

American National Standard



ANSI/AAMI/ ISO 11137-1: 2006/(R)2015 & A1:2013 & A2:2019 (Consolidated Text)

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

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 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.

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American National Standard

ANSI/AAMI/ISO 11137-1:2006/(R)2015 and ANSI/AAMI/ISO
11137-1:2006/A1:2013/A2:2019 (Consolidated Text)
(Combined revision [in whole or in part]
of ANSI/AAMI/ISO 11137:1994 and A1:2002 and ANSI/AAMI/
ISO TIR15843:2000)

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

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AAMI

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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

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Association for the Advancement of Medical Instrumentation
4301 N Fairfax Drive, Suite 301
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www.aami.org

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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 I136:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI I151:2004	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 TR 62348:200x ¹	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 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	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	ANSI/AAMI BE78:2002	Minor technical variations
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 10993-19:200x ¹	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO TS 10993-20:200x ¹	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 11137-2:200x ¹	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 200x ¹	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 200x ¹	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 200x ¹	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 200x ¹	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 200x ¹	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 18472:200x ¹	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

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:

<i>Cochairs</i>	Lisa Foster Byron J. Lambert, PhD
<i>Members</i>	Chris B. Anderson, St Jude Medical Inc. Leonard S. Berman, PhD, Pall Medical Paul William Boentges, BS, Cardinal Health (MP&S) Anne F. Booth, MS, Conmed Corporation John Broad, NAMSA Trabue D. Bryans, AppTec Virginia C. Chamberlain, PhD, VC Chamberlain & Associates (Independent Expert) Rod Chu, MDS Nordion Gary N. Cranston, Consulting & Technical Svcs/PCS Greg Crego, Ethox Corporation Kate Davenport, Northview Biosciences Douglas D. Davie, Sterilization Validation Services Brian R. Drumheller, CR Bard Barry P. Fairand, PhD (Independent Expert) Lisa Foster, Sterigenics International Ruth Garcia, Steris Corporation Joyce M. Hansen, JM Hansen & Associates (Independent Expert) Thomas L. Hansen, Terumo Medical Corporation Doug F. Harbrecht, Boston Scientific Corporation Deborah A. Havlik, Hospira Inc Arthur H. Heiss, PhD, Bruker BioSpin Corporation Craig M. Herring, Johnson & Johnson Carolyn L. Kinsley, Pharmaceutical Systems Inc. Byron J. Lambert, PhD, Guidant Corporation/Cardiac Rhythm Management Jeff Martin, Alcon Laboratories Inc. David Ford McGoldrick, BS, Abbott Laboratories James E. McGowan, Jr., BS, MBA, Sterility Assurance Laboratories Inc. Joseph M. Mello, Ethide Laboratories Inc. Russell D. Mills, Zimmer Inc. Gerry A. O'Dell, MS, Gerry O'Dell Consulting (Independent Expert) Frank Peacock, Jr., Bausch & Lomb Inc. Bryant Pearce, Clearant Inc. Manuel Saavedra, Jr., Kimberly-Clark Corporation Zenius V. Seliokas, Stericon Inc. Jon Seulean, Cobe Sterilization Services Inc. Harry L. Shaffer, Sterilization Consulting Services William N. Thompson, TYCO Healthcare/Kendall

Alternates

Richard L. Weisman, Fresenius Medical Care NA Dialysis Products Division
Patrick B. Weixel, FDA/CDRH
James L. Whitby, MA, MB, FRCP, University of Western Ontario (Independent Expert)
Thelma Wilcott, Becton Dickinson & Company
John Andrew Williams, BS, Baxter Healthcare Corporation
Martell Kress Winters, BS, SM, Nelson Laboratories Inc.
Lisa Baryschpolec, Johnson & Johnson
Harry F. Bushar, PhD, FDA/CDRH
Charles Cogdill, Boston Scientific Corporation
John DiCaro, TYCO Healthcare/Kendall
Joyce Kay Elkins, Zimmer Inc.
Niki Fidopiastis, Sterigenics International
Donna Horner, Guidant Corporation/Cardiac Rhythm Management
Joseph A. Hutson, Cardinal Health (MP&S)
Orlando C. Johnson, Hospira Inc.
Bert Kingsbury, Terumo Medical Corporation
Ezra Koski, A, Cobe Sterilization Services Inc.
Mary Malarkey, FDA/CDRH
Mary S. Mayo, CR Bard
Consuelo Lorraine McChesney, BS, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Dave Parente, NAMSA
Timothy Ramsey, BS, Northview Biosciences
Mark Seybold, Baxter Healthcare Corporation
Ralph Stick, AppTec
John W. Walker, Steris Corporation
Wendy Wangsgard, PhD, Nelson Laboratories Inc.
David Weppner, Ethox Corporation

AAMI Sterilization Standards Committee

Cochairs

Victoria M. Hitchins, PhD
William E. Young

Members

Trabue D. Bryans, AppTec
Virginia C. Chamberlain, PhD, VC Chamberlain & Associates (Independent Expert)
Nancy Chobin, RN, CSPDM, St. Barnabas Healthcare System (Independent Expert)
Anne M. Cofiehl, CRCST, FCS, International Association of Healthcare Central Service Materiel Management
Charles Cogdill, Boston Scientific Corporation
Ramona Conner, RN, MSN, CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Association for Professionals in Infection Control and Epidemiology
Kimbrell Darnell, CR Bard
Lisa Foster, Sterigenics International
James M. Gibson, Jr., JM Gibson Associates
Barbara J. Goodman, RN, BS, CNOR (Independent Expert)
Joel R. Gorski, PhD, NAMSA
Deborah A. Havlik, Hospira Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Richard M. Johnson, MSc, BSc, Abbott Laboratories
Lois Atkinson Jones, MS (Independent Expert)
Byron J. Lambert, PhD, Guidant Corporation/Cardiac Rhythm Management
Colleen Patricia Landers, RN, Canadian Standards Association
David Liu, Johnson & Johnson
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Thomas K. Moore, Getinge USA
Barry F.J. Page, Barry Page Consulting (Independent Expert)
Nancy J. Rakiewicz, Ethox Corporation
Phil M. Schneider, 3M Healthcare
Michael H. Scholla, Dupont Nonwovens
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, Propper Manufacturing Co Inc.
Frank Sizemore, American Society for Healthcare Central Service Professionals

Gregory O. Stecklein, MS, MSM, Cardinal Health (MP&S)
 William N. Thompson, TYCO Healthcare/Kendall
 John W. Walker, Steris Corporation
 James L. Whitby, MA, MB, FRCP, University of Western Ontario (Independent Expert)
 Thelma Wilcott, Becton Dickinson & Company
 Martell Kress Winters, BS, SM, Nelson Laboratories Inc.
 William E. Young (Independent Expert)

Alternates

Lloyd Brown, TYCO Healthcare/Kendall
 Lina C. Bueno, Dupont Nonwovens
 Craig M. Herring, Johnson & Johnson
 Clark W. Houghtling, Steris Corporation
 Danny Hutson, Cardinal Health (MP&S)
 Jim Kaiser, Bausch & Lomb Inc.
 Susan G. Klacik, AS, BS, International Association of Healthcare Central Service Materiel
 Management
 Joseph J. Lasich, BS, Alcon Laboratories Inc.
 Chiu Lin, PhD, FDA/CDRH
 Lisa N. Macdonald, Becton Dickinson & Company
 Ralph Makinen, Guidant Corporation/Cardiac Rhythm Management
 Mary S. Mayo, CR Bard
 David Ford McGoldrick, BS, Abbott Laboratories
 Jerry R. Nelson, MS, PhD, Nelson Laboratories Inc.
 Jeff Peltier, Boston Scientific Corporation
 Janet Prust, 3M Healthcare
 Mike Sadowski, Baxter Healthcare Corporation
 Ralph Stick, AppTec
 Jason Voisinet, Ethox Corporation
 Valerie Welter, Hospira Inc.
 William T. Young, Sterigenics International

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.

Concurrent with the development of the U.S. position on the ISO 11137 series, the AAMI Radiation Sterilization Working Group (AAMI ST/WG 02) decided to adopt the three parts verbatim. Together, these documents supersede ANSI/AAMI/ISO 11137:1994 (and 2002 amendment), AAMI TIR27:2001, AAMI/ISO TIR13409:1996 (and 2000 amendment), and AAMI/ISO TIR15844:1998.

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 product*.

This first edition, together with ISO 11137-2 and ISO 11137-3, cancels and replaces ISO 11137:1995.

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}Co or ^{137}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.

1.2.3 This part of ISO 11137 does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.

1.2.4 This part of ISO 11137 does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

NOTE Attention is also drawn to the existence, in some countries, of regulations laying down safety requirements for occupational safety related to radiation.

1.2.5 This part of ISO 11137 does not specify requirements for the sterilization of used or reprocessed devices.

2 Normative references

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

ISO 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

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

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process*

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

3 Terms and definitions

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

3.1

absorbed dose dose

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

NOTE 1 The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 J/kg.

NOTE 2 For the purposes of this part of ISO 11137, the term dose is used to mean “absorbed dose.”

3.2

bioburden

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

[ISO/TS 11139:2006]

3.3

biological indicator

test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[ISO/TS 11139:2006]

3.4

calibration

set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

[VIM:1993, definition 6.11]

3.5

change control

assessment and determination of the appropriateness of a proposed alteration to product or procedure

[ISO/TS 11139:2006]

3.6

correction

action to eliminate a detected nonconformity

NOTE A correction can be made in conjunction with corrective action (3.7).

[ISO 9000:2005]

3.7

corrective action

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

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

NOTE 2 Corrective action is taken to prevent recurrence whereas “preventive action” (3.24) is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action.

[ISO 9000:2005]

3.8

D value

D_{10} value

time or radiation dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

NOTE For the purpose of the ISO 11137 series, the *D* value refers to the radiation dose necessary to achieve the 90 % reduction.

[ISO/TS 11139:2006]