


American
National
Standard



ANSI/AAMI
2700-1:2019

Medical Devices and
Medical Systems—Essential
safety and performance
requirements for
equipment comprising the
patient-centric integrated
clinical environment
(ICE)—Part 1: General
requirements and
conceptual model

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:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

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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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the Standards Monitor Online monthly newsletter. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the AAMI Standards Monitor Online.

Medical Devices and Medical Systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model

Approved 11 July 2019 by
AAMI

Approved 29 July 2019 by
American National Standards Institute, Inc.

Abstract: This standard specifies general requirements, a model, and framework for integrating equipment to create an INTEGRATED CLINICAL ENVIRONMENT (ICE), as defined in 3.6. This standard specifies the characteristics necessary for the safe integration of MEDICAL DEVICES and other equipment, via an electronic interface, from different MANUFACTURERS into a single medical system for the care of a single high acuity PATIENT. This standard establishes requirements for a medical system that is intended to have greater error resistance and improved PATIENT safety, treatment efficacy, and workflow efficiency than can be achieved with independently used MEDICAL DEVICES. This series of standards establishes requirements for design, verification, and validation processes of a model-based integration system for an INTEGRATED CLINICAL ENVIRONMENT. This series of standards is intended to define the requirements essential for safety and thereby facilitate regulatory acceptance.

Keywords: ICS, interoperability, integrated clinical environment, ICE

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This standard, AAMI 2700-1:2019, is based on reaffirmation of "ASTM F2761-9(2013), *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*, and transfer of the standard from ASTM to AAMI.

AAMI 2700-1:2019 contains references to future parts of F2761. For example:

"ASTM 2761 is expected to part of a series of standards, under the general title Medical Devices and Medical Systems—Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) ..."

With the transfer of the standard to AAMI 2700-1:2019, it is anticipated that future parts will be developed within the AAMI 2700 family of standards and named accordingly.

This document was approved and published when it was held by ASTM as F2761, but it is now an AAMI standard, published as AAMI 2700-1. The original content and formatting has been maintained, so there are some variations from the typical AAMI style. The AAMI Interoperability Working group has been charged to revise this new AAMI American national standard.

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Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Interoperability Working Group

The publication of AAMI 2700-1 as a new American National Standard was initiated by ASTM as F2761-09:2013. This standard was reviewed and reaffirmed by the AAMI Medical Device Interoperability Working Group.

At the time this document was published, the AAMI committee **Medical Device Interoperability Working Group** had the following members:

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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ASTM shall not be held responsible for identifying any or all such patent rights.

This ASTM standard was prepared by ASTM Committee F29, *Anaesthetic and Respiratory Equipment*, Subcommittee F29.21, *Devices in the Integrated Clinical Environment*. This work is based in part on concepts developed within the CIMIT Program^[8] on Interoperability and the Massachusetts General Hospital program on Medical Device “Plug-and-Play” Interoperability (“MD PnP” program, founded 2004) with information disseminated through publications, workshops, and website.^{[8],[9], [28],[37]}

This is the first edition.

F2761 is expected to be part of a series of standards, under the general title Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE):

- *ASTM F2761, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 1: General requirements and conceptual model (this standard)*
- *ASTM F—, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 2: Requirements for network control and equipment interface*
- *ASTM F—, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 3: Requirements for device models*
- *ASTM F—, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 4: Requirements for supervision*
- *ASTM F—, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 5: Requirements for safe and reliable integration*

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN THIS STANDARD OR AS NOTED: SMALL CAPS.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this standard, the auxiliary verb:

“shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

“should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

“may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses, and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

NOTE Attention is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

MEDICAL DEVICES are essential for the practice of modern medicine. Some MEDICAL DEVICES utilize open networking standards for communication to provide data for the electronic health record. However, unlike the interoperable “plug-and-play” environment of modern computers and consumer electronics, most acute care MEDICAL DEVICES are not designed to interoperate. MEDICAL DEVICES typically utilize proprietary protocols for system integration. These approaches do not provide the comprehensive integration capabilities necessary for safe, cross-MANUFACTURER MEDICAL DEVICE integration for data communication and MEDICAL DEVICE control for the care of a single high acuity PATIENT.

This standard series establishes the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an INTEGRATED CLINICAL ENVIRONMENT intended to facilitate cross-MANUFACTURER MEDICAL DEVICE interoperability. This series of standards focuses especially on communication of PATIENT data and on equipment command and control, as well as on the functionality necessary for the seamless creation of an INTEGRATED CLINICAL ENVIRONMENT.

The approach defined and described by this series of standards for the INTEGRATED CLINICAL ENVIRONMENT (ICE) includes provisions for error resistance, and continual improvements in PATIENT safety, treatment efficacy and workflow efficiency based on device interoperability. ^[30]

1. *Scope

This standard specifies general requirements, a model and framework for integrating equipment to create an INTEGRATED CLINICAL ENVIRONMENT (ICE), as defined in 3.6. This standard specifies the characteristics necessary for the safe integration of MEDICAL DEVICES and other equipment, via an electronic interface, from different MANUFACTURERS into a single medical system for the care of a single high acuity PATIENT. This standard establishes requirements for a medical system that is intended to have greater error resistance and improved PATIENT safety, treatment efficacy and workflow efficiency than can be achieved with independently used MEDICAL DEVICES. ^[8]

This series of standards establishes requirements for design, verification, and validation processes of a model-based integration system for an INTEGRATED CLINICAL ENVIRONMENT.

This series of standards is intended to define the requirements essential for safety and thereby facilitate regulatory acceptance.

NOTE These requirements were derived to support the clinical scenarios or clinical concepts of operations described in Annex B.

Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. However, parties to agreements based on this standard are encouraged to investigate the possibility of applying more recent editions of the normative documents indicated below. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices -- Application of risk management to medical devices*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62304:2006, *Medical device software – Software life cycle processes*

ISO 11135, *Medical Devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control – Radiation sterilization*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

ISO 11991, *Guidance on airway management during laser surgery of upper airway*

ISO 14155-1, *Clinical investigation of medical devices for human subjects -- Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans*

ISO 14408, *Tracheal tubes and related treatments designed for resistance to ignition by a laser - Requirements for marking, labeling and accompanying information*

ISO 14971, *Medical devices – Applications of risk management to medical devices Terms and definitions*