UL 2800-1

STANDARD FOR SAFETY

Medical Device Interoperability

Standard for Safety for Medical Device Interoperability, UL 2800-1

Second Edition, Dated June 10, 2022

Summary of Topics

This is the Second Edition of ANSI/UL 2800-1, the Standard for Medical Device Interoperability, dated June 10, 2022.

The new requirements are substantially in accordance with Proposal(s) on this subject dated November 5, 2021.

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Standard for Medical Device Interoperability

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Approved American National Standard

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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.

This ANSI/UL Standard for Safety consists of the Second Edition. The most recent designation of ANSI/UL 2800-1 as an American National Standard (ANSI) occurred on June 10, 2022. 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.

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Preface

This is the joint AAMI/UL Standard for Medical Device Interoperability, AAMI/UL 2800-1. It is the second edition of AAMI 2800-1 and the second edition of UL 2800-1.

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.

This standard has been approved by the American National Standards Institute as an American National Standard.

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This list represents the membership at the time the Committee balloted on the final text of this edition. Since that time, changes in the membership may have occurred.

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1 Introduction

1.1 The AAMI/UL 2800 series of standards covers the interoperability of medical products. AAMI/UL 2800-1 is the general standard that specifies a baseline set of requirements for assuring safe and secure interoperability for interoperable medical systems. The requirements in the AAMI/UL 2800-1 standard are supplemented by the requirements in additional AAMI/UL 2800 standards. These additional standards are intended to be used in conjunction with the general standard and applied as needed. While this introduction applies to all of the AAMI/UL 2800 series of standards, the scope section of each additional standard describes what is covered by that standard.

1.2 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, the AAMI/UL 2800 series of standards establishes a baseline set of requirements for assuring safe and secure interoperability.

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 the AAMI/UL 2800 series of standards. 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 and security characteristics. Finally, it requires that each stakeholder clearly communicates to the other stakeholders the information required to assure interoperability.

1.5 The requirements in the AAMI/UL 2800 series of standards are intended to apply to medical devices, as well as other connected infrastructure elements, and interoperable medical systems constructed from these. The AAMI/UL 2800 series of standards is intended to be used by individual stakeholders.

1.6 The AAMI/UL 2800 series of standards employ a lifecycle process approach to organizing requirements. In addition to a set of broad management functions, the standards provide for a set of interoperability planning, realization, deployment, and monitoring activities. These activities also incorporate cross-cutting requirements for security and risk management. The standards recognize that a given organization may be responsible for only a part of the full range of activities required for an interoperable medical system. Furthermore, the organization's interoperable medical products may provide only a specific or limited functionality. To accommodate this, the standards provide for flexibility in the scope, sequence, and interaction of these activities. Finally, the standards provide requirements and supplementary guidance on key clinical and engineering properties of an interoperable medical system that are essential to assuring safe and secure interoperability and provide guidance on lifecycle activities.

1.7 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 the AAMI/UL 2800 series of standards may be integrated into the organization's processes previously established for meeting quality and risk management and product-specific requirements.

1.8 As part of complying with the AAMI/UL 2800 series of standards, an organization will need to understand its specific role in the interoperability ecosystem, as well the role of the various other stakeholders. It is essential that responsibilities for meeting specific requirements are unambiguously communicated to other stakeholders. The standards include requirements for disclosure and other communications. These may be helpful in for identifying contractual requirements with other stakeholders.

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 the AAMI/UL 2800 series of standards 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 these standards.

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

AAMI/UL 2800-1-1, *Standard for Risk Concerns for Interoperable Medical Products*

AAMI/UL 2800-1-2, *Standard for Interoperable Item Development Life Cycle*

AAMI/UL 2800-1-3, *Standard for Interoperable Item Integration Life Cycle*

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 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 61508, *Functional Safety Of Electrical/Electronic/Programmable Electronic Safety-Related Systems - Part 1: General Requirements*

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*

IEC/TR 80002-1, *Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software*

ISO 14971, *Standard for Medical Devices – Application of Risk Management to Medical Devices*

ISO/IEC 15026-3, *Systems and software engineering – Systems and software assurance – Part 3: System integrity levels*

ISO 26262-1, *Road vehicles – Functional safety – Part 1: Vocabulary*

ISO/IEC/IEEE 42010, *Systems and software engineering – Architecture description*

ISO/IEE Guide 51, *Safety aspects – Guidelines for their inclusion in standards*

4 Terms and Definitions

4.1 ACTOR – An active or passive entity, human or non-human, capable of initiating action or providing data, potentially in response to commands.

NOTE 1: An interoperable item is a special case of non-human actor.

NOTE 2: Health IT systems including Electronic Medical Record systems or Physician Order Entry systems are examples of non-human actors that may not be interoperable items.

NOTE 3: Medical devices are examples of non-human actors (which may or may not comply with the requirements of this Standard, i.e., may or not be interoperable items).

NOTE 4: Operators and patients are examples of human actors.

NOTE 5: Actors may be distinguished by context of use including development context of use actors (e.g., interoperable medical system manufacturers), deployment context of use actors (e.g., clinicians, bio-medical engineers, etc.)

4.2 ALARM CONDITION – State of the alarm system when it has determined that a potential or actual hazardous situation exists for which operator awareness or response is required.

NOTE 1: An alarm condition can be invalid, i.e. a false positive alarm condition.

NOTE 2: An alarm condition can be missed, i.e. a false negative alarm condition.

4.3 ALARM LIMIT – Threshold used by an alarm system to determine an alarm condition.

4.4 ALARM SETTINGS – alarm system configuration, including but not limited to:

a) Alarm limits;

b) The characteristics of any alarm signal inactivation states; and

c) The values of variables or parameters that determine the function of the alarm system.

NOTE: Some algorithmically-determined alarm settings can require time to be determined or re-determined.

4.5 ALARM SIGNALING – Action taken by the alarm system to generate an alarm signal at the operator's position.

4.6 ALARM SIGNAL – Type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition.

4.7 ALARM SYSTEM – Parts of ME equipment or a ME system that detect alarm conditions and, as appropriate, generate alarm signals.

4.8 ARCHITECTURE VIEW – Artifact within the interoperability architecture expressing the architecture from the perspective of specific set of concerns.

4.9 ARCHITECTURE VIEWPOINT – Constraints establishing the conventions for the construction, interpretation, and use of an architecture view to frame a specific set of concerns.

4.10 ASSURANCE – Grounds for justified confidence that a claim has been or will be achieved.

NOTE: Assurance activities include verification and validation activities that provide objective evidence for claims reflected in interoperable item SSOs and interoperability specification.

4.11 AUTHENTICATION/AUTHENTICATED/AUTHENTICITY – The process of verifying the identity of an entity.

4.12 AUTHENTICATION OF INFORMATION – Sensitive data is any critical security parameter that can compromise the use and security of the product such as passwords, keys, seeds for random number generators, authentication data, personally identifiable information and any data whose disclosure could jeopardize the security properties of the product.

4.13 AUTHORIZATION/AUTHORIZED – [Source: CNSSI-4009 via AAMI TIR57]

4.14 AVAILABILITY/AVAILABLE – [Source: SP 800-53; SP 800-53A; SP 800-27; SP 800-60; SP 800-37; FIPS 200; FIPS 199; 44 U.S.C., Sec. 3542 via AAMI TIR57]

4.15 CLINICAL CARE – Patient contact and/or management, which corresponds to a block of activity (session) directly related to:

a) Diagnosis of disease or other conditions,