Technical Information Report

AAMI TIR33:2005

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose—Method VD_{max}

Association for the Advancement of Medical Instrumentation

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose—Method VD_{max}

Approved 21 December 2005 by
Association for the Advancement of Medical Instrumentation

Abstract: This technical information report is intended to prepare the industry for extending application of the VD_{max} method contained in ANSI/AAMI/ISO 11137-2:2006, which is for use with selected doses of 15 kGy and 25 kGy, to the following additional doses: 17.5, 20, 22.5, 27.5, 30, 32.5, and 35 kGy.

Keywords: radiation, VD_{max}, substantiation

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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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 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
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ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
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ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	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/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical

International designation	U.S. designation	Equivalency
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
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ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
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ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	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 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production
[2]Final approval pending

Committee representation

Association for the Advancement of Medical Instrumentation
Sterilization Standards Committee

The development of AAMI TIR33:2005 as an AAMI technical information report was initiated by the AAMI Radiation Sterilization Working Group (ST/WG 02) under the auspices of the AAMI Sterilization Standards Committee (AAMI/ST).

Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Radiation Sterilization Working Group** had the following members:

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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.

Introduction

This document is intended to be used in conjunction with ANSI/AAMI/ISO 11137, *Sterilization of health care products Radiation sterilization* (series). One of the activities encompassed within the standard is the selection of the sterilization dose to be applied to health care products.

ANSI/AAMI/ISO 11137-2:2006 includes Method VD_{max} for the substantiation of 25 kGy as a sterilization dose (termed VD_{max}^{25}) for products with an average bioburden less than or equal to 1,000, and VD_{max}^{15} for the substantiation of 15 kGy as a sterilization dose for products with low average bioburden (less than or equal to 1.5).

This TIR parallels and extends ANSI/AAMI/ISO 11137-2; it provides a methodology for the substantiation of a range of sterilization doses. Included are 15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, and 35 kGy; each of these sterilization doses is valid only for a specified unique range of average bioburden on product.

The method described in this report is a simple approach to dose substantiation to attain a sterility assurance level (SAL) of 10^{-6} at the selected sterilization dose, (e.g. 25 kGy for VD_{max}^{25}). The application of this method is not limited by batch size or production frequency, and the number of product units irradiated in the verification dose experiment remains constant. The method employs as its basis the standard distribution of resistances (SDR) on which Method 1 is also founded and embodies the following three principles:

— Existence of a direct link between the outcome of the verification dose experiment and the attainment of an SAL of 10^{-6} at the sterilization dose.

— Possession of a level of conservativeness at least equal to that of the SDR.

— For a given bioburden, use of a maximum verification dose (VD_{max}) commensurate with substantiation of a selected sterilization dose.

This approach to sterilization dose substantiation was first outlined by Kowalski and Tallentire (1999), and from subsequent evaluations involving computational techniques (Kowalski, Aoshuang, and Tallentire, 2000), it was concluded that the method is safe and yields unambiguous results. An overview of the method is provided in Kowalski and Tallentire (2000); application of the VD_{max} approach to doses other than 25 kGy is discussed in Kowalski and Tallentire (2003).

The method described here and designated VD_{max} procedurally comprises elements that closely parallel those of dose-setting Method 1. One key area of difference is the number of product units used in the verification dose experiment. In the computer evaluations referred to above, changing the verification SAL value had little effect on the substantiation outcome, and this finding led to a sample size of 10 product units being chosen for subsequent field evaluations and, ultimately, as the basis of the sampling plan described in this document. Manufacturers of health care products who intend to use the protocols contained in this technical information report are reminded that the requirements for all users of radiation sterilization contained in ANSI/AAMI/ISO 11137 apply to the manufacture and control of production batches for which a sterilization dose is substantiated by this method. In particular, one requirement states that products shall be manufactured in circumstances such that the bioburden is controlled. Compliance with the requirements for properly controlling the quality of raw materials and the manufacturing environment, and for establishing the basic properties of the packaging material, is essential.

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose—Method VD_{max}

1 Scope

1.1 Inclusions

This technical information report (TIR) describes a method of substantiating a selected dose for a sterility assurance level (SAL) of 10^{-6} for radiation sterilization of health care products. This TIR also specifies a method of dose auditing to demonstrate the continued effectiveness of the sterilization dose.

NOTE 1—This method of sterilization dose substantiation may be used to meet the product qualification requirements specified in ANSI/AAMI/ISO 11137.

NOTE 2—This TIR is considered informative, and use of the terms shall, should, and so forth should be considered only within the context of this TIR. That is, if the decision is made to use this method of substantiation, then this method should be followed according to the requirements (shall) and recommendations (should) set forth in this TIR.

1.2 Exclusions

This method, as described, is for the substantiation of the specified doses only and cannot be used to substantiate other sterilization doses. The method cannot be used for the substantiation of a selected dose when the average bioburden estimate of the entire product unit does not meet the requirements for the selected dose.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this TIR. For dated references, subsequent amendments to or revisions of any of these publications do not apply. However, parties to agreements based on this TIR are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI standards.

ANSI/AAMI/ISO 11137-1, *Sterilization of health care products—Radiation—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*

ANSI/AAMI/ISO 11137-2, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose*

ANSI/AAMI/ISO 11137-3, *Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects*

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

ANSI/AAMI/ISO 11737-2, *Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the validation of a sterilization process*

3 Terms and definitions

For the purposes of this TIR the following terms and definitions apply.

3.1 absorbed dose: Quantity of ionizing radiation energy imparted per unit mass of matter.

NOTE—The unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to absorption of 1 joule per kilogram.

[ANSI/AAMI/ISO 11137-1]

