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

INTERPRETATIONS OF AAMI STANDARDS
AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. 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.
Sterilization of health care products—Chemical indicators—Part 1: General requirements

Developed by
Association for the Advancement of Medical Instrumentation

Approved 10 September 2014 by
American National Standards Institute, Inc.

Abstract: Specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances.

Keywords: acceptance criteria, dry heat, ethylene oxide, performance requirements, radiation, steam
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.
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glossary of equivalent standards</td>
<td>iv</td>
</tr>
<tr>
<td>Committee representation</td>
<td>v</td>
</tr>
<tr>
<td>Background of AAMI adoption of ISO 11140-1:2014</td>
<td>vii</td>
</tr>
<tr>
<td>Foreword</td>
<td>viii</td>
</tr>
<tr>
<td>Introduction</td>
<td>ix</td>
</tr>
<tr>
<td>1 Scope</td>
<td>1</td>
</tr>
<tr>
<td>2 Normative references</td>
<td>1</td>
</tr>
<tr>
<td>3 Terms and definitions</td>
<td>2</td>
</tr>
<tr>
<td>4 Categorization</td>
<td>4</td>
</tr>
<tr>
<td>5 General requirements</td>
<td>5</td>
</tr>
<tr>
<td>6 Performance requirements</td>
<td>8</td>
</tr>
<tr>
<td>7 Test methods</td>
<td>9</td>
</tr>
<tr>
<td>8 Additional requirements for process (Type 1) indicators</td>
<td>12</td>
</tr>
<tr>
<td>9 Additional requirements for single critical process variable (Type 3) indicators</td>
<td>15</td>
</tr>
<tr>
<td>10 Additional requirements for multicritical process variable (Type 4) indicators</td>
<td>15</td>
</tr>
<tr>
<td>11 Additional requirements for steam integrating (Type 5) indicators</td>
<td>16</td>
</tr>
<tr>
<td>12 Additional requirements for ethylene oxide integrating (Type 5) indicators</td>
<td>17</td>
</tr>
<tr>
<td>13 Additional requirements for emulating (Type 6) indicators</td>
<td>17</td>
</tr>
<tr>
<td>Annex A (normative) Method for demonstrating shelf-life of the product</td>
<td>19</td>
</tr>
<tr>
<td>Annex B (informative) Examples of testing indicators</td>
<td>20</td>
</tr>
<tr>
<td>Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators specified in ISO 11138 (all parts) and microbial inactivation</td>
<td>21</td>
</tr>
<tr>
<td>Annex D (informative) Rationale for the liquid-phase test method for low temperature steam and formaldehyde indicators</td>
<td>27</td>
</tr>
<tr>
<td>Annex E (informative) Relationship of indicator and indicator system components</td>
<td>28</td>
</tr>
<tr>
<td>Bibliography</td>
<td>29</td>
</tr>
</tbody>
</table>
Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation
Chemical Indicators Working Group

The adoption of ISO 11140-1:2014 as an American National Standard was initiated by the AAMI Chemical Indicators Working Group of the AAMI Sterilization Standards Committee. The AAMI Chemical 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 Chemical Indicators Working Group (U.S. Sub-TAG for ISO/TC 198/WG 6, Chemical indicators) played an active part in developing the ISO standard.

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

Chair: Richard Bancroft
Kristen Singleton, PhD

Members: Richard Bancroft, STERIS Corp.
Robert Bradley, CBET, Mesa Laboratories
Marc Chaunet, TSO3 Inc.
Nancy Chobin, RN CSPDM, St. Barnabas Healthcare System
Charles Codgill, Coviden
Kevin Corrigan, Advanced Sterilization Products
Jacqueline Daley, Sinai Hospital of Baltimore
Kimbell Darnell, CR Bard Inc.
Mary Ann Drosnoke, MS Olympus America Inc.
Márcia Ann Frieze, Case Medical, Inc.
Gloria H. Frost, PhD DABT, Cardinal Health
J.C. Fulghum, Hospira
Joel R. Gorski, PhD, NAMSA
Rachel Hill, Carefusion
Charles Hughes, SPS Medical Supply Corp.
Nupur Jain, Intuitive Surgical Inc.
Geetha Jayan, Phd, FDA/CDRH
Steven Kirckof, 3M Healthcare
Susan Klacik, CCSMC FCS ACE, IAHCSMM
Colleen Patricia Landers, RN, Landers Consulting CSA
Stephen Loes, Sterilucent, Inc.
Teckla Maresca, LPN CSPDM, St. Clare’s Health System
Albert May, Anderson Products Inc.
Patrick McCormick, PhD, Bausch & Lomb Inc.
Emily Mitzel, MS, Nelson Laboratories, Inc.
Frank Myers, UC San Diego Healthcare Systems
William Peiserich, Zimmer, Inc.
Manuel Saavedra, Jr., Halyard Health
Phil Schneider, Lexamed Ltd.
Andrew Sharavara, PhD, Propper Manufacturing Company Inc.
Kristen Singleton, Steritec Products Manufacturing, Inc.
Kimberly Smith, PA
Gary J. Socola, SPS HIGHTOWER Validation Testing & Lab Services, Inc.
Andy Sun, SciCan Ltd.
Donna Swenson, BS CRCST CHL, Ace
Jania Torresblanca, CSPDM, University of Michigan Health System/CW Mott Children’s Hospital
Dennis Wildes, St. Jude Medical
Cheryl Work, Becton Dickenson Medical
Martha Young, Martha L. Young, LLC

Alternates: Heide Ames, STERIS Corp.
Tim Carlson, BD Medical – Medical Surgical Systems
NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.
Background of AAMI adoption of ISO 11140-1:2014

As indicated in the foreword to the main body of this document (page x), 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 Technical Committee 198, Sterilization of health care products, to fill a need to specify requirements for chemical indicators intended for use with sterilization processes employing steam, ethylene oxide, \( \gamma \)- or \( \beta \)-radiation, steam-formaldehyde, vaporized hydrogen peroxide, or dry heat.

U.S. participation in this ISO TC 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 U.S. TAG for ISO/TC 198 supports the requirements provided in this document.


The main differences between ANSI/AAMI/ISO 11140-1:2014 and ANSI/AAMI/ISO 11140-1:2005 include use of the term “type” rather than “class” to describe the use of indicators according to their intended use, in order to emphasize that the six categories are not hierarchical, yet retaining the concept of describing indicators by six numerical categories. An optional additional prefix to the these six categories of indicators is now specified; the three prefixes that can be optionally added are listed in Table 1. The use of the term “indicator” versus the term “indicator system” has been redefined and clarified to make the terms more intuitive. There have been some changes to the performance requirements for type 1 indicators for steam, EO, and vaporized hydrogen peroxide processes, significant changes to the performance requirements for type 5 indicators for steam processes and EO processes, and deletion of the requirements for type 5 indicators for dry heat processes.

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.

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, 4301 N. Fairfax Drive, Suite 310, Arlington, VA 22201-1633.

NOTE—Beginning with the foreword on page viii, this American National Standard is identical to ISO 11140-1:2014.
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. 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 (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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’s adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, Sterilization of health care products.

This third edition cancels and replaces the second edition (ISO 11140-1:2005), which has been technically revised.

ISO 11140 consists of the following parts, under the general title Sterilization of health care products — Chemical indicators:

— Part 1: General requirements
— Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
— Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
— Part 5: Class 2 indicators for Bowie and Dick-type air removal tests

ISO 11140-2 has been withdrawn and replaced by ISO 18472.
Introduction

This part of ISO 11140 specifies performance requirements and/or test methods for chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, γ or β radiation, low temperature steam and formaldehyde or vaporized hydrogen peroxide.

Additional requirements for indicators intended for use with other sterilization methods (e.g. other forms of moist heat sterilization) are not specifically provided in this part of ISO 11140; however, the general requirements will apply.

The requirements for specific test indicators (e.g. Bowie-Dick test indicators and indicator systems) are covered in other parts of ISO 11140.

Standards for sterilizers and for the validation and process control of sterilization describe performance tests for sterilizers and methods of validation and routine control, respectively.

This part of ISO 11140 is intended for manufacturers of chemical indicators and specifies the general requirements for chemical indicators. The categorization structure for chemical indicators is used solely to denote the characteristics and intended use of each type of indicator when used as specified by the manufacturer. This categorization has no hierarchical significance. The chemical indicators described in this part of ISO 11140 are categorized into six types. The chemical indicators within each of these categorizations are further subdivided by the sterilization process for which they are designed to be used. This part of ISO 11140 defines the requirements for Type 1 and Types 3 to 6. In subsequent parts of ISO 11140, the requirements for Type 2 indicators are categorized by their intended use. The use of the indicators and indicator systems, specified in this part of ISO 11140, is described in for example the ISO 11135, the ISO 17665- series, ISO 15882, EN 285, and EN 13060.

Resistometers are used to characterize the performance of the chemical indicators described in this part of ISO 11140, with the exception of Type 2 indicators. Requirements for resistometers are specified in ISO 18472. Resistometers differ from sterilizers. As sterilizers cannot duplicate resistometer conditions they should not be used to test the performance of chemical indicators. Sterilizers from different manufacturers and of different ages have significantly different cycle profiles; for example, prolonged preconditioning phases. Resistometers allow for precise control of the specific test cycle sequences in order to study the effect of process parameters on indicator performance under controlled, repeatable conditions. Guidance on the selection, use and interpretation of the results of chemical indicators is given in ISO 15882. Users of chemical indicators are expected to make reference to this part of ISO 11140.
Sterilization of health care products — Chemical indicators — Part 1: General requirements

WARNING — The use of this part of ISO 11140 can involve hazardous materials, operations and equipment. This part of ISO 11140 does not purport to address all of the safety problems associated with their use. It is the responsibility of the user of this part of ISO 11140 to determine the applicability of national or regional regulatory requirements and to establish appropriate occupational health and safety practices prior to use of any hazardous materials, operations and/or equipment.

1 Scope

This part of ISO 11140 specifies general requirements and test methods for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process. They are not dependent for their action on the presence or absence of a living organism.

NOTE 1 Biological test systems are regarded as those test systems which are dependent for their interpretation on the demonstration of the viability of an organism. Test systems of this type are considered in the ISO 11138-series for biological indicators (BIs).

The requirements and test methods of this part of ISO 11140 apply to all indicators specified in subsequent parts of ISO 11140, unless the requirement is modified or added to by a subsequent part, in which case the requirement of that particular part will apply.

Relevant test equipment is described in ISO 18472.

NOTE 2 Additional requirements for specific test indicators/indicator systems (Type 2 indicators) are given in ISO 11140-3, ISO 11140-4 and ISO 11140-5.