.
- For some process designs, the lethality of the process relies completely on storage conditions and time (post introduction of EO) to effectively provide the requisite sterility assurance level. In addition, the lethality provided during the storage period within the sterilization/aeration cabinets may also act simultaneously in providing the aeration method. There are also a number of specialized and novel equipment designs necessary to remove EO from a flexible sterilization bag that vary considerably from the methods described in 11135. New considerations may arise regarding the identification of worst-case aeration processes, as well as subsequent validation.

Introduction

As a result of a revision to ANSI/AAMI/ISO 11135-1, the exclusion in the document stating “This part of ISO 11135 does not cover sterilization by injecting ethylene oxide or mixtures containing ethylene oxide directly into individual product packages,” was revised to state, “This International Standard does not cover sterilization by injecting EO or mixtures containing EO directly into packages **or a flexible chamber**.” The addition of the flexible chamber to the international standard clarified the intent that ANSI/AAMI/ISO 11135 should only be applied to traditional fixed sterilization chambers, and that ANSI/AAMI/ISO 14937:2009/(R)2013 should be used for the requirements and guidance related to these types of EO processes. Ethylene oxide sterilization is a long-standing sterilization process, and EO sterilization within flexible sterilization bags has been used commercially since the 1960s. However, little published information was available to provide guidance on adequately addressing development, validation, and routine control of these EO systems. Therefore, the Industrial EO Sterilization Working Group chose to develop a technical information report (TIR) that addresses these aspects as a prelude to the eventual development of an international standard.

During the development of the TIR, there was strong objection by some to the use of EO sterilization within a flexible sterilization bag; therefore, this document does *not* represent a committee or national consensus. Most of this objection centered around two specific areas of concern. The first objection was the lack of workplace safety information that is provided in this TIR. The decision not to include safety related details within this TIR is consistent with the position that has been taken in other industrial sterilization standards or guidance documents. Information related to the safe use of EO in the workplace is readily available (see https://www.osha.gov/SLTC/ethyleneoxide/) and its use falls under the regulatory auspices of OSHA (29 CFR 1910.1047) (2005). Additional information related to the carcinogenic properties of EO can be found in World Health Organization, 2008.

The second objection was related to the dearth of published information related to EO sterilization in flexible sterilization bags that documented its efficacy or repeatability. The biggest differences between traditional EO sterilization and this non-traditional method are the use of the flexible sterilization bag with a very low concentration of EO and the absence of significant air removal during the process. While there is not significant literature related to this process in particular, there is considerable literature on the efficacy and repeatability of EO sterilization in general, even under conditions that are somewhat similar to those used during EO sterilization in a flexible sterilization bag ([1] and [2]). During the development of this TIR, two articles were published ([5] [6]) that have particular relevance to this process. The expectation is that as the TIR is used, additional information will be made public to further substantiate its efficacy and repeatability, as well as to refine how the processes are developed, validated and routinely controlled.

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

1 Scope

This TIR includes information to be considered during the development, validation, and routine control of EO sterilization processes that are performed using gas diffusion within individually sealed flexible sterilization bags.

2 Terms and definitions

2.1
abatement system
device that is attached to the exhaust from the sterilization/aeration cabinet and connected to the outside atmosphere. It is designed to absorb and/or react with the EO gas exhausted from the cabinet and reduce the amount of EO exhausted to the external atmosphere

2.2
aeration cycle
part of the sterilization process, after the sterilization portion of the cycle, during which EO and/or its reaction products dissipate from the device(s)

2.3
chemical integrator
demonstrates that the sterilization parameters over a specified range of sterilization cycles have been met in a specified sterilization wrap, container, cassette, or pouch

2.4
dunnage
material that duplicates the weight, volume, thermal characteristics, EO absorption characteristics, surface geometry and tortuosity, and other critical properties of the devices being tested

2.5
effectively impermeable
term used to describe a bag material that does not allow for diffusion of EO during the sterilization cycle

2.6
EO cartridge
single use, hermetically sealed container that holds a predetermined weight of EO. The EO cartridge is designed to be manually activated through the flexible material of the flexible sterilization bag, releasing 100 % EO

2.7
exposure time
period for which the process parameters (temperature, relative humidity, and EO concentration) are maintained within specified tolerances

