

American National Standard

ANSI/AAMI/ UL 2800-1-2: 2022

Standard for Interoperable
Item Development Life
Cycle



Standard for Interoperable Item Development Life Cycle

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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

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Committee representation

Association for the Advancement of Medical Instrumentation

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

The publication of AAMI/UL 2800-1-2:2022 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.

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Standard for Interoperable Item Development Life Cycle

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 and security 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 development lifecycle requirements for assuring safe and secure interoperability for interoperable items.

3 Referenced Publications

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/UL 2800-1, *Medical Device Interoperability*

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

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

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

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

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

4 Terms and Definitions

4.1 Defined terms are located in AAMI/UL 2800-1.

5 Interoperable Item Development Life-Cycle Activities

5.1 Interoperable item concept and context of use development

5.1.1 Interoperable item synopsis and scope

5.1.1.1 interoperable item synopsis – A use specification shall be provided that contains:

- a) A high-level description of the function of the interoperable item and the extent to which the interoperable item is designed to support, either directly or indirectly, one or more medical functions;
- b) A description of the scope of medical situations and patient profiles for which the interoperable item is designed for use;
- c) The role that external and internal interoperability plays in achieving the function of the interoperable item; and
- d) Any reasonably foreseeable misuse of the interoperable item, including misuse related to interoperability.

NOTE 1: The language in the use specification may provide a basis for regulatory statements of related to intended use and indications for use.

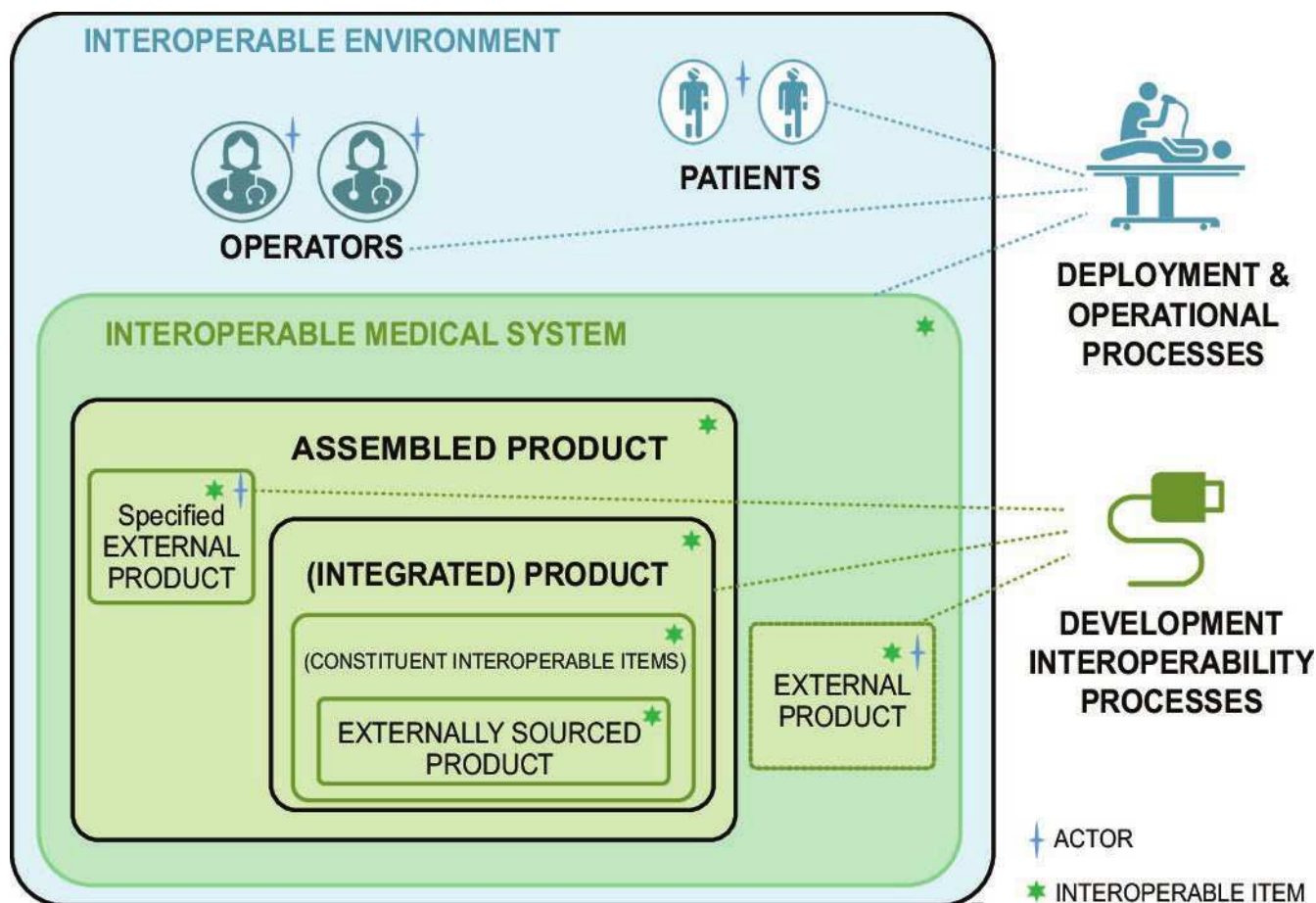
NOTE 2: The use specification should contribute to satisfaction of the Standard for Medical Devices – Application of Risk Management to Medical Devices, ISO 14971.

NOTE 3: The use specification is somewhat analogous to the device description (occurring in US regulatory context).

NOTE 4: [Figure 5.1](#) provides a schematic representation of the interoperable environment.

Figure 5.1

Interoperable Environment Ontology



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5.1.1.2 Preliminary interoperable item boundary identification – The interoperable item boundary shall be documented in conformance with the Annex for Interoperability Architecture Specification of AAMI/UL 2800-1-3. This preliminary identification of the interoperable item boundary views the item as a black box and does not address the particular architecture or arrangement of internal interoperable components of the item.

5.1.2 Interoperable item operational context of use description

5.1.2.1 The following information about human actors that interact with the interoperable item through its interfaces shall be specified:

- The actors that directly interact with the interoperable item during its operation to achieve its functional objectives and utilize its services;
- The actors that directly interact with the interoperable item during [provisioning, configuration, maintenance] of the interoperable item;
- The interaction points on the interoperable item boundary that are relevant for each actor; and

d) The objectives of the actor with respect to its interactions with the device.

5.1.2.2 The following information about automated actors that interact with the interoperable item shall be specified:

- a) External automated actors that directly interact with the interoperable item to achieve its functional objectives and utilize its services;
- b) The interaction points on the interoperable item boundary that are relevant for each external automated actor; and
- c) The objectives of the actor with respect to its interactions with the device.

5.1.3 Interoperable item development context of use description

5.1.3.1 Interoperability frameworks with which the interoperable item is to be aligned shall be specified.

5.1.3.2 Other constraints on the interoperability architecture, requirements, objective evidence for safety and security, and assurance shall be identified including:

- a) Interoperability technology that is to be used in the interoperable item; and
- b) Interoperability standards to which conformance is to be claimed.

5.1.4 Identification of interoperable item medical and SSOs

5.1.4.1 The medically-related functional goals of the interoperable item shall be specified and disclosed.

5.1.4.2 The functional goals of the interoperable item related to supporting interoperability and reuse (including reusable services for achieving safe/secure interoperability) shall be specified.

5.1.4.3 For each of the medically-related functional goals of the interoperable item, the relationships and dependences between the functional goals for interoperability and reuse shall be specified for the purpose identifying the medically related functional goals that are relevant to compliance.

5.1.4.4 The interoperability-related SSOs of the Interoperable item (the interoperable item SSOs) shall be specified. These goals shall be traced to the hazardous situations associated with the interoperable item.

5.1.4.5 The interoperable item SSOs specified in [5.1.4.4](#) shall consider the candidate SSOs in AAMI/UL 2800-1-1.

5.1.4.6 The goals related to labelling and instructions for use that capture assumptions that the interoperable item makes about risk controls implemented by the interoperable item's external entities shall be specified as external measures.

5.1.5 Specification of interoperable item-context interactions

5.1.5.1 Interactions between the interoperable item and its context that illustrate the goals of the interoperable item from the point of view of the interoperable item's external actors shall be documented. The interactions shall be documented at a level of abstraction suitable for supporting an understanding of the all stakeholders of the interoperable item's primary functions and modes of use.

5.1.5.2 The interactions provided in [5.1.5.1](#) shall conform to the following criteria:

- a) All interaction points declared in the interoperable item boundary ([5.1.1.2](#)) are exercised by the interactions, and all interactions trace to relevant interaction points;

- b) All medical and interoperability functional goals are exercised by the interactions, and interactions trace to relevant functional goals;
- c) All interoperable item SSOs are exercised by the interactions, and interactions trace to relevant SSOs;
- d) For each interaction, the initiator of the interaction (the particular item or external entity) shall be documented;
- e) Expectations related to the temporal nature of the interactions shall be documented including:
 - 1) The periodicity or aperiodicity of the interaction; and
 - 2) Anticipated bounds on response times.
- f) Expectations related to authorization of entities to participate in interactions shall be documented;
- g) The nature of data and control information exchanged in entity-interoperable item interactions shall be characterized;
- h) Important changes in interoperable item states or modes that result from interactions shall be documented;
- i) Conceptual assumptions (to be indicated as external measures) and required behavior of the interoperable item with respect to its context shall be documented in terms of pre/post-conditions associated with the interoperable item's interaction points; and
- j) Both normal and exceptional behavior shall be documented as necessary to cover primary risk control functions.

5.1.6 Interoperable item risk analysis

5.1.6.1 Identify potential sources of harm

5.1.6.1.1 The potential for harm that can be directly caused by the interoperable item's output (or lack of output) through its interfaces shall be documented.

5.1.6.1.2 Any anticipated harm that may indirectly result from the interoperable item failing to meet its stated functional objectives for its operator and interoperability interfaces shall be documented to an appropriate level of detail appropriate based on the interoperable item's use specification.

5.1.6.2 Identify potential hazards from control actions and data outputs

5.1.6.2.1 A high-level description of all control actions (e.g., actuations) and data outputs that the interoperable item performs directly in the context of use through interaction points in support of the interoperable item goals shall be provided. The nature of the control action and the potential for harm shall be documented.

5.1.6.2.2 A high-level description of all data and operational instructions that the interoperable item communicates through operator interaction points in support of the interoperable item goals shall be provided.

5.1.6.2.3 A high-level description of all data and command signals communicated through interoperability interaction points in support of the interoperable item goals shall be provided.

5.1.6.3 Preliminary hazard analysis – interoperable item functional hazard analysis

5.1.6.3.1 Data and control flow paths from interoperable item inputs to outputs as reflected by the interoperable item's declared interaction points shall be documented for the purpose of supporting preliminary hazard analysis.

5.1.6.3.2 Control loops associated with the interoperable item's control objectives and the objectives of the interoperable item in its anticipated contexts shall be documented for the purpose of supporting preliminary hazard analysis.

5.1.6.3.3 A preliminary hazard analysis of the interoperable item shall be performed that satisfies the following objectives:

- a) Potential hazardous conditions of each control action of the interoperable item shall be identified. The characterization shall consider situations when the control action is incorrectly provided, incorrectly omitted, or provided at an incorrect time.
- b) The notions of state internal to the interoperable item (the interoperable item's state model) that the internal logic of the interoperable item will use to model the state of the patient and control objectives (e.g., set points) shall be identified.
- c) The analysis shall determine potential causes for interoperable item hazardous control actions that may arise from failures internal to the interoperable item, including failure of the interoperable item to maintain an appropriate correspondence between the interoperable item's state model of the context of use and the actual interoperable item context of use
- d) The analysis shall determine potential causes for interoperable item hazardous control actions that may arise from incorrect use of the interoperable item's external interoperability interaction points, failures of communication function associated with the interoperable item's external interoperability interaction points, and receipt of incorrect information through interoperable item's external interoperability points.

5.1.6.3.4 Documentation of hazardous situations and associated safety/security goals shall be provided that satisfies the following objectives:

- a) Each hazardous situation is characterized in terms of specific interoperable item state or event and context of use state (that may reference the state of entities in the interoperable item's operational context of use) that may lead to a specified harm;
- b) Item safety/security goals whose realization:
 - 1) Are the responsibility of the interoperable item manufacturer; and
 - 2) Will provide an appropriate risk mitigation for the hazardous situation;and
- c) Labelling and instructions for external measures that indicate:
 - 1) The responsibility of the interoperable item manufacturer to appropriately disclose instructions for controls; and
 - 2) The responsibility of the interoperable item's external entities to realize the controls.

5.1.7 Interoperability file information

5.1.7.1 Information resulting from the activities in the preceding sections shall be maintained in the interoperability file.

NOTE: Information may include the following without limitation:

- a) Use specification;
 - 1) Preliminary interoperable item boundary definition (with external and internal entities identified) phrased using the