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, referred 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—Quality management—Medical device nomenclature data structure

Abstract: This International Standard provides rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.

Keywords: medical device, nomenclature, data structure
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
Symbols and nomenclature for medical devices


At the time this document was published, the AAMI Symbols and nomenclature for medical devices Work Group had the following members:

Cochair: Chuck Sidebottom, PPO Standards LLC

Members:
Jennifer Benolken, Smiths Medical
Joe Cesa, Halyard Health
Lena Cordie, Qualitas Professional Services
Jeff Eggleston, Medtronic Inc Campus
Abimbola Farinde
Chris Flahive, Chris Flahive Associates
Dave Geraghty, Spacelabs Healthcare
Gottlieb Glauninger, Eli Lilly & Company
Aaron Guggemos, Boston Scientific Corporation
Leighton Hansel
Megan Hayes, Medical Imaging & Technology Alliance a Division of NEMA
Christopher Heckert, Zimmer Inc
Denise Johnson, St Jude Medical Inc
Kristi Kistner, Amgen Inc
Dan Laelle, Nonin Medical Inc
Barb Majchrowski, Draeger Medical Systems Inc
Nick Momcilovic, GE Healthcare
Dave Osborn, Philips Electronics North America
Nancy Pressly, FDA/CDRH
Bradley Royds, Baxter Healthcare Corporation
Nancy Stark, Clinical Device Group Inc
Chandresh Thakur, Becton Dickinson & Company
Daidi Zhong, Chongqing University

Alternates:
Amy Deuchler, Baxter Healthcare Corporation
Evan Jacobs, FDA/CDRH
Mike Jaffe, Cardiorespiratory Consulting LLC
James Mattler, Eli Lilly & Company
Michael McCauley, St Jude Medical Inc
Cindy Miller, Amgen Inc
Dale Miller, Zimmer Inc
Denis Moloney, Boston Scientific Corporation
Bradford Spring, Becton Dickinson & Company

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 ANSI/AAMI adoption of ISO 15225:2016

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 3, Symbols and nomenclature for medical devices, to provide rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.

U.S. participation in ISO TC210/WG3 is organized through the U.S. Technical Advisory Group to TC210/WG3, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

ANSI/AAMI/ISO 15225:2016 was approved by the American National Standards Institute (ANSI) on 7 July 2016.

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.
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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This third edition of this International Standard based on experience gained from utilization of the second edition cancels and replaces the second edition (ISO 15225:2010), which has been technically revised. The following major changes have been made:

— Template terms have been removed as the hierarchy within the GMDN is now managed with the use of ‘collective terms’.

— ‘Device category’ has been removed as this provides no benefit for navigation and its value has now been superseded by the use of ‘collective terms’.

— The prefix ‘preferred’ has been removed from term in the document and the word ‘term’ now denotes the primary identifier for generic device groups of medical devices.

— ‘Collective terms’ can now be used by medical device regulators and other users to select larger groups of medical devices and analyse larger sets of data. ‘Terms’ however remain the only way to identify generic device groups of medical devices.

— ‘Device type’ data specification has been removed as it is outside the scope of the GMDN dataset, but remains a concept to which GMDN data are linked.
Introduction

This International Standard is intended to assist competent authorities, conformity assessment bodies, healthcare providers and manufacturers in the submission and exchange of information. It is intended that the information covered by this International Standard be available in the public domain.

This third edition of this International Standard is based on experience gained from utilization of the second edition.

The requirements contained in this International Standard are applicable to the development and updating of an international nomenclature and have been prepared specifically for construction of the Global Medical Device Nomenclature (GMDN).
Medical devices—Quality management—Medical device nomenclature structure

1 Scope

This International Standard specifies rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, healthcare providers and end users.

This International Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein.

The requirements contained in this International Standard are applicable to the development and maintenance of an international nomenclature for medical device identification.

This International Standard does not include the nomenclature itself, which is provided as a separate data file.

2 Normative references

The following documents, in whole or in part, are normatively referenced in the document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.


3 Terms and definitions

For the purposes of this document, the following terms and definitions apply¹.

3.1 character
member of a set of elements used for the organization, control or representation of data

[SOURCE: ISO/IEC 8859-1:1998, 4.3]

3.2 code
system of alpha, alphanumeric or numeric characters and rules by which information is represented, communicated, or both

3.3 collective term
term provides a multi-hierarchical structure to search for appropriate generic device group terms by using broad common features or characteristics

¹ In this International Standard, many terms are used which have their basis in regulatory statutes, e.g. “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature is used.