Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits
This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit www.aami.org.
Sterilization of health care products—Radiation sterilization—
Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits

Abstract: Describes approaches to the selection and auditing of a sterilization dose that may reduce the number of product items required while maintaining assurance of attaining the desired sterility assurance level (SAL). This approach addresses sampling plans for verification dose experiments and sterilization dose audits. In addition the approaches to adopting a product into an established product family are defined.

Keywords: sterility, bioburden, radiation, health care products, dose, audits, product adoption, design verification, procedures
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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years.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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301,
Arlington, VA 22203-1633

© 2016 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. 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, contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: (703) 525-4890

Printed in the United States of America

ISBN 1-57020-618-X
Glossary of equivalent standards

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
Committee representation

Association for the Advancement of Medical Instrumentation
Radiation Sterilization Working Group

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

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

Cochair: Mike Scholla, Dupont Protection Technologies

Members:
- Richard Bancroft, Steris Corporation
- Trabue Bryans, BryKor LLC
- Nancy Chobin, St Barnabas Healthcare System
- Phil Cogdill, Medtronic Inc Campus
- Ramona Conner, Association of Perioperative Registered Nurses
- Jackie Daley, Sinai Hospital of Baltimore
- Kim Darnell, CR Bard
- Gordon Ely, MiMedx Group
- Lisa Foster, Adiuvo Quality Sterilization Consulting
- Joel Gorski, NAMS A
- Joyce Hansen, Johnson & Johnson
- Doug Harbrecht, Sterility Assurance LLC
- Deborah Havlik, Hospira Worldwide Inc
- Sue Klacik, IAHC SMM
- Byron Lambert, Abbott Laboratories
- Colleen Landers, Timmins & District Hospital
- Michelle Luebke, Baxter Healthcare Corporation
- Jeff Martin, Alcon Laboratories Inc
- Patrick McCormick, Bausch & Lomb Inc
- Janet Prust, 3M Healthcare - Saint Paul, MN
- Nancy Rakiewicz, IUVO BioScience
- Andrew Sharavara, Propper Manufacturing Co Inc
- Mark Smith, Getinge USA
- Joani Spear, B Braun of America Inc
- Stacy Wiehle, Boston Scientific Corporation
- Sid Wiggs
- Martell Winters, Nelson Laboratories Inc
- Bill Young, Sterigenics International

Alternates:
- Suzanne Butler, Boston Scientific Corporation
- Aaron Dement, Sterigenics International
- Dave Dion, Cardinal Health (MP&S)
- Ken Eddington, NAMS A
- Diane Faire-Swiat, Cardinal Health (MP&S)
- Danny Hutson, Becton Dickinson & Company
- Natalie Lind, IAHC SMM
- Jeffrey Marx, Steris Corporation
- Mary Mayo, CR Bard
- Gerry McDonnell, Johnson & Johnson
- David McGoldrick, Abbott Laboratories
- Jerry Nelson, Nelson Laboratories Inc
- Patrick Polito, IUVO BioScience
- Karen Polkinghorne, Dupont Protection Technologies
- Mike Sadowski, Baxter Healthcare Corporation
- Mike Schoene, Bausch & Lomb Inc
- Craig Wallace, 3M Healthcare

© 2016 Association for the Advancement of Medical Instrumentation
At the time this document was published, the AAMI Radiation Sterilization Working Group had the following members:

**Cochairs:**
Emily Craven, Nordion Inc
Pat Weixel, FDA/CDRH

**Members:**
Ed Arscott, NAMSA
Simon Bogdansky, Allo Source
Curt Bogue, Cook Inc
Anne Booth, Booth Scientific Inc
Riley Brown, St Jude Medical Inc
Trabue Bryans, BryKor LLC
Harry Bushar
David Cardin, Zimmer Inc
Sarah Chamberlain, Accuratus Labs Services
Denise Cleghorn, Boston Scientific Corporation
Gary Cranston, Consulting & Technical Services/PCS
Greg Crego, IUVO BioScience
Elaine Daniell, CR Bard
Douglas Davie, Sterilization Validation Services
Jeffrey DelGaudio, Medtronic Inc Campus
Darci Diage, Direct Flow Medical Inc
Dave Dion, Cardinal Health (MP&S)
Francesco Famosi, Arthrex Inc
William FitzGerald, FitzGerald & Associates Ltd
Lisa Foster, Adjuvo Quality & Sterilization Consulting
Matthew Freeman, Terumo BCT
Shelley Green, WuXi AppTec Inc
Joyce Hansen, Johnson & Johnson
Doug Harbrecht, Sterility Assurance LLC
Deborah Havlik, Hospira Worldwide Inc
Donna Horner, Abbott Laboratories
Betty Howard, Steris Corporation
Carolyn Kinsley, LexaMed Ltd
Jeff Martin, Alcon Laboratories Inc
Patrick McCormick, Bausch & Lomb Inc
Nicole McLees, 3M HealthCare
Rusty Mills, GE Healthcare
Larry Nichols, Nutek Corporation
Gerry O’Dell, Gerry O’Dell Consulting
Kevin O’Hara, Sterigenics International
Dave Parente, Ecolab
Kimberly 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
Liza Salerno, Accuratus Labs Services
Harry Shaffer, Sterilization Consulting Services
Michael Sprague, Ethide Laboratories Inc
Sopheak Srun, Quality Tech Services Inc
Fenil Sutaria, Medline Industries Inc
Jill Warren, WuXi AppTec Inc
Bud Weisman, Fresenius Medical Care
Beverly Whitaker, Indigo Consulting Group LLC
Martell Winters, Nelson Laboratories Inc

**Alternates:**
MarJean Boyter, Fresenius Medical Care -
Carolyn Braithwaite-Nelson, Spectranetics Corporation
Rachel Brewer, IUVO BioScience
Claudia Camp, Stryker Instruments Division
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.

For a complete copy of this AAMI document, contact AAMI at +1-977-249-8226 or visit www.aami.org.
Introduction

This technical information report (TIR) is intended to be used in conjunction with the ANSI/AAMI/ISO 11137 series. One of the activities encompassed within this series is the selection and routine auditing of the sterilization dose to be applied to health care products, and, in relation, the number of product items to be used to assure the sterility assurance level (SAL) is attained. A primary manufacturer might wish to reduce this number.

The guidance contained within this TIR provides strategies by which the primary manufacturer may reduce the total number of product items to be tested for establishing and maintaining the sterilization dose with alternative sampling plans. The approach to alternative sampling plans given in this TIR employs alternative sampling plans that are statistically equivalent to the sample size of 100 product items as described in Methods 1 and 2 of ANSI/AAMI/ISO 11137-2, even though a different number of products is tested. However, if there is a dose audit failure when using this approach, there is no provision for the augmentation of the sterilization dose. In this situation, the dose must be re-established or another validation method utilized.

The TIR also provides guidance by which the primary manufacturer may adopt new products or redesigned products into an established product family with a technical evaluation. Based upon the technical evaluation the method to be used to adopt the product into the family can be determined.


NOTE—This technical information report is not a standard and the material contained herein is not normative in nature. The committee has in a few places used the term "shall" based on their knowledge of requirements contained in relevant standards and/or regulatory requirements.
Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits.

1 Scope

This TIR describes approaches to the selection and auditing of a sterilization dose that may reduce the number of product items required while maintaining assurance of attaining the desired sterility assurance level (SAL). This approach addresses sampling plans for verification dose experiments and sterilization dose audits. Additionally, guidance for adopting a product into an existing product family and maintenance of product families is provided.

2 Normative references


3 Terms and definitions

For the purposes of this TIR, the following terms and definitions apply:

3.1 augmentation
Action taken to increase the sterilization dose based upon the results obtained from a sterilization dose audit.

3.2 bioburden
Population of viable microorganisms on or in product and/or a sterile barrier system.

3.3 candidate product
The product being examined for adoption into an existing product family.

3.4 false positive
Test result interpreted as growth arising from the product, or portions thereof, tested when either growth resulted from extraneous microbial contamination or turbidity occurred from interaction between the product, or portions thereof, and the test medium.

3.5 health care product
Medical device(s), including in vitro diagnostic medical device(s), or medical product(s), including biopharmaceuticals.

© 2016 Association for the Advancement of Medical Instrumentation AAMI TIR35:2016