Technical Information Report

AAMI TIR28:2001

Product adoption and process equivalency for ethylene oxide sterilization

AAMI
Association for the Advancement of Medical Instrumentation

Product adoption and process equivalency for ethylene oxide sterilization

Approved 24 December 2001 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI technical information report (TIR) provides guidance for the adoption of a new or modified product into an existing validated sterilization process and for the determination of equivalency of a sterilization process as conducted in different equipment. Its guidance is intended to augment ANSI/AAMI/ISO 11135:1994, *Medical devices—Validation and routine control of ethylene oxide sterilization,* and to expand on the areas of product adoption and process equivalency that are not addressed in ANSI/AAMI/ISO 11135:1994.

Keywords: adoption, equivalency, process equivalency, product adoption, product family

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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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Contents

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

Note—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations

International designation	U.S. designation	Equivalency
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607: 200x[1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2001	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Sterilization Standards Committee

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 TIR does not necessarily imply that all working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this TIR does not constitute endorsement by the federal government or any of its agencies.

Introduction

This document is part of a series of reports intended to be used in conjunction with ANSI/AAMI/ISO 11135:1994, *Medical devices—Validation and routine control of ethylene oxide sterilization*. The other reports in the series are:

— AAMI TIR14:1997, *Contract sterilization for ethylene oxide*

— AAMI TIR15:1997, *Ethylene oxide sterilization equipment, process considerations and pertinent calculations*

— AAMI TIR16:2000, *Process development and performance qualification for ethylene oxide sterilization—Microbiological aspects*, and

— AAMI TIR 20:2001, *Parametric release for ethylene oxide sterilization*.

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 equivalency of the sterilization process as conducted with different equipment. Although these areas are not specifically addressed by ANSI/AAMI/ISO 11135:1994 (AAMI, 1994), they are important industry practices that are used to reduce the expense and time associated with the validation 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 that was used to validate the ethylene oxide (EO) sterilization process. Product adoption has been a longstanding practice in the industry. Although it has been addressed in individual papers (Lowery and DeRisio, 1982; Burgess and Reich, 1993) it has not been addressed in a guidance document. Therefore, this TIR will address how product can be adopted into an existing EO process.

The process equivalency section of this TIR will provide guidance on the level of validation testing required on the basis of the equivalence of the sterilization process and/or equipment. It will also provide guidance on how to determine the equivalence of the process and/or equipment.

NOTE—This TIR is considered “informative,” and the use of the terms “shall,” “should,” and so forth should be considered within the context of this TIR only. That is, if the decision is made to use a particular method presented in this TIR, then the method should be followed with adherence to the requirements (“shall”) and recommendations (“should”) as set forth in this TIR. The term “must” refers to regulatory requirements.

Product adoption and process equivalency for ethylene oxide sterilization

1 Scope

This TIR addresses medical devices that are processed by ethylene oxide sterilization using conventional or parametric product release. The document applies to the following situations for the sterilization of medical devices:

— a new product is being added to the previously validated process;

— changes to validated products are being evaluated;

— a previously validated process is being moved to a different facility and/or equipment; and

— 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. This document does not address the equivalency of two or more sterilization processes run in the same or different sterilization process equipment.

2 References and bibliography

ANSI/AAMI/ISO 10993-7:1995, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals, 2ed.*

ANSI/AAMI/ISO 11135:1994, *Medical devices—Validation and routine control of ethylene oxide sterilization, 3ed.*

ANSI/AAMI/ISO 11737-1:1995, *Sterilization of medical devices—Microbiological methods—Part 1: Estimation of population of microorganisms on products, 1ed.*

AAMI ST67:200X,[2] *Sterilization of medical devices—Requirements for products labeled 'STERILE.'* (In preparation.)

AAMI TIR14:1997, *Contract sterilization for ethylene oxide, 1ed.*

AAMI TIR15:1997, *Ethylene oxide sterilization equipment, process considerations, and pertinent calculations, 1ed.*

AAMI TIR16:2000, *Process development for ethylene oxide sterilization—Microbiological aspects, 1ed.*

AAMI TIR19:1998, *Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals, 1ed.*

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[2] AAMI expects to publish this standard in the second quarter of 2002 following completion of appropriate approval processes.

