Introduction into IEC 62304
Software life cycle for medical devices

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SPIQ

Agenda

- Current Picture
- Regulatory requirements for medical device software
- IEC 62304 Overview
- IEC 62304 Key concepts
- Summary
- References
- Q&A

Current Picture

Current picture in medical device industry

- Dramatic increase in compliance and regulatory requirements
- Diverse regulatory requirements for different countries
- Increased number of recent recalls were software related
- Increasing number of medical devices which are pure SW products
- FDA raises expectation on software testing methodologies
- Opinion that software development in medical device industry is behind other mission critical industries such as aviation
- For vendor:

No choice be compliant!

Regulatory Requirements

FDA (US) requirements on medical device software

Quality System Requirements (QSR) aka GMP

- for medical devices
  - ➔ 21 CFR § 820.30 Design Control:
    Design validation shall include software validation and risk analysis …

- software used in manufacturing and process control
  - ➔ 21 CFR § 820.70 production and process controls:
    When computers or automated data processing systems are used as part of production or the ***quality system***, the manufacturer shall validate computer software for its intended use according to an established protocol.

- in general
  - ➔ 21 CFR PART 11 Electronic Records & Signatures

also Excel Sheets

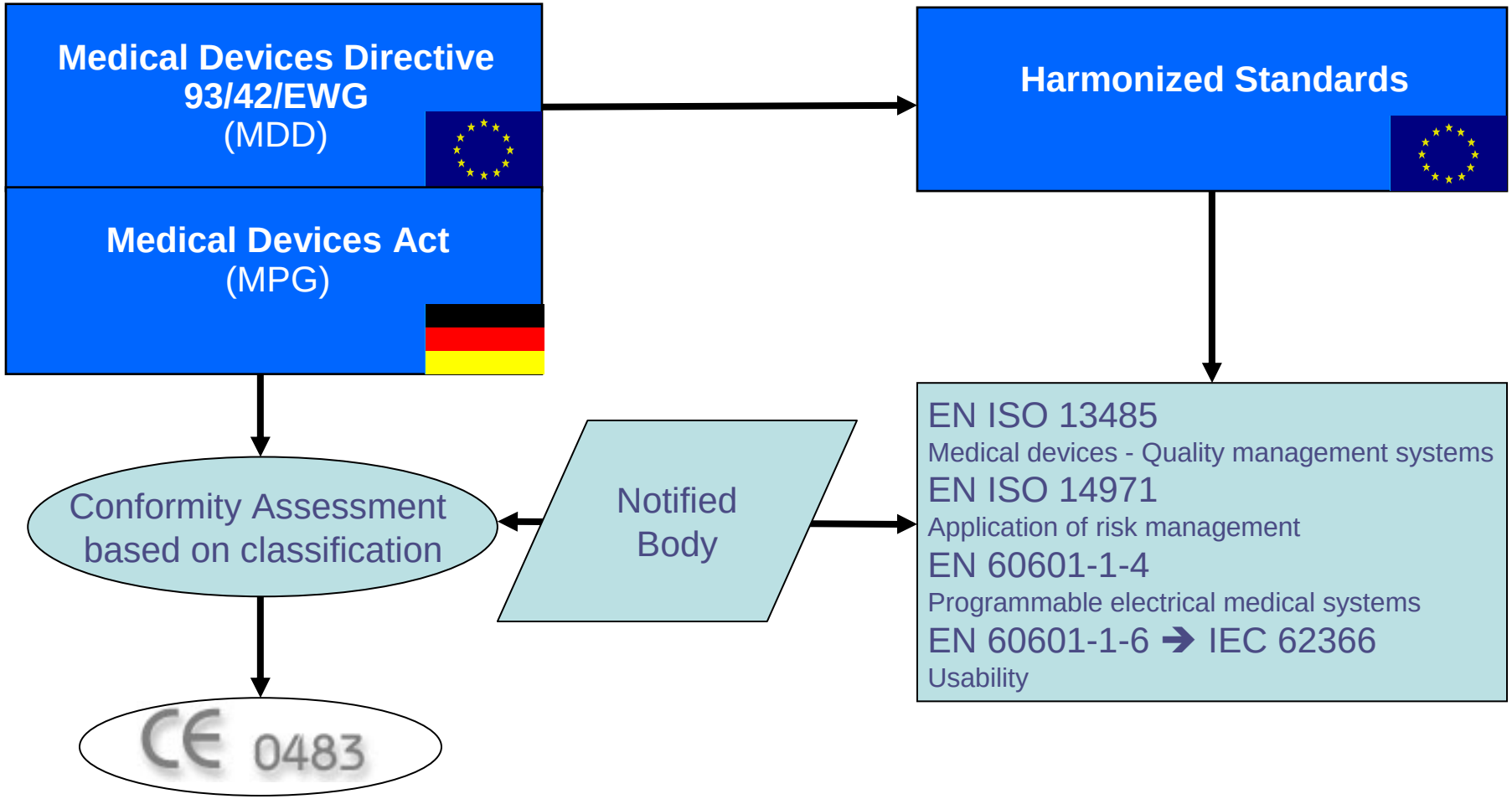
FDA compliance

- Application of 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 against manufacturer's method

- For medical device software
  - ➔ ISO 13485, ISO 14971, IEC 62304

- Software used in manufacturing and process control
  - ➔ ISO 13485
  - ➔ GAMP5
    - ➔ **Off-the-shelf**
    - ➔ **Customized**
    - ➔ Custom made

EU requirements on medical device software

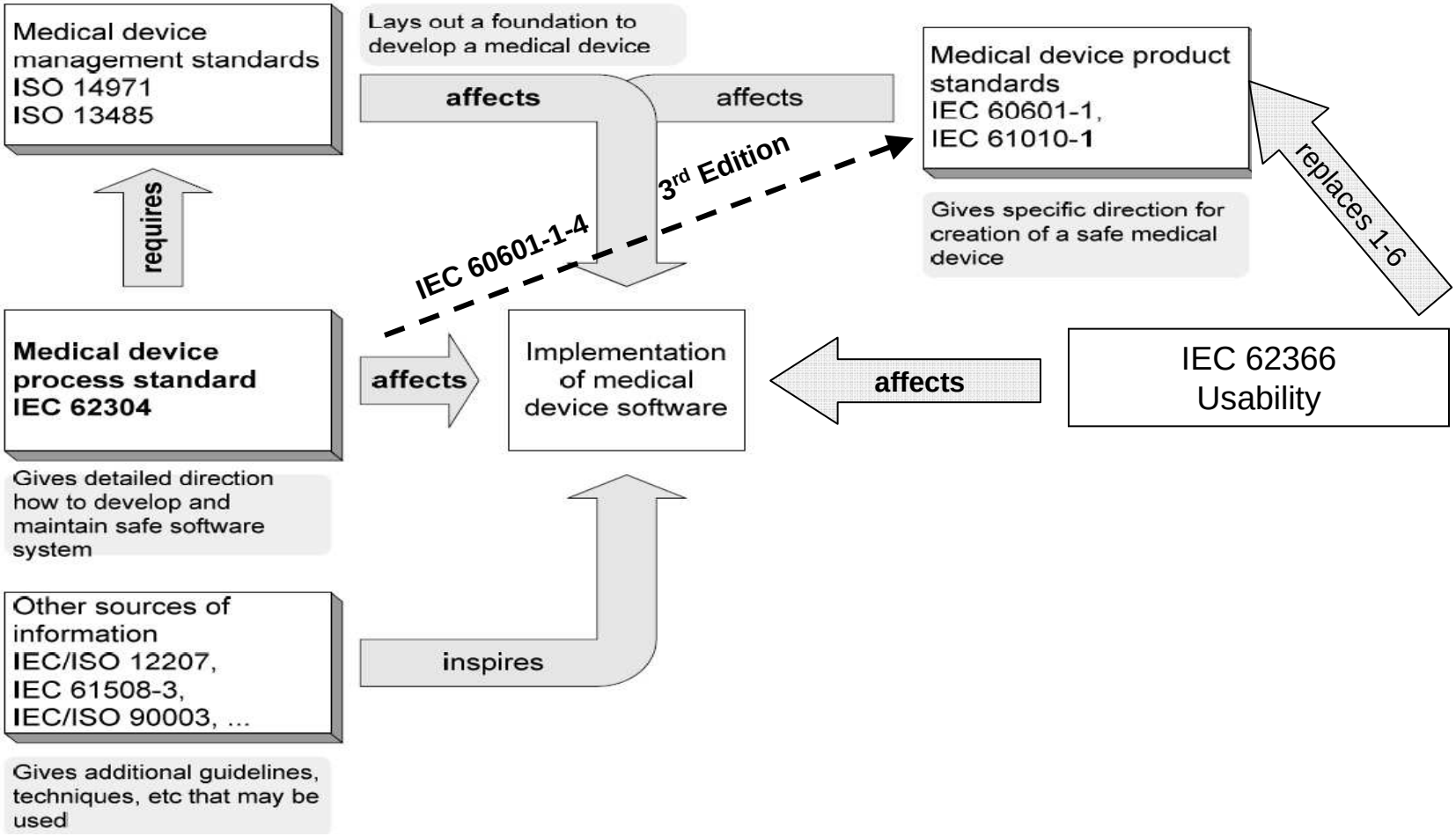


IEC 62304 Overview

IEC 62304 – key facts

- Medical device software – software life cycle processes
- successor of AAMI SW68 (US national standard)
- IEC since May 2006
- EN since March 2007
- harmonized in EU standard 93/42/EWG (MDD) soon
- plugs into IEC 60601-1 Edition 3 others will follow
- development driven by FDA recognized by FDA
- likely to emerge as the single global standard for medical device software engineering
- comply once …use many times!
- guidance paper being prepared

IEC 62304 – Relationship to other standards



IEC 62304 – General requirement

- There is no known method to guarantee 100 % SAFETY for any kind of software. There are three major principles which promote SAFETY for MEDICAL DEVICE SOFTWARE:

  - **RISK MANAGEMENT**
  - **QUALITY MANAGEMENT**
  - **SOFTWARE ENGINEERING**

IEC 62304 – Scope

Purpose	This standard defines the **life cycle requirements** for medical device software. The set of – **processes,** – **activities, and** – **tasks** described in this standard establishes a common framework for medical device software life cycle processes.
Field of Application	This standard applies to: – **the development and maintenance of medical device software,** – to the development and maintenance of medical device software when software **is itself a medical device** or when software **is an embedded or integral part** of the final medical device, – does not cover validation and final release of the medical device, even when the medical device consists entirely of software.

IEC 62304 – Out of scope

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

- What is a medical device??
  - Also in scope supporting tools (I&C) for the medical device
  - Internal process / manufacturing software are not medical devices but
    ➔ process can be used as well – voluntary standard

IEC 62304 – Core processes

- Software development process
- Software maintenance process
- Software risk management process
- Software configuration management process
- Software problem resolution process

IEC 62304
Key Concepts

IEC 62304 – Key concepts

- Safety Classification of Software System and Software Items 

- Software Risk Management 

- Unknown Software (SOUP) 

- The software life cycle doesn't end with product release
  - Maintenance
  - Problem resolution

Software Safety Classification

IEC 62304 – Software safety classification

- RISK: combination of the severity of injury and the probability of its occurrence
  - no consensus on how to determine the probability of occurrence of software failures using traditional statistical methods.
  - therefore, SOFTWARE SYSTEM classification is based on the severity of the HAZARD resulting from failure of the software, assuming that the failure will occur (100% probability)

- Software safety class for **Software System** and **Software Items** according to the possible effects on the **patient**, **operator**, or other people resulting from a HAZARD to which the SOFTWARE SYSTEM can contribute.
  - Class A: No injury or damage to health is possible
  - Class B: Non-SERIOUS INJURY is possible
  - Class C: Death or SERIOUS INJURY is possible

IEC 62304 – Software safety classification

- SERIOUS INJURY: injury or illness that directly or indirectly:
  a) is life threatening,
  b) results in permanent impairment of a body function or permanent damage to a body structure, or
  c) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

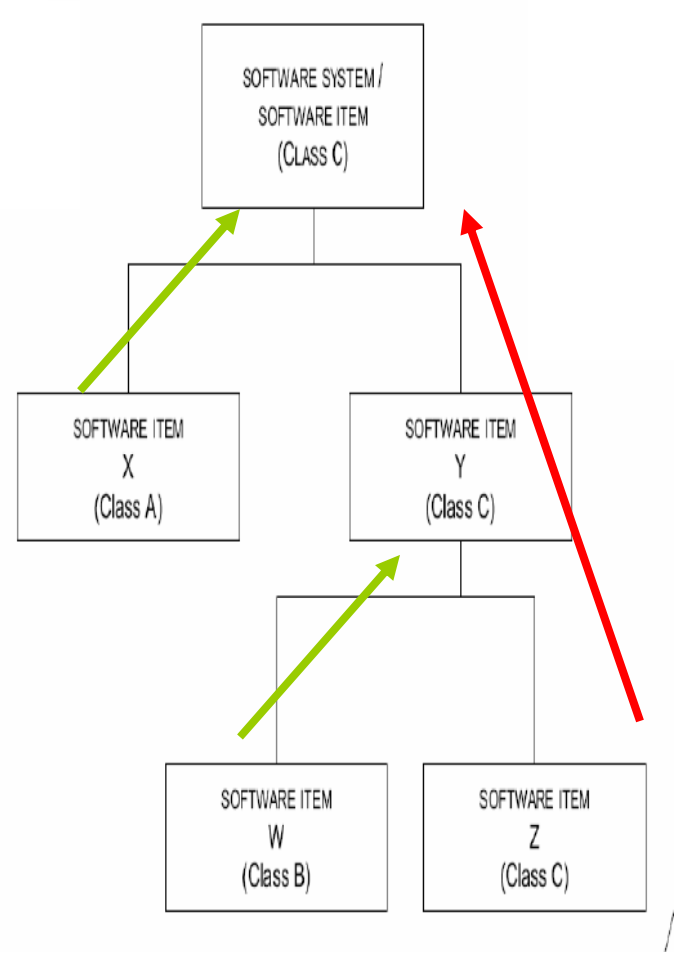
- NOTE: Permanent impairment means an irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

IEC 62304 – Software safety classification?

- determines the PROCESSES to be used during
  - the development; and
  - maintenance of software.
- e.g., architecture for class B, C and component test for class B, C initialization of variables as SW verification acceptance criteria for C
- less rigor process for class A software!

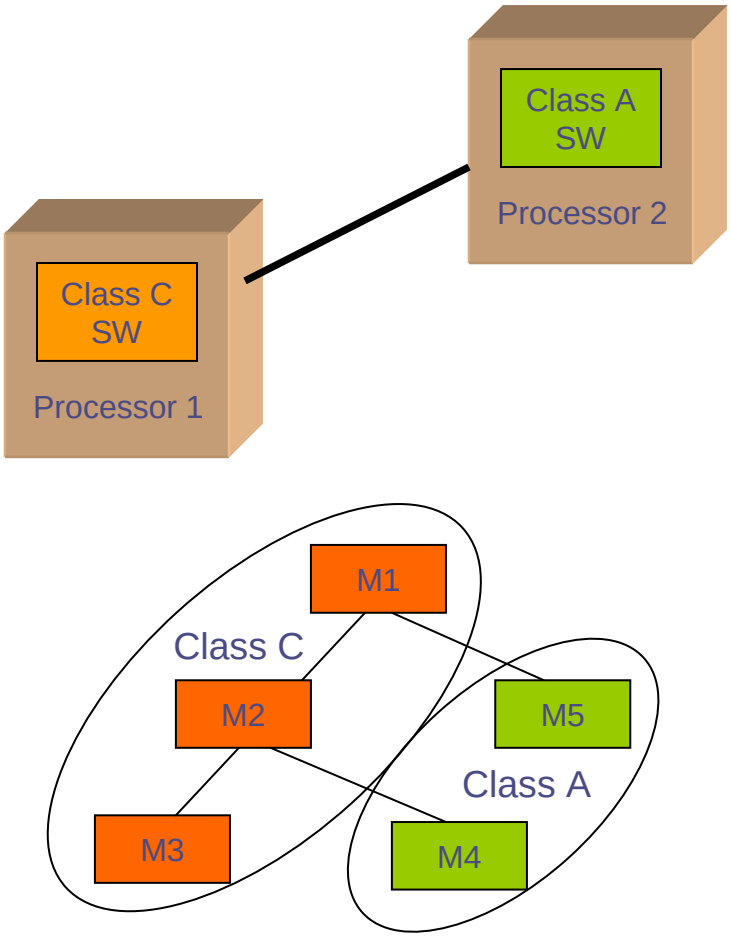
- when a **software system is decomposed into software items,** such **software items shall inherit the software safety classification of the original software item** (or software system)
  - unless the manufacturer documents a rationale for classification into a different software safety class.

IEC 62304 – Assign safety class to software items



- Safety Classification Principles:
  - No adverse side effects caused by X and W.
  - No hazard contributing effects by X and W.
  - Rationale for classification of X and W required!
  - Z includes all software system contributions to hazards.
  - software system inherits “worst” safety class.

IEC 62304 – Software safety classification – best practice



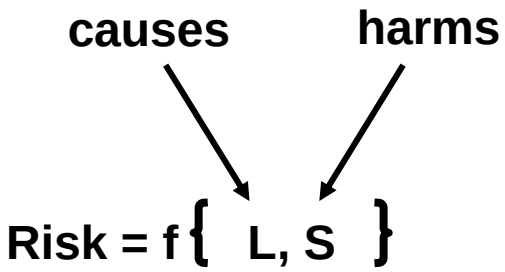
- Segregation of critical SW
  - ➔ clear communication interfaces helps for rationale
  - ➔ cluster critical SW
- Middle grained approach for item
  - ➔ to fine gets impractical
  - ➔ to coarse gets in trouble with SOUP and SW risk management
- Foster reuse of critical components
  - ➔ to save cost
- Introduce automated (unit) testing
  - ➔ i.e. with continuous integration

Software Risk Management

IEC 62304 – Software risk management

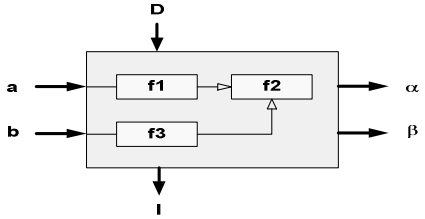
- Software risk management in addition to:
  - ISO 14971 Risk Management!
- additional requirements for RISK CONTROL for software,
  - including software that has been identified during the RISK ANALYSIS as potentially contributing to a hazardous situation,
  - or software that is used to control MEDICAL DEVICE RISKS.
- Rationale behind it:
  - SW developers needs to understand minimum requirements for RISK CONTROL measures implemented in software;
  - ISO 14971 does not address RISK CONTROL of software
- Corresponds to Design Risk Management (Bottom Up)
- Today's practice typically Functional Risk Management (Top Down)

ISO 14971 – Risk management



Risk = combination of the likelihood (**L**) of occurrence of harm and the severity (**S**) of that harm [ISO 14971]

(1) Identify risks re patient / user safety based on



Functional Analysis

(2) Use risk graph as risk evaluation measure

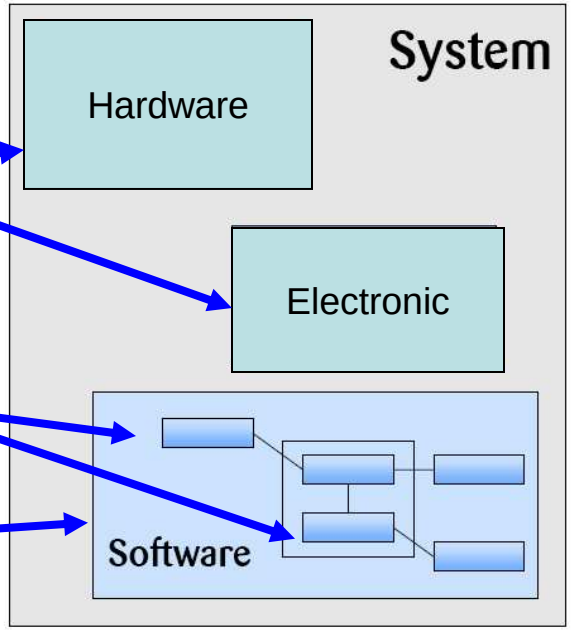
(3) Move risks from red to green area

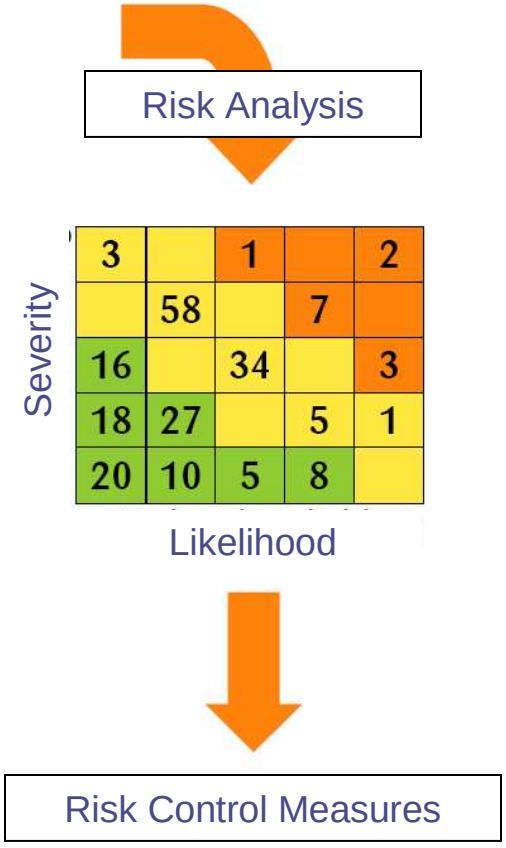
LIKELIHOOD					
	Frequent			Intolerable Region	
	Probable				
	Remote		ALARP		
	Improbable	Broadly acceptable region			
	Incredible				
		Negligible	Light	Modest	Severe
		Severity			

ALARP = As Low As Reasonable Practical

IEC 62304 – Software risk management principle

- same principle for HW and electronic Design-FMEA
- identify software items contributing to hazardous situation
- requires knowledge of architecture





IEC 62304 – Software risk management using FMEA tool

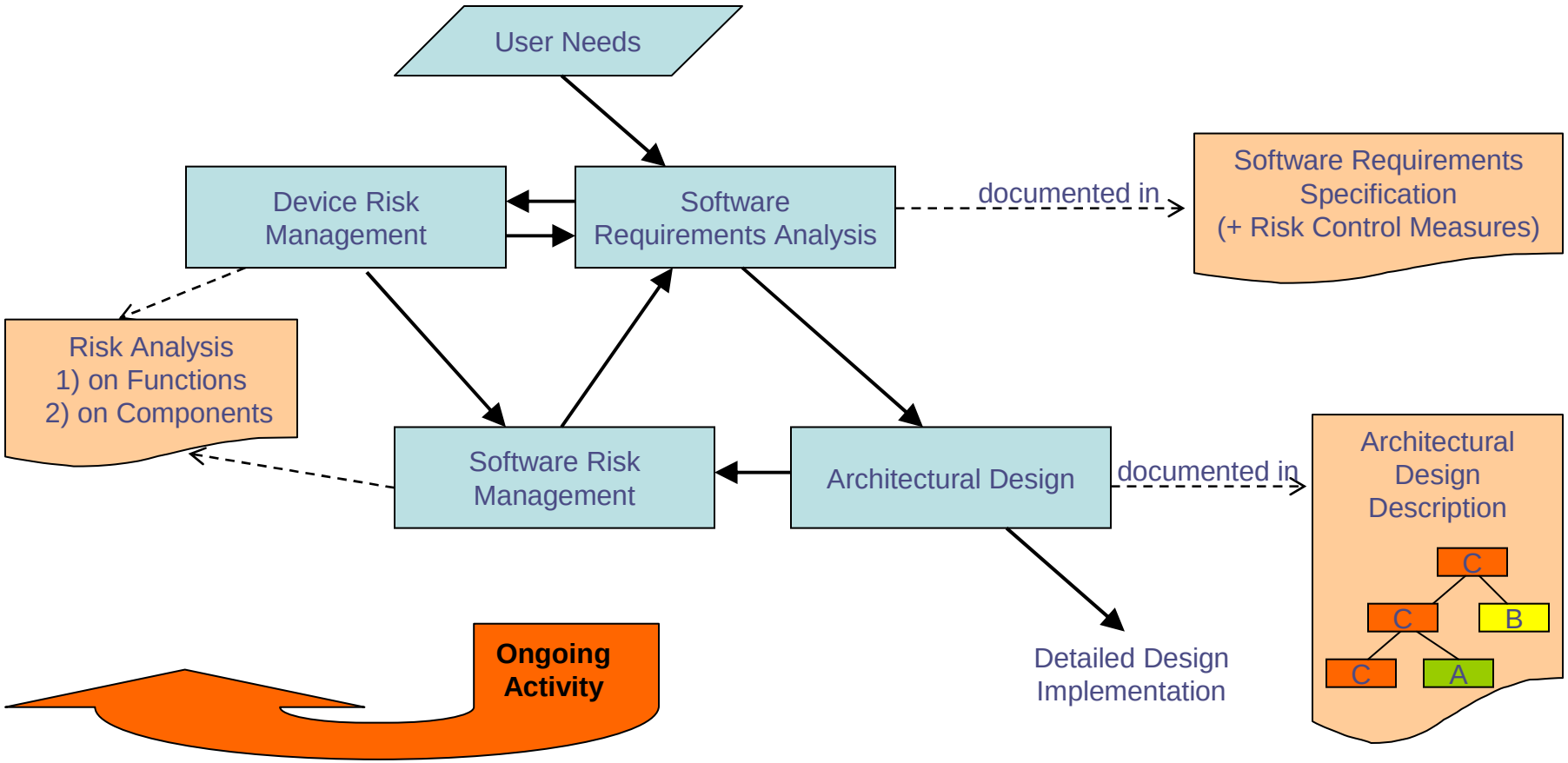
- Used in hardware development
- Most common risk analysis method
- Analyzes the effect of component failure
  - Bottom-up analysis
- Presented in tabular format:
  - Failure Mode
  - Effect on System
  - Cause of Failure
  - Method of Control
- Done by running many meeting with a variety of experts

Ref.#	Item/Function	Failure Mode	Effect on System	Cause	Methods of Control
1	Surgery Case	Does not finish in time	OR time exceeded	Unreliable interrupt source; too much computation; interference from other tasks	Check for loop overrun; system performance measurements; choice of operating system
2	Image import	Wrong orientation	Wrong location penetrated	image information not readable	Exception if information is not available

Software causes

Failure Mode and Effects Analysis

IEC 62304 – Software risk management example process



SOUP

IEC 62304 – SOUP concept

- SOUP – Software of Unknown Provenance
  - that is already developed and generally available and that has not been developed for the purpose of being incorporated into the MEDICAL DEVICE (also known as “off the-shelf software”)
  - or software previously developed for which adequate records of the development PROCESSES are not available

- Additional requirements for SOUP
  - Configuration management of SOUP: vendor, title, version, …
  - Specify functional and performance requirements of SOUP item
  - Specify SYSTEM hardware and software required by SOUP item
  - include in software risk management
  - Evaluate list of anomalies if failure or unexpected result is contributing to a hazardous situation

IEC 62304 – SOUP best practice

- Include SOUP requirements in deal with 3rd party SW supplier
  - shall provide bug list
  - shall allow audits
  - prepare for increased requirements
  - knock out criteria for many large standard COTS suppliers
- Specify scope of SOUP
  - template for SOUP description
  - for example, also practical for declaring license policy
- Configuration management
  - add SOUP software to your SCCS

IEC 62304
QM System Mapping

IEC 62304 – QM System mapping example

SW development process	SOP Software Life Cycle
SW maintenance process	SOP Change Management Process / CAPA process
SW risk management process	SOP Risk Management Process
SW configuration management process	SOP SCCS
SW problem resolution process	During development ➔ SOP Issues Management After release ➔ SOP Change Management / CAPA

SOP = Standard Operating Procedure

Summary

Summary

- IEC 62304 emerging as the de facto standard in medical software
- Many FDA 510(k) submission reference already IEC 62304
- Adopts safety elements from defense industry (DOD)
- Understanding not trivial at a first glance, but seems practicable
- FMEA tool from hardware engineering makes sense for SW as well
- SOUP handling implies trade-off between make or buy
- Class C requirements are hard to achieve for standard SW like mainstream OS and standard IDE's
- Not much difference between class C and B in regard to effort
- Where does software end and electronics begin
  - firmware, device drivers, micro code, FPGA, CPLD
- Not a standalone engineering standard requires ISO ….

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Thank you!

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