American National Standard

ANSI/AAMI SW91:2018

Classification of defects in health software

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 Online monthly newsletter. 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 Standards Monitor Online.

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Abstract: Provides a common language for the classification of defects occurring in health software.

Keywords: medical device, software, defects, classification, taxonomy

AAMI Standard

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Committee representation

Association for the Advancement of Medical Instrumentation

Software Defect Classification Working Group

The publication of AAMI SW91 as a new American National Standard was initiated by the AAMI Software Defect Classification Working Group under the auspices of the AAMI Software and Information Technology Committee. At the time this standard was published, the **AAMI Software Defect Classification Working Group** had the following members:

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Lisa Simone

Members:
Pat Baird, Philips
Frank Clay, Philips Healthcare
Lena Cordie, Qualitas Professional Services LLC
Plamena Entcheva-Dimitrov, Preferred Clinical Research LLC
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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.

Foreword

Another set of health information is compromised, another medical device unexpectedly reboots, another set of patient data results are mixed up, another device fails to perform as intended. News stories bring reports of medical device failures, and increasingly, these failures appear to be related to software quality. Use of software across the sector continues to grow. The popularity of medical- and health-related applications is exploding due to the ubiquity of portable devices and platforms, creating new business opportunities and expanding the diversity of software developers and manufacturers.

Hacking, privacy, and stolen patient information are obvious newer threats. However, analysis of past failures over the last several decades shows that similar root causes of software failures continue to occur despite new tools and methods to improve software quality. It is difficult to determine what these failures have in common, in part because no common language has been adopted and used across the industry to discuss and characterize failures. Knowledge learned is not routinely shared or leveraged across the medical device sector to improve the quality of software. A purpose for this standard is to provide the method to help address this.

The Institute of Medicine Report on Health IT and Patient Safety called for the development of measures to assess and monitor the safety of health IT. Their third recommendation was that "the ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available" [12].

The report also states that "[a]nother area necessary for making health IT safer is the development of measures. Inasmuch as the committee's charge is to recommend policies and practices that lead to safer use of health IT, the nation needs reliable means of assessing the current state and monitoring for improvement. Currently, no entity is developing such measures" [12].

A common method to identify and report the software-related defects that lead to or are associated with medical device failures could be beneficial in gathering useful data on the causes of software-related device failures. Existing methods for classifying defects focus on capturing the attributes of the defect, such as the priority, severity, and probability of recurrence, and the process activities during which these defects are inserted into the software. The values of these attributes are easily bounded. When attempting to describe the type of defect, however, values to characterize the defect are less clearly defined.

Companies often have a method to describe the defects they identify in their medical devices. However, how defects are identified and characterized may not be the same from company to company. Without a common language, it is difficult to gather and analyze common defect and failure information in a broader context, which makes it very challenging to determine if the type and number of defects seen by a company is unusual. It is possible that all companies are experiencing the same types of failures and that industry-wide training and tools could be developed to reduce the incidence of defects. Without a way to gather such information, the strength and usefulness of such methods and tools cannot be fully realized.

To address this, AAMI established a Working Group to identify a common language to describe software defects. The goal was to develop a language that is comprehensive enough to capture the defects currently being identified, and at the same time, flexible enough to allow for expansion as technology and development methods evolve. The language is intended to be neutral with respect to development methodology, programming language, and application domain so as to make it useful for a diverse set of stakeholders. Although the standard has been developed for use with health software, there is nothing specific to health software in the taxonomy.

Once individuals, companies, and communities use the same language, means can be developed to aggregate the data in a way that benefits not only medical device manufacturers, but also tool developers, consultants, trainers, and regulators. As a consequence, data and methods can be compared with peers to identify where processes can be improved. Improvements can be monitored across multiple projects and years in order to ensure these improvements are effective. The end goal is higher quality and safer software for patients and for the users of the systems that we develop.

The content of the taxonomy was developed following several guiding principles. Existing taxonomies were leveraged as appropriate, and validation activities were performed on the taxonomy using several of these existing taxonomies. The inclusion criteria for defects were based on offering an optimal depth of detail that includes many types of defects without requiring a rigid hierarchy that quickly becomes outdated. These topics are explored in Annex G.

NOTE—This foreword does not contain provisions of the ANSI/AAMI SW91, *Classification of Defects in Health Software*, but it does provide important information about the development and intended use of the document.

Classification of defects in health software

1 Scope

This document identifies a defect classification system, or taxonomy, that can be used to classify the types of defects that might exist in software. The taxonomy applies to defect root causes in all types of software (including third-party software, medical device software, test software, and manufacturing software) throughout the software development lifecycle.

The classification system is meant to be neutral with respect to

- programming language,
- methodology,
- product,
- intended use,
- risk (the consequences of failure), and
- regulatory status.

The use of a common taxonomy allows industry-wide aggregation of defect occurrence data that can be used to improve software quality. Some examples of ways in which this may be accomplished are presented as use cases in Annex A.

The way in which the standard is to be used is not prescribed. The taxonomy does not attempt to classify the severity of defects, as the consequences of any defect can only be evaluated within the context of the software's intended use. It does not attempt to describe methodologies for analyzing root cause, managing defect resolution, or assigning risk. It does not attempt to categorize defects in quality system processes.

Several annexes are included for information. Annexes B, C, and D are provided to illustrate how the taxonomy can be used to categorize various types of software problems. Annex E provides examples of cause analysis using the taxonomy. Annex F provides a reference table of all defect categories and codes, and Annex G provides the rationale for the types of defects that are in scope for the standard.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

3.1
ANOMALY
any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experiences. ANOMALIES may be found during, but not limited to, the review, test, analysis, compilation, or use of SOFTWARE PRODUCTS or applicable documentation

[SOURCE: IEEE 1044:1993, definition 3.1; IEC 62304:2006, definition 3.2]

3.2
COMPONENT
a subroutine, function, macro, program, program segment, method, thread, process, or any other sensible processing component