

American National Standard

ANSI/AAMI/ UL 2800-1: 2022

Standard for Medical
Device Interoperability



Standard for Medical Device Interoperability

Approved 20 May 2022 by
AAMI

Approved 10 June 2022 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

© 2022 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact the Copyright Clearance Center.

Copyright © 2022 Underwriters Laboratories Inc.

UL's Standards for Safety are copyrighted by UL. Neither a printed nor electronic copy of a Standard should be altered in any way. All of UL's Standards and all copyrights, ownerships, and rights regarding those Standards shall remain the sole and exclusive property of 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 February 25, 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 978-1-57020-843-0

Contents

Page

Committee representation	iv
AAMI Standard	v
1 Introduction	1
2 Scope	2
3 References	2
4 Terms and Definitions	3
5 (Leadership) Management Responsibility	16
6 Interoperability Information	17
7 Interoperability Management	19
8 Interoperability Realization Processes	22
9 Design, Development, and Implementation of Interoperability	24
10 Interoperability of Externally Sourced Products	33
11 Provisioning, Deployment, and Operation	34
12 Testing and Review	36
13 Traceability and Release	38
14 Interoperability Performance Monitoring and Control of Changes	39
Annex A (Informative) Stakeholder Activities	42
Annex B (Informative) Guidance on Declaration of Products and Services	49
Annex C (Informative) Clinical Context Concepts	55
Annex D (Informative) Risk Management Guidance	59

Committee representation

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

The publication of AAMI/UL 2800-1:2022 as a new American National Standard was initiated by the AAMI/UL Joint Committee for Medical Device Interoperability, JC 2800.

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.

Cochairs: Diana P. Jordan
Ovidiu Munteanu

Members: Dave Arney, CIMIT (MGH Anesthesia & Biomedical Engineering)
Oliver Christ, Prosystem AG
R Cooper, Eurofins E&E North America
Holly Drake, Dexcom Inc.
Sherman Eagles, SoftwareCPR
Scott Eaton, Mindray DS USA Inc
Kenneth Fuchs, Draeger Medical Systems Inc.
Julian Goldman, Massachusetts General Hospital
Pamela K. Gwynn, UL LLC
John Hatcliff, Kansas State University
Jacob Johnson, Kaiser Permanente
Diana Pappas Jordan (JC Cochair), Underwriters Laboratories Inc.
Edmund Kienast, National E-Health Transition Authority (NEHTA)-Australia
Todd Konieczny, Intertek Testing Services
Patty Krantz, Medtronic Inc.
Insup Lee, University of Pennsylvania
Marina Lee, Staubli Electrical Connectors, Inc.
Ovidiu Munteanu JC Cochair, AAMI
Steve Nichols, GE Healthcare
Geetha Rao, Springborne Life Sciences
Tracey Rausch, DocBox Inc.
Daniel Rubery, NxStage Medical, Inc.
Patricia A. Sena (JC Project Manager), Underwriters Laboratories Inc.
Elliot Sloane, Center for Healthcare Information Research & Policy
Erin Sparnon, ECRI
Sandy Weininger, US FDA/CDRH

NOTE—Participation by federal agency representatives in the development of this technical information report 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.

Standard for Medical Device Interoperability

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.

©IEC. This material is reproduced from IEC 60601-1 - 8:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

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.

©IEC. This material is reproduced from IEC 60601-1-8:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

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

©IEC. This material is reproduced from IEC 60601-1-8:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

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

Adapted by UL from ISO/IEC/IEEE 42010-2011 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.

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.

Adapted by UL from ISO/IEC/IEEE 42010-2011 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.

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.

©IEC. This material is reproduced from ISO/IEC 15026-1:2019 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

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,
- b) Cure, alleviation, mitigation, treatment/therapy, or prevention of disease,
- c) Compensation for an injury or handicap,
- d) Replacement or modification of the anatomy or of a physiological process, or
- e) Intended to affect the structure or any function of the body of the patient.

4.16 COMPUTATIONAL VIEW – An aspect of the interoperability architecture that provides a decomposition in terms of logical functional as interactions between those functions.

NOTE 1: The Computational View is based on concepts from the ISO/IEC 10746 RM-ODP Computational View. However, this Standard does to require compliance to ISO/IEC 10746.

NOTE 2: The Computational View captures what is commonly referred to as a functional architecture, where interactions between functional elements are captured in terms of programmatic interfaces.

NOTE 3: For an overview of the notions of architectural view and viewpoint see ISO/IEC/IEEE 40210.

4.17 CONFIDENTIALITY – The property that data, information or software is not made available or disclosed to unauthorized individuals, entities, or processes.

4.18 CONSTITUENT INTEROPERABLE ITEM – A member of the collection of interoperable items integrated to form the realization of an encompassing interoperable item [see definition of interoperable item(b)].

4.19 DEPLOYMENT CONTEXT OF USE – Actors, processes, and health-delivery objectives that may impact the safe and secure use of the interoperable medical product as part of deployment activities.

NOTE 1: Deployment context of use activities are summarized in Annex A.

NOTE 2: In typical cases, the deployment context of use refers to the context of use in a Health Delivery Organization and addresses the use of the interoperability solution to support medical functions as well as the configuration, deployment, and maintenance of the interoperability solution.

4.20 DEVELOPMENT CONTEXT OF USE – Organizations, processes, technologies, interoperability frameworks, and

business relationships that may influence or use the interoperable medical product as part of development activities.

NOTE: Development context of use Activities are summarized in Annex [A](#), and detailed in AAMI/UL 2800-1-2 and AAMI/UL 2800-1-3.

4.21 DISCLOSURE – Planned and managed release of information between the organization originating the interoperable item and stakeholder organizations to support the safe and secure use of the interoperable item in its development context of use or deployment context of use.

NOTE 1: See the Annex for Guidance on Interoperability File of AAMI/UL 2800-1-2 and the Annex for Guidance on Disclosure of AAMI/UL 2800-1-2.

NOTE 2: ISO 14971 Information for Safety, IEC 80001 Responsibility Agreements and Information for Assurance are addressed by the disclosures of this Standard.

NOTE 3: Disclosures support "risk hand-offs" between organizations and are key element of supporting cross-organization risk management for interoperable medical systems.

4.22 EFFECTIVENESS – Ability to produce the intended result for the patient and the responsible organization. Reasonable assurance that a device is successful in producing a desired or intended result when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

©IEC. This material is reproduced from IEC 80001-1:2010 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

4.23 ERROR – Deviation from an item interoperability specification that is observable on an interface of the interoperable item.

NOTE 1: An error originating in an interoperable item's context may propagate into the interoperable item through its interface inputs.

NOTE 2: An error may propagate out of an interoperable item over an interface due to either:

- a) A fault internal to the interoperable item; or
- b) An error propagating into the interoperable item from its context that is passed through the interoperable item or transformed into an error of different character.

4.24 ERROR PROPAGATION SPECIFICATION – Summary of inward and outward flowing interoperability-related errors that may manifest on the interoperable item's interfaces.

NOTE: See Annex [D](#) of AAMI/UL 2800-1-2 the purpose of the error propagation specification in the context of broader risk management activities. See the Annex for Guidance on Interoperability File of AAMI/UL 2800-1-2 for relationship of the error propagation specification to other work products.

4.25 EXTERNAL MEASURE – Measure separate and distinct from the interoperable item that reduces or mitigates the risks resulting from the interoperable item or usage of the interoperable item within its development context of use or deployment context of use.

NOTE 1: The means by which an external measure is to be achieved will typically be communicated through instructions for use and will typically coincide with ISO 14971 Information for Safety.

NOTE 2: Interoperable item SSOs and external measures are designed in concert with the intent that the interoperable item will be able to achieve its SSOs if the external measures are achieved.

NOTE 3: External measures represent obligations of the agents in the context of the interoperable item whereas SSOs represent obligations on interoperable item, given that external measures are achieved. The organization producing the interoperable item also has the obligation of communicating the external measures clearly.

Adapted by UL from ISO 26262-1:2018 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.

4.26 EXTERNAL PRODUCT – An anticipated non-human actor or specified interoperable item with which the interoperable medical product interacts but is not provided with the interoperable medical product.

NOTE – An external product may be specified as an accessory to be provisioned by the user of the interoperable medical product (such as a sensor device) or be a part of the interoperable environment within which the interoperable medical product is used (such as an electronic medical record system).

4.27 EXTERNALLY SOURCED PRODUCT – Either a constituent interoperable item in an interoperable medical product or an external product that is specified as necessary to proper use of the interoperable medical product that is placed on the market by an external party that is not part of the organization.

4.28 FUNCTIONAL SAFETY CONCEPT – Design of functional safety including independence aspects, allocation to items within the architecture, risk controls, and their interaction necessary to achieve SSOs.

Adapted by UL from ISO 26262-1:2018 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

4.29 HAZARDOUS SITUATION – Circumstance in which people, property, or the environment are exposed to one or more hazard(s).

©IEC. This material is reproduced from ISO/IEC Guide 51:2014 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved

4.30 IDENTIFICATION/IDENTIFIED – See authenticated.

4.31 IDENTIFIER – *[Source – Adapted from RFC 2828 (referring to data, but is generalized for this document)]*

4.32 IDENTITY – A particular presentation of an operator or interoperable item. An identity may be a unique reference to the operator or interoperable item, especially binding when proved through authentication.

4.33 IDENTITY CLAIM – Assertion or statement of the state or fact of being the same one as described.

4.34 INFORMATION VIEW – An aspect of the interoperability architecture that describes:

- a) The primary data elements exchanged between constituent interoperable items and between the interoperable item and its context; and
- b) Operations on those data elements.

NOTE 1: The information view is based on concepts from the ISO/IEC 10746 RM-ODP information view. However, this Standard requires compliance to ISO/IEC 10746.

NOTE 2: The information view may also capture important internal state of an interoperable item that is necessary to specify

constraints on the interoperable item's interoperability behavior.

NOTE 3: For an overview of the notions of architectural view and viewpoint see ISO/IEC/IEEE 40210.

4.35 INTEGRATOR – Natural or legal person carrying out the activity of interoperable item integration. See [A](#).

4.36 INTEGRITY – The assurance that data can only be altered by authorized entities.

4.37 INTENDED USE [intended purpose] – Use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer.

©ISO. This material is reproduced from ISO 14971-1:2019 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.

4.38 INTERACTION – An action between an interoperable item and its context taking place over one of the interoperable item's interfaces. See the Annex for Interoperability Architecture Specification of AAMI/UL 2800-1-3.

NOTE: An interaction involves the participation of both the interoperable item and an actor in its context. When the actor in the context is an another interoperable item, the interaction occurs over an interoperability interface.

4.39 INTERACTION BEHAVIORAL SPECIFICATION – Constraints on the interactions between an interoperable item and its context over its interfaces specified in terms of interface contracts.

NOTE: Specifications of interactions over the interoperability interfaces of an interoperable item are stated in terms of interface contracts.

4.40 INTERACTION PARAMETER SPECIFICATION – Part of an interaction specification that specifies the parameters and accompanying characteristics of a particular interaction. See the Annex for Interoperability Architecture Specification of AAMI/UL 2800-1-3.

4.41 INTERACTION POINT – Interoperability architecture feature defined for the purpose of stating constraints and assumptions on data and control [information] that flow across an interoperable item's boundary.

Each interaction point is specified as exactly one of the following types:

- a) Physiological – Supports machine-to-patient interactions associated with sensing or actuation capabilities related to the physiology of the patient;
- b) Operator – Supports machine-to-human interactions for commands or information exchange between the interoperable item and operator; or
- c) Interoperability – Supports machine-to-machine interactions.

An interoperability interaction point consists of one or more related interoperability interfaces.

4.42 INTERACTION SPECIFICATION – Characteristics of an interaction given at a level of precision that are sufficient to:

- a) Determine if interoperable items participating in the interaction comply with the specification; and
- b) Exclude undesirable behaviors leading to violations of safety-related and security-related properties. See the Annex for Interoperability Architecture Specification of AAMI/UL 2800-1-3.

Interaction specifications are accompanied by interface contracts that constrain the behavior of interactions over interfaces.

4.43 INTERFACE CONTRACT – Behavioral constraints on the interactions between an interoperable item and its context over one of its interoperability interfaces.

NOTE 1: An interface contract imposes obligations on both the interoperable item and its clients. An Interface contract will typically establish pre-conditions that clients of the interoperable item must achieve before or at the initiation of an interactions, and post-conditions that the interoperable item must achieve given that associated pre-conditions are satisfied.

NOTE 2: An interface contract may include constraints on data exchanged during an interaction, temporal ordering of interactions on the interoperability interface, timing constraints on the interaction or sequence of interactions, and exceptional behavior and error return codes.

4.44 INTERFACE SPECIFICATION – Collection of interaction specifications, associated interface contracts, and engineering and technology aspects of the interface realization.

4.45 INTEROPERABILITY ARCHITECTURE – Constraints and rules determining the organization of a set of interoperable items, their designed interoperable interactions with each other, and their intended interactions with environment. The interoperability architecture provides a decomposition at the granularity at which interoperable items may be exchanged and reused according to their designed interoperability.

NOTE 1: An interoperability architecture may be defined using a variety of methods including annotated graphical models or textual constraints as long as the precision is sufficient to determine compliance to this Standard. The interoperability architecture may be incorporated into a more comprehensive architecture description that addresses non-interoperability-related aspects.

NOTE 2: The rules and constraints of an interoperability architecture capture designed interoperability variabilities that allow multiple interoperability architecture instances to be compliant with an interoperability architecture. This concept enables a set of related interoperability architecture instances to be addressed determining compliance to this Standard.

4.46 INTEROPERABILITY ARCHITECTURE CONFIGURATION – Specific restriction of one or more interoperability variabilities of an interoperability architecture.

NOTE: An interoperability architecture configuration is a refinement of an interoperability architecture that restricts the set of conformant interoperability architecture instances for a particular purpose. Examples of common restrictions include bounding the number or types of medical devices that can connect with a platform, or restricting the applications that may be executed simultaneously with a high-criticality application. Such restrictions may be useful for scoping the use of an interoperability framework for a particular set of related applications whose assurance will be addressed collectively.

4.47 INTEROPERABILITY ARCHITECTURE INSTANCE – An interoperability architecture configuration where no interoperability variabilities remain.

NOTE 1: An interoperability architecture instance represents a concrete realization whose behavior can be accessed via testing.

NOTE 2: An instance of an interoperability architecture for an interoperable medical system may be executed at the point-of-care to provide a particular clinical function.

NOTE 3: Compliance of an interoperable item to this standard addresses the safety and security properties of all interoperability architecture instances that conform to the interoperable item's interoperability architecture.

4.48 INTEROPERABILITY BINDINGS – Planned association of two or more interoperable items over designated interoperability interfaces of the interoperable items.

4.49 INTEROPERABILITY ECOSYSTEM – Stakeholders whose products and services enable interoperability.

4.50 INTEROPERABILITY FILE – One or more information repositories either containing or referencing records generated to demonstrate compliance to the requirements of this Standard.

4.51 INTEROPERABILITY FRAMEWORK – Consists of a managed collection of interoperability assets including:

- a) Items designed to be integrated in different configurations in conformance with a interoperability architecture;
- b) Processes conforming to life-cycle objectives of this Standard for coordinating life-cycle activities across the framework items to increase effective and trustworthy reuse of items and associated specification, risk management, and assurance results; and
- c) Assets, shared across the development of the framework items, for supporting interoperability-related aspects of development and assurance.

NOTE: The notion of an INTEROPERABILITY FRAMEWORK supports the notions of platform-based development, product lines and product families (e.g., as described in ISO/IEC 26550), and families of items developed around a common interoperability interfacing framework (e.g., IEEE 11073).

4.52 INTEROPERABILITY INTERFACE – An engineered mechanism for information exchange that provides all or part of a realization of an interoperability interaction point.

NOTE 1: An interoperability interaction point will often be realized in terms of multiple interfaces that address different levels of abstraction. For example, an interoperability interaction point for reporting physiological data from a medical device may include network transport layer interfaces, middleware service interfaces, and data description interfaces.

NOTE 2: The granularity of an interface specified for the purposes of compliance with this Standard may be determined by following guidance in the Annex for Architecture Definition Guidance of AAMI/UL 2800-1-3 and the Annex for Interoperability Architecture Specification of AAMI/UL 2800-1-3.

4.53 INTEROPERABILITY SCENARIOS SPECIFICATIONS – Partial specification of an interoperable medical system or family of related interoperable medical systems describing an intended application of interoperability that may be evaluated under this Standard.

NOTE 1: An interoperability scenario specification may serve to normalize use cases, requirements, and architectural approaches for the purpose of establishing community consensus for particular applications.

NOTE 2: An interoperability scenario specification may be used as input to the later design and realization of an interoperable medical system which may benefit from reuse of the artifacts developed in and may claim compliance to the interoperability scenario specification. See Annex B.

NOTE 3: An interoperability scenario specification may include as aspects of use specification, interoperability architecture, interoperable, and the like.

4.54 INTEROPERABILITY VARIABILITY – Designed feature within the INTEROPERABILITY ARCHITECTURE allowing variations in the set of conforming instances.

4.55 INTEROPERABLE APPLICATION SPECIFICATION – A summary of the important characteristics related to the use of the interoperable medical product within stated interoperability scenario specifications.

4.56 INTEROPERABLE ENVIRONMENT – The managed collection of interoperable products and associated

services that can be integrated in one or more configurations to enable interoperable use of a specific interoperable medical product.

4.57 INTEROPERABLE ITEM (ITEM) – A realization of an item interoperability specification for interoperable hardware, software or system to which the contents of this Standard are applied. This may take one of two forms:

- a) It may not be further decomposed with respect to interoperability and compliance with this Standard; or
- b) It may be a collection of interoperable items integrated in accordance with integration life-cycle activities.

NOTE: A member of the collection of the integrated interoperable items in (b) is referred to as a constituent interoperable item.

4.58 INTEROPERABLE ITEM BOUNDARY – The division between the realization of the interoperable item and external actors, as defined by the interoperable item's interaction points.

NOTE: The boundary may help scope the assurance, risk management, and disclosure responsibilities of the interoperable item manufacturer by indicating the engineering features under the interoperable item manufacturer's direct control.

4.59 INTEROPERABLE ENVIRONMENT – The managed collection of interoperable products and associated services that can be integrated in one or more configurations to enable interoperable use of a specific interoperable medical product.

4.60 INTEROPERABLE MEDICAL PRODUCT – Output that is intended for, or required by, a customer, for supporting the development and deployment of an interoperable item for medical purpose.

NOTE: Common examples of interoperable medical products include:

- a) An interoperable item supporting a medical purpose;
- b) An interoperable medical system (as a special case of interoperable item);
- c) An interoperability framework; and
- d) Work products or services related to the stakeholder activities in Annex A.

4.61 INTEROPERABLE MEDICAL SYSTEM – An item consisting of one or more integrated (sub)-items (and is therefore decomposable) with a clinical intended use.

4.62 INTEROPERABLE USE SPECIFICATION – A summary of the important characteristics related to the context of use of the interoperable medical product that serves as input for determining item interoperability specifications.

4.63 ITEM INTEROPERABILITY SPECIFICATION – Collection of artifacts which are necessary and sufficient to:

- a) Define the item's interoperability-related functionality and interfaces;
- b) Integrate the interoperable item with or as part of another interoperable item and to carry out associated safety and security assurance activities, including those that determine that the item's conditions of acceptability have been satisfied; and
- c) Specify controls that are required to ensure safety and security during the deployment, operation, and maintenance of the item.

NOTE: Specification artifacts may include requirements, interface specifications including interface contracts that capture conditions

of acceptability, technical instructions, risk management information, and operating instructions, and constraints on the technical, clinical, and operating environment needed to achieve safety.

4.64 IT-NETWORK [INFORMATION TECHNOLOGY NETWORK] – A system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes.

Adapted by UL from IEC 61907:2009 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved

NOTE: The scope of the IT-NETWORK in this document is defined by the responsible organization based on where the health software in the IT-NETWORK is located and the defined use of the IT-NETWORK. It can contain IT infrastructure, home health, or general computing components or systems not intended by design to be used in a healthcare setting. See also [7.2](#).

4.65 MANUFACTURER – Natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME equipment, assembling and configuring an ME system, or adapting ME equipment or an ME system, regardless of whether these operations are performed by that person or on their behalf by another person(s).

Adapted by UL from IEC 60601-1:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

4.66 MEDICAL ELECTRICAL EQUIPMENT [ME EQUIPMENT] – Electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

- a) Provided with not more than one connection to a particular supply mains; and
- b) Intended by its manufacturer to be used:
 - 1) In the diagnosis, treatment, or monitoring of a patient; or
 - 2) For compensation or alleviation of disease, injury or disability, or other condition.

NOTE 1: In some jurisdictions, ME Equipment may meet the definition of a medical device as defined in a particular jurisdiction.

NOTE 2: Equipment, when mentioned in this Standard, should be taken to include ME equipment.

Adapted by UL from IEC 60601-1:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

4.67 MEDICAL ELECTRICAL SYSTEM [ME SYSTEM] – Combination, as specified by its manufacturer, of items of equipment, at least one of which is ME equipment to be inter-connected by functional connection or by use of a multiple socket-outlet.

Adapted by UL from IEC 60601-1:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved.

4.68 OBJECTIVE EVIDENCE – Data supporting the existence or verity of something.

NOTE: OBJECTIVE EVIDENCE can be obtained through observation, measurement, testing, or other means.

©ISO. This material is reproduced from ISO 14971-1:2019 with permission of the American National Standards Institute (ANSI) on behalf of the International Organization for Standardization. All rights reserved.

4.69 ORGANIZATION – An entity with responsibility for placing on the market an interoperable medical product intended to be used in accordance with an interoperable application specification.

4.70 OPERATIONAL CONTEXT OF USE – A sub-context of the deployment context of use related specifically to the point-of-care. Actors, processes, and health-delivery objectives and use cases that may impact the safe and secure use of the interoperability solution [generic term encompassing both item and interoperability framework] as part of delivery of care to the patient in interoperable item operation activities.

4.71 OPERATOR – Someone who, under authority of the responsible organization, controls the function of a machine, process or system in a specified manner.

NOTE 1: Different categories of operator include:

- a) A medical professional;
- b) A patient if appropriately authorized; and
- c) Service personnel if appropriately authorized.

NOTE 2: An operator may take control or receive information from the machine, process, or system in a venue outside of the responsible organization (i.e., in home care).

4.72 OPERATOR IDENTITY/IDENTIFICATION – Person-specific information used to distinguish an individual operator. Operator identifiers include username, badge number, and/or other identifiers generated by ADT or EMPI.

4.73 PASSWORD – 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.

4.74 PATIENT – Living being (person or animal) undergoing a medical, surgical or dental procedure.

NOTE: A patient can be an operator.

©IEC. This material is reproduced from IEC 60601-1:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved

4.75 PATIENT ASSOCIATION – The process of establishing a patient identity within an interoperable item for the purpose of identifying the patient under care.

4.76 PATIENT DISASSOCIATION – The process of dissolving the logical relationship between an interoperable item and the patient under care previously established by a patient association process.

NOTE: Patient disassociation will likely involve clearing patient identity information and medical information linked to the patient identity.

4.77 PATIENT EPISODE – The period of time between and patient association and patient disassociation during which the medical functions of the interoperable item are dedicated to care-giving for the patient under care.

4.78 PATIENT ID – The identity claim of a patient.

4.79 PATIENT IDENTIFICATION – The process of matching the patient with the patient identifier information (see also patient identity verification).

4.80 PATIENT IDENTIFIER – An item of person-specific information used to distinguish an individual patient. Patient identifiers include name (given name, family name, and/or middle name), DOB, MRN, location, other identifiers generated by ADT or EMPI.

4.81 PATIENT IDENTITY – Selected data elements associated with a patient to uniquely identify that patient among other patients within a Health Delivery Organization. Selected data elements (patient identifiers) – usually the name (given name, family name, and/or middle name), birth date, SSN, MRN, and sometimes the gender for a single patient. Patient identity can be either verified or un-verified. (See patient identity verification.)

4.82 PATIENT IDENTITY VERIFICATION – The process of matching patient identifiers that were input to the ME system with a trusted source of patient information (ADT/EMPI) to ensure the patient is accurately identified.

4.83 PATIENT UNDER CARE – The particular patient whose care is being addressed by the interoperable item while it is performing its clinical function.

4.84 PHYSIOLOGICAL ALARM CONDITIONS – Alarm condition arising from a monitored patient-related variable.

©IEC. This material is reproduced from IEC 60601-1-8:2020 with permission of the American National Standards Institute (ANSI) on behalf of the International Electrotechnical Commission. All rights reserved

4.85 POTENTIALLY HAZARD CONDITION – Conditions on the state of an interoperable item that may lead to a violation of the interoperable items interoperability specification and/or indirectly to patient harm.

NOTE 1: The term potentially hazard condition generalizes the notion of fault or root cause to address the fact that an interoperable item may not know the potential patient harms associated with interoperable medical systems into which it is integrated. In such cases, the objectives of interoperable item development center around (a) developing technical specifications (captured in the interoperable item interoperability specification) that are appropriate for the intended use of the interoperable item and (b) mitigating potentially hazard conditions that could lead to violations of the technical specification.

NOTE 2: A potentially hazard condition may represent a precondition for a risk concern.

4.86 PROTECTED HEALTH INFORMATION (PHI) – Protected health information (PHI), also referred to as personal health information, generally refers to demographic information, medical histories, test and laboratory results, mental health conditions, insurance information, and any information about health status, provision of health care, or payment for health care that is created or collected by an entity, or their representative, and can be linked to a specific individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history.

Source: <https://www.hhs.gov/hipaa/for-professionals/faq/2042/what-personal-health-information-do-individuals/index.html>

4.87 PROVENANCE – A record of the original source and chain of possession of data – combination of authenticity, integrity, and no-repudiation for every entity that has processed the data – a chain of authentication of information.

4.88 REFERENCE ARCHITECTURE – An interoperability architecture for an interoperability framework that serves a schema and establishes constraints on interoperable item and interoperable medical system instances that are compliant with the interoperability framework.

4.89 RELEASE CRITERIA – Conditions and traceability relationships on the interoperable item interoperability specification, interoperable item realization and associated work products and disclosures that are to be achieved and substantiated with objective evidence before the interoperable item is released.

NOTE 1: Release criteria include primary conditions and relationships to be assessed when determining compliance to this