
11th Conference of the
Global Harmonization Task Force

**International standards and
guidance that address
Medical Device Software**

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Standards in the regulated medical device industry

Overview

- How are standards used in regulation?
- What is IEC 62304:2006, *Medical device software -- Software life-cycle processes*, and how does it fit with other medical device standards?
- What regulatory impact could IEC 62304 have?
- What are the future standards relating to medical software?

How are standards used in regulation?

- Why are standards important?
 - Help to ensure compatibility, interchangeability, or basic safety
 - Capture “tried and true” solutions to reoccurring problems
 - Harmonize technical regulation



How are standards used in regulation?

- Voluntary regulatory standards:
 - Usually developed through a broad consensus-based process
 - Establish a “mutually agreed upon” minimal level of safety and/or performance
 - Provide a “presumption of conformity”
 - Decision to use the standard remains at the discretion of the manufacturer



How are standards used in regulation?

- Voluntary regulatory standards:
 - Once a manufacturer chooses to claim compliance with a “voluntary” standard, that claim is legally binding
 - Notified Bodies and Competent Authorities use the recognized standard as a “yardstick” against which to measure the manufacturer’s method

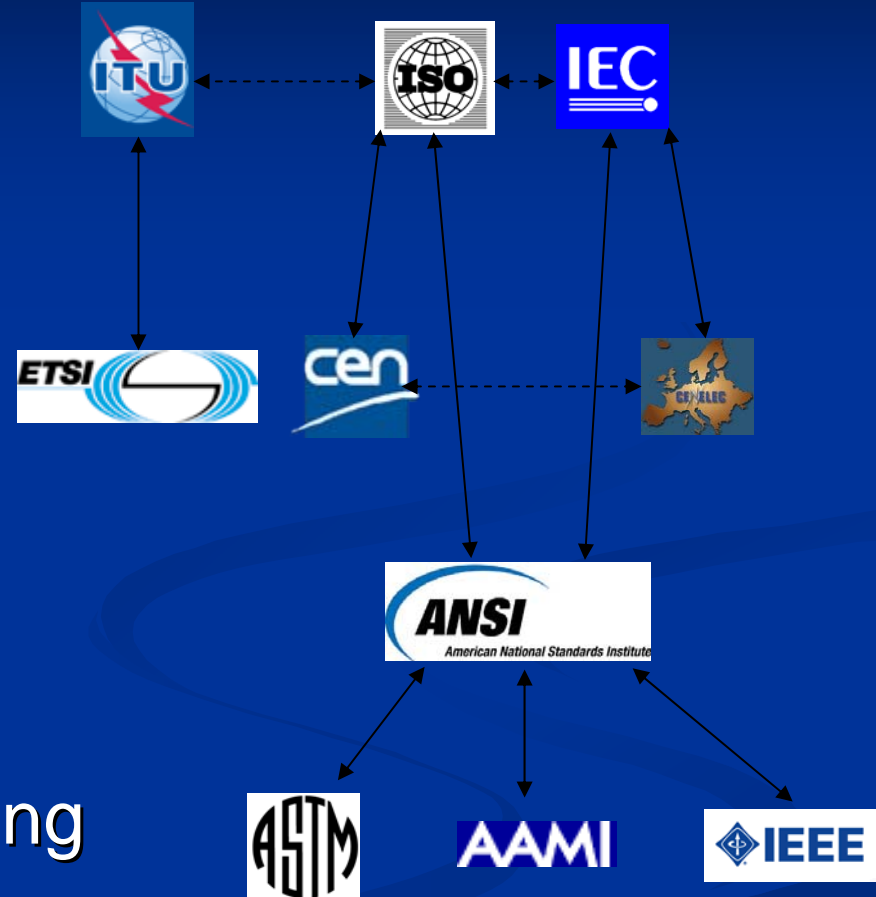
Who are the key organizational players?

International organizations

Regional organizations

National body

Other Standards Developing Organizations (SDOs)



IEC 62304 - background

- IEC 62304:2006, *Medical device software -- Software life-cycle processes*
 - Based on:
 - ANSI/AAMI/SW 68:2001, *Medical Device Software -- Software Life Cycle Processes*
 - ISO/IEC 12207:1995, *Information Technology -- Software Life Cycle Processes*
 - Developed by an ISO/IEC Joint Working Group

IEC 62304 - background

- Approximately 20 experts from 6 or 7 countries actively participated for 4 plus years
- Represents current “state of the practice” in medical device software
- Approved in both ISO and IEC with no negative votes

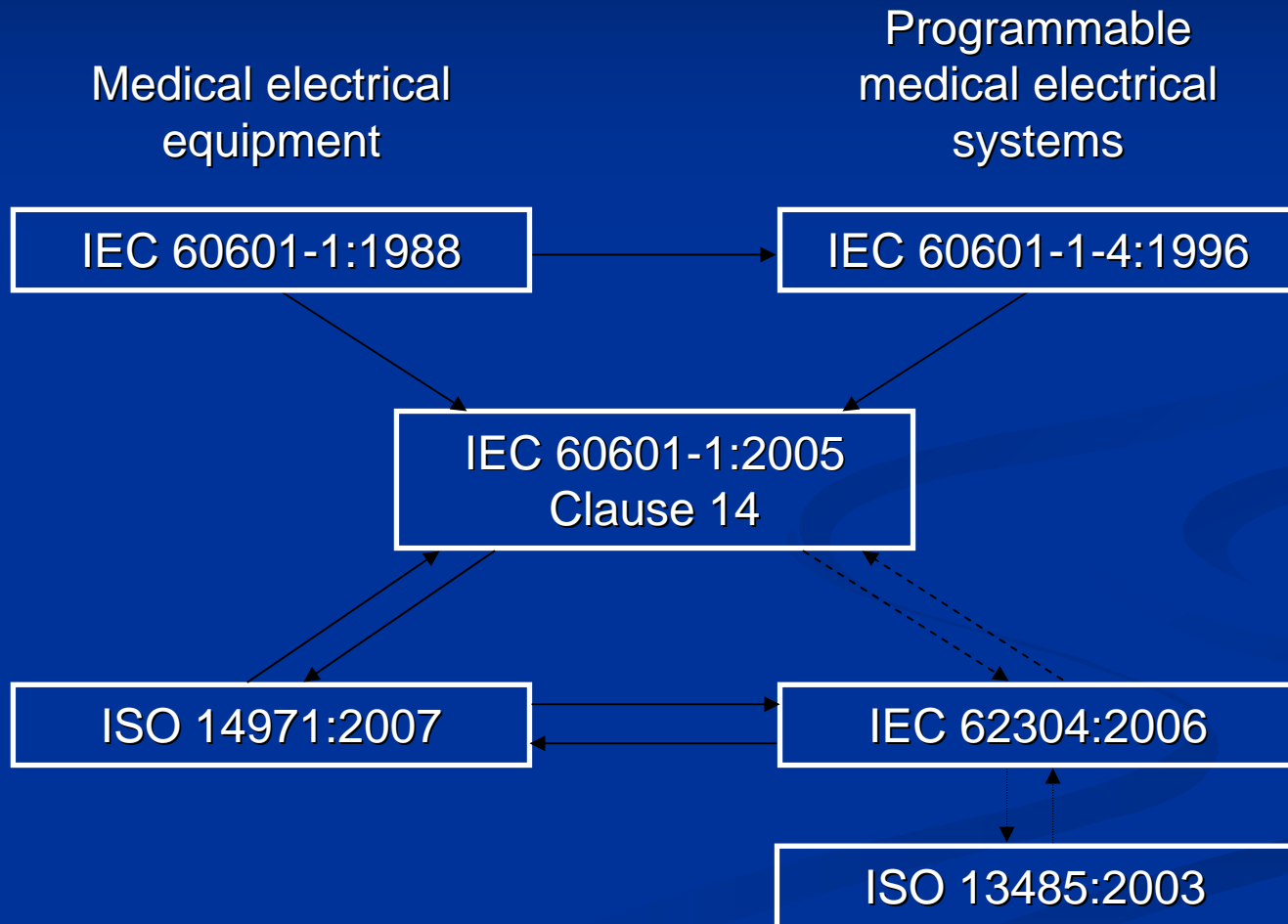
IEC 62304 - What is it?

- A framework – processes, activities and tasks necessary in the software life cycle
- Identifies requirements for what needs to be done and what needs to be documented
- Specifies a software safety classification method

IEC 62304 - What is not in it?

- Does not prescribe how to accomplish requirements
- Does not require a specific software life cycle
- Does not specify documents

How does IEC 62304 fit with other medical device standards?



How does IEC 62304 fit with other medical device standards?

- IEC 62304 is also applicable to:
 - Software used in active implantable medical devices covered by ISO 14708
 - Software which is classified as a medical device in its own right

What regulatory impact could IEC 62304 have?

Example: FDA's extent of recognition of IEC 62304 ¹⁾

SOFTWARE DOCUMENTATION	LEVEL OF CONCERN		
	Minor	Moderate	Major
Software Description	See Guidance	See Guidance	See Guidance
Device Hazard Analysis	See Guidance	See Guidance	See Guidance
Software Requirements Specification	See Guidance	See Guidance	See Guidance
Architectural Design	Don't Submit	Don't Submit	See Guidance
Design Specification	Don't Submit	Don't Submit	See Guidance
Traceability	Don't Submit	Don't Submit	See Guidance
Development	Don't Submit	Don't Submit	Don't Submit
Validation, Verification and Testing (VV&T)	Don't Submit	Don't Submit	See Guidance
Revision History	Don't Submit	Don't Submit	See Guidance
Unresolved Anomalies	Don't Submit	Don't Submit	See Guidance
Release Version Number	See Guidance	See Guidance	See Guidance

"See Guidance" - Follow the recommendations contained in the guidance document.

"Don't Submit" - Manufacturer is NOT required to submit the indicated software documentation.

1) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.cfm?ID=16876>



What regulatory impact could IEC 62304 have?

- New revision to EU medical device directives recognizes the need for special attention to software

“Taking account of the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement.”

“For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.”

- Notified Bodies are already beginning to use IEC 62304 as a “yardstick” against which to measure manufacturer’s software lifecycle processes

What's coming next?

- More standards and guidance on risk and software
 - Medical devices on networks
 - Software risk management

Medical devices on networks

- IEC 80001: Application of risk management to information technology (IT) networks incorporating medical devices
 - Apply risk management throughout the life cycle of IT-networks incorporating medical devices.
 - Process to define responsibilities for parties
 - Achieve necessary properties such as safety, effectiveness, data & system security and interoperability
 - Joint working group between IEC 62A and ISO 215
 - First meeting held in January 2007
 - Schedule for approved standard, 2010

Guidance for software risk management

- IEC Technical Report 80002: Guidance on the application of ISO 14971 to medical device software
 - Starting from AAMI TIR32
 - Updating for ISO 14971 2nd Ed. and IEC 62304
 - Joint working group between IEC 62A and ISO 210
 - First meeting held in May 2007
 - Schedule for approved TR is 2009

Tomorrow's Medical Device World

- Integration of medical devices and information management technology enables globalization of health care.
 - Networked medical devices
 - Off the shelf (OTS) software
 - Patch management / cyber security
 - Electronic patient records
 - Where does the device end / classification
 - Plug and play medical devices
 - Network services as medical devices
 - Remote management of chronic disease
 - eHealth – new healthcare paradigms
- And results in new risks that can be addressed by standardization

