

Technical Information Report

AAMI TIR76: 2021

Sterilization of health care
products—Radiation—
Substantiation of a
selected sterilization dose
at a specified sterility
assurance level:
Method VD_{max}^{SD-S}

Sterilization of health care products—Radiation— Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VD_{\max}^{SD-S}

Approved 31 March 2021 by
AAMI

Abstract: This technical information report describes a method for substantiating a selected sterilization dose that achieves maximally a selected sterility assurance level (SAL) for radiation sterilization of healthcare products and a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

Keywords: radiation sterilization, sterilization, dose, sterility assurance level, SAL, Method VD_{\max}^{SD-S}

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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 22203-1633.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203-1633
www.aami.org

© 2021 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-276-0793.

Printed in the United States of America

ISBN 978-1-57020-818-8

This is a preview. [Click here to purchase the full publication.](#)

Contents

Page

Committee representation	iv
Foreword	viii
Introduction	ix
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Definition and maintenance of product families for sterilization dose substantiation and sterilization dose auditing	2
5 Selection and testing of product for substantiating and auditing a selected sterilization dose	2
6 Method VD_{\max}^{SD-S} —Substantiation of a selected sterilization dose at a specified sterility assurance level	2
7 Maintaining process effectiveness	12
8 Worked examples for the Method VD_{\max}^{SD-S} CT	16
Annex A (informative) Rationale for removal of confirmatory dose experiment for two positive tests of sterility	21
Annex B (informative) Method VD_{\max}^{SD-S} calculation tool: Background information and guidance on use	23
Annex C (informative) Screenshots of entries into the Method VD_{\max}^{SD-S} CT for the procedure for multiple and single production batches	27
Annex D (informative) Tabulations of approximate upper limit average bioburden values for sets of selected sterilization doses	32
Bibliography	36

Tables

Table 1—Line locations in the Calculation Inputs – Part 1 Panel of the CT	4
Table 2—Line locations in the Calculation Outputs – Part 1 Panel of the CT	4
Table 3—Line locations in the Calculation Inputs – Part 2 Panel of the CT	5
Table 4—Line locations in the Calculation Outputs – Part 2 Panel of the CT	5
Table 5—Calculations inputs – Part 1 of the CT	16
Table 6—Calculations outputs – Part 1 of the CT	17
Table 7—Calculations inputs – Part 2 panel of the CT	17
Table 8—Calculations output – Part 2 panel of the CT	17
Table 9—Calculations inputs – Part 1 panel of the CT	18
Table 10—Calculations outputs – Part 1 panel of the CT	18
Table 11—Calculations inputs – Part 2 panel of the CT	18
Table 12—Calculations outputs – Part 2 panel of the CT	18
Table 13—Calculations inputs – Part 1 panel of the CT	19
Table 14—Calculations outputs – Part 1 panel of the CT	19
Table 15—Calculations inputs – Part 2 panel of the CT	19
Table 16—Calculations outputs – Part 2 panel of the CT	19
Table 17—Sterilization dose audit following which augmentation of the sterilization dose was required	20

Committee representation

Association for the Advancement of Medical Instrumentation

Radiation Sterilization Working Group

This technical information report was developed by the AAMI Radiation Sterilization Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

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

Cochairs: Emily Craven
Elaine Daniell

Members: Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
Dean Bird, Olympus America Inc
Jody Birks, Eagle Medical Inc
Tim Bollnow, Intuitive Surgical Inc
Carolyn Braithwaite-Nelson, Philips
Trabue Bryans, BryKor LLC
Nicholas Brydon, Nick Brydon Consulting LLC
Richard Burgess, BSI Healthcare
Robb Calabro, AbbVie
Glenn Calvert, West Pharmaceutical Services, Inc.
David Cardin, Cook Inc
Denise Cleghorn, Boston Scientific Corporation
Gary Cranston, Consulting & Technical Services/PCS
Emily Craven, Boston Scientific Corporation
Greg Crego, IUVO BioScience
Elaine Daniell, EDan-SA LLC
Douglas Davie, Sterilization Validation Services
Jeffrey DelGaudio, Cardinal Health
April Doering, Cantel Inc
Zachary Dukerich, Arthrex Inc
Niki Fidopiastis, NAMSA
Lisa Foster, Adiuvo QS & SA Consulting
Chad Geiger, DexCom Inc
Jacob Gibbons, Genentech Inc
Amy Gravley, DEKRA Certification
Michael Graybill, 3M Health Care
Chris Haas, Getinge USA
Douglas Harbrecht, Sterility Assurance LLC
Michael Harding, DEKRA Certification
Deborah Havlik, DA Havlik Consulting
Trang Hoang, Edwards Lifesciences
Mollie Holter, MicroBio Consulting LLC
Crystal Hostler, Mesa Laboratories Biological Indicator Division- Bozeman Facility
Betty Howard, STERIS Corporation
Karla Klueber, Sanford Healthcare
Ezra Koski, Terumo BCT
Mark Krocko, Mevex Corporation
Vu Le, Abbott Laboratories
John Logar, Johnson & Johnson
Ilva Mane, Medline Industries Inc
Jeffrey Martin, Sterilization and Quality System Consulting LLC
Mauricio Martinez, Smiths Medical
Patrick McCormick, Bausch & Lomb Inc
Susan Messier, Ethide Laboratories