

Medical Device Integration: References, Resources, and Standards

Introduction

As medical technology and information systems become increasingly intertwined in the healthcare delivery setting, it is more important than ever to keep abreast of the existing sources of information related to integrating medical devices with each other and with IT systems.

The CE-IT Community (www.ceitcollaboration.org) has developed the following document to serve as a clearinghouse of Standards, Profiles, guidance documents, and other references intended primarily for Clinical Engineers, System Integrators and IT personnel approaching projects which integrate medical device system with information technology systems. The resources outlined in the document may be useful to these professionals as they develop requirements for their systems or specify requirements for vendors and/or system integrators in Requests for Proposals (RFP). Some of the documents listed may also inform other system engineering processes.

Chapter 1 – provides a list of general systems, safety, and requirements engineering references, not specific to medical device integration.

Chapter 2 – provides a list of key Standards and Standards Profiling organizations addressing Medical Device Integration.

Chapter 3 – provides a list of key References directly applicable to Medical Device Integration.

Chapter 4 – provides a list of applicable FDA and NIST documents

Chapter 5 – provides a list of other FDA documents

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This is not intended to be a static document. The document will be updated periodically as new standards and resources are developed.

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1 GENERAL REFERENCES

1.1 [Computational Technology for Effective Healthcare](#), National Research Council, National Academies Press, 2009

- Keywords
 - Principles for Success
 - Focus on improving care; technology secondary
 - Seek incremental gains from incremental effort
 - Record data to be used for care and research
 - Design for human and organizational factors
 - Support the cognitive functions of all caregivers
 - Architect systems to support disruptive change
 - Architect data for re-interpretation
 - Seek and develop technologies that identify and eliminate ineffective processes
 - Seek and develop technologies that clarify the context of data
 - Automation
 - Decision support
 - Data mining
 - Trust (impact in automation)
- Value added to requirements processes
 - Report speaks to deficiencies in (and therefore informs potential changes to) acquisition processes the authors saw in many organizations: “Poorly understood or defined requirements, poor development processes, and failures to adopt iterative or evolutionary or user-centered design are often seen... many attempts to deploy health care IT have not taken into account the systems engineering issues inherent in viewing health care as a complex, adaptive system.” (p 59)

1.2 [End User Validation Requirements for COTS Software](#)

- Keywords
 - COTS: Commercial Off the Shelf
- Value added to requirements processes
 - Describes importance of validation by end user beyond what is claimed by manufacturer

1.3 [Free Interoperability Requirements for the Enterprise \(MD FIRE\)](#)

- Keywords
 - Request for Proposal (RFP)
 - Physiologic closed loop control
 - Performance testing
 - Compliance
 - Architecture
 - Health IT Standards Panel (HITSP)
 - Certification Commission for Health IT (CCHIT)
- Value added to requirements processes
 - Provides a white paper, sample RFP, and contracting language requirements to promote the adoption of fully interoperable medical devices and systems in support of patient safety.

1.4 [High-Confidence Medical Devices: Cyber-Physical Systems for 21st Century Health Care](#), Network and Information Technology Research and Development Program (NITRD), 2009

- Keywords
 - High Confidence Software and Systems
 - V&V in the presence of change
 - Certification
 - Holistic cyber-physical systems
 - Research challenges
- Value added to requirements processes
 - Informs re: challenges being addressed in the research sector. From the Executive Summary: “The authors of this report, senior scientists of the NITRD Program’s High Confidence Software and Systems (HCSS) Coordinating Group (CG), point to fundamental scientific and technical challenges posed by the rapidly expanding digital environment in medicine and health care. They identify critical research advances that are needed to enable the design and manufacture of new generations of increasingly complex, interconnected, and interoperating medical device cyberphysical systems that will offer innovative new capabilities and function far more safely, securely, and reliably than today’s medical devices.”

1.5 [Patient Safety – Achieving a New Standard for Care](#), Institute of Medicine, National Academies Press, 2004

- Keywords
 - National Health Information Infrastructure (NHII)
 - Health Care Data Standards
 - Near Miss Analysis
 - Patient Safety Reporting Systems
- Value added to requirements processes
 - Provides Institute of Medicine recommendations for increasing patient safety through the use of IT.

1.6 [Requirements Engineering: A Roadmap](#)

- Keywords
 - Eliciting requirements
 - Elicitation techniques
 - Prototyping
 - Non-functional requirements
 - Stakeholders
- Value added to requirements processes
 - The paper focuses on then-current research addressing the fundamental problem facing requirements engineering: “The primary measure of success of a software system is the degree to which it meets the purpose for which it was intended. Broadly speaking, *software systems requirements engineering* (RE) is the process of discovering that purpose, by identifying stakeholders and their needs, and documenting these in a form that is amenable to analysis, communication, and subsequent implementation. There are a number of inherent difficulties in this process. Stakeholders (including paying customers, users and developers) may be numerous and distributed. Their goals may vary and conflict, depending on their perspectives of the environment in which they work and the tasks they wish to accomplish. Their goals may not be explicit or may be difficult to articulate, and, inevitably, satisfaction of these goals may be constrained by a variety of factors outside their control.”

1.7 [Resilience Engineering](#), E Hollnagel, D Woods, and N Leveson, Ashgate Publishing, 2006

- Keywords

- Emergence
- Emergent system properties
- Robustness
- Sacrifice judgments (e.g., production vs safety)
- Buffering capacity
- Margin
- Accident models
- System-as-imagined vs. System-as-actually-operated
- Value added to requirements processes
 - Provides insight into system level considerations and examples of practices that can be implemented to inform the development of resilient systems.

1.8 [Safely implementing health information and converging technologies](#)

- Keywords
 - Adverse events directly caused by HIT
 - Technology-related adverse events
 - Workflow
 - CPOE
- Value added to requirements processes
 - Joint Commission Sentinel Event Alert re: the risks involved in planning HIT installations

1.9 [Safeware: System Safety and Computers](#), N Leveson, Addison Wesley, 1995

- Keywords
 - Software myths
 - Flaws in the safety culture
 - Common-cause failures
 - Common-mode failures
 - Preliminary Hazard Analysis (PHA)
 - System Hazard Analysis (SHA)
 - Subsystem Hazard Analysis (SSHA)
 - Reliability
 - 1. Redundancy
 - 2. Standby spares
 - 3. Safety factors
 - Near miss
 - Risk
 - Accident models
 - Active vs latent failures
 - Slips
 - Air Safety Reporting System (ASRS)
 - Fault tree Analysis (FTA)
 - Hazards and Operability Analysis (HAZOP)
 - Failure Modes and Effects Analysis (FMEA)
 - Completeness Criteria for Requirements Analysis
 - Human-Machine Interface
 - Verification of Safety
 - 1. Dynamic Analysis
 - 2. Static Analysis
- Value added to requirements processes
 - Informs requirements engineer regarding risks and risk reduction strategies for software-based systems

1.10 [Software for Dependable Systems – Sufficient Evidence?](#), National Research Council, National Academies Press, 2007

- **Keywords**
 - Dependability
 - Claims
 - Evidence
 - Systems thinking
 - Transparency
 - Accountability
 - Coupling and complexity
 - Criticality creep, e.g., may occur on blurring of distinction between safety-critical and mission-critical features (p 58)
 - Domain assumptions
 - Goal-based assurance vs. process-based assurance
 - Best practices
- **Value added to requirements processes**
 - Provides requirements engineer with insight into what to require from a technology provider to assure satisfaction of dependability requirements
 - “Those claiming dependability [should] make available the details of their claims, criteria, and evidence ... The willingness of a supplies to provide such data, and the clarity and integrity of the data that the supplier provides, will be a strong indication of its attitude to dependability.” (p 11)

1.11 [Software Verification and Validation for Practitioners and Managers](#), S Rakitin, Artech House, 2001

- **Keywords**
 - Development models
 - Inspection processes
 1. Requirements inspection
 2. Test script inspection
 - Configuration management
 - Testing
 - Reliability growth
 - Attributes of Good Requirements Specifications
- **Value added to requirements processes**
 - Instructs regarding the importance of requirements engineering to project success
 - Software Development Best Practices (not the complete outline)
 1. Define requirements first
 2. Risk management
 3. Peer reviews
 4. Project-wide visibility of project plan

1.12 [The Human Factor](#), K Vicente, Routledge, 2006

- **Keywords**
 - Safety-critical psychology
 - Learning organization
 - Aviation Safety Reporting System (ASRS)
- **Value added to requirements processes**
 - Provides Insights into organizational issues that must be addressed along with the strictly technical, e.g.,
 1. One problem that led to the *Challenger* disaster: “... the burden of proof had shifted, without anyone realizing it: in the past, engineers had always been required to prove to

- their managers that it was safe to go ahead with the launch, but that night, the engineers were put in the position where they had to prove it wasn't safe to launch..." (p 187)
2. "... a technological system won't succeed unless sufficient attention is paid to organizational issues, such as how decisions about safety are made in the face of outside pressures." (p 189)

1.13 [The Mythical Man-Month](#), F Brooks, Addison Wesley, 1995

- **Keywords**
 - Second system effect
 - Conceptual integrity
 - Rapid prototyping to identify requirements
 - Incremental development
 - Brooks' Law
 - Essential and accidental development difficulties
- **Value added to requirements processes**
 - A series of essays that has provided insights into software engineering practices that have and have not worked and that has stood the test of time

1.14 [The Need for Flexible Requirements in Dependable Systems](#)

- **Keywords**
 - Dependability requirements
 - ALARP
 - Dependability cases
 - Goal Structuring Notation
- **Value added to requirements processes**
 - Provides information regarding ways to elicit and model non-functional requirements.

2 KEY INTEROPERABILITY ORGANIZATIONS

2.1 ISO

ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards.

ISO is a network of the national standards institutes of 162 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organization that forms a bridge between the public and private sectors. Many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. Other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.

2.2 IEEE 11073

ISO/IEEE 11073 standard family defines parts of a system, with which it is possible, to exchange and evaluate vital signs data between different medical devices, as well as remote control these devices.

2.3 HL7

HL7 provides standards for interoperability intended to improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among healthcare providers, government agencies, the vendor community, SDOs and patients.

2.4 NEMA (DICOM)

The DICOM Standards Committee creates and maintains international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM is a cooperative standard. Connectivity works because vendors cooperate in testing via either scheduled public demonstrations, over the Internet, or during private test sessions.

2.5 Continua Health Alliance

Continua Health Alliance is a non-profit, open industry coalition of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. Continua is dedicated to establishing a system of interoperable personal health solutions.

2.6 ASTM International

ASTM International is a source for technical standards for materials, products, systems, and services. Known for their high technical quality and market relevancy, ASTM International standards have an important role in the information infrastructure that guides design, manufacturing and trade in the global economy. Within ASTM, F29 is responsible for medical device interoperability standards.

2.7 HITSP

The Healthcare Information Technology Standards Panel (HITSP) is a cooperative partnership between the public and private sectors formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

2.8 CCHIT

The Certification Commission for Health Information Technology established the first comprehensive, practical definition of what capabilities were needed in these systems. The certification criteria were developed through a voluntary, consensus-based process engaging diverse stakeholders, and the Certification Commission was officially recognized by the Federal government as a certifying body.

3 KEY INTEROPERABILITY REFERENCES

3.1 IHE Patient Care Devices Technical Framework v1.1

- Keywords
 - Device Enterprise Communication
 - Alarm Communication Management
 - Point of Care Infusion Verification
 - Implantable Device Cardiac Observation
 - DICOM
 - HL7
 - Nomenclature
 - Semantics
 - Terminology
 - Terminology Mapping
 - Interface
- Value added to requirements processes
 - This specification addresses the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety, quality of care and lowering the cost of development and implementation. PCD develops standards-based interoperability specifications enabling communications for regulated point of care medical devices.

3.2 IHE Radiology Technical Framework v9.0

- Keywords
 - DICOM
 - HL7
 - Scheduled Workflow
 - Patient Information Reconciliation
 - Post-processing
 - Evidence Documents
 - Radiation Exposure Monitoring
 - Consistent Presentation of Images
 - Image Fusion
 - Portable Data for Imaging
- Value added to requirements processes
 - IHE Radiology was formed in 1998 to address issues of interoperability and information sharing that impact the quality of care in medical imaging. It has developed and documented standards-based solutions to these problems and organized testing and education to foster their adoption.

3.3 IHE Information Technology Infrastructure Technical Framework v6.0

- Keywords

- HL7
- Consistent Time
- Audit Trail and Node Authentication
- Retrieve Information for Display
- Enterprise User Authentication
- Patient Identifier Cross Referencing
- Patient Demographic Synchronization
- Patient Demographics Query
- Patient Demographics Management
- Cross Enterprise Document Sharing
- Document Digital Signature
- Document Media Interchange
- Value added to requirements processes
 - Supplies messaging architecture for sharing healthcare information. An infrastructure interoperability component represents a common IT function that is used as a building block for a variety of use cases. These components may be embedded in an application, but are often deployed as a shared resource within a RHIO or Health Information Exchange.

3.4 IHE Cardiology Technical Framework v2.1

- Keywords
 - Cardiac Catheterization
 - Echocardiography
 - ECG
 - Stress Testing
 - DICOM
 - HL7
- Value added to requirements processes
 - Addresses information sharing, workflow and patient care in cardiology.

3.5 HITSP/IS77: Remote Monitoring Interoperability Specification

- Keywords
 - Nomenclature
 - Semantics
 - Terminology
 - Terminology Mapping
 - Interface
- Value added to requirements processes
 - The Healthcare Information Technology Standards Panel (HITSP) is a cooperative partnership between the public and private sectors. The Panel was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

3.6 Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2

- Keywords
 - Semantics
 - Interface
 - XML
 - Object Oriented
 - MLLP
- Value added to requirements processes
 - Standards for electronic interchange of clinical, financial, and administrative information among health care oriented computer systems.

3.7 Health Level Seven (HL7) Version 2.6 Ch7 Observation Reporting

- Keywords
 - Semantics
 - Interface
 - MLLP
 - OBX
- Value added to requirements processes
 - Standards for electronic interchange of clinical, financial, and administrative information among health care oriented computer systems.

3.8 ISO/IEEE 11073-10101:2004(E) Health informatics Point-of-care medical device communication Part 10101: Nomenclature, First Edition.

- Keywords
 - Nomenclature
 - Terminology
 - Terminology Mapping
 - Interface
- Value added to requirements processes
 - This standard covers nomenclature architecture for point-of-care medical device communication. It defines the overall architecture of the organization and relationships among nomenclature components and provides specifications of semantics and syntaxes.

3.9 ISO/IEEE 11073-10201:2004(E) Health informatics Point-of-care medical device communication Domain information model

- Keywords
 - Point of Care Medical Device
 - Application Entity
 - Interface
 - OSI
- Value added to requirements processes

- This standard addresses the definition and structuring of information that is communicated or referred to in communication between application entities. Provides a common representation of all application entities present in the application processes within the various devices independent of the syntax. The definition of association control and lower layer communication is outside the scope of this International Standard.

3.10 ISO/IEEE 11073-20101:2004(E) Health informatics - Point-of-care medical device communication - Part 20101: Application profile - Base standard

- Keywords
 - OSI
 - Presentation Layer
 - Session Layer
- Value added to requirements processes
 - Provides the upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC). ISO/IEEE 11073-20101:2004 is the base standard of the ISO/IEEE 11073-20000 medical device application profiles (MDAP), as harmonized through the Committee for European Normalization (CEN) and ISO.

3.11 ISO/IEEE 11073-20601-2008 Health informatics Personal health device communication Part 20601: Application profile Optimized exchange protocol

- Keywords
 - Personal Health Device
 - Interface
- Value added to requirements processes
 - Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard defines a common framework for making an abstract model of personal health data available in transport-independent transfer syntax required to establish logical connections between systems and to provide presentation capabilities and services needed to perform communication tasks. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

3.12 Continua Design Guidelines: v1.0 June 2009

- Keywords
 - Nomenclature
 - Semantics
 - Terminology
 - Terminology Mapping
 - Interface
 - Home Health Devices

- Value added to requirements processes
 - Certified devices in the areas of Health and Fitness, Chronic Disease Management, Aging Independently. Home health devices certified by Continua will be interoperable.

3.13 NEMA PS 3.1-3.18:2008, Digital Imaging and Communications in Medicine (DICOM) Set

- Keywords
 - DICOM
 - Interface
- Value added to requirements processes
 - Provides a specification for imaging devices such as Radiology, Cardiology, Pathology, Endoscopy to exchange images in an open format.

3.14 Integrating Device Data Into the Electronic Medical Record: A Developer's Guide to Design and a Practitioner's Guide to Application. J. Zaleski, John Wiley & Sons, 2009

- Keywords
- Value added to requirements processes

4 RELEVANT FDA AND NIST DOCUMENTS

The following FDA Guidance documents impact requirements in some way. For each of these documents, the following information is included:

- Scope and applicability
- Intended Audience
- Impact on Requirements

4.1 [Glossary of Computerized System and Software Development Terminology](#)

4.2 [Cybersecurity for Networked Medical Devices Containing Off-the-Shelf Software, Jan 2005](#)

Scope and applicability:

A growing number of medical devices are designed to be connected to computer networks. Many of these networked medical devices incorporate off-the-shelf software that is vulnerable to cyber security threats such as viruses and worms. These vulnerabilities may represent a risk to the safe and effective operation of networked medical devices and typically require an ongoing maintenance effort throughout the product life cycle to assure an adequate degree of protection. FDA is issuing this guidance to clarify how existing regulations, including the Quality System (QS) Regulation, apply to such cyber security maintenance activities.

This guidance outlines general principles that we consider to be applicable to software maintenance actions required to address cyber security vulnerabilities for networked medical devices—specifically, those that incorporate off-the-shelf (OTS) software. The guidance is organized in question-and-answer format, providing responses to questions that have frequently been posed to FDA staff.

Intended audience:

- Device manufacturers who incorporate OTS software into their medical devices
- Healthcare organizations - IT network administrators who are responsible for connecting medical devices to the healthcare organization's network.
- IT vendors who develop networking equipment that could be used in a healthcare environment

Impact on requirements process:

- Identifies general requirements for medical devices that use OTS software and are to be connected to a healthcare organization's IT network, specifically with respect to network security

4.3 General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Jan 2002.

Scope and applicability:

This guidance outlines general validation principles that the FDA considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices.

The scope of this guidance is somewhat broader than the scope of validation in the strictest definition of that term. Planning, verification, testing, traceability, configuration management, and many other aspects of good software engineering discussed in this guidance are important activities that together help to support a final conclusion that software is validated.

This guidance recommends an integration of software life cycle management and risk management activities. Based on the intended use and the safety risk associated with the software to be developed, the software developer should determine the specific approach, the combination of techniques to be used, and the level of effort to be applied. While this guidance does not recommend any specific life cycle model or any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software life cycle.

Where the software is developed by someone other than the device manufacturer (e.g., off-the-shelf software) the software developer may not be directly responsible for compliance with FDA regulations. In that case, the device manufacturer needs to assess the adequacy of the off-the-shelf software developer's activities and determine what additional efforts are needed to establish that the software is validated for the device manufacturer's intended use.

This guidance applies to:

- Software used as a component, part, or accessory of a medical device;
- Software that is itself a medical device (e.g., blood establishment software);
- Software used in the production of a device (e.g., programmable logic controllers in manufacturing equipment); and
- Software used in implementation of the device manufacturer's quality system (e.g., software that records and maintains the device history record).

This document is based on generally recognized software validation principles and applies to any software related to a regulated medical device.

Intended audience:

This guidance provides useful information and recommendations to the following individuals:

- Persons subject to the medical device Quality System regulation
- Persons responsible for the design, development, or production of medical device software
- Persons responsible for the design, development, production, or procurement of automated tools used for the design, development, or manufacture of medical devices or software tools used to implement the quality system itself
- FDA Investigators
- FDA Compliance Officers
- FDA Scientific Reviewers

Impact on requirements process:

- Defines general principles of software validation - which are based on testing software against defined requirements.
- Requirements therefore, need to be expressed in terms which allow for adequate validation based on intended use and risk.
- Defines how the software development, software validation, and risk management processes all need to be integrated together.
- Defines the terms “requirement” and “specification” as follows:

A **requirement** can be any need or expectation for a system or for its software. Requirements reflect the stated or implied needs of the customer, and may be market-based, contractual, or statutory, as well as an organization's internal requirements. There can be many different kinds of requirements (e.g., design, functional, implementation, interface, performance, or physical requirements). Software requirements are typically derived from the system requirements for those aspects of system functionality that have been allocated to software. Software requirements are typically stated in functional terms and are defined, refined, and updated as a development project progresses. Success in accurately and completely documenting software requirements is a crucial factor in successful validation of the resulting software.

A **specification** is defined as “a document that states requirements.” (See 21 CFR §820.3(y).) It may refer to or include drawings, patterns, or other relevant documents and usually indicates the means and the criteria whereby conformity with the requirement can be checked. There are many different kinds of written specifications, e.g., system requirements specification, software requirements specification, software design specification, software test specification, software integration specification, etc. All of these documents establish “specified requirements” and are design outputs for which various forms of verification are necessary.

4.4 [Off-The-Shelf Software Use in Medical Devices](#), Sept 1999

Scope and applicability:

Off-the-Shelf Software (OTS software) – is defined as a generally available software component, used by a medical device manufacturer for which the manufacturer can not claim complete software life cycle control.

OTS software is commonly being considered for incorporation into medical devices as the use of general purpose computer hardware becomes more prevalent. The use of OTS software in a medical device allows the manufacturer to concentrate on the application software needed to run device-specific functions. However, OTS software intended for general purpose computing may not be appropriate for a given specific use in a medical device. The medical device manufacturer using OTS software generally gives up software life cycle control, but still bears the responsibility for the continued safe and effective performance of the medical device.

This guidance document was developed to address the many questions asked by medical device manufacturers regarding what they need to provide in a pre-market submission to the FDA when they use OTS software. The specific response to these questions depends on the medical device in question and the impact on patient, operator, or bystander safety if the OTS software fails. Thus, the answer to the question, “What do I need to document?” may differ and is based on the risk analysis that is an integral part of designing a medical device. The detail of documentation to be provided to FDA and the level of life cycle control necessary for the medical device manufacturer increase as severity of the hazards to patients, operators, or bystanders from OTS software failure increases. This document lays out in broad terms how the medical device manufacturer can consider what is necessary to document for submission to the agency. A BASIC set of need-to-document items is recommended for all OTS software, and a detailed discussion is provided on additional (SPECIAL) needs and responsibilities of the manufacturer when the severity of the hazards from OTS software failure become more significant.

Many of the principles outlined herein may also be helpful to device manufacturers in establishing design controls and validation plans for use of off-the-shelf software in their devices. This guidance discusses key elements reviewers should look for in the submission thereby providing a common baseline from which both manufacturers and reviewers can operate. This should improve predictability of agency interaction with sponsors regarding applications involving OTS software.

This guidance reflects a safety-based approach to risk management and is designed to be consistent with international standards on risk management. Existing international standards indicate that the estimation of risk should be considered as the product of the severity of harm and the probability of occurrence of harm. Probabilities of occurrence

are calculated based on clinical and engineering considerations. On the clinical side, manufacturers use patient populations, user skill sets, labeling and risk benefit analysis to calculate risk and acceptable risk levels. On the software engineering side, probabilities of occurrence would normally be based on software failure rates. However, software failures are systematic in nature and therefore their probability of occurrence can not be determined using traditional statistical methods.

Intended audience:

- Medical device manufacturers
- FDA Investigators
- FDA Compliance Officers
- FDA Scientific Reviewers

Impact on requirements process:

This guidance document defines specific documentation for OTS software included in a medical device that device manufacturers need to provide to FDA as part of a premarket submission (510k) or a pre-market approval (PMA) process.

Part of this documentation includes information related to the specific requirements implemented by the OTS software.

4.5 [Devices: General Hospital and Personal User Devices; Reclassification of Medical Device Data System](#)

- Keywords
 - Medical Device Data System (MDDS)
 - Class I, II, III Controls
 - Draft Software Policy
- Value added to requirements processes
 - Provides requirements engineer with understanding of FDA proposal and rationale for identifying new type of medical device, the MDDS, and how it would be regulated.

4.6 [Draft Guidance for Industry and FDA Staff – Radio-Frequency Wireless Technology in Medical Devices, Jan 2007](#)

- Keywords
- Value added to requirements processes

4.7 [Guidance for Industry - Wireless Medical Telemetry Risks and Recommendations](#)

- Keywords
- Value added to requirements processes

4.8 [Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf \(OTS\) Software"](#)

- Keywords
- Value added to requirements processes

4.9 [Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management](#)

- Keywords
 - Human Factors Engineering (HFE)
 - Empirical HFE Approaches
- Value added to requirements processes
 - Describes risk management approaches as applied to user interface issues

4.10 [Reference Information for the Software Verification and Validation Process](#)

- Keywords
 - Independent V&V
- Value added to requirements processes
 - NIST document for software V&V.

4.11 [Reminder from FDA: Cybersecurity for Networked Medical Devices is a Shared Responsibility](#)

5 OTHER FDA RECOGNIZED STANDARDS

5.1 ANSI/UL 1998, [Software in Programmable Components](#)

- Keywords
 - Programmable components
- Value added to requirements processes

5.2 IEC 60601-1-1:2000, [Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems](#)

- Keywords
- Value added to requirements processes

5.3 IEC 60601-1-4:2000, [Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, edition 1.1](#)

- Keywords
- Value added to requirements processes

5.4 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](#)

- Keywords
- Value added to requirements processes

5.5 ANSI/AAMI/IEC 62034:2006, [Medical device software - Software life cycle processes](#)

- Keywords
 - IEEE 12207
 - Risk analysis
 - Security
 - Serious injury
 - Software of unknown provenance (SOUP)
- Value added to requirements processes
 - Defines the life cycle requirements for medical device software

5.6 ANSI/AAMI/ISO 14971:2007, [Medical devices - Application of risk management to medical devices](#)

- Keywords
 - Harm
 - Hazard
 - Medical device
 - Residual risk
 - Risk
 - Risk analysis
 - Risk assessment
 - Risk control
 - Risk management
 - Risk management file
 - Safety

- Value added to requirements processes
 - Provides manufacturers with a framework with which to manage risks of medical devices.

5.7 [ANSI/AAMI/ISO 15223-1:2007 , Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied.](#)

- Keywords
- Value added to requirements processes

5.8 “Health Insurance Reform: Security Standards, Final Rule”, DHHS

- Keywords
- Value added to requirements processes

5.9 “Standards for Privacy of Individually Identifiable Health Information; Final Rule”,
DHHS

- Keywords
- Value added to requirements processes

6 OTHER INFORMATIVE STANDARDS

Note: Some of the following have yet to be adopted. The meaning of trailing acronyms follows:

CD: Committee Draft

CDV: Committee Draft for Vote

DIS: Draft International Standard

FDIS: Final Draft International Standard

DTR: Draft Technical Report

6.1 [AAMI TIR18: Guidance on electromagnetic compatibility \(EMC\) of medical devices to assist clinical engineers and other biomedical personnel in evaluation of the radiated frequency \(RF\) electromagnetic environment in health care facilities](#)

- Keywords
 - Electromagnetic compatibility (EMC)
 - Radio-frequency (RF)
 - Clinical engineering
- Value added to requirements processes
 - Helps clinical engineers and other biomedical personnel evaluate the radiated radio-frequency (RF) electromagnetic environment in their individual health care facilities and implement actions needed to minimize electromagnetic interference (EMI) problems.

6.2 ASTM F2761:2009 [Essential safety requirements for equipment comprising the patient-centric integrated clinical environment \(ICE\) — Part 1: General requirements and conceptual model](#)

- Keywords
 - Patient-centric
 - Device models
 - Real time decision support
 - ICE-compatible equipment
 - Qualification test
 - Safety interlocks
 - System readiness
 - Plug-and-play
 - Forensic data logging
 - Clinical context
 - Clinical scenarios
 - Clinical concept of operations
 - Smart alarms
 - Programmable closed loop control
- Value added to requirements processes
 - Identifies and provides standards-based information regarding the key capabilities of a high-acuity patient-centric integrated clinical environment, e.g., comprehensive data acquisition for the EMR and the integration of devices to enable real-time decision support, safety interlocks, and closed-loop control.

6.3 IEC 80001 CD: Application of risk management for IT-networks incorporating medical devices

- Keywords
 - Risk management
 - ISO 14971
 - Responsible organization
 - Configuration management
 - Change management
 - Interoperability
 - Medical-IT network maintainer
 - Responsibility agreement
- Value added to requirements processes
 - Defines the roles, responsibilities, and activities necessary when integrating medical devices into an IT network.

6.4 IEC/TR 80002-1:2009: Medical device software – Guidance on the application of ISO 14971 to medical device software

- Keywords
 - ISO 14971
 - Safety cases
 - Risk management
 - Failsafe
 - Safety-related software
- Value added to requirements processes
 - Technical report providing guidance for the application of the risk management requirements in ISO 14971 to medical device software.

6.5 IEEE 1012: Standard for Software Verification and Validation

- Keywords
 - Verification
 - Validation
- Value added to requirements processes
 - Although specific to software, concepts are extensible to systems level work as well.

6.6 IEEE 1028: Standard for Software Reviews

- Keywords
 - Entry criteria
 - Exit criteria
- Value added to requirements processes
 - Defines systematic review process applicable to software acquisition, supply, development, operation, and maintenance.

6.7 IEEE 1063: Standard for Software User Documentation

- Keywords
 - Concept of operations
 - Error messages
 - Format

- Value added to requirements processes
 - Provides minimum requirements for structure, content, and format of user documentation.

6.8 IEEE 1220: Standard for the Application and Management of the Systems Engineering Process

- Keywords
 - Specification tree
 - Drawing tree
 - Interface specification
 - System breakdown structure
 - Requirement
 - Requirements analysis
 - Requirements validation
 - Specification
 - Unprecedented system
- Value added to requirements processes
 - Defines the interdisciplinary tasks that are required throughout a system's life cycle to transform customer needs, requirements and constraints into a systems solution.

6.9 IEEE 1233: Guide for Developing System Requirements Specifications

- Keywords
 - Well-formed requirement
 - Derived requirement
 - Baseline
 - Constraint
 - Traceability
- Value added to requirements processes
 - Provides guidance for the development of requirement to satisfy an expressed need.

6.10 IEEE 1362: Guide for Information Technology – Systems Definition – Concept of Operations (ConOps) Document

- Keywords
 - Concept analysis
 - N² diagram
 - Problem domain
 - Scenario
- Value added to requirements processes
 - Describes the format and contents of the ConOps, a user-oriented document system characteristics from a user viewpoint.

6.11 FDA Recognized Laboratory Standards – Software

Recognition Number	Category	Title of Standard	Reference Number and Date	Effective Date	Standards Development Organization
13-11	Software	Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard	AUTO3-A	09/09/2008	CLSI
13-12	Software	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard	AUTO4-A	09/09/2008	CLSI
13-13	Software	Laboratory Automation: Electromechanical Interfaces; Approved Standard	AUTO5-A	09/09/2008	CLSI
13-14	Software	Point-of-Care Connectivity	POCT1-A2	09/09/2008	CLSI
13-15	Software	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition	GP19-A2	09/09/2008	CLSI
13-16	Software	Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems	LIS01-A	09/09/2008	CLSI
13-17	Software	Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard-Second Edition	LIS02-A2	09/09/2008	CLSI
13-18	Software	Standard Guide for Selection of a Clinical Laboratory Information Management System	LIS03-A	09/09/2008	CLSI
13-19	Software	Standard Guide for Documentation of Clinical Laboratory Computer Systems	LIS04-A	09/09/2008	CLSI
13-20	Software	Standard Specification for Transferring Clinical Observations Between Independent Computer Systems	LIS05-A	09/09/2008	CLSI
13-21	Software	Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems	LIS06-A	09/09/2008	CLSI
13-22	Software	Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory	LIS07-A	09/09/2008	CLSI
13-23	Software	Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems	LIS08-A	09/09/2008	CLSI
13-24	Software	Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures	LIS09-A	09/09/2008	CLSI

Medical Device Integration: References, Resources, and Standards

Recognition Number	Category	Title of Standard	Reference Number and Date	Effective Date	Standards Development Organization
13-25	Software	<u>Managing and Validating Laboratory Information Systems; Approved Guideline</u>	AUTO8-A	03/18/2009	CLSI
13-26	Software	<u>Autoverification of Clinical Laboratory Test Results; Approved Guideline</u>	AUTO 10-A	03/18/2009	CLSI
13-27	Software	<u>IT Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard</u>	AUTO11-A	03/18/2009	CLSI
13-28	Software	<u>Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard</u>	AUTO9-A	03/18/2009	CLSI
13-29	Software	<u>Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems</u>	LIS01-A2	09/08/2009	CLSI

7 RELEVANT JOURNALS

- 7.1 [*Biomedical Instrumentation & Technology \(BI&T\)*](#)
- 7.2 [*Health Informatics Journal*](#)
- 7.3 [*IEEE Software*](#)
- 7.4 [*IEEE Computer*](#)
- 7.5 [*IEEE Transactions on Information Technology in Biomedicine*](#)
- 7.6 [*Journal of the American Medical Informatics Association*](#)
- 7.7 [*Journal of Healthcare Information Management*](#)