ANSI/AAMI/ISO 16142-2: 2017

Medical devices—
Recognized essential principles of safety and performance of medical devices—Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
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 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.

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.
Medical devices—Recognized essential principles of safety and performance of medical devices—Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

Abstract: This part of ISO 16142, which includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This standard identifies and describes the six general essential principles of safety and performance that apply to all medical devices, including IVD medical devices (in vitro diagnostic).

Keywords: medical device, essential principles, IVD
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.

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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. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation

General aspects stemming from the application of quality principles to medical devices

The publication of AAMI/ISO 16142-2:2017 as a new American National Standard was initiated by the AAMI General aspects stemming from the application of quality principles to medical devices Work Group, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO) ISO/TC210 WG2. U.S. representatives from the AAMI General aspects stemming from the application of quality principles to medical devices Work Group participate as US experts on the ISO committee.

At the time this document was published, the AAMI General aspects stemming from the application of quality principles to medical devices Work Group had the following members:

Cochair: Carol Herman (through October 2016)
Dave Osborn (pro-tem)

Members:
- Kathie Bardwell, Steris Corporation
- Ali Calik, Bausch & Lomb Inc
- Ujjal Chakravartty, Halyard Health
- Lena Cordie, Qualitas Professional Services
- Vijay Damodaran, Eli Lilly & Company
- Aaron Dement, Sterigenics International
- Ron Grandbois, 3M Healthcare
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- Russ Rainey, Halyard Health
- Daniel Wright, Kimberly-Clark Corporation

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.

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Background of ANSI/AAMI adoption of ISO 16142-2:2017

As indicated in the foreword to the main body of this document (page vii), the International Standards Organization (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 ISO Technical Committee 210, Quality management and corresponding general aspects for medical devices, Work Group 2, General aspects stemming from the application of quality principles to medical devices, provides for the inclusion of the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This document identifies and describes the six general essential principles of safety and performance that apply to all medical devices, including IVD medical devices.

U.S. participation in ISO TC210/WG2 is organized through the U.S. Technical Advisory Group to TC210/WG2, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.


AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

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

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

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

NOTE—Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 16142-2:2017.
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 voluntary nature of standards, 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.

This document was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This document builds on ISO 16142-1, which cancels and replaces ISO/TR 16142:2006.

A list of all parts in the ISO 16142 series can be found on the ISO website.
Introduction

Standards and standardization processes can be made more effective by developing a better understanding of the needs and requirements of those who use or who are affected by standards. Improvements in standards will contribute to global harmonization efforts at all levels.

Continuous innovation is key to the advancement of medical device technology, contributing to more effective healthcare. Ideally, standards supporting or referenced in regulatory requirements are developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

The timely development of medical device standards and their periodic revision make medical device standards effective and efficient tools for supporting regulatory systems and for achieving globally compatible regulation.

Voluntary standards and guides can assist manufacturers to comply with legal requirements. If the standards are accepted within a given regulatory system, compliance with such standards can be deemed to satisfy the legal requirements. The regulatory acceptance does not, of itself, imply that such standards are mandatory.

Medical device standards represent a consensus on requirements that foster innovation while protecting public health.

Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, can be facilitated by the appropriate use of relevant medical device standards. This is based on the premise that

— standards are based on experience or, in other words, are retrospective,

— innovation can present unanticipated challenges to experience,

— rigid, mandatory, application of standards can deter innovation,

— operation of a quality management system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health,

— quality management systems include provisions that address both innovation and experience, and

— such provisions of quality management systems include field experience, risk analysis and risk management, phased reviews, documentation and record keeping, as well as the use of product and process standards.

The essential principles of safety and performance of medical devices were originally developed by the Global Harmonization Task Force (GHTF), revised in 2012 to harmonize regulatory requirements for medical devices worldwide, and now archived by the International Medical Device Regulators Forum (IMDRF). Thus, an update of the original ISO/TR 16142:2006, based on those essential principles, was needed to keep the document in line with the updated essential principles.

In discussing the revision of ISO/TR 16142:2006, ISO/TC 210 decided that the information included was, at the time of writing, in a state of consensus between the stakeholders and had matured enough to elevate the document from a Technical Report (TR) to an International Standard.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in Clause 3: bold.

In this document, the conjunctive "or" is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb
— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document,

— “may” is used to describe a permissible way to achieve compliance with a requirement or test, and

— “must” is used to describe an external constraint, but is not mandatory for compliance with this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.
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Medical devices—Recognized essential principles of safety and performance of medical devices—Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

1 Scope

This document, which includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This document identifies and describes the six general essential principles of safety and performance (see Table B.1) that apply to all medical devices, including IVD medical devices (in vitro diagnostic).

This document also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process, which are relevant to IVD medical devices.

NOTE During the design process, the manufacturer selects which of the listed design and manufacturing principles apply to the particular medical device and documents the reasons for excluding others.

This document is intended for use as guidance by medical device manufacturers, standards development organizations, authorities having jurisdiction, and conformity assessment bodies.

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 2859 (all parts), Sampling procedures for inspection by attributes

ISO 3951 (all parts), Sampling procedures for inspection by variables

ISO 11135, Sterilization of health-care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11137 (all parts), Sterilization of health care products—Radiation

ISO 11138 (all parts), Sterilization of health care products—Biological indicators

ISO 11140 (all parts), Sterilization of health care products—Chemical indicators

ISO 11607 (all parts), Packaging for terminally sterilized medical devices

ISO 11737 (all parts), Sterilization of medical devices—Microbiological methods

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