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 programs 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, reference 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 a reference, 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 if 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—Radiation—Part 3: Guidance on dosimetric aspects of development, validation and routine control


Keywords: health care products, medical equipment, sterilization, radiation, gamma, electron beam, bremsstrahlung, x-ray, dosimeter, dosimetry
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.

Published by
AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2017 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

ISBN 978-1-57020-690-0
## 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 on the adoption of ISO 11137-3:2017</td>
<td>viii</td>
</tr>
<tr>
<td>Foreword</td>
<td>ix</td>
</tr>
<tr>
<td>Introduction</td>
<td>x</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, definitions and symbols</td>
<td>1</td>
</tr>
<tr>
<td>4 Measurement of dose</td>
<td>4</td>
</tr>
<tr>
<td>5 Establishing the maximum acceptable dose</td>
<td>8</td>
</tr>
<tr>
<td>6 Establishing the sterilization dose</td>
<td>9</td>
</tr>
<tr>
<td>7 Installation qualification</td>
<td>10</td>
</tr>
<tr>
<td>8 Operational qualification</td>
<td>11</td>
</tr>
<tr>
<td>9 Performance qualification</td>
<td>16</td>
</tr>
<tr>
<td>10 Routine monitoring and control</td>
<td>24</td>
</tr>
<tr>
<td>Annex A (informative) Mathematical modelling</td>
<td>25</td>
</tr>
<tr>
<td>Annex B (informative) Tables of references for dosimetry-related testing during IQ/OQ/PQ</td>
<td>27</td>
</tr>
<tr>
<td>B.1 Installation qualification</td>
<td>27</td>
</tr>
<tr>
<td>Annex C (informative) Tolerances associated with doses used in sterilization dose setting/substantiation in ISO 11137-2</td>
<td>30</td>
</tr>
<tr>
<td>Annex D (informative) Application of dose measurement uncertainty in setting process target doses</td>
<td>31</td>
</tr>
<tr>
<td>Bibliography</td>
<td>36</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

Sterilization Standards Committee

The publication of AAMI/ISO 11137-3 as a new American National Standard was initiated by the AAMI Sterilization Standards Committee, 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 Radiation sterilization working group played an active part in developing ISO 11137-3.

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

Cochair: Mike Scholla

Members:
- Brett Anderson, Cochlear Ltd
- Hank Balch, University Health System
- Richard Bancroft, Steris Corporation
- Garry Bassi, CMC Sterilization Ltd
- Stacy Bohl, Boston Scientific Corporation
- Trabue Bryans, BryKor LLC
- Tim Carlson, Becton Dickinson & Company
- Phil Cogdill, Medtronic Inc Campus
- Sean Colwell, WuXi AppTec Inc
- Ramona Conner, Association of Perioperative Registered Nurses
- Lena Cordie, Qualitas Professional Services LLC
- Jackie Daley
- Gordon Ely, MiMedx Group
- Lisa Foster, Adiuvo QS & SA Consulting
- Joel Gorski, NAMSA
- Joyce Hansen, Johnson & Johnson
- Clark Houghtaling, Cosmed Group Inc
- Sue Klacik, IAHCSMM
- Byron Lambert, Abbott Laboratories
- Michelle Luebke, Baxter Healthcare Corporation
- Patrick McCormick, Bausch & Lomb Inc
- Gerry McDonnell, Johnson & Johnson
- Gerry O’Dell, Gerry O’Dell Consulting
- Adrian Ponce, Verrix LLC
- Janet Prust, 3M Healthcare
- Nancy Rakiewicz, IUVO Bioscience
- Mike Scholla, DuPont Protection Solutions
- Joan Spear, B Braun of America Inc
- Sid Wiggs, Wiggs, Sid - 453204
- Bill Young, Sterigenics International
- Roberto Zumbado, Philips

Alternates:
- Jonathan Bull, Johnson & Johnson
- Greg Crego, IUVO Bioscience
- Aaron Dement, Sterigenics International
- Jeffrey Marx, Steris Corporation
- Kim Patton, Becton Dickinson & Company
- ChristineRender, Cosmed Group Inc
- Mike Sadowski, Baxter Healthcare Corporation
- Sharon Van Wicklin, Association of Perioperative Registered Nurses
- Craig Wallace, 3M Healthcaress

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.
Radiation sterilization working group

At the time this document was published, the AAMI Radiation sterilization working group had the following members:

**Cochairs:** Emily Craven
Elaine Daniell

**Members:**
Keith Anderson, Smiths Medical
Ed Arscott, NAMSA
Anne Booth, Booth Scientific Inc
Carolyn Braithwaite-Nelson, Spectranetics Corporation
David Brodersen, LexaMed
Riley Brown, St Jude Medical Inc
Trabue Bryans, BryKor LLC
Harry Bushar
Rob Calabro, AbbVie
David Cardin, Cook Inc
Sarah Chamberlain, Accuratus Labs Services
Denise Cleghorn, Boston Scientific Corporation
Debbie Cotton, Baxter Healthcare Corporation
Gary Cranston, Consulting & Technical Services/PCS
Emily Craven, Mevex Corporation
Greg Crego, IUVO BioScience
Elaine Daniell, CR Bard
Douglas Davie, Sterilization Validation Services
Darci Diage, Direct Flow Medical Inc
Dave Dion, Cardinal Health
Gordon Ely, MMedx Group
Trisha Fair, Cantel Inc.
Francesco Famosi, Arthrex Inc
William FitzGerald, FitzGerald & Associates Ltd
Lisa Foster, Adiuvo QS & SA Consulting
Matthew Freeman, Terumo BCT
Rob Grizzle, Terumo BCT
Doug Harbrecht, Sterility Assurance LLC
Deborah Hawk, Hospira, a Pfizer Company
Betty Howard, Steris Corporation
John Logar, Johnson & Johnson
Jeff Martin, Sterilization and Quality System Consulting LLC
Patrick McCormick, Bausch & Lomb Inc - Rochester, NY
Nicole McLees, 3M Healthcare
Rusty Mills, GE Healthcare
Larry Nichols, Company for Individuals
Gerry O'Dell, Gerry O’Dell Consulting
Kevin O’Hara, Sterigenics
Dave Parente, Ecolab
Kim Patton, Becton Dickinson & Company
Michelle Peterson, Stryker Instruments Division
Rudy Pina, Dynatec Scientific Labs Inc
Keith Reiner, Terumo Americas Corporate
Jody Rupert, WL Gore & Associates Inc
Manny Saavedra, Halyard Health
Harry Shaffer, Sterilization Consulting Services
Michael Sprague, Ethide Laboratories Inc
Sopheak Srun, Quality Tech Services Inc
Fenil Sutaria, Medline Industries Inc
Jill Warren, WuXi AppTec Inc
Bud Weisman, Fresenius Medical Care
Pat Weixel, FDA/CDRH
Beverly Whitaker, Indigo Consulting Group LLC
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.
Background on the adoption of ISO 11137-3:2017

As indicated in the foreword to the main body of this document (page ix), 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 an ISO and International working group, ISO/TC 198/WG2, Radiation sterilization.

U.S. participation in ISO/TC 198/WG2 is organized through the U.S. Technical Advisory Group to ISO/TC 198, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

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

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr, Suite 301, Arlington, VA 22203-1633.

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

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

This second edition cancels and replaces the first edition (ISO 11137-3), which has been technically revised.

A list of all parts in the ISO 11137 series can be found on the ISO website.
Introduction

An integral part of radiation sterilization is the ability to measure dose. Dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or an International Standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental considerations on dosimeter response is known and taken into account. Process parameters are established and applied based on dose measurements. This document provides guidance on the use of dose measurements (dosimetry) during all stages in the development, validation and routine control of the radiation sterilization process.

Requirements in regard to dosimetry are given in ISO 11137-1 and ISO 11137-2 and ISO/TS 13004. This document gives guidance to these requirements. The guidance given is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being 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 ISO 11137-1, ISO 11137-2 and ISO/TS 13004.
American National Standard
ANSI/AAMI/ISO 11137-3:2017

Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects of development, validation and routine control

1 Scope

This document gives guidance on meeting the requirements in ISO 11137-1 and ISO 11137-2 and in ISO/TS 13004 relating to dosimetry and its use in development, validation and routine control of a radiation sterilization process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11137-1, Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2, Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose

ISO/TS 13004, Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose: Method VDmaxSD

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

3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in ISO 11137-1 and ISO 11137-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:


— ISO Online browsing platform: available at http://www.iso.org/obp

3.1 General

3.1.1 absorbed dose
quantity of ionizing radiation energy imparted per unit mass of a specified material

[SOURCE: ISO 11137-1:2006, 3.1, modified]

3.1.2 combined standard measurement uncertainty
standard measurement uncertainty (3.1.13) that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

[SOURCE: VIM 2012, 2.31]