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Live Webinar*

**How to do an Effective Hazard Analysis to meet FDA
and ISO13485:2003 Risk Management Requirement**

Wednesday, September 7, 2011

10:00 AM PDT | 01:00 PM EDT

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Course Disclaimer

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Risk Management

Process of:

- identifying
- reducing
- managing
- and verifying

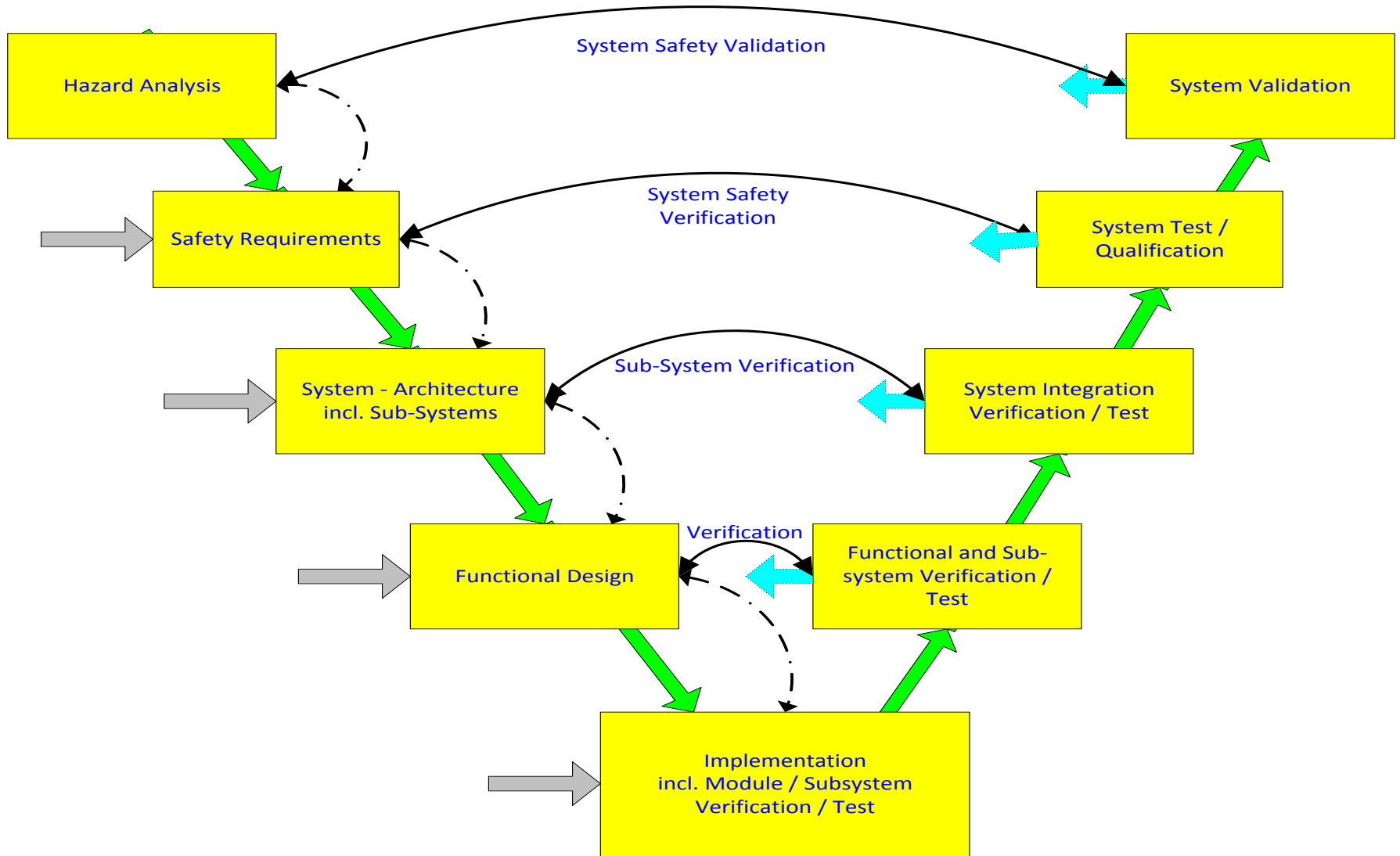
risk and risk reduction throughout the device development and deployment (the entire product life cycle).

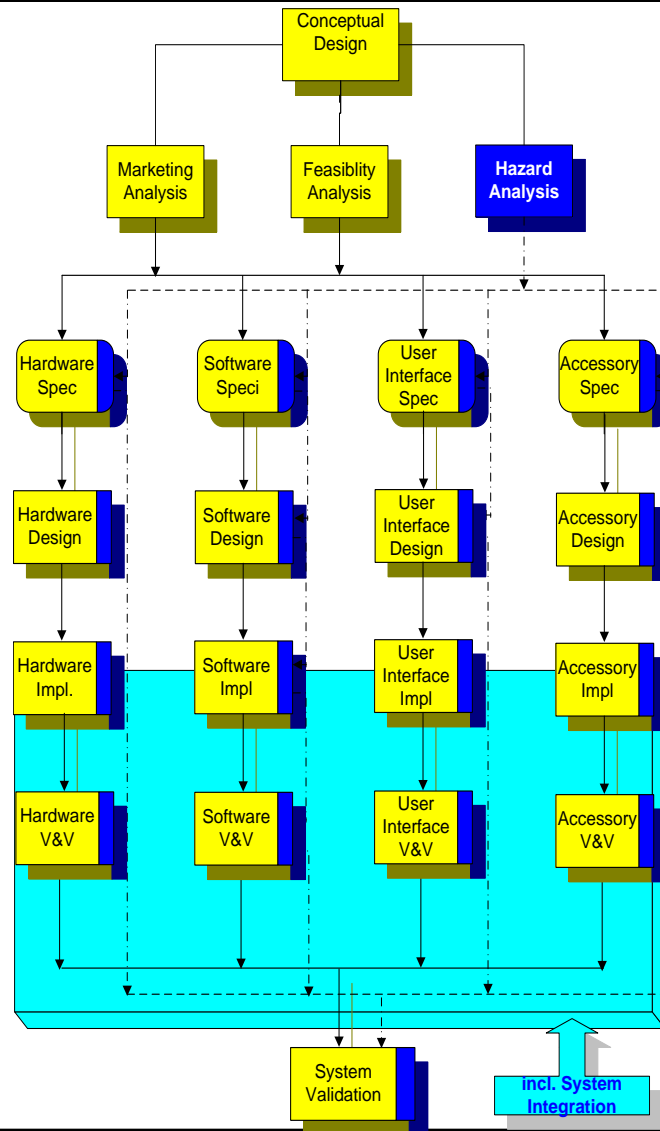
Purpose

- How to integrate Risk Management into an existing QA system
- The Risk Management life cycle
- How to perform an effective Hazard Analysis
- Achieving compliance with minimized effort and high effectiveness

Is Risk Management mandatory?

- ISO 13485:2003 states in 7.1 "The organization shall establish documented requirements for **risk management** throughout product realization. Records arising from risk management shall be maintained."
- QSR (21 CFR 820.30) Design Controls states that Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. ...
- ...Design validation shall include software validation and **risk analysis**, where appropriate.





Risk Management does not end here !

- **Post-production information**

The manufacturer shall establish and maintain a systematic procedure to review information gained about the medical device or similar devices in the post-production phase.

The results of this evaluation shall be recorded in the risk management file.

How to integrate Risk Management

- Separate set of SOPs and WIs
 - May lead to a separation of RM and other QA activities
 - Cumbersome if combined activities occur (e.g. design reviews)

- Integration into existing or new SOPs / WIs
 - Frequent update may be necessary

Risk Management Plan

- The scope of the plan, identifying and describing the medical device and the life cycle phases for which this plan is applicable
- A verification plan
- Allocation of responsibilities
- Requirements for review of risk management activities and
- Criteria for risk acceptability
- Deliverables and activities (Documentation, audits, reviews)
- Resource allocation

Hazard and Risk Analysis

- A systematic methodology to:
 - Identify potential causes of harm (Hazard Identification) including hypothetical sequences of events leading to a hazard
 - Estimate the severity of the hazard
 - Rate the risk of the unmitigated hazard (severity times probability)
 - Identify possible risk mitigations
 - Rate the resulting risk of the mitigated hazard (severity times probability)

Hazard Analysis: Preparation

- Define as much information as possible before the first meeting
- Define Scope, Use environment, Qualitative and Quantitative Properties
- Set up risk rating schema including probability and severity ratings
- Identify hazard groups (inclusion and exclusion) like energy, environment, biologics, user environment

Hazard Analysis: Preparation

- Define use environment
 - Environmental conditions
 - User type (Nurse, M.D., Tech, ...)
 - User environment (ER, Ambulatory, Patient controlled)
- Identify Past problems with Similar Devices
 - ECRI, MDR, MAUDE
 - Standards
 - Scientific and non-scientific articles
 - Experience

Hazard Analysis: Preparation Team Composition

- Not only developers - include
 - Management
 - Clinical
 - Engineering
 - Service / Marketing
 - Human Factors
 - Legal
- Invite and provide pre-meeting information
 - Scope
 - Methodology
 - “Framework”

Hazard Analysis

- NOT a one-time activity but an ongoing process
 - Revisit the Hazard Analysis multiple times during design, implementation, verification and life of the device
 - Documents the maturity of the RM process
 - Should be available to ALL team members
 - Various functions should be able to request review
 - Review results have to flow back into development / manufacturing / service / training

Hazard Analysis: Scope Definition

■ Clinical Boundaries

- Inclusion criteria
- Exclusion criteria

■ Physical Boundaries

- Mains connection / grid
- Connected devices

■ Implicit Assumptions

- Sabotage / maintenance / installation
- User skill

Hazard Analysis: Device Environment

- Define use environment
 - Environmental conditions
 - User type (Nurse, M.D., Tech, ...)
 - User environment (ER, Ambulatory, Patient controlled ...)
- Identify Past problems with Similar Devices
 - ECRI, MDR, MAUDE
 - Standards
 - Scientific and non-scientific articles
 - Experience

Hazard Analysis: Hazard Identification

- Scope of Analysis
- Identification of unmitigated hazards
- Identification of potential hazard sources (cause analysis)
- Grouping and structuring hazard list (use ISO14971)
- Multiple hazards / multiple causes
- Chain-of-event hazards

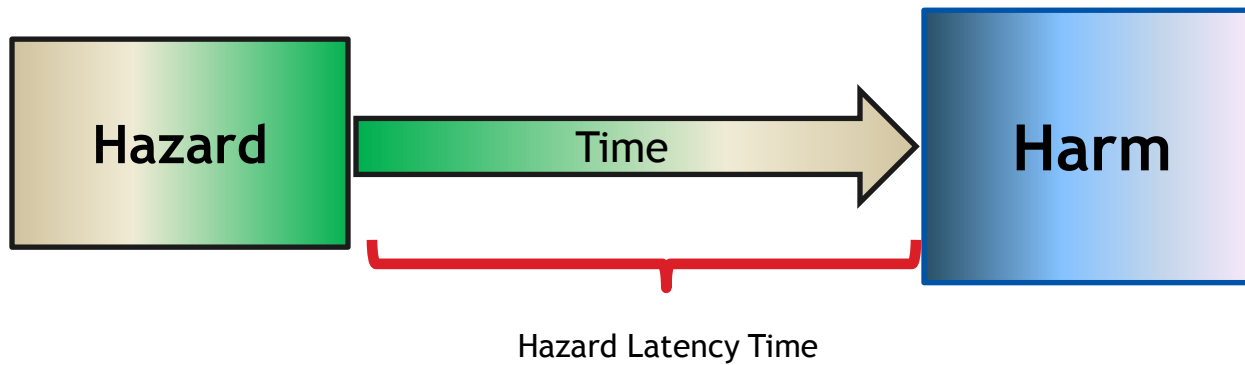
Hazard Analysis: What is a Hazard ?

- Difficulty to identify level at which a hazard is defined:
 - Cell hypoxia
 - Loss of blood circulation
 - Cardiac fibrillation
 - Electric shock
 - Loss of mains isolation
 - Degradation of isolation material
- Hazard: Harm after latency time and lowest clinical level
- Hazard Cause: Highest technical / organizational level

Hazard Characteristics

- Resulting Harm
- Hazard latency time
- Hazard cause
 - Hazard cause grouping like ISO14975:
 - Energy hazards
 - Biological and chemical hazards
 - Operational hazards (Functional)
 - Information hazards (Labeling)
- Observability

Harm turns into Hazard



Hazard Analysis: Determining Risk

- Risk = Severity * Probability

		Severity			
		I Catastrophic	II Critical	III Marginal	IV Negligible
Likelihood	A – frequent				
	B – probable				
	C – occasional				
	D – remote				
	E – improbable				
	F – incredible				

Hazard Analysis: Qualitative vs. Quantitative

- Only use qualitative assessment if:
 - Data is available to quantify the Probability or Risk
 - Data is verifiable
 - Data is specific to hazard scenario

- This leaves a qualitative assessment in 99.9% of the cases

Hazard Analysis: Mitigation

- Inherent safe design
- Protection measures including alarms
- User information about residual risks

Hazard Analysis: Requirements (mitigations)

- Define the device functionality and documentation
 - Functional requirements
 - Efficacy requirements
 - **Safety requirements**
 - Documentation requirements

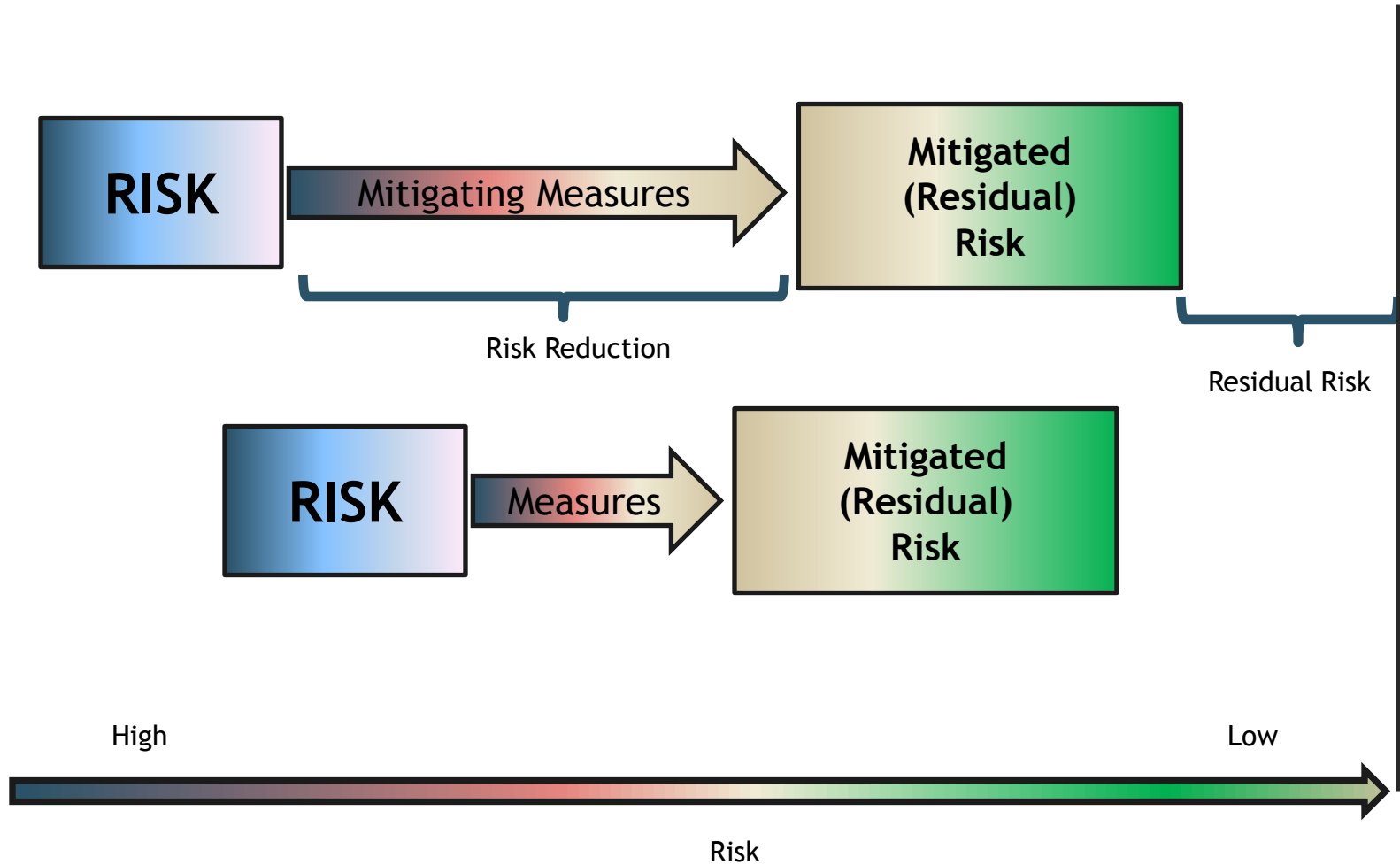
Hazard Analysis: Post Mitigation Risk Assessment

Mitigated Risk = Mitigated Severity * Mitigated Probability

Risk Reduction = Unmitigated Risk - Mitigated Risk

Safety Integrity depends on Risk Reduction

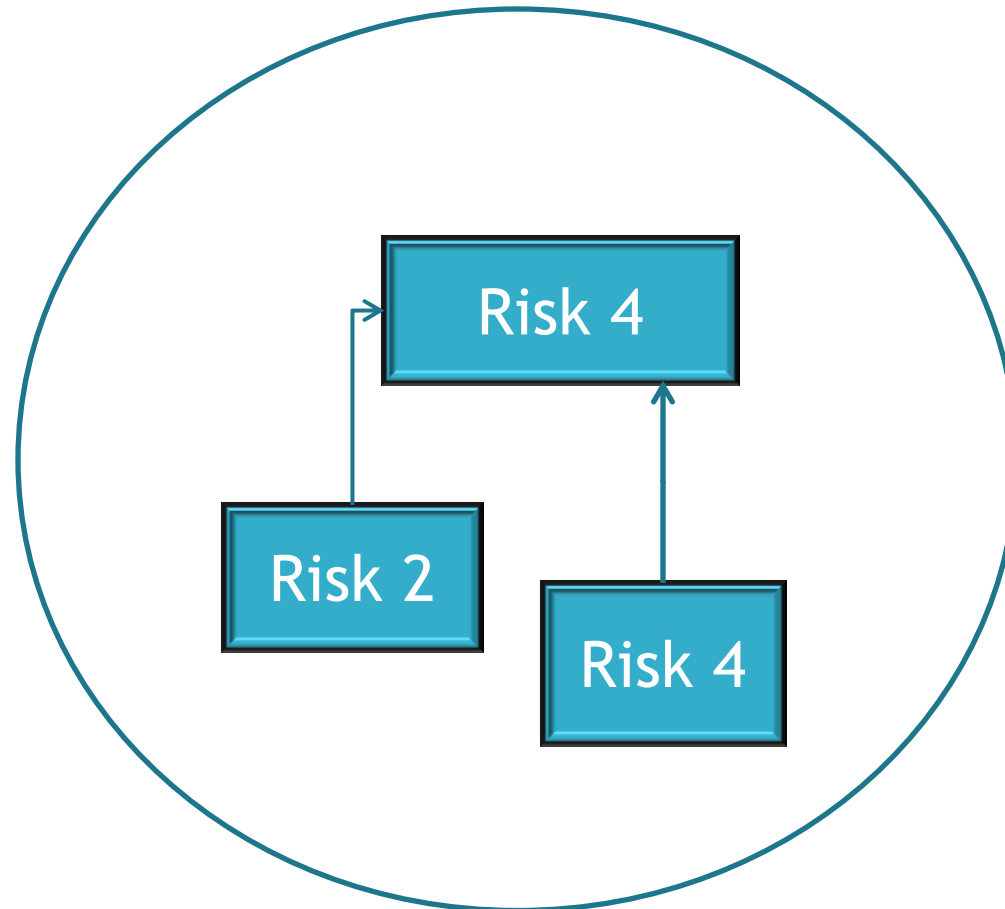
Hazard Analysis: Risk Reduction



Risk Inheritance

- **IEC 62304:** When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further 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. Such a rationale shall explain how the new SOFTWARE ITEMS are segregated so that they may be classified separately.

Risk Inheritance



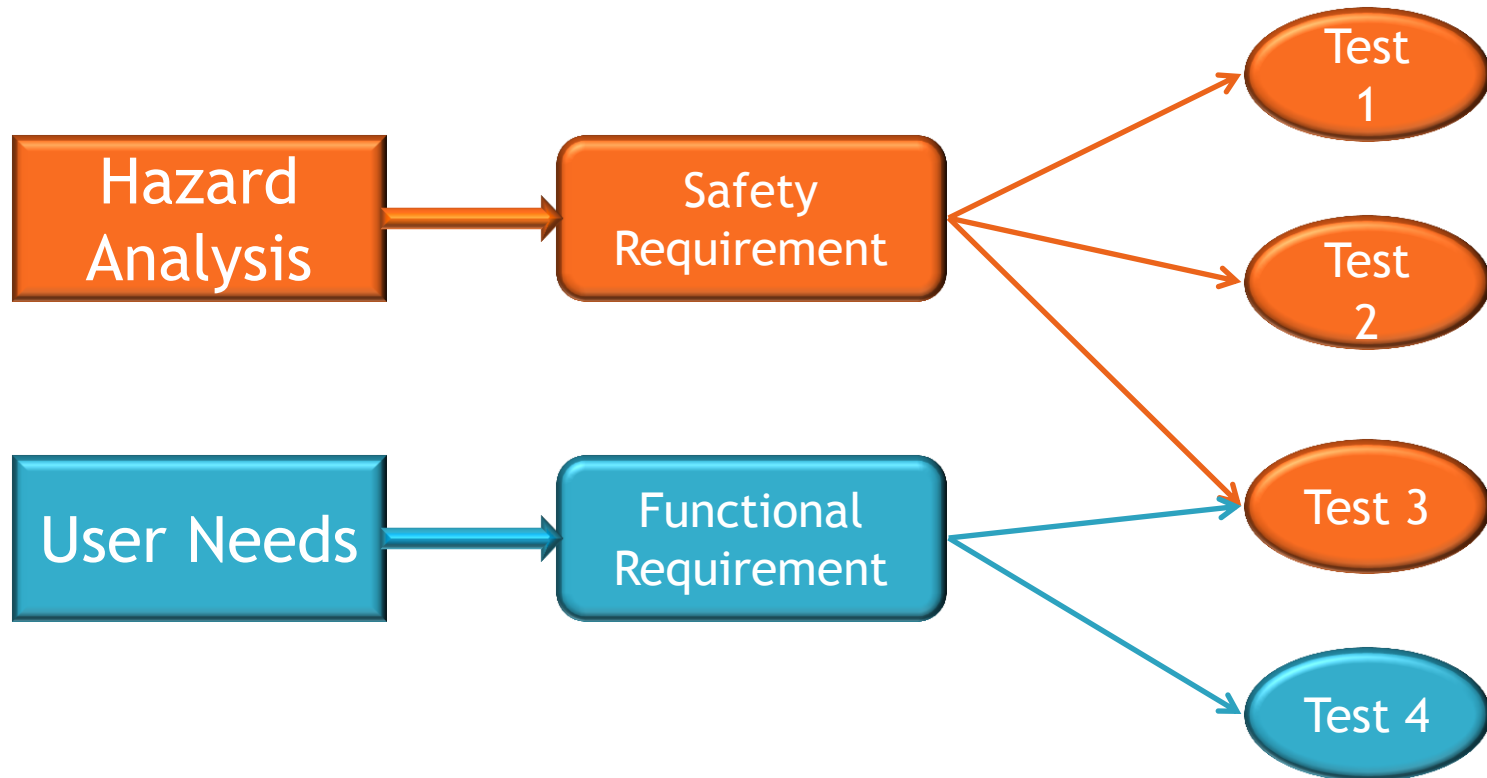
Implementation

- Reviews (documented)
- Audits
- Documentation of risk related design decisions
- Identification of new hazard generated by design

Verification and Validation

- Amount of Rigor for Safety Requirements
- Traceability
- Big three “C”s
 - Completeness
 - Correctness
 - Coverage

Requirements Traceability



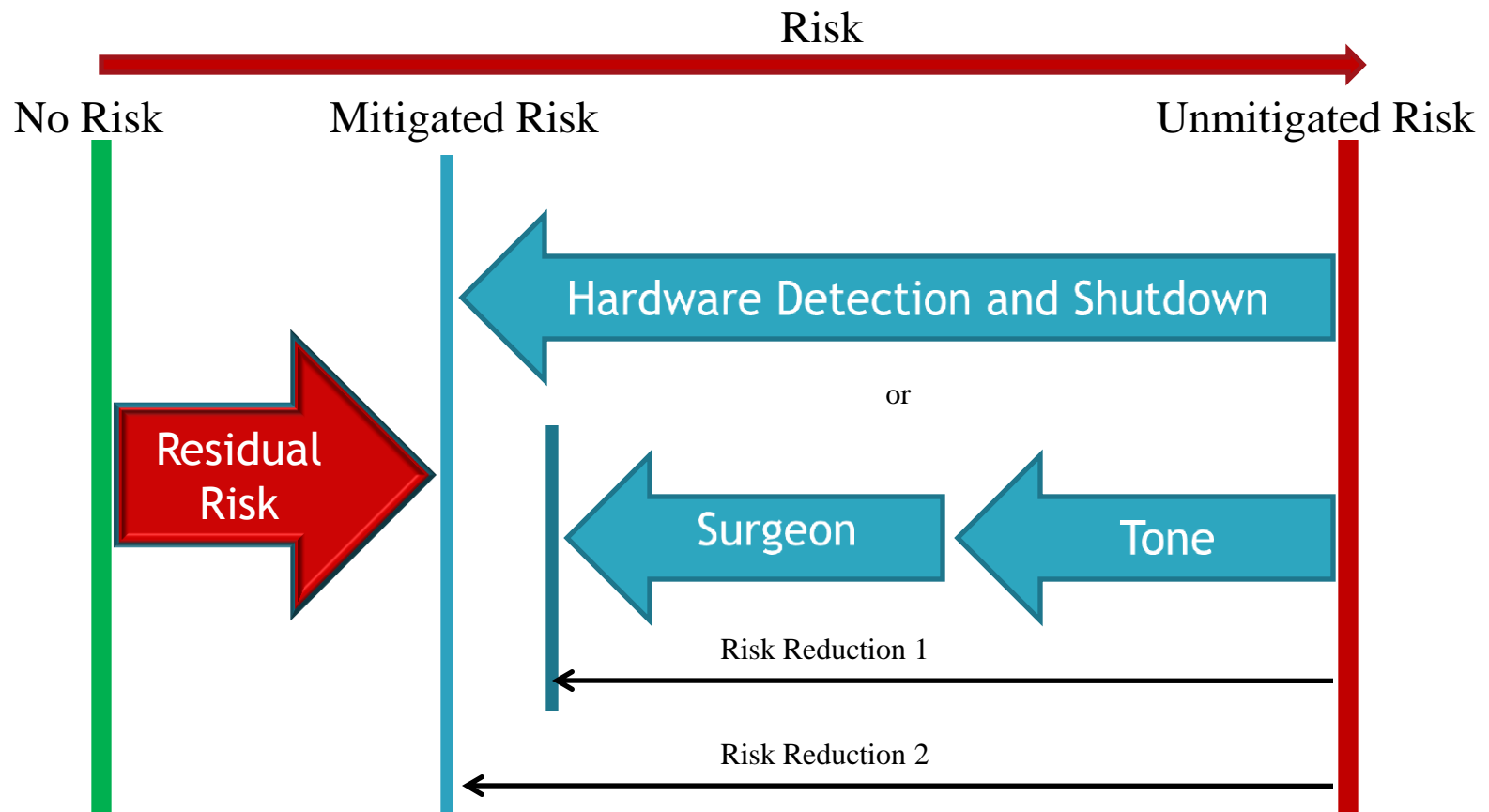
Traceability

- Hazard (n)
 - Mitigations ($m*n$)
 - Requirements ($l*m*n$)
 - Test cases ($k*l*m*n$)
 - Test report ($j*k*l*m*n$)

Risk Management Report

- Traceability for each hazard to the risk analysis
- The final (at the end of the development) risk evaluation
- The implementation and verification of the risk control measures
- The assessment that the residual risk(s) is acceptable

Risk Management Report: Residual Risk



Review and Certification

- Reviews are integral part of the Risk Management Process
(Milestones)
 - Hazard Analysis review
 - Specification review
 - Test plan review
 - Test report review
 - Final project review

- Release / Release to formal verification

Potential Problems

- Missed hazards
 - False or incomplete hazard identification
 - Overconfidence in the process
 - Misunderstanding / different understanding of hazard cause / effect relationships
 - Omission of low criticality hazards
 - Misunderstanding the use environment
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Tips and Tricks

- Use ISO 14971 as template for your Risk Management SOP
 - Adopt ISO 14971 terminology
 - Appoint a Risk Manager
 - Include a Risk Management Section into every document you produce
 - Specifications
 - Meeting minutes
 - Define trigger events for Hazard Analysis Review
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Tips and Tricks

- Identify and label safety critical items originating in hazard analysis (components, requirements, software, documentation)
 - Don't be over-confident in the Risk Management Process
 - Use comments in the Risk Analysis Table to document the rationale behind the rating
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Questions

- If there are any further questions which we were not able to get to today please feel free to contact me through Global CompliancePanel



Past Webinars from Markus Weber

- The Recorded Version of this webinar (streaming) is available from Global Compliance Panel.
- Recorded Webinars :
 - *Risk Management during device design according to ISO14971*
 - *Hazard Analysis - A practical guide*
 - *Hazard Analysis vs. FMECA - Differences and Commonalities*
 - *Residual Risk and Risk based Verification*
- Please Use this link for additional information -

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