IEC 62304
Medical Device Software Development Life Cycle

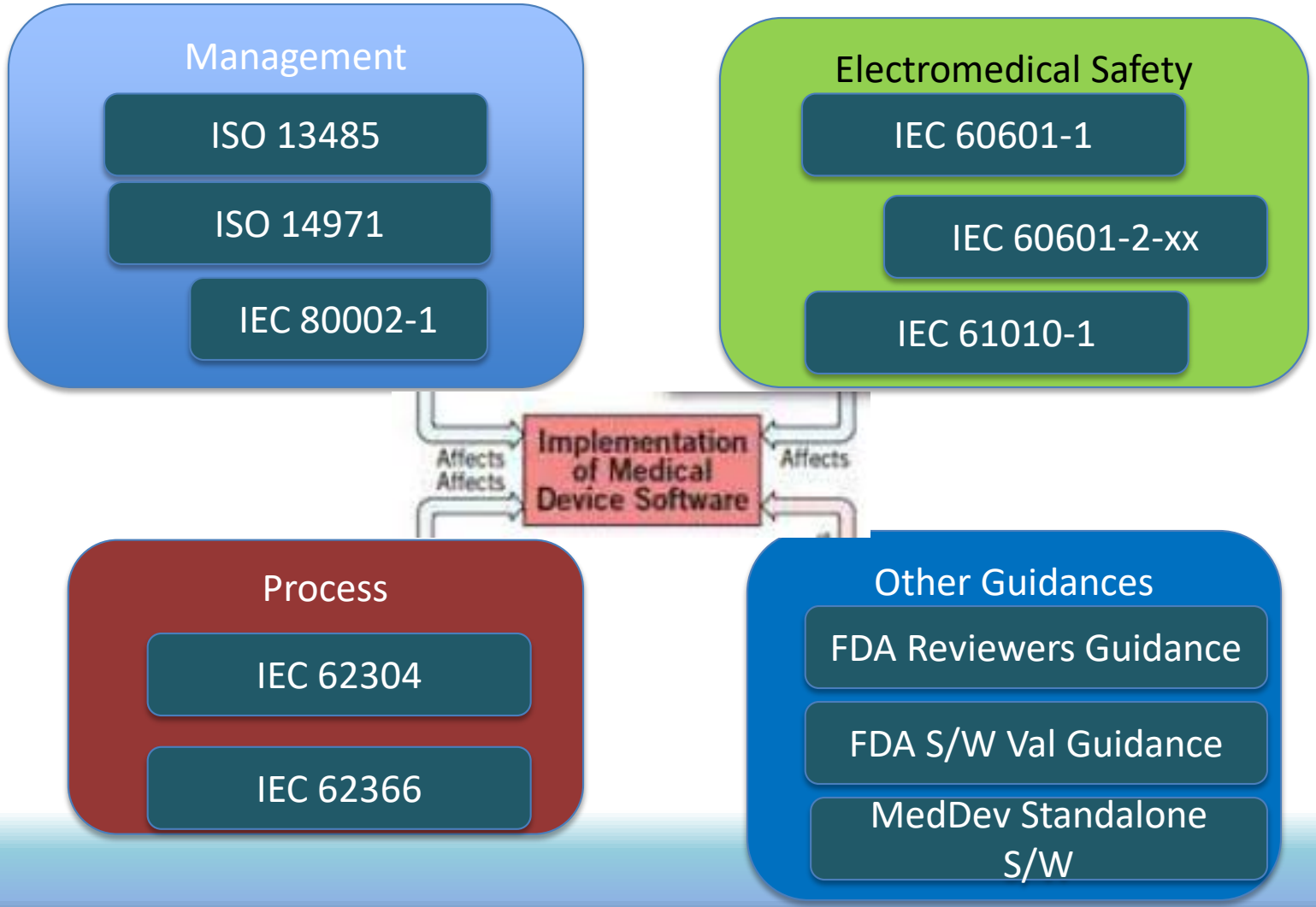
Agenda

- Objectives
- Relationship with other Standards
- Organisation of the Standard
- General Approach of the Standard
- Applicability of the Clauses
- EUMDD, QSR, ISO 13485 Map to IEC 62304

Objectives

- Understand 62304 compliance with respect to “the big picture” and to Projects
- Ability to Enhance Product Submissions
- Apply 62304 to the QMS for audits
- Retain 62304 Key Principles for Use with Projects

Relationship with Other Standards



Relationship with Other Standards

ISO 13485(2012/2016): Quality Management System

ISO 14971(2007/2012) : Risk Management

IEC/TR 80002-1(2009): Guidance on 14971/MD S/W

IEC 62304(2006+AC:2008/2015): Medical Device Software – Software Life Cycle Processes

IEC 62366(2007/2015): Medical Device Usability Engineering

Relationship with Other Standards

FDA Reviewers Guidance

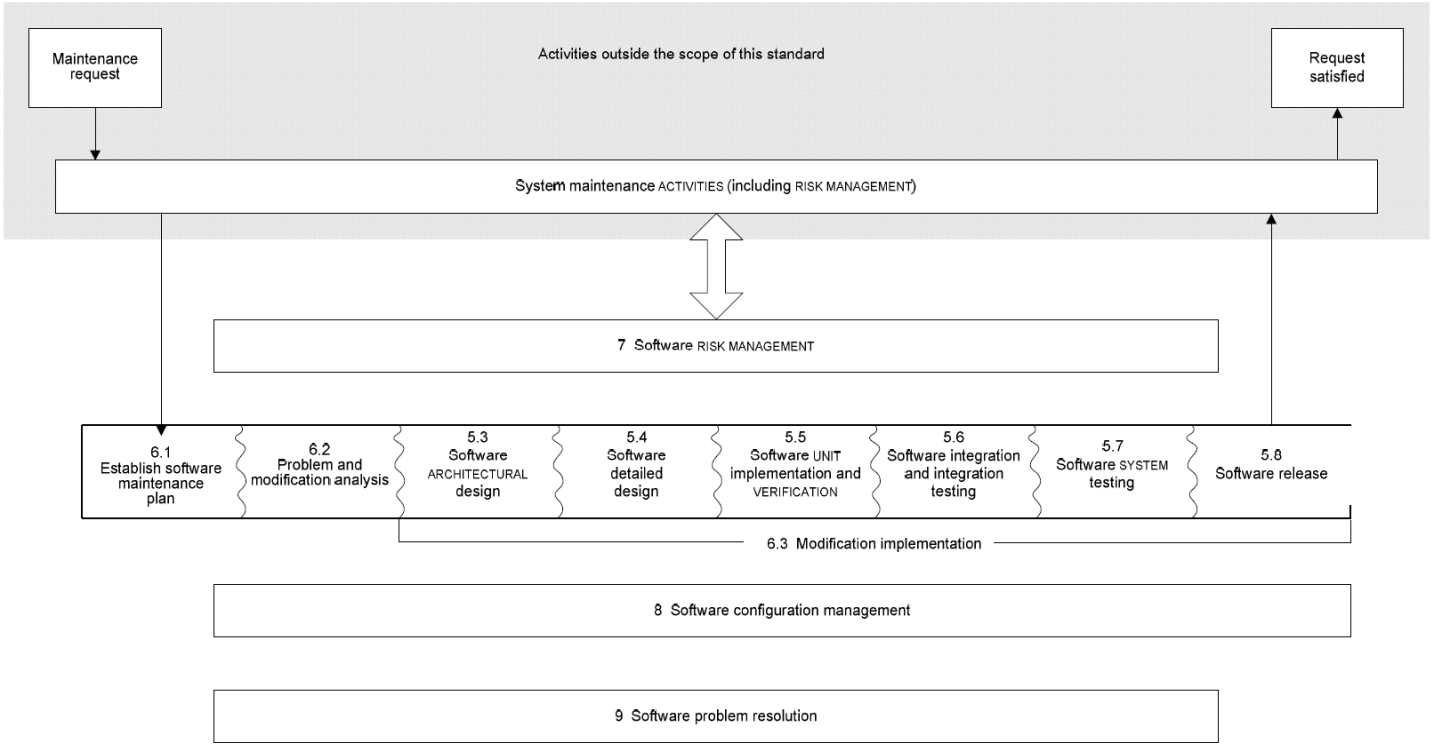
- Alignment of 62304 Classes with Level Of Concern
- Alignment of 62304 with Submission Deliverables

FDA Software Validation Guidance

- Alignment of 62304 with FDA S/W Val incl SOUP

Organisation of The Standard

9 Sections, 4 Annexes



General Approach of the Standard

- Plan the Software Development
- Preliminary Risk Analysis
- Figure out the software architecture
- Assess Software Safety Risk Class
- Develop /Risk Manage per Risk Class

Clauses

1. Scope
2. Normative References
3. Terms & Definitions
4. General Requirements
5. Software Development Process
6. Software Maintenance Process
7. Software Risk Management Process
8. Software Configuration Management Process
9. Software Problem Resolution Process

Scope

- Defines the life cycle requirements for MEDICAL DEVICE SOFTWARE.
- The set of PROCESSES, ACTIVITIES, and TASKS described establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.
- When software is stand alone or embedded/integral in a medical device
- Does not cover validation and final release
- Compliance determined by inspection of all required documentation including RMF and assessment of PROCESSES, ACTIVITIES, and TASKS required for the software safety class.

References

- ISO 14971 – Normative - that's it.
  - Which edition (2007/2012) applies?
    - 2007: Everyone BUT EU
    - 2012: EU
- EN 62366 – Informative reference
  - Which edition (EN 62366:2007/EN 62366-1:2015)?
    - 2015: Everyone BUT EU, referenced in 2015
    - 2007: EU – but actually not mentioned in 2006

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