American National Standard

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

AAMI
Advancing Safety in Healthcare Technology

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.

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

Approved 4 June 2017 by
AAMI

Approved 31 July 2017 by
American National Standards Institute, Inc.

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.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-671-9

Contents

Page

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
Laila Gurney, GE Healthcare
Alberto Gutierrez, FDA/CDRH
Megan Hayes, Medical Imaging & Technology Alliance a Division of NEMA
Carol Herman, AAMI
Eamonn Hoxey, Johnson & Johnson
Kristi Kistner, Amgen Inc
Dan Laelle, Nonin Medical Inc
Mary Mayo, CR Bard
Beth Nichols, Abbott Laboratories
Susumu Nozawa, Becton Dickinson & Company
Dave Osborn, Philips Electronics North America
Luann Pendy, Medtronic Inc WHQ Campus
Ed Reverdy, Boston Scientific Corporation
Barb Smith, Getinge USA
Chandresh Thakur, CareFusion
Lynne Thomas, Integrated Medical Systems
Radhakrishna Tirumalai, US Pharmacopeia Convention Inc
John Williams, Baxter Healthcare Corporation
Daidi Zhong, Chongqing University

Alternates:
Khalil Ahmed, Bausch & Lomb Inc
Cathy Clevenger, Eli Lilly & Company
Theresa Dennis, Sterigenics International
Don Ertl, Medtronic Inc WHQ Campus
Lisa Foster, Adiuvo QS & SA Consulting
Rich Gardner, GE Healthcare
Erin Keith, FDA/CDRH
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.