Technical Information Report

AAMI TIR39:2009/(R)2017

Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

AAMI
Advancing Safety in Healthcare Technology

Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

Approved 3 September 2009 and reaffirmed 19 October 2017 by
AAMI

Abstract: This technical information report provides guidance on selecting the appropriate form of microbial challenge to use in a validation process and the appropriate inoculation sites for that microbial challenge.

Keywords: microbial, validation, inoculation, biological indicators, SAL

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that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about 5 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

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-363-3

Contents

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	ANSI/AAMI ES60601-1:2005	Major technical variations
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 TIR60878:2003	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 RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	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 10993-10:2002 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 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	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	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 17665-1:2006	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

Committee representation

Association for the Advancement of Medical Instrumentation

Microbiological Methods Working Group

This technical information report (TIR) was developed by the AAMI Microbiological Methods 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 Microbiological Methods Working Group** had the following members:

Cochairs

Kimbrell Darnell
Martell Kress Winters, BS SM

Members

Anne F. Booth, MS, Conmed Corporation
Carolyn Braithwaite, CaridianBCT Sterilization Services Inc.
Trabue D. Bryans, WuXi AppTec
Sandra Budden, Alcon Laboratories Inc.
Gary J. Chilson, Ethox International Inc.
Charles Cogdill, Boston Scientific Corporation
Gary N. Cranston, Consulting & Technical Services/PCS
Kimbrell Darnell, CR Bard
Sylvie Dufresne, PhD, TSO3 Inc.
Niki Fidopiastis, Sterigenics International
Steve N. Goldstine, PhD, Steve Goldstine Consultants (Independent Expert)
Joyce M. Hansen, JM Hansen & Associates
Thomas L. Hansen, Terumo Medical Corporation
Deborah A. Havlik, Hospira Worldwide Inc.
Katherine E. Hill, 3M Healthcare
Victoria M. Hitchins, PhD, FDA/CDRH
Robert Dennis Houlsby, Abbott Laboratories
Brent Huberty, St. Jude Medical Inc.
Carolyn L. Kinsley, LexaMed
Roland C. Kippenhan, Minntech Corporation
Reynaldo Lopez, Cardinal Health (MP&S)
Gerald E. McDonnell, PhD, Steris Corporation
Joseph M. Mello, Ethide Laboratories Inc.
Russell D. Mills, Zimmer Inc.
Gerry A. O'Dell, MS, Gerry O'Dell Consulting
Dave Parente, NAMSA
Miriam Rozo, Johnson & Johnson
Terri Rymer, Baxter Healthcare Corporation
Manuel Saavedra, Jr., Kimberly-Clark Corporation
Michael J. Schoene, Bausch & Lomb Inc.
Zenius V. Seliokas, Stericon Inc.
Barb Smith, Getinge USA
Radhakrishna S. Tirumalai, U.S. Pharmacopeial Convention Inc.
Nuong Van Trinh, Covidien
Donald Tumminelli, SPS Medical Supply Corporation
Richard L. Weisman, Fresenius Medical Care Renal Therapies Group
Martell Kress Winters, BS SM, Nelson Laboratories Inc.
Curtrice Zeigler, Becton Dickinson & Company

Alternates

Christopher Anderson, Johnson & Johnson
Nancy Blaszko, Sterigenics International
April J. Doering, St. Jude Medical Inc.
Steven J. Elliott, WuXi AppTec

J.C. Fulghum, Hospira Worldwide Inc.
Marilyn J. Gould, PhD, Consulting & Technical Services/PCS
Renate Johnson, Boston Scientific Corporation
Amy Karren, Nelson Laboratories Inc.
Bert Kingsbury, Terumo Medical Corporation
Maggie Ladd, BA BS, Kimberly-Clark Corporation
Sharon K. Lappalainen, FDA/CDRH
Helene Leblond, TSO3 Inc.
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Ruby Medina, Cardinal Health (MP&S)
Laurie Nawrocki, NAMSA
Susan E Norton, Bausch & Lomb Inc.
Richard T. O'Donnell, Steris Corporation
Ken Paddock, Baxter Healthcare Corporation
Lorra Parliament, Becton Dickinson & Company
Patrick Polito, Ethox International Inc.
Harry L. Shaffer, JM Hansen & Associates
David Silor, Zimmer Inc.
Kelvin J. Witcher, 3M Healthcare

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

Cochairs
Victoria M. Hitchins, PhD
William E. Young

Members
Trabue D. Bryans, WuXi AppTec
Peter A. Burke, PhD, Steris Corporation
Nancy Chobin, RN CSPDM, St. Barnabas Healthcare System (Independent Expert)
Charles Cogdill, Boston Scientific Corporation
Ramona Conner, RN MSN CNOR, Association of periOperative Registered Nurses
Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology
Kimbrell Darnell, CR Bard
Lisa Foster, Sterigenics International
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Worldwide Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Danny Hutson, Cardinal Health (MP&S)
Lois Atkinson-Jones, MS (Independent Expert)
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Canadian Standards Association
Lisa N. Macdonald, Becton Dickinson & Company
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Rainer Newman, Johnson & Johnson
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Ethox International Inc.
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Company Inc.
Mark N. Smith, Getinge USA
William N. Thompson, Covidien
James L. Whitby, MA MB FRCP (Independent Expert)
Martell Kress Winters, BS SM, Nelson Laboratories Inc.

Alternates
Lloyd Brown, Covidien
Glenn W. Calvert, Becton Dickinson & Company

Dave Dion, Cardinal Health (MP&S)
Steven J. Elliott, WuXi AppTec
Thomas J. Frazar, Johnson & Johnson
Kathy Hoffman, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc.
Joseph J. Lasich, BS, Alcon Laboratories Inc.
Natalie Lind, IAHCSMM
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc.
Karen Polkinghorne, Dupont Nonwovens
Mike Sadowski, Baxter Healthcare Corporation
John R. Scoville, Jr., Steris Corporation
Jason Voisinet, Ethox International Inc.
Craig A. Wallace, 3M Healthcare
Valerie Welter, Hospira Worldwide Inc.
William E. Young, Boston Scientific Corporation

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report was developed by the AAMI Microbiological Methods Working Group under the auspices of the AAMI Sterilization Standards Committee.

Manufacturers of medical devices labeled as sterile have the responsibility to validate processes for the sterilization of their products. In the case of medical devices that are labeled as reusable and intended to be reprocessed, the written instructions for sterilization must also be validated.

The objective of this TIR is to provide medical device manufacturers information on the appropriate microbial challenge to use in sterilization validation processes, the selection of appropriate inoculation sites for that challenge, and the means to qualify a method for liquid inoculation.

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 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.

AAMI and ANSI procedures require that standards be reviewed every 5 years and, if necessary, revised to reflect technological advances that may have occurred since publication.

The concepts incorporated in this technical information report should not be considered inflexible or static. This technical report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington VA 22203-1633.

NOTE—This foreword does not contain provisions of AAMI TIR39:2009, titled *Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices*, but it does provide important information about the development and intended use of the document.

Introduction

The objective of studies designed to validate a sterilization process is to provide data showing that the sterilization method and process parameters are capable of producing the desired sterility assurance level (SAL). Most often, this can be achieved through inoculation with biological indicators placed in various difficult-to-sterilize, accessible locations on or in the medical device during the validation studies. In other situations, placement of biological indicators in the appropriate locations is not possible. In those cases, a microbial challenge may be directly inoculated onto the device using a liquid suspension. The objective of studies designed to validate a sterilization process is to provide data showing that the sterilization method and process parameters are capable of producing the desired Sterility Assurance Level (SAL). A number of AAMI documents mention this direct inoculation approach or provide protocols for these types of studies, or do both (e.g., ANSI/AAMI/ISO 14161:2009 and ANSI/AAMI ST55:2003/(R)2008).

This document provides further guidance on factors to be considered in choosing the form of microbial challenge and its placement on or in the product.

Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

1 Scope

1.1 General

This technical information report (TIR) provides guidance for selecting the appropriate type of microbial challenge to use in a sterilization validation process, the selection of appropriate inoculation sites, and the methods for inoculation and recovery of inoculated microorganisms from these sites.

1.2 Exclusions

1.2.1 The recommendations in this TIR are addressed to manufacturers of medical devices for sterilization validation testing and are not intended as guidance for routine or field testing of device sterilization.

1.2.2 This TIR does not cover microbial challenges or inoculation processes used for validation of cleaning or disinfection of medical devices.

2 Normative references

The following referenced document is indispensable for the application of this document. The latest edition of the referenced document (including any amendments) applies. Members of the International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) maintain registers of currently valid International Standards.

ANSI/AAMI/ISO 11737-1, *Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products.*

3 Terms and definitions

For the purposes of this TIR, the following definitions and abbreviations apply.

3.1 bioburden: Population of viable microorganisms on or in product and/or sterile barrier system.

[ANSI/AAMI/ISO TIR 11139:2006]

3.2 biological indicator: Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.

[ANSI/AAMI/ISO TIR 11139:2006]

3.3 establish: To determine by theoretical evaluation and confirm by experimentation.

[ANSI/AAMI/ISO TIR 11139:2006]

3.4 health care product: Medical device, including *in vitro* diagnostic medical device, or medicinal product, including biopharmaceutical.

[AAMI/ISO TIR 11139:2006]

3.5 inoculated carrier: Supporting material on or in which a defined number of viable test organisms have been deposited.

[ANSI/AAMI/ISO 11138-1:2006]