American National Standard

ANSI/AAMI/ISO 11138-1:2006/(R)2010

Sterilization of health care products—Biological indicators—Part 1: General requirements

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 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*.

American National Standard

ANSI/AAMI/ISO 11138-1:2006/(R)2010
(Revision of ANSI/AAMI ST59:1999)

Sterilization of health care products—Biological indicators—Part 1: General requirements

Approved 9 December 2005 by
Association for the Advancement of Medical Instrumentation

Approved 22 March 2006 and Reaffirmed 22 April 2010 by
American National Standards Institute, Inc.

Abstract: Specifies general production, labeling and performance requirements for the manufacture of biological indicators and suspensions intended for use in the validation and monitoring of sterilization cycles.

Keywords: carrier, primary pack, culture, D value, survivor, CFU, population, resistometer

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.

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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.

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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 60601-2-04:2002	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 texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
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 10993-2:200x[2]	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	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 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
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	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	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
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations

International designation	U.S. designation	Equivalency
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 13488:1996	ANSI/AAMI/ISO 13488:1996	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/TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	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 17665-1:200x[1]	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

Committee Representation

Association for the Advancement of Medical Instrumentation
Biological Indicators Working Group

The adoption of ISO 11138-1:2006 as an American National Standard was initiated by the AAMI Biological Indicators Working Group of the AAMI Sterilization Standards Committee. The AAMI Biological Indicators Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Biological Indicators Working Group (U.S. Sub-TAG for ISO/TC 198/WG 4) played an active part in developing the ISO standard.

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

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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.

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Background of AAMI adoption of ISO 11138-1:2006

As indicated in the foreword to the main body of this document (page xi), 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 11138-1:2006 was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for an international standard specifying general production, labelling, test methods and performance requirements for the manufacture of biological indicators (including inoculated carriers and suspensions) intended for use in the validation and monitoring of sterilization cycles. Biological indicators are fundamental in the measurement of the sterilization process in that they are required for the demonstration of Sterility Assurance Levels as part of validation studies and also play a key role in the routine release of sterilization loads.

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 U.S. TAG for ISO/TC 198 made considerable contributions to this standard and supports the requirements for biological indicators specified in this document.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of the final Draft International Standard (FDIS) of ISO 11138-1:2006, the AAMI Biological Indicator Working Group decided to adopt this document verbatim as a revision of ANSI/AAMI ST59:1999, *Sterilization of health care products-Biological indicators — Part 1: General.* (The AAMI Biological Indicator Working Group previously developed deviations to ISO 11138-1:1994 to create ANSI/AAMI ST59:1999).

The ISO 11138:2006 biological indicator standards series was developed as the result of the joint revision of the ISO 11138:1994-1995 series of biological indicator standards (Parts 1-3) and the EN 866:1997-2000 series of biological indicator standards (Parts 1-8). The revised ISO 11138:2006 series of standards consist of the following parts:

> ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*
>
> ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*
>
> ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*
>
> ISO 11138-4, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*
>
> ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

Major changes that were made to the predicate ISO and CEN series during the revision process which are incorporated into the revised ISO 11138:2006 series of standards include:

a) Elimination of EN 866-4:1999, *Biological systems for testing sterilizers and sterilization processes — Part 4: Particular systems for use in irradiation sterilizers*. (Radiation biological indicators can

demonstrate ISO 11138:2006 compliance by complying with the provisions of ISO 11138-1:2006 even though there is no specific subpart for irradiation).

b) Elimination of EN 866-7:1999 and EN 866-8:1999, *Biological systems for testing sterilizers and sterilization processes — Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers* and *Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers*.

c) Inclusion of specific information pertaining to self-contained biological indicators in ISO 11138-1:2006.

d) Inclusion of a table with consolidated labeling requirements in ISO 11138-1:2006.

e) Provision for use of biological indicators deviating from the specified minimum population and/or resistance criteria providing all other requirements of ISO 11138:2006 are met and the deviation is clearly indicated in the product labeling.

f) Allowance for the calculation of D value by either the Holcomb-Spearman-Karber, Limited Holcomb-Spearman-Karber or Stumbo-Murphy-Cochran procedures as indicated in Annex D, 11138-1:2006.

g) Allowance for the use of dual species biological indicators with appropriate documentation.

h) Removal of the performance requirements for resistometers in ISO 11138:2006 Parts 2-4 (resistometer performance requirements are contained in ISO 18472:2006).

i) Removal of the $\log_{10}$ population × D value ≥ 10 requirement in ISO 11138-3:2006 (moist heat) and 11138-4:2006 (dry heat).

j) Provision for use of a liquid (rather than vapor phase) test method for characterization of biological indicators used in the low temperature steam and formaldehyde process in ISO 11138-5:2006.

The primary differences between ANSI/AAMI/ISO 11138-1:2006 and ANSI/AAMI ST59:1999 are indicated in c), d), and e) above.

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

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO 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 come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page xi, this American National Standard is identical to ISO 11138-1:2006.

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 11138-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11138-1:1994), which has been technically revised.

ISO 11138 consists of the following parts, under the general title *Sterilization of health care products — Biological indicators*:

— *Part 1: General requirements*

— *Part 2: Biological indicators for ethylene oxide sterilization processes*

— *Part 3: Biological indicators for moist heat sterilization processes*

— *Part 4: Biological indicators for dry heat sterilization processes*

— *Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

Introduction

This part of ISO 11138 specifies general requirements for production, labeling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes. Subsequent parts of ISO 11138 provide additional specific requirements for biological indicators for defined sterilization processes.

A graphic description of a biological indicator and its components is presented in Annex F. The presentation includes the two types of biological indicator which are covered by ISO 11138. This shows that inoculated carriers can be presented directly to the sterilizing agent without prior packaging, or included in a primary package that permits access by the sterilizing agent.

The resistance characteristics depend on the type of test organism, its numbers, the method of preparation and the effects of the primary package. Advice on selection, use and interpretation of results of biological indicators can be found in ISO 14161[7].

For any individual sterilization process, including those covered in subsequent parts of ISO 11138, the resistance of the biological indicator will also depend on its microenvironment during testing. In theory, this could lead to an infinite variation in the preparation of biological indicators. Moreover, a sterilization process could be manipulated in infinite variety to suit each possible set of conditions to which products could be exposed. It has therefore been routine practice to manufacture biological indicators that, when exposed to a set of conditions in a defined sterilization process, provide resistance characteristics expressed as D values and, where relevant, z values. Such values are set out in the subsequent parts of ISO 11138.

ISO 11138, parts 1 to 5 represent the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing this International Standard.

Biological indicators for specific sterilization processes not covered by reference test conditions in subsequent parts of ISO 11138 should comply with the general requirements in this part, including the resistance testing procedures. Such biological indicators might not be well enough described, or might be used for novel sterilization processes, or might be represented by isolated bioburden microorganisms. If microorganisms other than risk group 1 (WHO,1993[27]) are included in these biological indicators, the appropriate containment and safety levels must be met.

Standards exist providing requirements for the validation and control of sterilization processes (see Bibliography).

NOTE Some countries or regions might have published other standards covering requirements for sterilization or biological indicators (see Bibliography).

Sterilization of health care products — Biological Indicators — Part 1: General requirements

1 Scope

1.1 General

1.1.1 This part of ISO 11138 provides general requirements for production, labeling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes.

1.1.2 This part of ISO 11138 specifies basic and common requirements that are applicable to all subsequent parts of ISO 11138. Requirements for biological indicators for particular specified processes are provided in the subsequent parts of ISO 11138. If no specific subsequent part is provided, this part applies.

NOTE National or regional regulations may apply.

1.2 Exclusions

This part of ISO 11138 does not apply to microbiological test systems for processes that rely on physical removal of microorganisms, e.g. filtration processes or processes that combine physical and/or mechanical removal with microbiological inactivation, such as use of washer disinfectors or flushing and steaming of pipelines. This part of ISO 11138, however, could contain elements relevant to such microbiological test systems.