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Technical Information Report

ANSI/AAMI/ISO TIR11139:2002

Sterilization of health care products—Vocabulary

AAMI Association for the Advancement of Medical Instrumentation

An ANSI Technical Report prepared by AAMI ANSI/AAMI/ISO TIR11139:2002

Sterilization of health care products—Vocabulary

Approved 25 March 2002 by
Association for the Advancement of Medical Instrumentation

Registered 7 June 2002 by
American National Standards Institute

Abstract: This AAMI technical information report provides definitions of terms in the field of sterilization technology. It is intended to contribute fundamentally toward mutual understanding among those preparing and using standards in the field of sterilization technology.

This technical information report is an adoption of ISO Technical Specification 11139:2001.

Keywords: batch, bioburden, bioburden estimate, biological indicator, calibration, change control, microbial characterization, chemical indicator, cleaning, culture conditions, *D* value, D_{10} value, development, environmental control, establish, exposure time, fault, health care product, inactivation, inoculated carrier, installation qualification, IQ, material safety data sheet, medical device, microorganism, operational qualification, OQ, parametric release, performance qualification, PQ, presterilization count, primary package, process challenge device, process parameter, process variable, product, product unit, recognized culture collection, reference microorganism, requalification, services, specify, sterile, sterility, sterility assurance level, SAL, sterilization, sterilization load, sterilization process, sterilizing agent, survivor curve, terminal sterilization, test for sterility, test of sterility, validation

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–176–5

ANSI Technical Report

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Publication of this ANSI Technical Report has been approved by the accredited standards developer (AAMI). This document is registered as a Technical Report series of publications according to the Procedures for the Registration of ANSI Technical Reports. This document is not an American National Standard and the material contained herein is not normative in nature.

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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 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	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 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	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	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical

International designation	U.S. designation	Equivalency
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x[1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	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 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2001	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	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 TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

The adoption of ISO Technical Specification 11139, first edition, 2001, as an AAMI technical information report and ANSI Technical Report was initiated by the AAMI Sterilization Terminology Working Group, under the auspices of the AAMI Sterilization Standards Committee, which also serves as the U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Sterilization Terminology Working Group and the Sterilization Standards Committee played an active role in developing the ISO Technical Specification.

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

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William E. Young

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO/TS 11139:2001

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 technical report.

ISO/TS 11139:2001 was developed by ISO Technical Committee 198, *Sterilization of health care products*, to provides writers of standards with definitions of terms in the field of sterilization and to contribute fundamentally towards mutual understanding amongst those preparing and using International Standards in the field of sterilization technology.

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 on behalf of the American National Standards Institute. The United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international documents as much as possible. Upon review of ISO/TS 11139, the AAMI Sterilization Standards Committee and the AAMI Sterilization Terminology Working Group decided to adopt ISO/TS 11139 verbatim as an AAMI technical information report.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page x, this ANSI Technical Report/AAMI technical information report is identical to ISO/TS 11139:2001.

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 3.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative documents:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years with a view to deciding whether it should be confirmed for a further three years, revised to become an International Standard, or withdrawn. In the case of a confirmed ISO/PAS or ISO/TS, it is reviewed again after six years at which time it has to be either transposed into an International Standard or withdrawn.

Attention is drawn to the possibility that some of the elements of this Technical Specification may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 11139 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Introduction

A sterile medical device is one which is free from 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. Nevertheless, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality systems (see, for example, ISO13485 and ISO 13488) or which have been subjected to a cleaning process as part of their reprocessing in a health care establishment may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

This Technical Specification is intended to be used in the preparation or revision of International Standards that include aspects of sterilization of health care products. The aim of this Technical Specification is to promote a coherent approach to the description of sterilization activities and harmonize the use of terminology in the field of sterilization technology.

In the preparation or revision of an International Standard that includes sterilization technology, first consideration should be given to the definitions within this Technical Specification. However, it may be necessary to deviate from the exact wording to meet the needs of a specific application, for example by the addition of an explanatory note. In this case, the terminology used should not be in conflict with this Technical Specification and the rationale for the deviation should be made clear to the user.

This is a generic Technical Specification, compiled to encompass the general field of sterilization technology, and not to replace established terms in specific applications.

Sterilization of health care products—Vocabulary

1 Scope

1.1 This Technical Specification provides writers of standards with definitions of terms in the field of sterilization technology.

It does not give provisions for the validation and routine control of a sterilization process, but is intended to contribute fundamentally towards mutual understanding among those preparing and using International Standards in the field of sterilization technology.

2 Definitions of core terms for use in the standards of ISO/TC198, *Sterilization of health care products*

2.1 batch: Defined quantity of bulk, intermediate, or finished product that is intended or purported to be uniform in character and quality, and which has been produced during a defined cycle of manufacture.

2.2 bioburden: Population of viable microorganisms on a product and/or a package.

2.3 bioburden estimate: Value established for the bioburden by applying a factor to a presterilization count to compensate for the efficiency of the defined technique used in the recovery of microorganisms.

2.4 biological indicator: Microbiological test system providing a defined resistance to a specified sterilization process.

2.5 calibration: Set of operations which establish, under specified conditions, the relationship between values indicated by a measuring system, or values represented by a material measure or a reference material, and the corresponding values of that quantity obtained from a reference standard.

2.6 change control: Formal assessment and determination of the appropriateness of a proposed alteration to product or procedure.

2.7 microbial characterization: General process by which microorganisms are grouped into broad categories.

NOTE—Categories may be based, for example, on the use of selective media, colony or cellular morphology, staining properties, or other characteristics.

2.8 chemical indicator: System that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process.

2.9 cleaning: Removal of contamination from an item to the extent necessary for further processing or for intended use.

2.10 culture conditions: Combination of growth medium and manner of incubation used to promote germination, growth, and/or multiplication of microorganisms.

NOTE—The manner of incubation may include the temperature, time, and any other conditions specified for incubation.

2.11 *D* value, D_{10} value: Time or radiation dose required to achieve inactivation of 90 % of a population of the test microorganism under stated exposure conditions.

2.12 development: Act of elaborating a specification in preparation for validation.

2.13 environmental control: Engineering and/or procedural systems implemented to control environmental contamination in manufacturing areas within specified limits.

NOTE—Such systems may include air and fluid filters, surface disinfection, personnel uniforms, and administrative procedures.

2.14 establish: Determine by theoretical evaluation and confirm by experimentation.

2.15 exposure time: Period for which the process parameters are maintained within their specified tolerances.

2.16 fault: One or more of the process parameters which lies outside its/their specified tolerance(s).

2.17 health care product: Medical device, medicinal product (pharmaceuticals including biologicals), and *in vitro* diagnostic medical device.

2.18 inactivation: Loss of ability of microorganisms to grow and/or multiply.

2.19 inoculated carrier: Supporting material on or in which a defined number of test microorganisms have been deposited.

2.20 installation qualification (IQ): Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

2.21 material safety data sheet: Document specifying the properties of a material, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the material safely.

2.22 medical device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;

— investigation, replacement, or modification of the anatomy or of a physiological process; and

— control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

2.23 microorganism: An entity, encompassing bacteria, fungi, protozoa, and viruses, of microscopic size.

2.24 operational qualification (OQ): Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

2.25 parametric release: Declaration that a product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances.

2.26 performance qualification (PQ): Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

2.27 presterilization count: Number of viable microorganisms found on product prior to sterilization.

2.28 primary package: Element of the packaging system that maintains the sterility of product.

2.29 process challenge device: Item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process, and used to assess the effective performance of the process.

2.30 process parameter: Specified value for a process variable.

NOTE—The specification for a sterilization process includes the process parameters and their tolerances.

2.31 process variable: Condition within a sterilization process, changes in which alter microbicidal effectiveness.

EXAMPLES—Time, temperature, pressure, concentration, humidity, wavelength.

2.32 product: Raw materials, intermediate products, sub-assemblies, and health care products.

2.33 product unit: Health care product, collection of products, or components contained within a primary package.

2.34 recognized culture collection: International depository authority under the Budapest Treaty on “The International Recognition of the Deposit of Microorganisms for the Purpose of Patent and Regulation.”

2.35 reference microorganism: Microbial strain obtained from a recognized culture collection.

2.36 requalification: Repetition of part of validation for the purpose of confirming the continued acceptability of a specified process.

2.37 services: Supplies from an external source, necessary for the correct function of sterilization equipment.

EXAMPLES—Electricity, water, compressed air, drainage.

2.38 specify: Stipulate in detail within an approved document.

2.39 sterile: Free from viable microorganisms.

2.40 sterility: State of being free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven [see **sterilization** (**2.42**)].

2.41 sterility assurance level (SAL): Probability of a single viable microorganism occurring on product after sterilization.

NOTE—SAL is normally expressed as 10^{-n}.

2.42 sterilization: Validated process used to render a product free from viable microorganisms.

NOTE—In a sterilization process, the nature of microbial inactivation is described by an exponential function. Therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero [see **sterility assurance level** (**2.41**)].

2.43 sterilization load: Product to be, or that has been, sterilized together using a given sterilization process.

2.44 sterilization process: Series of actions or operations required to achieve the specified requirements for sterility.

NOTE—This series of actions includes pretreatment of product (if necessary), exposure under defined conditions to the sterilizing agent, and any necessary post-treatment. The sterilizing process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

2.45 sterilizing agent: Physical or chemical entity, or combination of entities, that have sufficient microbicidal activity to achieve sterility under defined conditions.

2.46 survivor curve: Graphical representation of the inactivation of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions.

2.47 terminal sterilization: Validated process whereby product within its primary package is sterilized.

2.48 test for sterility: Test defined in an official Pharmacopoeia for product release following exposure to a sterilization process.

2.49 test of sterility: Test performed as part of development, validation, or requalification to establish the presence or absence of viable microorganisms on product units or portions thereof.

2.50 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.