American National Standard

ANSI/AAMI/ ISO 11137-3: 2017/(R)2023

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

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

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Abstract: Guidance on dosimetry for radiation sterilization of health care products.

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

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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

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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:

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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, 901 N. Glebe Road Suite 300, Arlington, VA 22203.

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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.

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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.

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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:

— IEC Electropedia: available at http://www.electropedia.org/

— 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]

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3.1.3
coverage factor
number larger than one by which a *combined standard measurement uncertainty* (3.1.2) is multiplied to obtain an *expanded measurement uncertainty* (3.1.7)

Note 1 to entry: A coverage factor is usually symbolized as “k” (see also the GUM:1995, 2.3.6).

3.1.4
direct dose measurement
measurement of *absorbed dose* (3.1.1) with a dosimeter at the location of interest

Note 1 to entry: For example, a direct measurement of minimum dose is made with a dosimeter at the minimum dose location in an irradiation container.

3.1.5
dose uniformity ratio
ratio of the maximum to the minimum *absorbed dose* (3.1.1) within the irradiation container

3.1.6
dosimetry system
interrelated elements used for determining *absorbed dose* (3.1.1), including dosimeters, instruments, associated reference standards and procedures for their use

[SOURCE: ISO/TS 11139:2006, 2.15]

3.1.7
expanded measurement uncertainty
product of a *combined standard measurement uncertainty* (3.1.2) and a factor larger than the number one

Note 1 to entry: The factor depends on the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

Note 2 to entry: The term “factor” in this definition refers to a coverage factor.

3.1.8
indirect dose measurement
measurement of *absorbed dose* (3.1.1) at a location remote from a directly measured dosimeter calculated by the application of factors

Note 1 to entry: For example, where the minimum dose in an irradiation container cannot easily be measured directly, a dosimeter placed in a remote location may be measured and factors applied to that measurement to calculate the minimum dose.

3.1.9
scan length
dimension of the irradiation zone, perpendicular to the scan width and direction of the electron beam at a specified distance from the accelerator window

Note 1 to entry: ISO/ASTM standards use “beam length” to mean the same thing that “scan length” means in this document. This document uses “scan length” for consistency with ISO 11137-1.

3.1.10
scan width
dimension of the irradiation zone in the direction that the beam is scanned, perpendicular to the beam length and direction of the electron beam at a specified distance from the accelerator window

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Note 1 to entry: ISO/ASTM standards use “beam width” to mean the same thing that “scan width” means in this document. This document uses “scan width” for consistency with ISO 11137-1.

3.1.11
simulated product
material with attenuation and scattering properties similar to those of the product, material or substance to be irradiated

Note 1 to entry: Simulated product is used as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for absorbed dose mapping, simulated product is sometimes referred to as “phantom material”.

Note 2 to entry: In this document, “dose mapping” is used for “absorbed dose mapping.”

3.1.12
spatial resolution
resolution in two dimensions

Note 1 to entry: Ability to detect change in dose in two dimensions.

3.1.13
standard measurement uncertainty
uncertainty of the result of a measurement expressed as a standard deviation

[SOURCE: VIM 2012, 2.30, modified]

3.1.14
uncertainty budget
statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination

Note 1 to entry: An uncertainty budget should include the measurement model, estimates and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty and any coverage factor.

[SOURCE: VIM 2012, 2.33]

3.2 Symbols

Symbol	Meaning
$D_{max,acc}$	maximum acceptable dose determined in accordance with ISO 11137-1:2006, 8.1
D_{ster}	sterilization dose determined in accordance with ISO 11137-1:2006, 8.2
D_{max}	direct measurement of maximum dose in a given irradiation container
D_{min}	direct measurement of minimum dose in a given irradiation container
D_{mon}	direct measurement of dose at the routine monitoring position
$R_{max/min}$	ratio of maximum to minimum dose (D_{max}/D_{min}) determined by dose mapping

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