

Technical Information Report

AAMI TIR40: 2009/(R)2016

Sterilization of health care
products—Radiation—
Guidance on dose setting
utilizing a Modified
Method 2

Sterilization of health care products—Radiation— Guidance on dose setting utilizing a Modified Method 2

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Abstract: This technical information report describes the approach for establishing a sterilization dose utilizing a modification of the fraction positive, incremental dosing method defined in Method 2 of ANSI/AAMI/ISO 11137-2.

Key words: radiation, dose setting, Modified Method 2

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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 Technical Corrigendum 1 and 2 | ANSI/AAMI ES60601-1:2005 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt) | Major technical variations C1 Identical to Corrigendum 1 and 2 |
| IEC 60601-1-2:2007 | ANSI/AAMI/IEC 60601-1-2:2007 | Identical |
| IEC 60601-2-2:2009 | ANSI/AAMI/IEC 60601-2-2:2009 | Identical |
| IEC 60601-2-4:2002 | ANSI/AAMI DF80:2003 | Major technical variations |
| IEC 60601-2-19:2009 | ANSI/AAMI/IEC 60601-2-19:2009 | Identical |
| IEC 60601-2-20:2009 | ANSI/AAMI/IEC 60601-2-20:2009 | Identical |
| IEC 60601-2-21:2009 | ANSI/AAMI/IEC 60601-2-21:2009 | Identical |
| IEC 60601-2-24:1998 | ANSI/AAMI ID26:2004/(R)2009 | Major technical variations |
| IEC 60601-2-47:2001 | ANSI/AAMI EC38:2007 | Major technical variations |
| IEC 60601-2-50:2009 | ANSI/AAMI/IEC 60601-2-50:2009 | Identical |
| IEC 80601-2-30:2009 | ANSI/AAMI/IEC 80601-2-30:2009 | Identical (with inclusion) |
| IEC 80601-2-58:2008 | ANSI/AAMI/IEC 80601-2-58:2008 | Identical |
| IEC/TR 60878:2009 | ANSI/AAMI/IEC TIR60878:2009 | Identical |
| IEC/TR 62296:2009 | ANSI/AAMI/IEC TIR62296:2009 | Identical |
| IEC 62304:2006 | ANSI/AAMI/IEC 62304:2006 | Identical |
| IEC/TR 62348:2006 | ANSI/AAMI/IEC TIR62348:2006 | Identical |
| IEC/TR 80002-1:2009 | ANSI/IEC/TR 80002-1:2009 | Identical |
| ISO 5840:2005 | ANSI/AAMI/ISO 5840:2005 | Identical |
| ISO 7198:1998 | ANSI/AAMI/ISO 7198:1998/2001/(R)2004 | Identical |
| ISO 7199:2009 | ANSI/AAMI/ISO 7199:2009 | Identical |
| ISO 8637:2004 | ANSI/AAMI/ISO 8637:2007 | Major technical variations |
| ISO 8638:2004 | ANSI/AAMI/ISO 8638:2007 | Major technical variations |
| ISO 10993-1:2009 | ANSI/AAMI/ISO 10993-1:2009 | Identical |
| ISO 10993-2:2006 | ANSI/AAMI/ISO 10993-2:2006 | Identical |
| ISO 10993-3:2003 | ANSI/AAMI/ISO 10993-3:2003/(R)2009 | Identical |
| ISO 10993-4:2002 and Amendment 1:2006 | ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009 | Identical |
| ISO 10993-5:2009 | ANSI/AAMI/ISO 10993-5:2009 | Identical |
| ISO 10993-6:2007 | ANSI/AAMI/ISO 10993-6:2007 | Identical |
| ISO 10993-7:2008 | ANSI/AAMI/ISO 10993-7:2008 | Identical |
| ISO 10993-9:1999 | ANSI/AAMI/ISO 10993-9:1999/(R)2005 | Identical |
| ISO 10993-10:2000 and Amendment 1:2006 | ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008 | Minor technical variations Identical |
| ISO 10993-11:2006 | ANSI/AAMI/ISO 10993-11:2006 | Identical |
| ISO 10993-12:2007 | ANSI/AAMI/ISO 10993-12:2007 | Identical |
| ISO 10993-13:1998 | ANSI/AAMI/ISO 10993-13:1999/(R)2004 | Identical |
| ISO 10993-14:2001 | ANSI/AAMI/ISO 10993-14:2001/(R)2006 | Identical |
| ISO 10993-15:2000 | ANSI/AAMI/ISO 10993-15:2000/(R)2006 | Identical |
| ISO 10993-16:1997 | ANSI/AAMI/ISO 10993-16:1997/(R)2009 | Identical |
| ISO 10993-17:2002 | ANSI/AAMI/ISO 10993-17:2002/(R)2008 | Identical |
| ISO 10993-18:2005 | ANSI/AAMI BE83:2006 | Major technical variations |
| ISO/TS 10993-19:2006 | ANSI/AAMI/ISO TIR10993-19:2006 | Identical |
| ISO/TS 10993-20:2006 | ANSI/AAMI/ISO TIR10993-20:2006 | Identical |
| ISO 11135-1:2007 | ANSI/AAMI/ISO 11135-1:2007 | Identical |
| ISO/TS 11135-2:2008 | ANSI/AAMI/ISO TIR11135-2:2008 | Identical |

| International designation | U.S. designation | Equivalency |
|---|--|-----------------------------|
| 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 |
| ISO/TS 11139:2006 | ANSI/AAMI/ISO 11139:2006 | Identical |
| ISO 11140-1:2005 | ANSI/AAMI/ISO 11140-1:2005 | Identical |
| ISO 11140-3:2007 | ANSI/AAMI/ISO 11140-3:2007 | Identical |
| ISO 11140-4:2007 | ANSI/AAMI/ISO 11140-4:2007 | Identical |
| ISO 11140-5:2007 | ANSI/AAMI/ISO 11140-5:2007 | Identical |
| 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 11737-2:2009 | ANSI/AAMI/ISO 11737-2:2009 | Identical |
| ISO 13408-1:2008 | ANSI/AAMI/ISO 13408-1:2008 | Identical |
| ISO 13408-2:2003 | ANSI/AAMI/ISO 13408-2:2003 | Identical |
| ISO 13408-3:2006 | ANSI/AAMI/ISO 13408-3:2006 | Identical |
| ISO 13408-4:2005 | ANSI/AAMI/ISO 13408-4:2005 | Identical |
| ISO 13408-5:2006 | ANSI/AAMI/ISO 13408-5:2006 | Identical |
| ISO 13408-6:2006 | ANSI/AAMI/ISO 13408-6:2006 | Identical |
| ISO 13485:2003 | ANSI/AAMI/ISO 13485:2003/(R)2009 | Identical |
| ISO 14155-1:2003 | ANSI/AAMI/ISO 14155-1:2003/(R)2008 | Identical |
| ISO 14155-2:2003 | ANSI/AAMI/ISO 14155-2:2003/(R)2008 | Identical |
| ISO 14160:1998 | ANSI/AAMI/ISO 14160:1998/(R)2008 | Identical |
| ISO 14161:2009 | ANSI/AAMI/ISO 14161:2009 | Identical |
| ISO 14708-3:2008 | ANSI/AAMI/ISO 14708-3:2008 | Identical |
| ISO 14708-4:2008 | ANSI/AAMI/ISO 14708-4:2008 | Identical |
| ISO 14937:2009 | ANSI/AAMI/ISO 14937:2009 | Identical |
| ISO/TR 14969:2004 | ANSI/AAMI/ISO TIR14969:2004 | Identical |
| ISO 14971:2007 | ANSI/AAMI/ISO 14971:2007 | Identical |
| ISO 15223-1:2007 and A1:2008 | ANSI/AAMI/ISO 15223-1:2007 and A1:2008 | Identical |
| ISO 15225:2000 and A1:2004 | ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006 | Identical |
| ISO 15674:2009 | ANSI/AAMI/ISO 15674:2009 | Identical |
| ISO 15675:2009 | ANSI/AAMI/ISO 15675:2009 | Identical |
| ISO 15882:2008 | ANSI/AAMI/ISO 15882:2008 | Identical |
| ISO 15883-1:2006 | ANSI/AAMI ST15883-1:2009 | Major technical variations |
| ISO/TR 16142:2006 | ANSI/AAMI/ISO TIR16142:2005 | Identical |
| ISO 17664:2004 | ANSI/AAMI ST81:2004 | Major technical variations |
| ISO 17665-1:2007 | ANSI/AAMI/ISO 17665-1:2006 | Identical (with inclusions) |
| ISO/TS 17665-2:2009 | ANSI/AAMI/ISO TIR17665-2:2009 | Identical |
| ISO 18472:2006 | ANSI/AAMI/ISO 18472:2006 | Identical |
| ISO/TS 19218:2005 | ANSI/AAMI/ISO 19218:2005 | Identical |
| ISO 22442-1:2007 | ANSI/AAMI/ISO 22442-1:2007 | Identical |
| ISO 22442-2:2007 | ANSI/AAMI/ISO 22442-2:2007 | Identical |
| ISO 22442-3:2007 | ANSI/AAMI/ISO 22442-3:2007 | Identical |
| ISO 25539-1:2003 and A1:2005 | ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009 | Identical |
| ISO 25539-2:2008 | ANSI/AAMI/ISO 25539-2:2008 | Identical |
| ISO 81060-1:2007 | ANSI/AAMI/ISO 81060-1:2007 | Identical |
| ISO 81060-2:2009 | ANSI/AAMI/ISO 81060-2:2009 | Identical |

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Association for the Advancement of Medical Instrumentation

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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 intended to be used in conjunction with ANSI/AAMI/ISO 11137, *Sterilization of health care products—Radiation sterilization* (series). This technical information report (TIR) describes dose-setting methods that may be used to establish the sterilization dose in accordance with one of the two approaches specified in 8.2 (Method 2A) or 8.3 (Method 2B) of ANSI/AAMI/ISO 11137-2:2006.

The basis of the dose-setting methods used in Methods 1 and 2 described in ANSI/AAMI/ISO 11137-2 owes much to the ideas first propounded by Tallentire (Tallentire, 1973; Tallentire, Dwyer, and Ley, 1971; Tallentire and Khan, 1978). Subsequent to these publications, standardized protocols were developed (Davis et al., 1981; Davis, Strawderman, and Whitby, 1984), which formed the basis of the dose-setting methods detailed in the AAMI Recommended Practice for Sterilization by Gamma Radiation (AAMI 1994, 1991).

Methods 2A and 2B of ANSI/AAMI/ISO 11137-2 use data derived from the inactivation of the microbial population in its natural state on product. Using Method 2 can result in a sterilization dose that is significantly less than the sterilization dose established through the use of either Method 1 or Method 2D_{max}. Thus, for products that are susceptible to radiation damage, Method 2 could be the most appropriate method of dose establishment. For a Method 2A dose establishment, 10⁶ product units are required, and for a Method 2B dose establishment, 580 are required (see ANSI/AAMI/ISO 11137-2:2006). The method described herein is a modification of Methods 2A and 2B, and uses a reduced number of product items to establish the sterilization dose.

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.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to AAMI, 1111 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of AAMI TIR40:2009, *Sterilization of health care products—Radiation—Guidance on dose setting utilizing a Modified Method 2*, but it does provide important information about the development and intended use of the document.

Sterilization of health care products—Radiation— Guidance on dose setting utilizing a Modified Method 2

1 Scope

1.1 Inclusions

This TIR describes a modification to Methods 2A and 2B of ANSI/AAMI/ISO 11137-2 that reduces the number of incremental doses needed to determine the minimum dose required to achieve a predetermined sterility assurance level (SAL).

This method of sterilization dose establishment may be used to meet the product qualification requirements specified in ANSI/AAMI/ISO 11137-2 when product bioburden is low in number or resistance and has demonstrated historical consistency.

1.2 Exclusions

This method of sterilization dose establishment is not to be used to meet the product qualification requirements specified in ANSI/AAMI/ISO 11137-2 when the product bioburden has not been evaluated.

2 Normative References

The following normative documents contain provisions that, through reference in this text, constitute provisions of this TIR. For dated references, the 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 following normative documents. For undated references, the latest edition of the normative document referred to applies. AAMI maintains a register of currently valid AAMI technical documents.

- a) ANSI/AAMI/ISO 11137-2, *Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.*
- b) ANSI/AAMI/ISO 11137-3, *Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects.*

For harmonization and ease of use, portions of the guidance provided in this TIR are written to align with the clauses of ANSI/AAMI/ISO 11137-2.