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 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 test methods 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 fume 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:

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.

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.
Abstract: Specifies general criteria to be applied in the estimation of the population of viable microorganisms on a medical device or component, raw material or package thereof. This estimation consists of both enumeration and characterization of the population.

Keywords: health care products, medical equipment, components, raw materials, packages, sterilization, tests, estimation, microorganisms, bioburden
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 five 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.
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.

<table>
<thead>
<tr>
<th>International designation</th>
<th>U.S. designation</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>International designation</td>
<td>U.S. designation</td>
<td>Equivalency</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>ISO 11137-1:200x¹</td>
<td>ANSI/AAMI/ISO 11137-1:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 11137-3:200x¹</td>
<td>ANSI/AAMI/ISO 11137-3:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 11138-1:200x¹</td>
<td>ANSI/AAMI/ISO 11138-1:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 11138-4:200x¹</td>
<td>ANSI/AAMI/ISO 11138-4:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 11138-5:200x¹</td>
<td>ANSI/AAMI/ISO 11138-5:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 17665-1:200x¹</td>
<td>ANSI/AAMI/ISO 17665-1:2006</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 18472:200x¹</td>
<td>ANSI/AAMI/ISO 18472:2006</td>
<td>Identical</td>
</tr>
</tbody>
</table>

¹In production
Committee representation

Association for the Advancement of Medical Instrumentation
Microbiological Methods Working Group

The adoption of ISO 11737-1:2006 as an AAMI Standard was initiated by the Microbiological Methods Working Group of the AAMI Sterilization Standards Committee (AAMI/ST), which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Microbiological Methods Working Group (U.S. Sub-TAG for ISO/TC 198/WG 8), chaired by Trabue Bryans and Kimbrell Darnell, played an active part in developing the ISO Standard.

Committee approval of this document 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 of the AAMI Sterilization Standards Committee had the following members:

**Cochairs:**
- Trabue D. Bryans
- Kimbrell Darnell

**Members:**
- Richard Alexander, Abbott Laboratories
- Julieta Banuelas, Dynatec Scientific Labs Inc.
- Paul William Boenges, BS, Cardinal Health (MP&S)
- Anne F. Booth, MS, Conmed Corp.
- John Broad, NAMSA
- Trabue D. Bryans, AppTec
- Sandra Budden, Alcon Laboratories Inc.
- Virginia C. Chamberlain, PhD, Independent Expert
- Gary N. Cranston, Consulting & Technical Svs/PCS
- Greg Crago, Ethox Corp.
- Kimbrell Darnell, CR Bard
- Kate Davenport, Northview Biosciences
- Douglas D. Dave, Sterilization Validation Services
- Sylvie Dufresne, TSO3 Inc.
- Niki Fidopiastis, Sterigenics International
- Steve N. Goldstine, PhD, DDS, Independent Expert
- Joyce M. Hansen, JM Hansen & Associates
- Thomas L. Hansen, Terumo Medical Corporation
- Deborah A. Havlik, Hospira Inc.
- Craig M. Herring, Johnson & Johnson
- R. Dennis Houlsby, BA, MA, Guidant Corporation/Cardiac Rhythm Management
- Anshu G. Khandpur, 3M Healthcare
- Carolyn L. Kinsley, Pharmaceutical Systems Inc.
- Gerald E. McDonnell, PhD, Steris Corporation
- James E. McGowan, Jr., BS, MBA, Sterility Assurance Laboratories Inc.
- Joseph M. Mello, Ethide Laboratories Inc.
- Russell D. Mills, Zimmer Inc.
- Cathy D. Nutter, FDA/CDRH
- Gerry A. O’Dell, MS, Independent Expert
- Manuel Saavedra, Jr., Kimberly-Clark Corporation
- Michael J. Schoene, Bausch & Lomb Inc.
- Zenius V. Seliokas, Stericon Inc.
- Mark Seybold, Baxter Healthcare Corporation
- Harry L. Shaffer, Sterilization Consulting Services
- Barb Smith, Getinge USA
- Nuong Van Trinh, TYCO Healthcare/Kendall
- Richard L. Weisman, Fresenius Medical Care NA Dialysis Products Division
- Thelma Wilcott, Becton Dickinson & Company
- Martell Kress Winters, BS, SM, Nelson Laboratories Inc.

**Alternates:**
- Solomon Alade, PhD, Alcon Laboratories Inc.
- Shelley Allen, AppTec
- Richard H. Bean, Zimmer Inc.
- Nancy Blaszko, Sterigenics International
- Carlos Chavez, PhD, Abbott Laboratories
Gary J. Chilson, Ethox Corp.
J.C Fulghum, Hospira Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Clark W. Houghtling, Steris Corporation
Danny Hutson, Cardinal Health (MP&S)
Renate Johnson, Guidant Corporation/Cardiac Rhythm Management
Bert Kingsbury, Terumo Medical Corporation
Marion L. Ladd, BA, BS, Kimberly-Clark Corporation
Linda Lavelle, Johnson & Johnson
Helene Leblond, TSO3 Inc.
Peter Lee, Baxter Healthcare Corporation
Mary S. Mayo, CR Bard
Susan E Norton, Bausch & Lomb Inc.
Dave Parente, NAMSA
Timothy Ramsey, BS, Northview Biosciences
Robert R. Reich, BS, MS, Pharmaceutical Systems Inc.
Wendy Wangsgard, PhD, Nelson Laboratories Inc.
Martha Young, 3M Healthcare
Curtrice Zeigler, Becton Dickinson & Company

AAMI Sterilization Standards Committee

Cochairs: Victoria M. Hitchins
William E. Young

Members: Trabue D. Bryans, AppTec
Virginia C. Chamberlain, PhD, VC Chamberlain & Associates, Independent Expert
Nancy Chobin, RN, CSPDM, St. Barnabas Healthcare System, Independent Expert
Anne M. Collett, CRGCT, FCS; International Association of Healthcare Central Service Material Management
Charles Cordill, 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, Independent Expert
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Richard M. Johnson, MSc, BSc, Abbott Laboratories
Lois Atkinson Jones, MS, Independent Expert
Byron J. Lambert, PhD, Guidant Corporation/Cardiac Rhythm Management
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, Independent Expert
Nancy J. Rakiewicz, Ethox Corp.
Phil M. Schneider, 3M Healthcare
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, Proper Manufacturing Co. Inc.
Frank Sizemore, American Society for Healthcare Central Service Professionals
Gregory O. Stecklein, MS, MSM, Cardinal Health (MP&S)
William N. Thompson, TYCO Healthcare/Kendall
John W. Walker, Steris Corporation
James L. Whitby, MA, MB, FRCP, University of Western Ontario, Independent Expert
Thelma Wilcott, Becton Dickinson & Company
Martell Kress Winters, BS, SM, Nelson Laboratories Inc.
William E. Young, Independent Expert

Alternates: Lloyd Brown, TYCO Healthcare/Kendall
Lina C. Bueno, Dupont Nonwovens
Craig M. Herring, Johnson & Johnson

© 2006 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI/ISO 11737-1:2006 vii
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.

PREVIEW COPY

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 +1-877-249-8226 or visit www.aami.org.
Background of AAMI adoption of ISO 11737-1:2006

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.

ISO 11737-1:1995 was developed by ISO Technical Committee 198 to fill a need for an international standard for determining the population of microorganisms on product prior to sterilization.

The major differences between this new, 2006 edition and the original, 1995 edition of the standard are:

1. The requirements and guidance on microbial characterization have been expanded. The 1998 edition included the requirement for characterization, but it was embedded in other sections and therefore was somewhat obscure. The 2006 edition has distinct sections that deal specifically and more thoroughly with means of microbial characterization.

2. The guidance on control of non-conforming product (i.e., “out-of-spec” results) is more detailed in the 2006 edition, and includes itemized information on how to investigate and handle lab errors as well as true adverse results.

3. A decision tree has been added to Annex A that addresses designing a bioburden method based on the nature of the product being tested and including guidance for choosing such things as agitation techniques or filtration versus plating.

4. A third annex has been added, which provides guidance on routine bioburden determination and information on interpretation of results. Much of this annex comes from Part 3 of ISO 11737, Guidance on evaluation and interpretation of bioburden results, which was published in 2004. Other portions of the Part 3 document have been added throughout the pertinent sections of the Part 1 document.

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


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 on this standard are invited and should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the ISO foreword on page x, this American National Standard is identical to ISO 11737-1:2006.
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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11737-1 was prepared by Technical Committee ISO/TC 198, Sterilization of health care products.

This second edition cancels and replaces the first edition (ISO 11737-1:1995) which has been technically revised and ISO 11737-3:2004 whose contents it now incorporates.

ISO 11737 consists of the following parts, under the general title Sterilization of medical devices—Microbiological methods:

— Part 1: Determination of a population of microorganisms on products
— Part 2: Tests of sterility performed in the validation of a sterilization process

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Introduction

A sterile medical device is one that is free of viable microorganisms. International standards that specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that, for certain processes used in manufacturing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process is monitored routinely and the equipment is maintained.

International Standards specifying procedures for the validation and routine control of the processes used for the sterilization of medical devices have been prepared (see, for example, ISO 11135, ISO 11137 series, and ISO 17665). However, it is important to be aware that exposure to a property validated and accurately controlled sterilization process is not the only factor associated with the provision of assurance that the product is sterile and, in this respect, suitable for its intended use. Furthermore, for the effective validation and routine control of a sterilization process, it is important to be aware of the microbiological challenge that is presented in the process, in terms of number, characteristics and properties of microorganisms.

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. A knowledge of bioburden can be used in a number of situations as part of:

— validation and revalidation of sterilization processes;
— routine monitoring for control of manufacturing processes;
— monitoring of raw materials, components or packaging;
— assessment of the efficiency of cleaning processes;
— an overall environmental monitoring program.

Bioburden is the sum of the microbial contributions from a number of sources, including raw materials, manufacturing of components, assembly processes, manufacturing environment, assembly/manufacturing aids (e.g., compressed gases, water, lubricants), cleaning processes, and packaging of finished product. To control bioburden, attention must be given to the microbiological status of these sources.

It is not possible to enumerate the bioburden exactly and, in practice, a determination of bioburden is made using a defined method. Definition of a single method for use in the determination of bioburden in all situations is not practicable because of the wide variety of designs and materials of construction of medical devices. Nor is it possible to define a single technique to be used in all situations for the removal of microorganisms in preparation for enumeration. Furthermore, the selection of conditions for enumeration of microorganisms will be influenced by the types of microorganism likely to be present on or in medical devices.

This part of ISO 11737 specifies the requirements to be met in the determination of bioburden. The requirements are the normative parts of this part of ISO 11737 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of this part of ISO 11737.
Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product

1 Scope

This part of ISO 11737 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material, or package.

NOTE 1—The nature and extent of microbial characterization is dependent on the intended use of the bioburden data. This part of ISO 11737 does not specify requirements for the enumeration or identification of viral or protozoan contaminants.

NOTE 2—Furthermore, the requirements specified in this part of ISO 11737 are not intended to address the removal and detection of the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy, and Creutzfeldt-Jakob disease.

This part of ISO 11737 does not specify requirements for the microbiological monitoring of the environment in which medical devices are manufactured.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, Measurement management system—Requirements for measurement processes and measuring equipment

ISO 13485:2003, Medical devices—Quality management systems—Requirements for regulatory purposes

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[ISO/TS 11139:2006, definition 2.2]

3.2 correction
action to eliminate a detected nonconformity

NOTE—A correction can be made in conjunction with a corrective action (3.4).

[ISO 9000:2005, definition 3.6.6]

3.3 correction factor
numerical value applied to compensate for incomplete removal from product and/or culture of microorganisms

3.4 corrective action
action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1—There can be more than one cause for a nonconformity.