American National Standard

ANSI/AAMI/UL 2800-1:2019

Standard for Safety for Medical Device Interoperability

Advancing Safety in Health 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 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.

Standard for Safety for Medical Device Interoperability

Approved 21 February 2019 by
AAMI

Registered 25 February 2019 by
American National Standards Institute, Inc.

Abstract: Specifies a baseline set of requirements for assuring safe and secure interoperability for Interoperable Medical Systems.

Keywords: interoperability requirements, medical systems, medical devices, interoperable systems

Commitment for Amendments

This Standard is issued jointly by the Association for the Advancement of Medical Instrumentation (AAMI) and Underwriters Laboratories Inc. (UL). Comments or proposals for revisions or any part of the standard may be submitted to AAMI and/or UL at any time. Revisions to this Standard will be made only after processing according to the Standards development procedures of AAMI and UL.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

This ANSI/UL Standard for Safety consists of the First Edition. The most recent designation of ANSI/UL 2800-1 as an American National Standard (ANSI) occurred on January 31, 2019. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page (front and back), or the Preface.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at https://csds.ul.com.

To purchase UL Standards, visit UL's Standards Sales Site at http://www. shopulstandards. com/ HowToOrder.aspx or call toll-free 1-888-853-3503.

Printed in the United States of America

ISBN 978-1-57020-711-2

Contents

Page

Annex O (Informative) INTEROPERABILITY ARCHITECTURE SPECIFICATION

Annex P (Informative) Engineering Properties of INTEROPERABLE MEDICAL SYSTEMS

Annex Q (Informative) Services for INTEROPERABLE MEDICAL SYSTEMS

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI/UL Joint Committee for Medical Device Interoperability, JC 2800

This Joint Standard was prepared by the Joint Committee for Medical Device Interoperability, JC 2800. The standard was formally approved by the Joint Committee and the efforts and support of the Joint Committee are gratefully acknowledged.

At the time this document was published, the **AAMI/UL Joint Committee for Medical Device Interoperability, JC 2800** had the following members:

Cochairs:
Diana Pappas Jordan
Wil Vargas

Members:
Dave Arney, CIMIT / MD PnP
Robert Canfield, ICU Medical
Oliver Christ, Prosystem AG
Rick Cooper, MET Laboratories, Inc
Sherman Eagles, SoftwareCPR
Scott Eaton, Mindray North America
Anura Fernando, UL LLC
Ken Fuchs, Draeger Medical Systems
Julian Goldman, Massachusetts General Hospital/Partners
John Hatcliff, Kansas State University
Jacon Johnson, Kaiser Permanente
Edmund Kienast, National E-Health Transition Authority
Todd Konieczny, Intertek
Patty Krantz, Medtronic
Insup Lee, University of Pennsylvania
Steve Nichols, GE Healthcare Technologies
Diana Pappas Jordan, Underwriters Laboratories Inc.
Geoff Pascoe, Deloitte Consulting
Geetha Rao, Springborne Life Sciences
Tracey Rausch, DocBox
John Rhoads, Philips Healthcare
Mike Robkin, Anakena Solutions
Daniel Rubery, NxStage Medical, Inc.
Patricia Sena (JC Project Manager), Underwriters Laboratories Inc.
Elliot Sloane, Foundation for Living, Wellness, and Health
Erin Sparnon, ECRI
Wil Vargas, AAMI
Sandy Weininger, FDA

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.

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.

1 Introduction

1.1 Multiple stakeholders may participate in the development, deployment, assembly, and operation of a medical system with interoperable elements. Such a system, referred to as an INTEROPERABLE MEDICAL SYSTEM, should minimize PATIENT risks, maintain clinical EFFECTIVENESS, ensure timely and adequate access to data while protecting its SECURITY, and enable adequate provision of care. In order to facilitate alignment of stakeholders around these aims, this Standard establishes a baseline set of requirements for assuring safe and secure interoperability.

1.2 The requirements in this Standard may be applied to medical devices, as well as other connected infrastructure elements, and interoperable medical systems constructed from these. The Standard can be used by an ORGANIZATION as detailed in Annex A.

1.3 Each stakeholder will need to determine the specific level and manner in which interoperability will be specified and assured for its INTEROPERABLE MEDICAL PRODUCTS. However, a specific system may be developed, assembled, deployed, and operated through a range of processes undertaken by multiple stakeholders. Specific activities in these processes assure interoperability. In order for stakeholders to collectively accomplish this, the processes need to be linked effectively.

1.4 Effective linkage of processes across multiple stakeholders is a core focus of this Standard. This first requires that each stakeholder adequately assesses and manages SAFETY, SECURITY AND ESSENTIAL PERFORMANCE vulnerabilities of its INTEROPERABLE MEDICAL PRODUCTS. Secondly, it requires that each stakeholder understands and conforms with interoperability aspects of disclosed specifications of an INTEROPERABLE MEDICAL PRODUCT with which it acquires or with which it interoperates, including the consequent SAFETY, SECURITY AND ESSENTIAL PERFORMANCE characteristics. Finally, it requires that each stakeholder clearly communicates to the other stakeholders the information required to assure interoperability.

1.5 This Standard employs a lifecycle process approach to organizing requirements. In addition to a set of broad management functions, the Standard provides for a set of interoperability planning, realization, deployment, and monitoring activities. These activities also incorporate cross-cutting requirements for SECURITY and risk management. The Standard recognizes that a given ORGANIZATION may be responsible for only a part of the full range of activities required for an INTEROPERABLE MEDICAL SYSTEM. Furthermore, its INTEROPERABLE MEDICAL PRODUCTS may provide only a specific or limited functionality. To accommodate this, the Standard provides for flexibility in the scope, sequence, and INTERACTION of these activities. Finally, the Standard provides requirements and supplementary guidance on key clinical and engineering properties of an INTEROPERABLE MEDICAL SYSTEM that are essential to assuring effective interoperability and provides guidance on lifecycle activities and artifacts to be generated.

1.6 Annex A lists activities within the INTEROPERABILITY ECOSYSTEM and indicates important process steps for assuring interoperability.

1.7 As part of complying with this Standard, an ORGANIZATION will need to understand its specific role in the INTEROPERABILITY ECOSYSTEM, as well the role of the various other stakeholders. Collectively, stakeholders that intend their products to be interoperable have shared responsibility for assuring interoperability for a particular INTEROPERABLE MEDICAL SYSTEM. Assuring this will require collaboration among all the stakeholders in the INTEROPERABILITY ECOSYSTEM. Hence it is essential that responsibilities for meeting specific requirements are unambiguously communicated among the stakeholders. This Standard also includes requirements for DISCLOSURE and other communications. These may be used for identifying contractual requirements among the stakeholders.

1.8 The requirements provide a baseline for assuring safe and secure interoperability throughout the lifecycle of the INTEROPERABLE MEDICAL SYSTEM. In order to meet these requirements, a set of lifecycle processes needs to be established. It is anticipated that many organizations in the INTEROPERABILITY ECOSYSTEM will also have requirements for formal quality and RISK MANAGEMENT processes, as well as those related to specific aspects of product development, such as usability, software development, electrical and biological SAFETY. The lifecycle processes in this Standard may be integrated into the