Technical Information Report

AAMI TIR28: 2016

Product adoption and process equivalence for ethylene oxide sterilization

AAMI
Advancing Safety in Healthcare Technology

AAMI Technical Information Report

AAMI TIR28:2016
(Revision of AAMI TIR28:2009/(R)2013)

Product adoption and process equivalence for ethylene oxide sterilization

Approved 18 November 2016 by
AAMI

Abstract: This technical information report provides guidance for the adoption of new or modified products into an existing validated sterilization process and for the determination of equivalence of a sterilization process as conducted with different equipment. Guidance is intended to augment the ANSI/AAMI/ISO 11135 series in the areas of product adoption and process equivalence.

Keywords: sterilization, ethylene oxide, product adoption, process equivalence, product family

AAMI Technical Information Report

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

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

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www.aami.org/standards/glossary.pdf

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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 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.

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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 TIR14:2009, Contract sterilization using ethylene oxide;
- AAMI TIR15:2009, Ethylene oxide sterilization equipment, process considerations, and pertinent calculations (currently under revision);
- AAMI TIR16:2009, Process development and performance qualification for ethylene oxide sterilization—Microbiological aspects (currently under revision); and
- 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 TIR28, 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. Correspondingly, the AAMI Industrial EO sterilization working group is updating its TIRs to take into account changes to the 11135 standard.

This TIR provides guidance for the adoption of new or modified products into an existing validated sterilization process and for the determination of equivalence of a sterilization process as conducted with different equipment. These areas are not addressed in depth by ANSI/AAMI/ISO 11135:2014, but they are important industry practices that are used to reduce the expense and time associated with the validation or requalification of an ethylene oxide sterilization process and are based on accumulated process knowledge.

The adoption of a new or modified product into an existing validated sterilization process involves the determination that the product is no more of a challenge than the product (i.e., master product or representative product) or process challenge device that was used in the performance qualification for the ethylene oxide sterilization process.

The process equivalence section of this TIR will provide guidance on how to establish equivalence between processes perfomed in separate equipment or sets of equipment and guidance on the level of microbiological performance qualification testing required. It also includes guidance on the maintenance of equivalence and requalification when equivalence has been established.

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 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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI TIR28:2016 titled *Product adoption and process equivalence for ethylene oxide sterilization*, but it does provide important information about the development and intended use of the document.

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Product adoption and process equivalence for 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 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 TIR addresses medical devices that are processed by ethylene oxide (EO) sterilization using conventional or parametric product release. The document applies to the following situations for the sterilization of medical devices:

a) a new product is being added to the previously validated process,

b) changes to validated products are being evaluated,

c) a previously validated process is being moved to a different facility or to different equipment, and

d) equivalency of a sterilization process is being evaluated.

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.

2 Terms and definitions

For the purposes of this AAMI TIR, the following terms and definitions apply:

2.1
candidate equipment
new or modified piece of equipment intended to deliver an existing validated process.

2.2
candidate product
new or modified product, including the packaging system, proposed for inclusion in the existing validated sterilization process.

2.3
EO processing category
collection of different product or product families that can be sterilized together (in the same EO sterilization process).

NOTE—All products within the processing category have been determined to present an equal or lesser challenge to the sterilization process than the challenge device for that category.

2.4
EO product family
group of products possessing characteristics that allow them to be sterilized using the same defined process conditions and determined to be similar or equivalent for validation purposes.

2.5
load configuration
totality of attributes defining the presentation of the product to the sterilization process. This configuration includes (a) the orientation of the product within the sterile barrier system (primary package); (b) the quantity and orientation of the primary package within the protective packaging (secondary or tertiary package); (c) the quantity, orientation, and placement of the product in the protective packaging on the sterilizer pallets (or within the carriers); and (d) the quantity and placement of the pallets (or carriers) within the vessel or area.

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2.6
packaging system
combination of the sterile barrier system and protective packaging.

2.7
process equivalence
documented evaluation that the same sterilization process can be delivered by two or more pieces of sterilization process equipment within defined parameters.

2.8
product adoption
process of formally including a candidate product into an existing validated EO processing category or EO product family.

2.9
sterilization process equipment
preconditioning area (if used), chamber or sterilizer, aeration area (if used), and their respective ancillary equipment.

3 Product adoption

The term usually associated with the introduction of a new or modified product (candidate product) into a validated sterilization process is “product adoption.” Product adoption has traditionally been used to reduce the level of performance qualification (PQ) required by grouping products into either EO product families or EO processing categories. This TIR describes the important aspects to the approach for product adoption, which also includes the establishment of EO product families and EO processing categories and the recommended maintenance of those families and categories.

3.1 Establishment of an EO product family

Products may be grouped into EO product families on the basis of similarities in configuration, materials, density, packaging, or difficulty of sterilization.

The following list provides guidance on the elements that may be considered when placing products into EO product families:

a) product design and function,

b) manufacturing method,

c) manufacturing environment or area,

d) material of construction,

e) packaging materials,

f) sterile barrier or protective packaging configuration,

g) density,

h) size and/or surface area, and

i) bioburden.

An EO product family may consist of various combinations of similar products. For example, an EO product family may contain a series of catheters that differ only in their sizes; a variety of products that are made in the same environment with the same material; or kits that contain various combinations of sponges, bowls, instruments, towels, drapes, and other items, and which differ within a family only in the types, quantities, and sizes of items included within the kits. The EO product family may be represented by a worst-case product (often called the “master product”), or the entire family is considered an equivalent challenge to the sterilization process and any product within the family can represent the family, or the product family can be represented by a process challenge device (PCD). The representative product or PCD would then be used as the basis for comparison of any candidate product (see ANSI/AAMI/ISO 11135:2014 (D.12.5.11.1).