Technical Information Report

AAMI TIR22:2007

Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices—Part 1 and Part 2:2006

Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care and/or processing of a medical device or system. A recommended practice does not address device performance *per se* but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

1. All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific need of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News.* The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News.*

AAMI Technical Information Report

AAMI TIR22:2007
(Revision of AAMI TIR22:1998
and TIR22:1998/A1:2001)

Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices—Part 1 and Part 2:2006

Approved 20 March 2007 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI Technical Information Report (TIR) provides interpretive guidance for the application of ANSI/AAMI/ISO 11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging* as well as for ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation and requirements for forming, sealing, and assembly processes.*

Keywords: barrier systems, closure, expiry date, microbial barrier, packaging system, validation

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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–279–6

Contents

Annexes

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 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated text)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	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 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	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)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
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 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
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 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
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 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production
[2]Final approval pending

Last updated 3/14/2007

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Packaging Working Group

This AAMI Technical Information Report (TIR) was developed by the Sterilization Packaging Working Group of the AAMI Sterilization Standards Committee. Committee approval of the TIR does not necessarily imply that all committee and working group members voted for its approval.

At the time this document was published, the **AAMI Sterilization Packaging Working Group** had the following members:

Cochairs:
Nick Fotis
Jackie Daly Johnson

Members:
Donald S. Barcan, DBI, Inc. (Donbar Industries, Inc.)
Heidi L. Betti, CST , CRCST, Mercy Hospital Center for Health
Bradley J. Bushman, Standard Textile Co Inc
Michele Dawn DeMeo, Hospital for Special Surgery
David Derr, Alcon Laboratories
Tim Early, Boston Scientific Corpoation
Joyce Kay Elkins, Zimmer, Inc.
Mary Jane Flament-Garcia, Hospira Inc
Nick Fotis, Cardinal Health (MP&S)
Thomas Gaiser, CR Bard
Jan Gates, Abbott Laboratories
Alison Neugaard Gitlin, Johnson & Johnson
Sean P. Gorman, Kimberly-Clark Corp.
Jackie Daly Johnson, Flexible Packaging Association
Amy Karren, Nelson Laboratories Inc.
Colleen Patricia Landers, RN, Central Service Association of Ontario
Curtis L. Larsen, Spartan Design Group
Helene Leblond, TSO3 Inc
Bob Massaglia, Terumo Medical Corporation
Jordan Montgomery, Medtronic, Inc.
Patrick J Nolan, CPP BS, DDL Inc.
Cathy D. Nutter, FDA/CDRH
Richard T. O'Donnell, Steris Corporation
Bobby Osburn, Department of Veterans Affairs National Center for Patient Safety
Barry F.J. Page, Barry Page Consulting
Dave Parente, NAMSA
Robert R. Reich, BS, MS, Pharmaceutical Systems Inc
Carl Resteghini, FACO Healthcare/Kendall
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Linda Stone, RN, BSPA, CNOR, Sibley Memorial Hospital
John Spitzley, J M Hansen & Assoc.
Ralph Stick, AppTec
Robert Thornburg, Becton Dickinson & Company
Jason Voisinet, Ethox Corp
Joan M. Woodcock, Bausch & Lomb Inc.

Alternates:
Heide M. Ames, Steris Corporation
Susanne Anderson, NAMSA
Ralph J. Basile, Healthmark Ind.
Lina C. Bueno, Dupont Nonwovens
Jeff Cavil, Cardinal Health
Sylvie Dufresne, TSO3 Inc
Victoria M. Hitchins, PhD, FDA/CDRH
George Kordares, AppTec
Wendy Mach, Nelson Laboratories
Robert Nelson, Hospira Inc
Michael Pohle, Johnson & Johnson

Russell R. Riescher, CR Bard
Manuel Saavedra, Jr., Kimberly-Clark Corporation
Jerry Selck, TYCO Healthcare/Kendall
Ram K. Singhal, Flexible Packing Association
Forrest Tabor, Zimmer Inc
Keith Vent, Bausch & Lomb

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.

AAMI Sterilization Committee

Cochairs: Victoria M. Hitchins
William E. Young

Members: Trabue D. Bryans, AppTec
Nancy Chobin, RN,CSPDM, St Barnabas Healthcare System
Anne M. Cofiell, CRCST, FCS, IAHCSMM
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
James M. Gibson, Jr., JM Gibson Associates
Barbara J. Goodman, RN, BS, CNOR
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Inc
Victoria M. Hitchins, PhD, FDA/CDRH
Joseph A. Hutson, Cardinal Health
Lois Atkinson Jones, MS
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Canadian Standards Association
David Liu, Johnson & Johnson
Jeff Martin, Alcon Laboratories Inc
Patrick J. McCormick, PhD, Bausch & Lomb Inc
Thomas K. Moore, Getinge USA
Barry F.J. Page, Barry Page Consulting
Nancy J. Rakiewicz, Ethox International Inc.
Phil M. Schneider, 3M Healthcare
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, Prober Manufacturing Co Inc
Frank Sizemore, American Society for Healthcare Central Service Professionals
William N. Thompson, TYCO Healthcare/Kendall
John W. Walker, Steris Corporation
James L. Whitby, MA, MB, FRCP, University of Western Ontario
Thelma Wilcutt, Becton Dickinson & Company
Martell Kaye Winters, B.S.,SM, Nelson Laboratories Inc

Alternates: Lloyd Brown, TYCO Healthcare/Kendall
Linda C. Bueno, Dupont Nonwovens
Craig M. Herring, Johnson & Johnson
Kathy Hoffman, Sterigenics International
Clark W. Houghtling, Steris Corporation
Danny Hutson, Cardinal Health (MP&S)
Jim Kaiser, Bausch & Lomb Inc
Susan G. Klacik, AS BS, IAHCSMM
Joseph J. Lasich, BS, Alcon Laboratories Inc
Chiu Lin, PhD, FDA/CDRH
Lisa N. Macdonald, Becton Dickinson & Company
Ralph Makinen, Guidant Corporation/Boston Science
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, MS PhD, Nelson Laboratories Inc
Janet Prust, 3M Healthcare

Mike Sadowski, Baxter Healthcare Corporation
Ralph Stick, AppTec
Jason Voisinet, Ethox International
Valerie Welter, Hospira Inc.
William T. Young, Boston Scientific Corporation

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.

Acknowledgments

The AAMI Sterilization Packaging Working Group thanks the members of the TIR Task Group for their efforts in bringing this technical information report to the working group. The task group was led by Jan Gates of Abbott Vascular and Jackie Daly Johnson of Beacon Converters, who represents the Flexible Packaging Association (FPA).

The task group members included Tim Early of Boston Scientific Corporation; Vickie Hitchins and Cathy Nutter of the FDA; Pat Nolan of DDL; Alison Neugaard Gitlin of Johnson and Johnson; Jordan Montgomery of Medtronic; Ram Singhal of FPA; and Dave Parente of NAMSA.

The task group thanks the following working group members for their guidance: Nick Fotis of Cardinal Health; Mike Scholla of Dupont; John Spitzley of J.M. Hansen Associates; Hal Miller of PACE Solutions; and Curt Larsen of Spartan Design Group.

Foreword

ANSI/AAMI/ISO 11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* and ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes* have been recognized as the global harmonized standards for packaging of terminally sterilized medical devices. Application of these two standards must be done in compliance with the regulatory requirements within the country or region where the sale of the medical device occurs.

ISO 11607-1:2006 and ISO 11607-2:2006 were developed by ISO Technical Committee (TC) 198, *Sterilization of health care products*, to fill a need for international standards for packaging for terminally sterilized medical devices. U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group (TAG) for ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). The United States made considerable contributions to the standards.

This Technical Information Report (TIR) is intended to provide guidance to the users of ANSI/AAMI/ISO 11607-1:2006 and 11607-2:2006 within the regulatory framework of the United States Food and Drug Administration. Additional guidance may be provided in specific areas for regulatory requirements outside of this jurisdiction.

This TIR is a revision of AAMI TIR22:1998 and AAMI TIR22/A1:2001, which provided guidance to ANSI/AAMI/ISO 11607:1997. The latter has been replaced by the aforementioned 11607-1 and -2 standards.

Guidance for ANSI/AAMI/ISO 11607, Packaging for terminally sterilized medical devices—Part 1 and Part 2:2006

1 Scope

This document specifically provides guidance on the application of ANSI/AAMI/ISO11607-1:2006, *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ANSI/AAMI/ISO 11607-2:2006, *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes* within the regulatory framework of the United States Food and Drug Administration that exists at the time of the publication of this document. A significant portion of this guidance can be applied to other regulatory frameworks that exist globally but the user must use their expertise in making the appropriate judgment on applicability.

2 Applicability and use

This document should be used in conjunction with ANSI/AAMI/ISO 11607-1:2006 and 11607-2:2006. Guidance to specific paragraphs/sections of the ANSI/AAMI/ISO 11607 standards requirements is noted. Sections 1–5 are general information; Sections 6-10 reflect the steps to be taken in developing the initial design; Section 11 gives guidance to those making a preformed sterile barrier system and to those who direct the filling and closing process of sterile barrier systems; Section 12 focuses on the evaluation of the completed and filled sterile barrier and packaging systems; and Section 13 addresses revalidation. The annexes contain educational information and references that are of interest at multiple steps or sections of this document.

3 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this TIR. For dated references, 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 normative documents indicated below. For updated references, the latest edition of the normative document referred to applies. AAMI maintains registers of currently valid AAMI technical documents.

3.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging,* ANSI/AAMI/ISO 11607-1:2006. Arlington (Vir.): AAMI, 2006. American National Standard.

3.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing, and assembly processes,* ANSI/AAMI/ISO 11607-2:2006. Arlington (Vir.): AAMI, 2006. American National Standard.

3.3 ASSOCIATION FOR THE ADVANCMENT OF MEDICAL INSTRUMENTATION. *Medical devices—Application of risk management to medical devices*, ANSI/AAMI/ISO 14971:2007. Arlington (Vir.): AAMI, 2007. American National Standard.

3.4 ASTM. *Standard guide for accelerated aging of sterile medical device packages,* ASTM F1980-02. West Conshohocken (Penn.): ASTM.

3.5 ASTM. *Standard test method for seal strength of flexible barrier materials,* ASTM F88-06. West Conshohocken (Penn.): ASTM.

3.6 TAPPI Dirt estimation chart. Norcross (Ga.): TAPPI, 2000.

