Technical Information Report

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

AAMI
Advancing Safety in Health Technology

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.

Keywords: radiation, dose setting, Modified Method 2

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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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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Committee representation

Association for the Advancement of Medical Instrumentation

Radiation Sterilization Working Group

This technical information report (TIR) was developed by the AAMI Radiation 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.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochair: Mike Scholla

Members:
Brett Anderson, Cochlear Ltd
Hank Balch, University Health System
Richard Bancroft, Steris Corporation
Garry Bassi, CMC Sterilization Ltd
Stacy Bohl, Boston Scientific Corporation
Trabue Bryans, BryKor LLC
Tim Carlson, Becton Dickinson & Company
Phil Cogdill, Medtronic Inc Campus
Sean Colwell, WuXi AppTec Inc
Ramona Conner, Association of Perioperative Registered Nurses
Lena Cordie, Qualitas Professional Services LLC
Jackie Daley
Gordon Ely, MiMedx Group
Lisa Foster, Adiuvo QS & SA Consulting
Joel Gorski, NAMSA
Joyce Hansen, Johnson & Johnson
Clark Houghtling, Cosmed Group Inc
Sue Klacik, IAHCSMM
Byron Lambert, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick McCormick, Bausch & Lomb Inc
Gerry McDonnell, Johnson & Johnson
Gerry O'Dell, Gerry O'Dell Consulting
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Mike Scholla, DuPont Protection Solutions
Joan Spear, B Braun of America Inc
Sid Wiggs, Wiggs, Sid - 453204
Bill Young, Sterigenics International
Roberto Zumbado, Philips

Alternates:
Jonathan Bull, Johnson & Johnson
Greg Crego, IUVO BioScience
Aaron Dement, Sterigenics International
Jeffrey Marx, Steris Corporation
Kim Patton, Becton Dickinson & Company
ChristineRender, Cosmed Group Inc
Mike Sadowski, Baxter Healthcare Corporation
Sharon Van Wicklin, Association of Perioperative Registered Nurses
Craig Wallace, 3M Healthcaress

Radiation sterilization working group

At the time this document was published, the **AAMI Radiation sterilization working group** had the following members:

Cochairs:
Emily Craven
Elaine Daniell

Members:
Keith Anderson, Smiths Medical
Ed Arscott, NAMSA
Anne Booth, Booth Scientific Inc
Carolyn Braithwaite-Nelson, Spectranetics Corporation
David Brodersen, LexaMed
Riley Brown, St Jude Medical Inc
Trabue Bryans, BryKor LLC
Harry Bushar
Rob Calabro, AbbVie
David Cardin, Cook Inc
Sarah Chamberlain, Accuratus Labs Services
Denise Cleghorn, Boston Scientific Corporation
Debbie Cotton. Baxter Healthcare Corporation
Gary Cranston, Consulting & Technical Services/PCS
Emily Craven, Mevex Corporation
Greg Crego, IUVO BioScience
Elaine Daniell, CR Bard
Douglas Davie, Sterilization Validation Services
Darci Diage, Direct Flow Medical Inc
Dave Dion, Cardinal Health
Gordon Ely, MiMedx Group
Trisha Fair, Cantel Inc.
Francesco Famosi, Arthrex Inc
William FitzGerald, FitzGerald & Associates Ltd
Lisa Foster, Adiuvo QS & SA Consulting
Matthew Freeman, Terumo BCT
Rob Grizzle, Terumo BCT
Doug Harbrecht, Sterility Assurance LLC
Deborah Havlik, Hospira, a Pfizer company
Betty Howard, Steris Corporation
John Logar, Johnson & Johnson
Jeff Martin, Sterilization and Quality System Consulting LLC
Patrick McCormick, Bausch & Lomb Inc
Nicole McLees, 3M Healthcare
Rusty Mills, GE Healthcare
Larry Nichols, Company for Individuals
Gerry O'Dell, Gerry O'Dell Consulting
Kevin O'Hara, Sterigenics
Dave Parente, Ecolab
Kim Patton, Becton Dickinson & Company
Michelle Peterson, Stryker Instruments Division
Rudy Pina, Dynatec Scientific Labs Inc
Keith Reiner, Terumo Americas Corporate
Jody Rupert, WL Gore & Associates Inc
Manny Saavedra, Halyard Health
Harry Shaffer, Sterilization Consulting Services
Michael Sprague, Ethide Laboratories Inc
SopheakSrun, Quality Tech Services Inc
Fenil Sutaria, Medline Industries Inc
Jill Warren, WuXi AppTec Inc
Bud Weisman, Fresenius Medical Care
Pat Weixel, FDA/CDRH

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Beverly Whitaker, Indigo Consulting Group LLC
John Williams, Medtronic
Martell Winters, Nelson Laboratories LLC
Roberto Zumbado, Philips

Alternates:

Chris Anderson, Johnson & Johnson
Agnieszka Baczek, Medline Industries Inc
Curt Bogue, Cook Inc
MarJean Boyter, Fresenius Medical Care
Rachel Brewer, IUVO BioScience
Angela Brightwell, Medtronic
Allison Diemert, Anthrex Inc
Brian Drumheller, Brookhaven Medical Inc
Diane Faivre-Swiat, Cardinal Health
Mike Graybill, 3M Healthcare
Fatima Hasanain, Sterigencis
Nichole Jackson, Ecolab
Tara Jacobson, St Jude Medical Inc
Satu King, Spectranetics Corporation
Chris Kobus, GE Healthcare
Ezra Koski, Terumo BCT
Vu Le, Abbott Laboratories
Elan Lopezcuba, Becton Dickinson & Company
Connie McChesney, Alcon Laboratories Inc
Brian McEvoy, Steris Corporation
Joseph Mello, Ethide Laboratories Inc
Astrid Merrifield, Boston Scientific Corporation
Ken Paddock, Baxter Healthcare Corporation
Dupeh Palmer-Ochieng, FDA/CDRH
Michelle Pierce, NAMSA
Robert Reich, LexaMed Ltd
Beth Ridgeway, Mesa Laboratories Biological Indicator Division
Mike Schoene, Bausch & Lomb Inc
Kristen Spigiel, Stryker Instruments Division
Mara Tafoya, WuXi AppTec Inc
Wendy Wangsgard, Nelson Laboratories LLC
Cas Woss, FitzGerald & Associates Ltd

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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 11137-2:2013.

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 1984, 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 items. 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 VD_{max}. Thus, for product types that are susceptible to radiation damage, Method 2 could be the most appropriate method of dose establishment. For a Method 2A dose establishment, 640 product items are required, and for a Method 2B dose establishment, 580 are required (see ANSI/AAMI/ISO 11137-2:2013). 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. Modified Methods 2A and 2B can each be completed with as few as 360 product items.

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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of AAMI TIR40:2018, *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.

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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.

3 Abbreviations, terms, and definitions

For purposes of this document, the terms and definitions given in ANSI/AAMI/ISO 11137-1 and the following apply.

3.1 Abbreviated terms

3.1.1 ***A:*** Dose to adjust the median ffp dose downward, to the FFP dose.

[ANSI/AAMI/ISO 11137-2:2013]