Sterilization of health care products — Radiation — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
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, referent 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. 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.
American National Standard

(Consolidated Text)
(Combined revision [in whole or in part]

Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

Approved 9 December 2005 by
Amendment 1 approved 13 December 2013
Association for the Advancement of Medical Instrumentation

Approved 23 December 2005 and Reaffirmed 20 April 2010 and 6 October 2015 by
Amendment 1 approved 30 December 2013
American National Standards Institute

Abstract: Specifies requirements for validation, process control, and routine monitoring in the radiation sterilization for health care products. It applies to continuous and batch type gamma irradiators using the radionuclides 60 Co and 137 Cs, and to irradiators using a beam from an electron or X-ray generator.

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

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¹In production
Committee representation

Association for the Advancement of Medical Instrumentation
Radiation Sterilization Working Group

The adoption of ISO 11137-1:2006 as an AAMI standard was initiated by the Radiation Sterilization 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 Radiation Sterilization Working Group (U.S. Sub-TAG for ISO/TC 198/WG 2), chaired by Lisa Foster and Byron Lambert, 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 Radiation Sterilization Working Group had the following members:

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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 of AAMI adoption of ISO 11137-1:2006

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.

The first edition of ISO 11137 was developed by ISO Technical Committee 198 to fill a need for an international standard for radiation sterilization of health care products. The standard was published in 1995 and was followed by several technical reports developed in ISO or in AAMI primarily to cover additional dose setting methods. During its systematic review of ISO 11137:1995 (adopted in the U.S. as ANSI/AAMI/ISO 11137:1994), ISO/TC 198 decided to revise the document by splitting it into three parts under the general title Sterilization of health care products—Radiation. The three parts are

- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices;
- Part 2: Establishing the sterilization dose; and
- Part 3: Guidance on dosimetric aspects.

In addition, content from some of the technical reports developed since the first edition was published has been incorporated into the latest standards.

Part 1 of ISO 11137 has many of the same requirements as ISO 11137:1995, but is organized differently and has new terminology, e.g., product families, processing categories, process definition, and performance qualification (per ISO 13485).

New technical content includes

- the addition of a new dose option, 15 kGy, in addition to 25 kGy, for the establishment of a sterilization dose using the dose substantiation method;
- operational qualification technical requirements;
- options and requirements in defining the frequency of bioburden determination and dose audits.

Additionally, ISO 11137-1 provides a more comprehensive definition of irradiation and process specifications, and clarifies the requirements for equipment requalification as well as the criteria for transferring dose between facilities.

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 11137-1:2006.
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 11137-1 was prepared by Technical Committee ISO/TC 198, Sterilization of health care products.


ISO 11137 consists of the following parts, under the general title Sterilization of health care products — Radiation:

Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

Part 2: Establishing the sterilization dose

Part 3: Guidance on dosimetric aspects
Introduction

A sterile medical device is one that is free of viable microorganisms. International Standards, which 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 medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices 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 medical device 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 medical device.

This part of ISO 11137 describes requirements that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization. Specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

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.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the products are sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

b) the microbiological status of incoming raw materials and/or components;

c) the validation and routine control of any cleaning and disinfection procedures used on the product;

d) the control of the environment in which the product is manufactured, assembled and packaged;

e) the control of equipment and processes;

f) the control of personnel and their hygiene;
g) the manner and materials in which the product is packaged;

h) the conditions under which product is stored.

This part of ISO 11137 describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities are described in documented work programs designed to demonstrate that the radiation process will consistently yield sterile products on treatment with doses falling within the predetermined limits.

The requirements are the normative parts of this part of ISO 11137 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 11137.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this part of ISO 11137 have been grouped together and are presented in a particular order, this part of ISO 11137 does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the program of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This part of ISO 11137 does not specify the particular individuals or organizations to carry out the activities.
Sterilization of health care products—Radiation—
Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

1 Scope

1.1 This part of ISO 11137 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

NOTE Although the scope of this part of ISO 11137 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

This part of ISO 11137 covers radiation processes employing irradiators using,

a) the radionuclide $^{60}\text{Co}$ or $^{137}\text{Cs}$,

b) a beam from an electron generator

or

c) a beam from an X-ray generator.

1.2 This part of ISO 11137 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See, for example, ISO 22442-1, ISO 22442-2, and ISO 22442-3.

1.2.1 This part of ISO 11137 does not detail specified requirements for designating a medical device as sterile.

NOTE Attention is drawn to regional and national requirements for designating medical devices as "sterile." See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.2 This part of ISO 11137 does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this part of ISO 11137 to have a complete quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, Clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices might require implementation of a complete quality management system and the assessment of that system by a third party.