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Standard



ANSI/AAMI/
UL 2800-1:
2019

Standard for Safety
for Medical Device
Interoperability



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.

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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.

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Standard for Safety for Medical Device Interoperability

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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.

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Committee representation

Association for the Advancement of Medical Instrumentation AAMI/UL Joint Committee for Medical Device Interoperability, JC 2800

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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 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

ORGANIZATION'S processes previously established for meeting quality and RISK MANAGEMENT and product-specific requirements.

1.9 The establishment of processes for assuring safe and secure interoperability should take into account the role of the ORGANIZATION in the INTEROPERABILITY ECOSYSTEM, and regulatory requirements applicable to the ORGANIZATION'S activities. It is not the intent of this Standard to imply the need for uniformity in the structure of different processes for assuring interoperability, uniformity of documentation or alignment of documentation to the clause structure of this Standard.

1.10 The above approach enables an ORGANIZATION to establish processes that are consistent with the role it plays in the INTEROPERABILITY ECOSYSTEM. It also enables the ORGANIZATION to manage its activities in a manner appropriate to the scope of its INTEROPERABLE MEDICAL PRODUCTS.

2 Scope

2.1 This Standard is applicable to INTEROPERABLE MEDICAL PRODUCTS, including assembled systems of INTEROPERABLE MEDICAL PRODUCTS that comprise or are intended to be incorporated into INTEROPERABLE MEDICAL SYSTEMS within an INTEROPERABLE ENVIRONMENT.

2.2 This Standard specifies a baseline set of requirements for assuring safe and secure interoperability for INTEROPERABLE MEDICAL SYSTEMS.

3 References

3.1 Any undated reference to a code or standard appearing in the requirements of this Standard shall be interpreted as referring to the latest edition of that code or standard.

3.2 The following standards are referenced in this Standard:

AAMI Standards

AAMI TIR57, *Technical Information Report: Principles for Medical Device security – Risk Management*

ASTM Standards

ASTM F2761, *Standard for Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model*

IEC Standards

IEC 60601-1, *Standard for Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*

IEC 60601-1-8, *Standard for Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*

IEC 62304, *Standard for Medical Device Software – Software Life Cycle Processes*

IEC 80001-1, *Standard for Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 1: Roles, Responsibilities and Activities*