American National Standard

ANSI/AAMI/ISO 11607-2:2019

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes

AAMI
Advancing Safety in Health Technology

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 healthcare 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:

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 needs 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.

American National Standard

ANSI/AAMI/ISO 11607-2:2019
(Revision of ANSI/AAMI/ISO 11607-2:2006/(R)2015 & A1:2014 (R)2016)

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes

Approved 2 May 2019 by
AAMI

Approved 24 May 2019 by
American National Standards Institute

Abstract: Specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized and maintain sterility to the point of use. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems, and packaging systems.

Keywords: sterile barrier systems, qualification, validation

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI 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.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203

Printed in the United States of America

ISBN 978-1-57020-720-4

Contents

Page

Committee representation

Association for the Advancement of Medical Instrumentation

Packaging Working Group

The adoption of ISO 11607-2 as an American National Standard was initiated by the AAMI Packaging Working Group. AAMI Packaging Working Group provides input to the AAMI Sterilization Standards Committee which is the responsible group for providing the U.S. input to the relevant group in ISO/TC 198, Sterilization of health care products. U.S. representatives from AAMI Packaging Working Group and the TAG played an active part in developing the ISO document.

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

Cochairs:
Jen Benolken
Jordan Montgomery

Members:
Anas Aljabo, CMC Sterilization Ltd
David Anundson, Smiths Medical
Ed Arscott, NAMSA
Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
D'J Ballard, Packaging Science Center Inc
Harshad Borgaonkar, Cantel Inc
Carolyn Braithwaite-Nelson, Philips (fka Spectranetics Corporation)
Danette Casper, Olympus American Inc
Jeff Cavil, Becton Dickinson & Company
Chris Chemberlen, Sterilization Validation Services
Xiaolan Chen, Advanced Sterilization Products
Jeremy Elwell, Stryker Instruments Division
Gordon Ely, GEM Consulting
Nick Fotis, Cardinal Health
Becky Gilsdorf, Healthmark Industries Company Inc
Kevin Grum, DuPont Tyvek Medical and Pharmaceutical Protection
Doug Harbrecht, Sterility Assurance LLC
Nyla Japp, Independent Expert
Jackie Johnson, Flexible Packing Association
Britt Jones, WuXi AppTec Inc
Jeff Klein, Edwards Lifesciences
Kelley Kuehne, Centurion Sterilization Services
Erin Kyle, Association of Perioperative Registered Nurses
Jean-Luc Lemyre, TSO3 Inc
Wendy Mach, Sotera Health LLC
Roger Martin, Sterilucent Inc
Bob Massaglia, Terumo Americas Corporate
Tom McElroy, IUVO BioScience
Rusty Mills, GE Healthcare
Jordan Montgomery, Medtronic Inc Campus
Joseph Moore, Baxter Healthcare Corporation
Brian Nissen, Quality Tech Services LLC
Cindy O'Leary-Swinson, WL Gore & Associates Inc
Rod Patch, Johnson & Johnson
Michael Piazza, Alcon Laboratories Inc
Tony Piotrkowski, STERIS Corporation

Mary Sheehan, BSI Healthcare
Carol Smith, Boston Scientific Corporation
Joan Spear, B Braun of America Inc
Steve Spencer, Owens & Minor
Oliver Stauffer, PTI Inspection Systems
Don Tumminelli, HIGHPOWER Validation Testing & Lab Services Inc
Steven Turtil, FDA/CDRH
Stephanie Volk, ConvaTec Inc
Don Williams, Kaiser Foundation Health Plan
Kristy Yates, 3M Healthcare
Zach Zott, Medline Industries Inc Roberto Zumbado, Philips

Alternates:
Susanne Anderson, NAMSA
Ralph Basile, Healthmark Industries Company Inc
Jen Benolken, DuPont Tyvek Medical and Pharmaceutical Protection
Jenny Berg, Sterilucent Inc
Greg Crego, IUVO BioScience
Douglas Davie, Sterilization Validation Services
Veronica Falkevitz, HIGHPOWER Validation Testing & Lab Services
Brad Fish, Bausch & Lomb Inc
Pankaj Gaur, Medtronic Inc Campus
Bonnie Heredia, Baxter Healthcare Corporation
Pal Khangaldy, Sotera Health LLC
Young Lee, FDA/CDRH
Sierra Mertz, B Braun of America Inc
Vanessa Molloy-Simard, TSO3 Inc
Dan Penny, Cardinal Health
Jimmy Quijas, Abbott Laboratories
Claudia Romero-Waas, BSI Healthcare
Jason Ruff, Boston Scientific Corporation
Richard Schule, STERIS Corporation
Ram Singhal, Flexible Packing Association
Maruti Sinha, Cantel Inc
Mischa Waas, Johnson & Johnson
Abbey Walton, Becton Dickinson & Company
Tina Yu, Advanced Sterilization Products

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

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

Cochairs:
Michael Scholla
Patrick Weixel

Members:
Anas Aljabo, PhD, CMC Sterilization Ltd
Brett Anderson, Cochlear Ltd
Richard Bancroft, STERIS Corporation
Marie Brewer (Independent Expert)
Trabue D. Bryans, BryKor LLC
Jon Burdack, PhD, Nanosonics Limited
Tim Carlson, Becton Dickinson & Company

Phil Cogdill, Medtronic Inc
Lena Cordie-Bancroft, Qualitas Professional Services LLC
Jacqueline Daley (Independent Expert)
Gordon Ely, GEM Consulting
Lisa Foster, Adiuvo QS & SA Consulting
Daniel Fowler, WuXi AppTec Inc
Joel R. Gorski, PhD, NAMSA
Joyce Hansen, Johnson & Johnson
Mollie Holter, MicroBio Consulting LLC
Stephanie Homuth (Independent Expert)
Gail Horvath, ECRI Institute
Clark Houghtling, Cosmed Group Inc
Susan G. Klacik, CCSMC, FCS, ACE, International Association of Healthcare Central Service Materiel Management
Erin Kyle, Association of periOperative Registered Nurses
Byron J. Lambert, PhD, Abbott Laboratories
Michelle Luebke, Baxter Healthcare Corporation
Patrick J. McCormick, Bausch & Lomb Inc
Leslie Nichols, Mayo Clinic
Gerry O'Dell, Gerry O'Dell Consulting
David Pickard, BSI Healthcare
Adrian Ponce, Verrix LLC
Janet Prust, 3M Healthcare
Nancy Rakiewicz, IUVO BioScience
Michael H. Scholla, MS, PhD, Dupont Protection Technologies
Linda Schultz, Northside Hospital Surgical Services Atlanta
Kristen Singleton, Getinge USA
Joan Spear, B Braun of America Inc
Patrick Weixel, FDA/CDRH
Sid Wiggs (Independent Expert)
Stephen Yeadon, Boston Scientific Corporation
William E. Young, Sotera Health LLC
Roberto Zumbado, Philips

Alternates:

Stacy Bohl, Boston Scientific Corporation
Greg Crego, IUVO BioScience
Dan Floyd, DuPont Protection Technologies
Bob Marrs, B Braun of America Inc
Gerry McDonnell, PhD, Johnson & Johnson
David McGoldrick, Abbott Laboratories
Kimberly Patton, Becton Dickinson & Company
Christine Render, Cosmed Group Inc
Claudia Romero-Waas, BSI Healthcare
Michael Sadowski, Baxter Healthcare Corporation
Mark Smith, Getinge USA
Craig Wallace, 3M Healthcare
Lisa Ward, STERIS Corporation
Jill Warren, WuXi AppTec Inc
Martell Kress Winters, SM, Sotera Health
Jon Wood, International Association of Healthcare Central Service Materiel Management

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.

Background of ANSI/AAMI adoption of ISO 11607-2:2019

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO/TC 198 to specify requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

U.S. participation in ISO/TC 198 is organized through the U.S. Technical Advisory Group, AAMI Sterilization Standards Committee, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of packaging for terminally sterilized medical devices. Upon review of ISO 11607-2:2019, the AAMI Sterilization Standards Committee and the AAMI Packaging Working Group decided to adopt it verbatim, as a first edition of ANSI/AAMI/ISO 11607-2:2019.

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

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “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 standard. “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.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, 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 comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page viii, this American National Standard is identical to ISO 11607-2:2019.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11607-2:2006), which has been technically revised. It also incorporates the amendment ISO 11607-2:2006/Amd.1:2014.

The main changes compared to the previous edition are as follows:

— terms and definitions for “process variable”, “process parameter” and “monitoring of processes” have been added;

— various definitions have been aligned with the latest version of ISO 11139;

— the terminology of “critical” process parameters has been discontinued and the concept of a process specification has been introduced to include all elements required to manufacture a product that consistently meets specifications.

A list of all parts in the ISO 11607 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Packaging for terminally sterilized medical devices should be designed and manufactured to ensure that the medical device can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. Medical devices delivered in a sterile state should have been manufactured, packed and sterilized by appropriate, validated methods. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation programme demonstrating the efficacy and reproducibility of all packaging and sterilization processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are sealing, capping or other closure systems, cutting, form/fill/seal, assembly processes and subsequent handling. This document provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. Guidance for ISO 11607 series can be found in ISO/TS 16775.

The term “sterile barrier system” was introduced in 2006 to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to health care facilities for use in internal sterilization are considered medical devices in many parts of the world.