Technical Information Report

AAMI TIR40: 2018/(R)2022

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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www.aami.org/standards/glossary.pdf

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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:

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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 11137-2:2013.

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, 350 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.

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]