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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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

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Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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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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Contents

Page

Committee representation.....	7
AAMI Standard.....	8
1 Introduction	9
2 Scope	10
3 References.....	10
4 Terms and Definitions	11
5 (Leadership) Management Responsibility	24
6 Interoperability Information	24
6.1 Controlled information	24
6.2 INTEROPERABILITY FILE.....	25
6.3 DISCLOSURE and communication.....	25
7 Interoperability Management.....	27
7.1 Scope of interoperability management.....	27
7.2 The INTEROPERABLE ENVIRONMENT	27
7.3 Processes for assuring safe and secure interoperability	28
8 Interoperability Realization Processes	30
8.1 Interoperability realization planning	30
8.2 RISK MANAGEMENT.....	31
8.3 Candidate SAFETY, SECURITY, AND ESSENTIAL PERFORMANCE OBJECTIVES	31
9 Design, Development and Implementation of Interoperability.....	39
9.1 Interoperability context of use	39
9.2 INTEROPERABILITY SPECIFICATION	42
9.3 Interoperability topology	44
9.4 Implementation for reusability	45
10 Interoperability of EXTERNALLY SOURCED PRODUCTS	47
10.1 Control of EXTERNALLY SOURCED PRODUCTS.....	47
10.2 Sourcing specifications	47
10.3 VERIFICATION and VALIDATION of externally sourced products.....	48
10.4 Responsibility for ongoing operation and maintenance	48
11 Provisioning, Deployment, and Operation.....	49
11.1 Provisioning, deployment and operation specifications	49
11.2 Clinical deployment	49
11.3 Operation	49
12 Testing and Review.....	50
12.1 Testing to interoperability specifications	50
12.2 Testing for suitability to context of use	51
12.3 Interoperability implementation review and change control	51
13 Traceability and Release	52
13.1 General	52
13.2 INTEROPERABLE APPLICATION SPECIFICATION	52
14 Interoperability Performance Monitoring and Control of Changes	53
14.1 Performance evaluation and monitoring.....	53
14.2 Information from monitoring	54
14.3 Incident response.....	54
15 Improvement of Processes	55

Annex A (Informative) Stakeholder Activities

A1 Development Context Activities.....	56
A1.1 INTEROPERABLE ITEM development	56
A1.2 INTEROPERABLE ITEM integration.....	57
A1.3 INTEROPERABLE MEDICAL SYSTEM development.....	58
A1.4 INTEROPERABILITY FRAMEWORK management	59

A2	Deployment Context Activities	59
A2.1	INTEROPERABLE ITEM acquisition/business management	59
A2.2	INTEROPERABLE ITEM technical administration	60
A2.3	INTEROPERABLE ITEM assembly	60
A2.4	INTEROPERABLE ITEM clinical administration.....	60
A2.5	INTEROPERABLE ITEM operation	61

Annex B (Informative) Guidance on Declaration of Products and Services

B1	Interoperability Ecosystem.....	62
B2	Entities Subject to Compliance Claims.....	62
B3	Categories of Claims of Compliance.....	65
B4	Attributes Establishing Relationships Between Compliance and ASSURANCE.....	65

Annex C (Informative) Guidance on INTEROPERABILITY FILE

C1	Background.....	67
C2	Listing of Named Work Products	67

Annex D (Informative) Guidance on DISCLOSURE

D1	Background.....	82
D2	Key Disclosures.....	82
D3	Example Disclosure Content	82

Annex E (Normative) Interoperability Realization Life-cycle Process

E1	INTEROPERABLE ITEM Development Life-Cycle Activities	84
E1.1	INTEROPERABLE ITEM concept and context of use development.....	84
E1.2	Development of item requirements and external interoperability specifications	88
E1.3	INTEROPERABLE ITEM realization	93
E1.4	INTEROPERABLE ITEM ASSURANCE.....	95
E2	INTEROPERABLE ITEM Integration Life-Cycle Activities	96
E2.1	Architecture and INTEROPERABLE ITEM integration concept development	96
E2.2	Architecture and integration specification	98
E2.3	Constituent INTEROPERABLE ITEM development	103
E2.4	INTEROPERABLE ITEM integration engineering	104
E2.5	INTEROPERABLE ITEM integration ASSURANCE	105
E3	Domain Engineering Life-Cycle Processes	105

Annex F (Informative) GUIDANCE ON RELEASE CRITERIA

F1	General.....	106
F1.1	INTEROPERABLE ITEM development activity RELEASE CRITERIA	106
F1.2	INTEROPERABLE ITEM Integration Activity RELEASE CRITERIA	108
F1.3	INTEROPERABLE MEDICAL SYSTEM RELEASE CRITERIA	109

Annex G (Informative) Testing Guidance

G1	General	110
G2	Scope of Testing.....	110
G3	Definitions and Abbreviations	110
G4	Prerequisites for Testing.....	110
G5	Component Testing	110

G6	System Testing (Integration Testing)	112
G7	Regression Testing (For addressing modifications to the system and/or a component).....	113
G7.1	More Granular Testing Details for Consideration	113
G7.2	SAFETY-Related Component Testing	114
G7.3	Basic SECURITY-related Testing	114

Annex H (Informative) RISK MANAGEMENT Guidance

H1	Overview	116
H2	Relationships to ISO 14971	118

Annex I (Informative) Common Fault Types

Annex J (Informative) Interoperability Usability Concepts

J1	Overview	123
J2	Recommendations	124

Annex K (Informative) SECURITY Principles

K1	SECURITY Elements of SSEPOS	126
K2	Relationship to UL 2900	127

Annex L (Informative) Clinical Context Concepts

L1	Requirements that Need to be Supported	128
L2	Informative Content	128

Annex M (Informative) Clinical Properties of INTEROPERABLE MEDICAL SYSTEMS

M1	Semantic Interoperability and Nomenclature	131
M1.1	Overview	131
M1.2	Recommendations	133
M2	PATIENT IDENTITY AND ASSOCIATION	135
M2.1	Overview	135
M2.2	Recommendations	135
M3	OPERATOR IDENTIFICATION, AUTHENTICATION, and AUTHORIZATION	137
M3.1	Overview	137
M3.2	Recommendations	138
M4	Operator IDENTIFICATION, AUTHENTICATION, and AUTHORIZATION	144
M4.1	Recommendations	144

Annex N (Informative) Architecture Definition Guidance

N1	Overview	150
N2	Topological Vocabulary Overview	151
N3	Examples	153
N3.1	INTEROPERABLE ITEM	153
N3.2	INTEROPERABLE MEDICAL SYSTEM	155
N3.3	INTEROPERABILITY FRAMEWORK	157
N4	Summary of Architectural Viewpoints	158
N5	Guidance on Use of Architecture Modeling Notations	159

Annex O (Informative) INTEROPERABILITY ARCHITECTURE SPECIFICATION

O1	Interoperability Viewpoint Guidance	160
O1.1	General guidance on interoperability view specification	160
O1.2	External interoperability – Specifying relationships between the product and its context	160
O1.3	Internal interoperability – Specifying the product’s CONSTITUENT INTEROPERABLE ITEM and their interoperability relationships	160
O2	Computational, Engineering, and Technology Viewpoint Guidance.....	161
O2.1	General	161
O2.2	COMPUTATIONAL VIEW – Computational objects.....	161
O2.3	COMPUTATIONAL VIEW – INTEROPERABILITY INTERFACES.....	161
O2.4	Guidance on decomposing interoperability view interoperability INTERACTION POINTS into COMPUTATIONAL VIEW interfaces and interactions	161
O2.5	INTERACTION SPECIFICATIONS	161
O2.6	Behavioral descriptions.....	162
O2.9	Engineering view – Node structure	162
O2.10	Engineering view – Channel structure	163
O3	Interactions with External Systems	163

Annex P (Informative) Engineering Properties of INTEROPERABLE MEDICAL SYSTEMS

P1	INTEROPERABLE ITEM Connectivity	165
P1.1	Overview	165
P1.2	Recommendations.....	166
P2	Safe States	170
P2.1	Overview	170
P2.2	Recommendations.....	170
P3	Time Synchronization.....	171
P3.1	Overview	171
P3.2	Recommendations.....	171
P4	Shared Resources and Data and Time Partitioning	172
P4.1	Overview.....	172
P4.2	Recommendations.....	173

Annex Q (Informative) Services for INTEROPERABLE MEDICAL SYSTEMS

Q1	General	175
Q1.1	ALARM SYSTEM Considerations	175
Q1.2	Management of ALARM CONDITIONS in an INTEROPERABLE MEDICAL SYSTEM	175
Q2	ALARM SIGNALING to OPERATOR.....	176
Q3	ALARM SYSTEM characteristics	176
Q3.1	Logging	176
Q3.2	Acknowledgment	176
Q3.3	Quality of service.....	177
Q3.4	Security	177
Q4	Intelligent ALARM SYSTEM	177
Q5	INTEROPERABLE ITEM Capabilities	177
Q6	INTEROPERABLE MEDICAL SYSTEM Maintenance and Diagnostics	178

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