The role of Risk Management in EN IEC 62304 by Robert Ginsberg, QAdvis

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Introduction of the speaker

Robert.Ginsberg@QAdvis.com

- 30+ years in SW Development
- 20+ years in Medical Device SW
- Co-author of IEC 62304, 80001-1, 80002-1 and 80002-2
- Working member of Cenelek TK-62

Key competence areas

- Turn key quality systems
- Sharepoint based
- Digital signatures
- Efficient and lean
- Validated and compliant

QMS in-the-cloud

- Project management
- Product software validation
- Regulated software validation
- Requirement managent
- Risk management
- Verification and validation
- SQA

System development

- Interim management
- Expert advise
- Audits/Mock audits/assessments
- Remediation, WL, Import detention, compliance projects
- PMA, 510k, CE-mark, EC-cert
- Vigilance, recall, post market surveillance
- Clinical evaluation/clinical expertise
- Standards (ISO 13485, ISO 14971, IEC 62304, IEC 62366, …)

QA&RA Consulting

- CE-marking
- ISO 13485
- EN 62304
  - SW life cycle
  - Risk management
- QSR
- Lean and Six sigma

Training/courses

- Training and Consulting
- In cooperation with Oriel Stat a Matrix

Oriel - Lean and Six Sigma

- Providing European representation for non-EU MedTech companies
- Active member of EAAR: European Association of Authorised Representatives

European Authorized Representation

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Before we start …

- There will be time for questions after the presentation
- You can use the chat function to contact the convener, Sebnem Hoffsten
- More complicated question, please call or email:
  - +46 8 621 01 05
  - robert.ginsberg@qadvis.com

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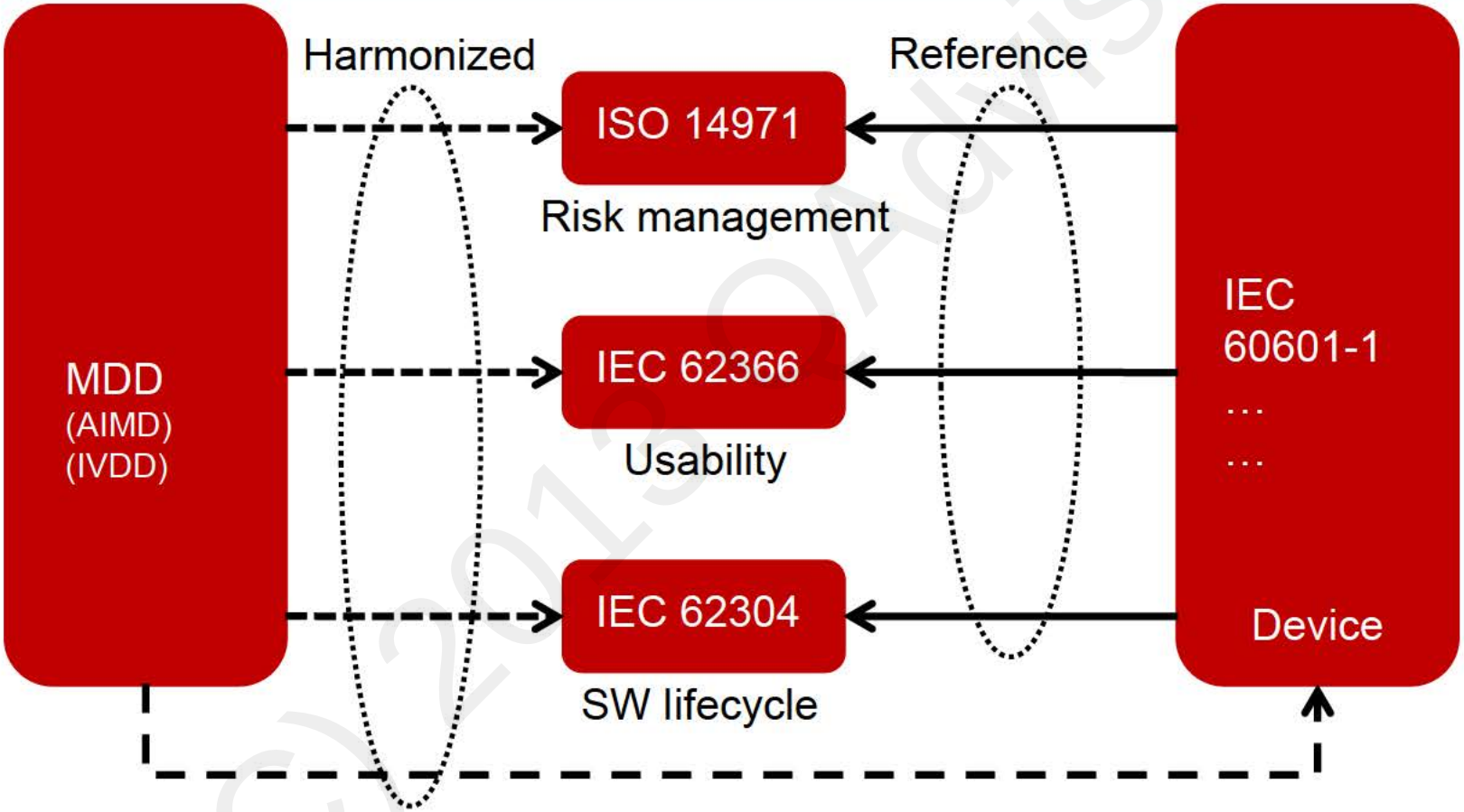
The Big Picture for software in a Medical Device regarding MDD



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IEC 62304 calls for RM activities through the whole development lifecycle

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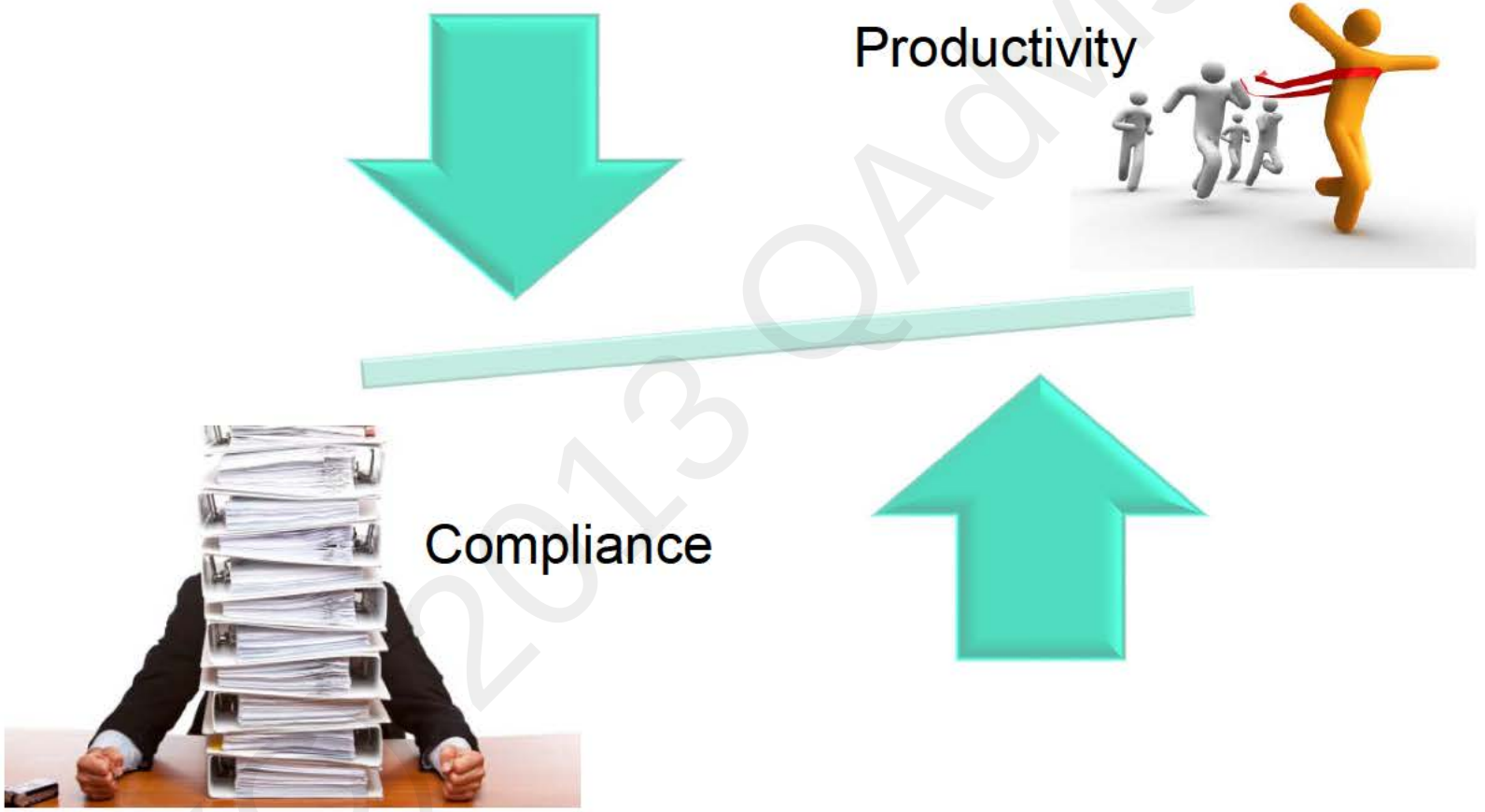
QA and SW engineers have to find efficient implementation of IEC 62304

It is challenging to find a proper level of effort for SW RM



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Risk mgmt can enable effective, safe and compliant V&V strategy

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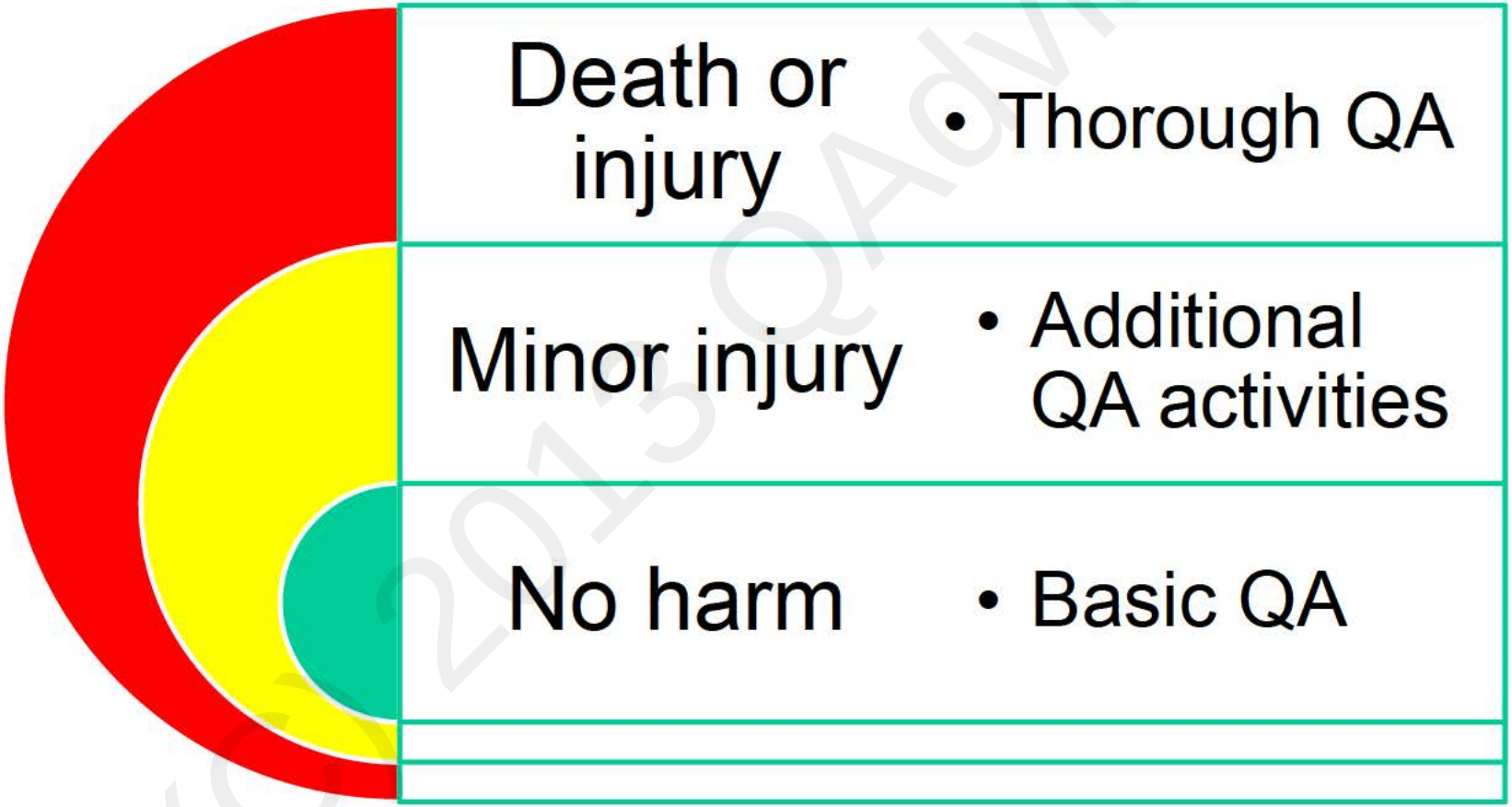
Use SW risk mgmt to regulate your efforts when testing the product



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Governments and Agencies are enforcing new regulation across time

EU-Commission/US Government
MDD/Public Health Service Act

Agencies
Medical Products Agency/FDA

Laws and Regulations
SFS 1993:584/21 CFR 820

Guidance docs
Standards – 13485, 14971, 62304

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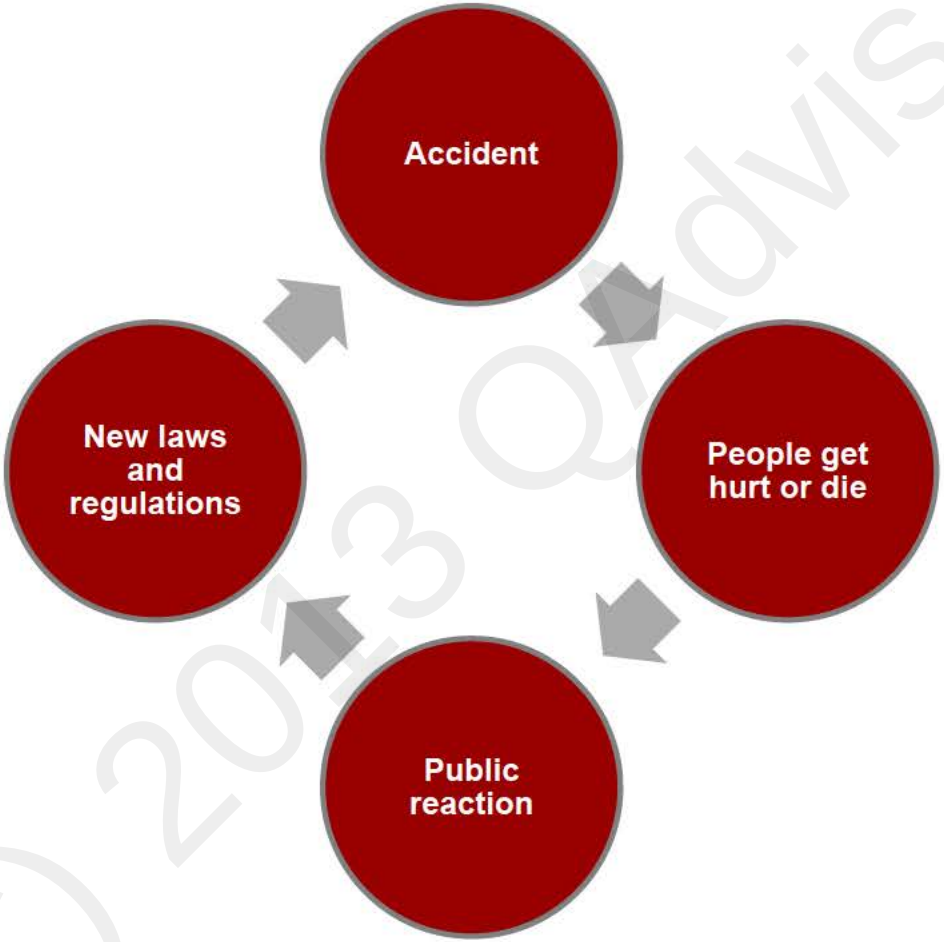
The Bar is Raised Over Time



Patient journal mix up caused death of a young woman

Case report: Socialstyrelsen 2007

”When Sofie came into ER, the treating doctor used the wrong patient journal. In the computerized journal system at the hospital there were two patients with similar names and social security numbers. Based on the contents of the wrong journal Sofie was treated with drugs that led to her death.”

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There is a new version of EN 14971 addressing acceptance criteria

SS-EN ISO 14971:2012 (E)

3. Risk reduction "as far as possible" versus "as low as reasonably practicable":

a) Annex D.8 to ISO 14971, referred to in 3.4, contains the concept of reducing risks "as low as reasonably practicable" (ALARP concept). The ALARP concept contains an element of economic consideration.
b) However, the first indent of Section 2 of Annex I to Directive 93/42/EEC and various particular Essential Requirements require risks to be reduced "as far as possible" without there being room for economic considerations.
c) Accordingly, manufacturers and Notified Bodies may not apply the ALARP concept with regard to economic considerations.

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Quality assurance techniques have a long history in the industry

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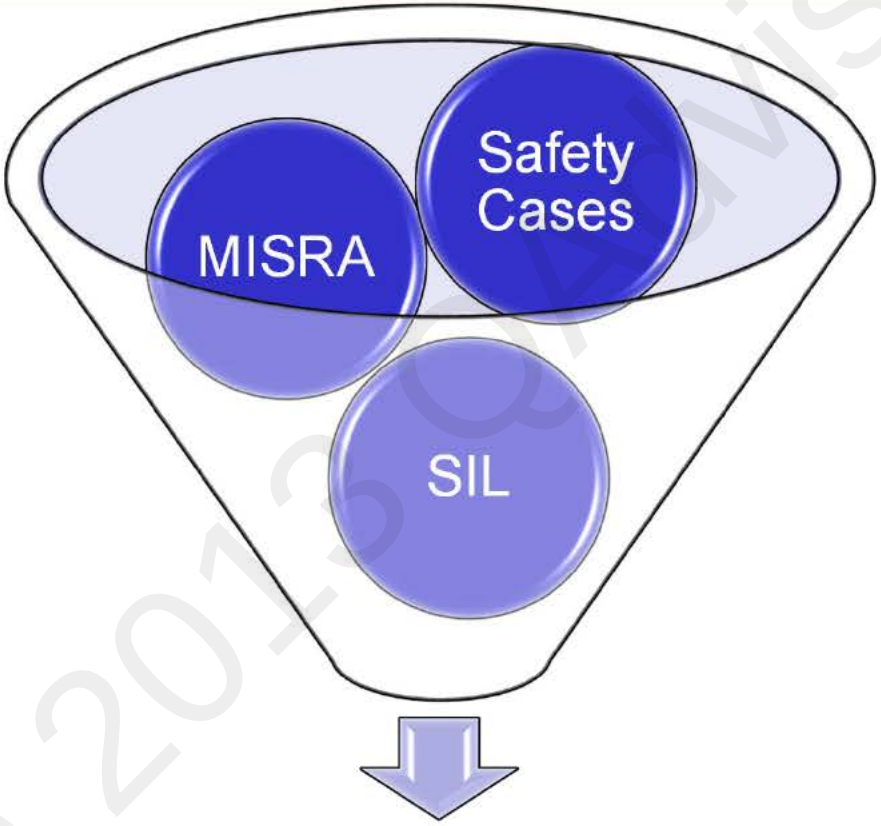
There is a migration of QA techniques to the Medical Device area



Medical Device guidelines

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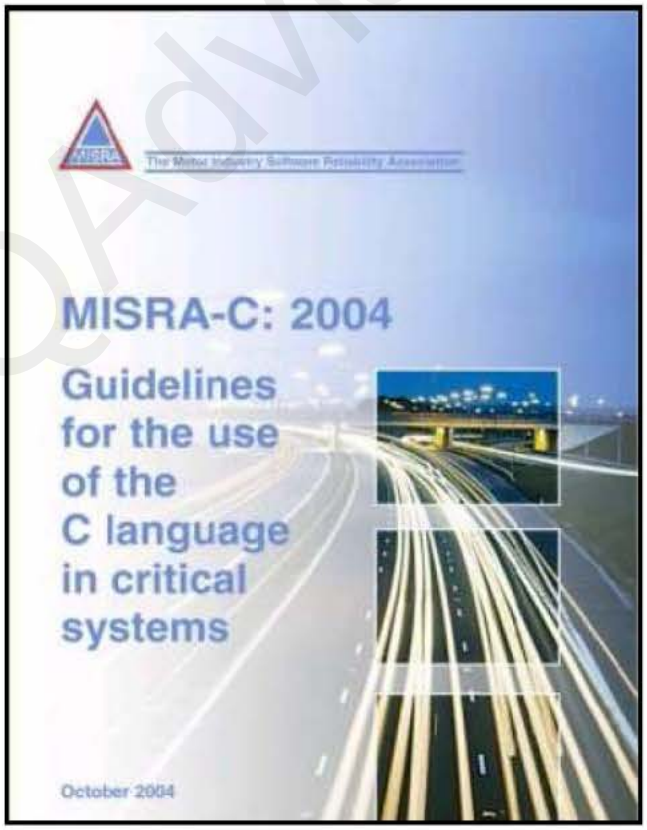
FDA is expecting static analyzers to be implemented as part of the V&V

MISRA-C:2004

- Guidelines for the use of the C language in critical systems

- October 2004



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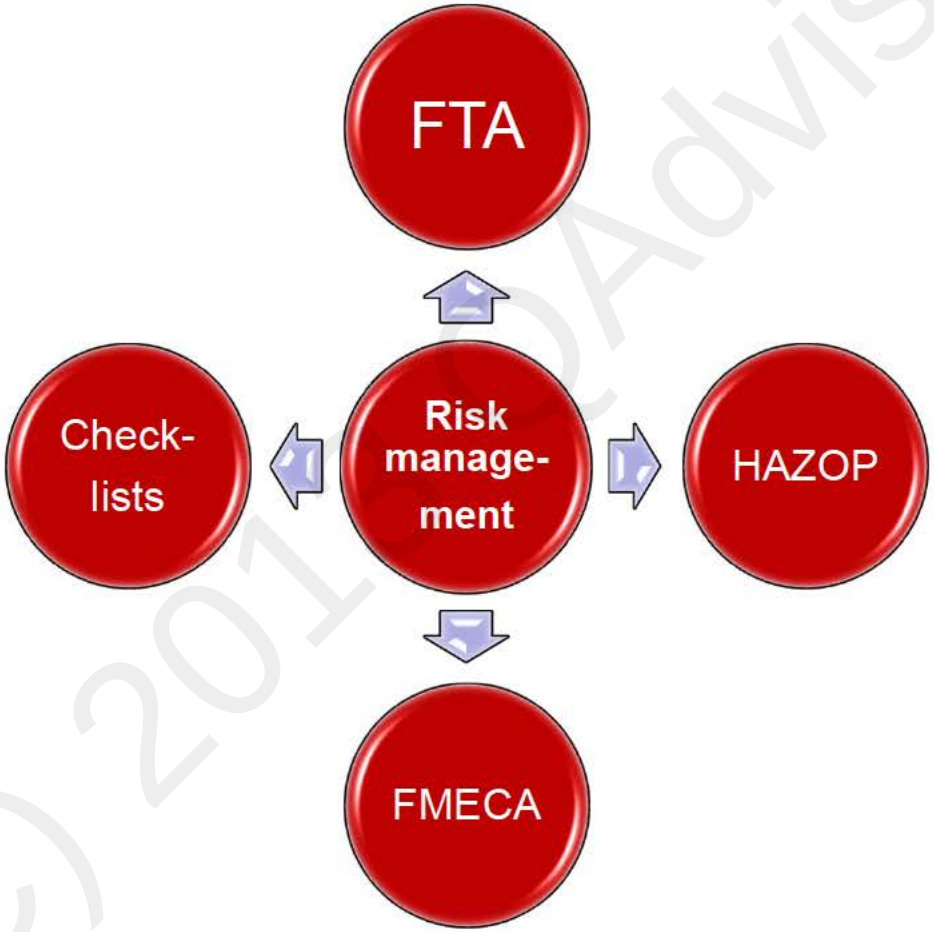
There is a number of techniques available for Risk Management



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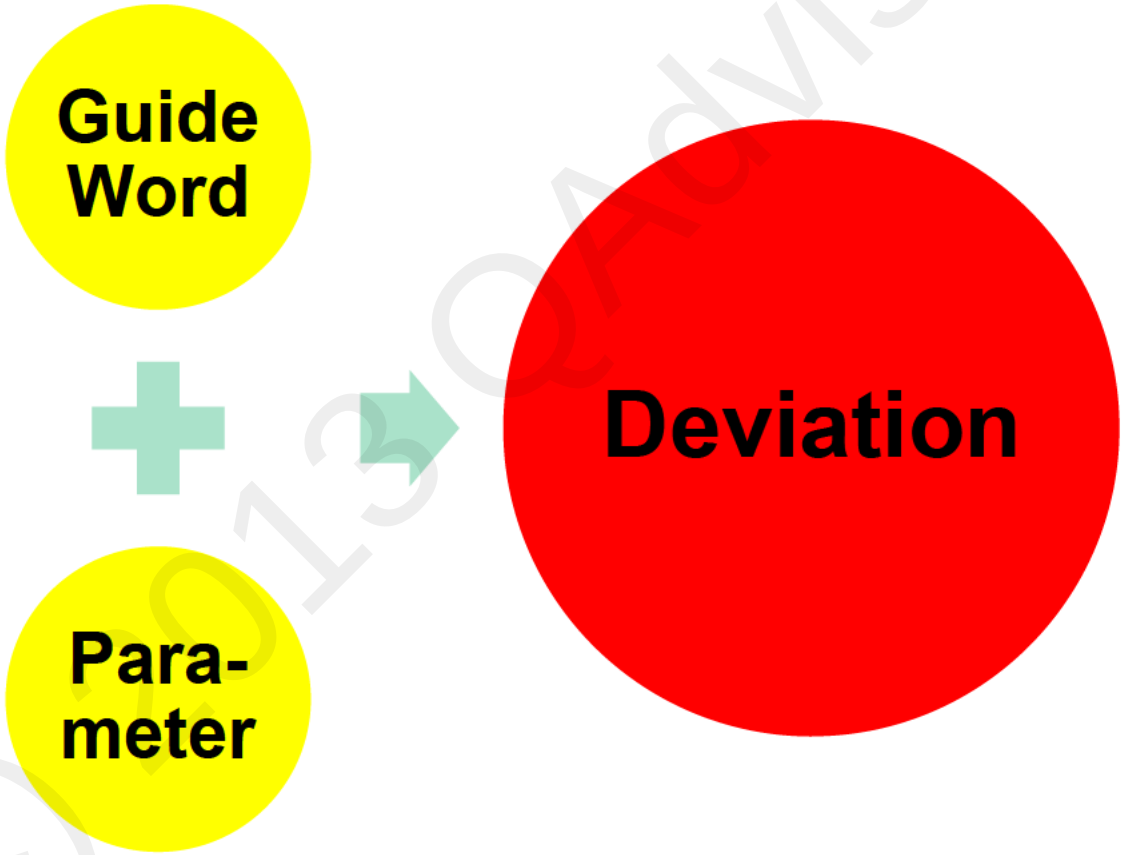
HAZOP Methodology use guide words as a “creativity trigger” for hazards



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HAZOP can be used for detecting usability related hazards

Study title: Patient Journal retrieval							Page: of		
Drawing no.:			Rev no.:				Date:		
HAZOP team:							Meeting date:		
Part considered: Hospital information system									
Design intent:			Material: Source:		Activity: Destination:				
No.	Guide-word	Element	Deviation	Possible causes	Conse-quences	Safeguards	Comments	Actions required	Action allocated to
1	Other than	Patient Identific-ation	Other patient than expected was selected	Similar social security number in picklist	Wrong treatment	Full social security no. has to be entered	Verification vs patient name still needed	Mandatory approval of correct patient name	RoGi

– Source: IEC 61882

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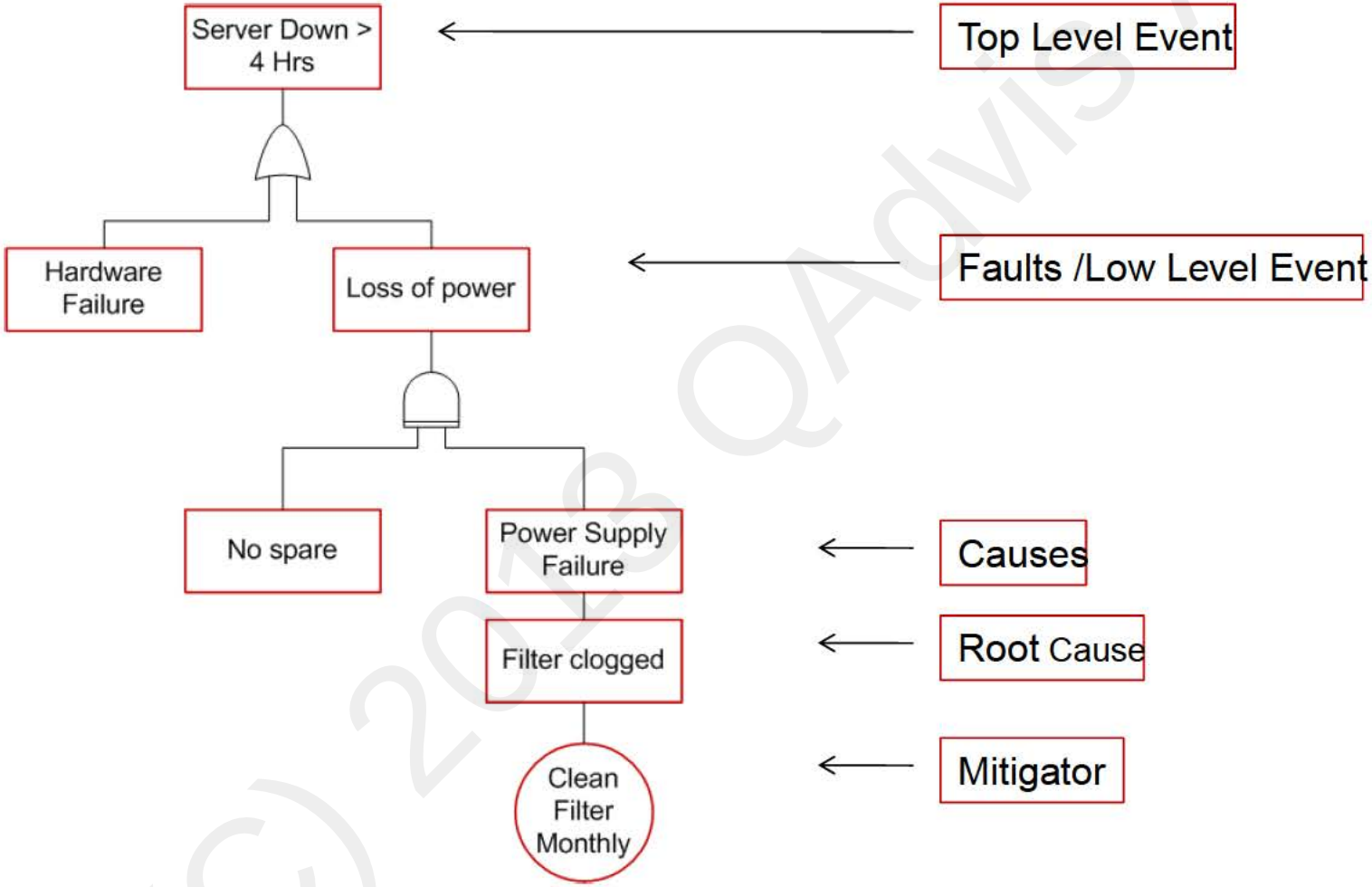
Fault Tree Analysis is a top down technique useful at early stages



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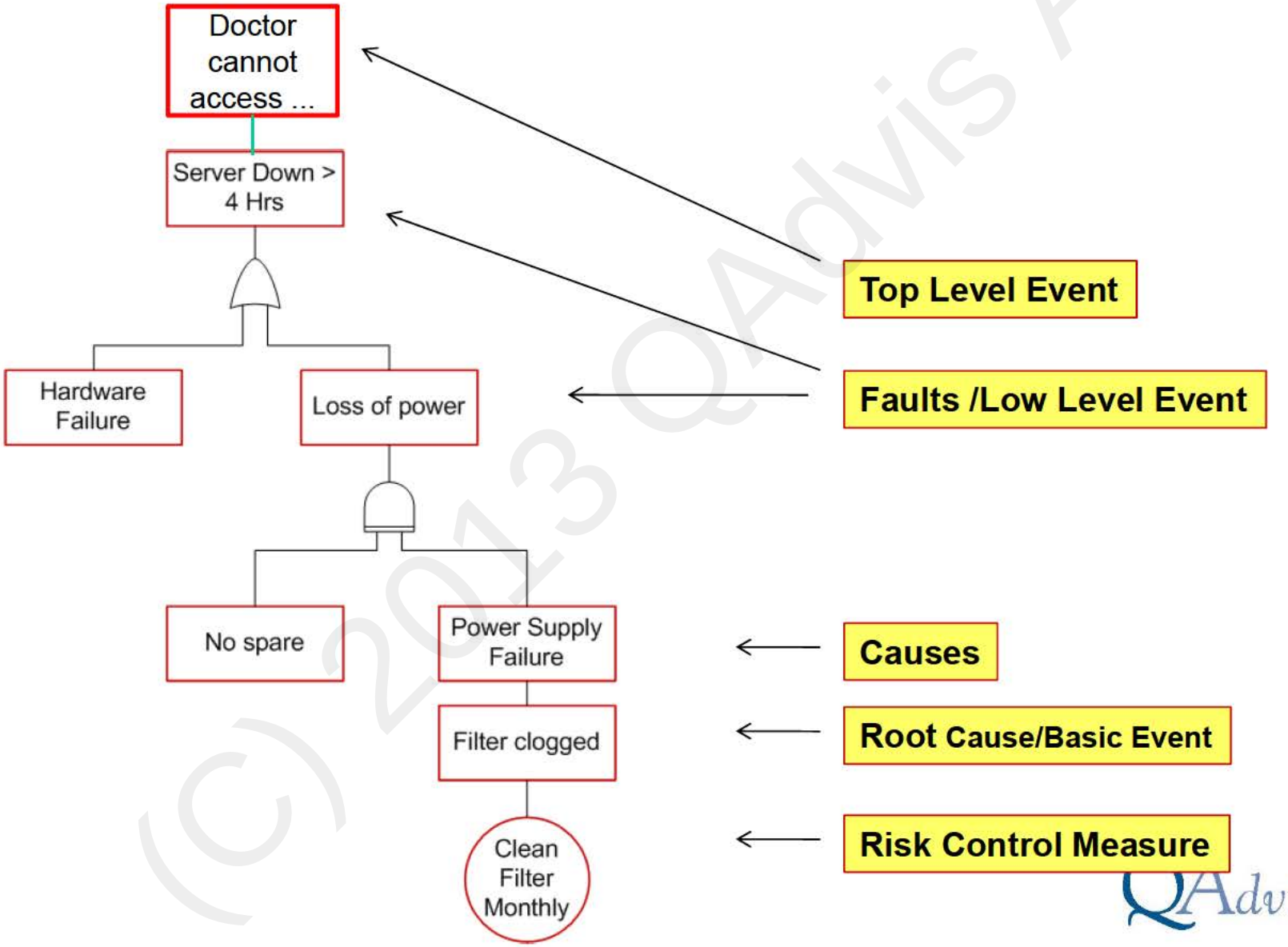
Example of a Fault Tree Analysis for:
Doctor cannot access patient records



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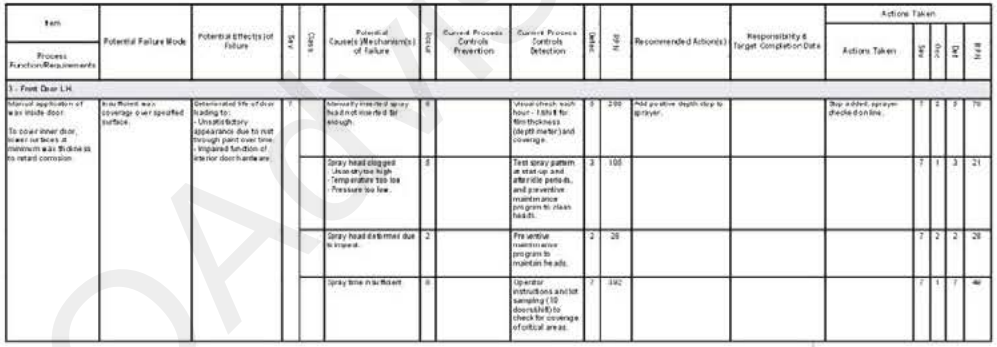
FMECA is a bottom up technique to find failure modes of components/items



Item / Process Function/Requirements	Potential Failure Mode	Potential Effect(s) of Failure	SEV	CLASS	Potential Cause(s) /Mechanism(s) of Failure	OCCUR	Current Process Controls Prevention	Current Process Controls Detection	DETEC	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	SEV	OCC	DET	RPN
3 - Front Door LH																	
Manual application of wax inside door. To cover inner door, sheet out faces at minimum wax thickness to retard corrosion	Insufficient wax coverage over specified surface.	Deteriorated life of door leading to: - Unsatisfactory appearance due to rust through paint over time. - Impaired function of interior door hardware.	7		Manually inserted spray head not inserted far enough.	8		Visual check each hour - 1.5thk ft for film thickness (depth meter) and coverage.	3	280	Add positive depth stop to sprayer.		Stop added, sprayer checks done line.	7	4	8	70
					Spray head clogged - Viscosity too high - Temperature too low - Pressure too low.	8		Test spray pattern at start up and after idle periods, and preventive maintenance program to clean heads.	3	168				7	1	3	21
					Spray head deformed due to impact.	2		Preventive maintenance program to maintain heads.	2	28				7	2	2	28
					Spray time insufficient	8		Operator instructions and lot sampling (10 doors/shift) to check for coverage of critical areas.	7	392				7	1	7	49

- Bottom up
- Risk ranking (probability * severity)
- Can become very detailed and cumbersome
- From the beginning oriented to HW
- Can be introduced when Items are defined

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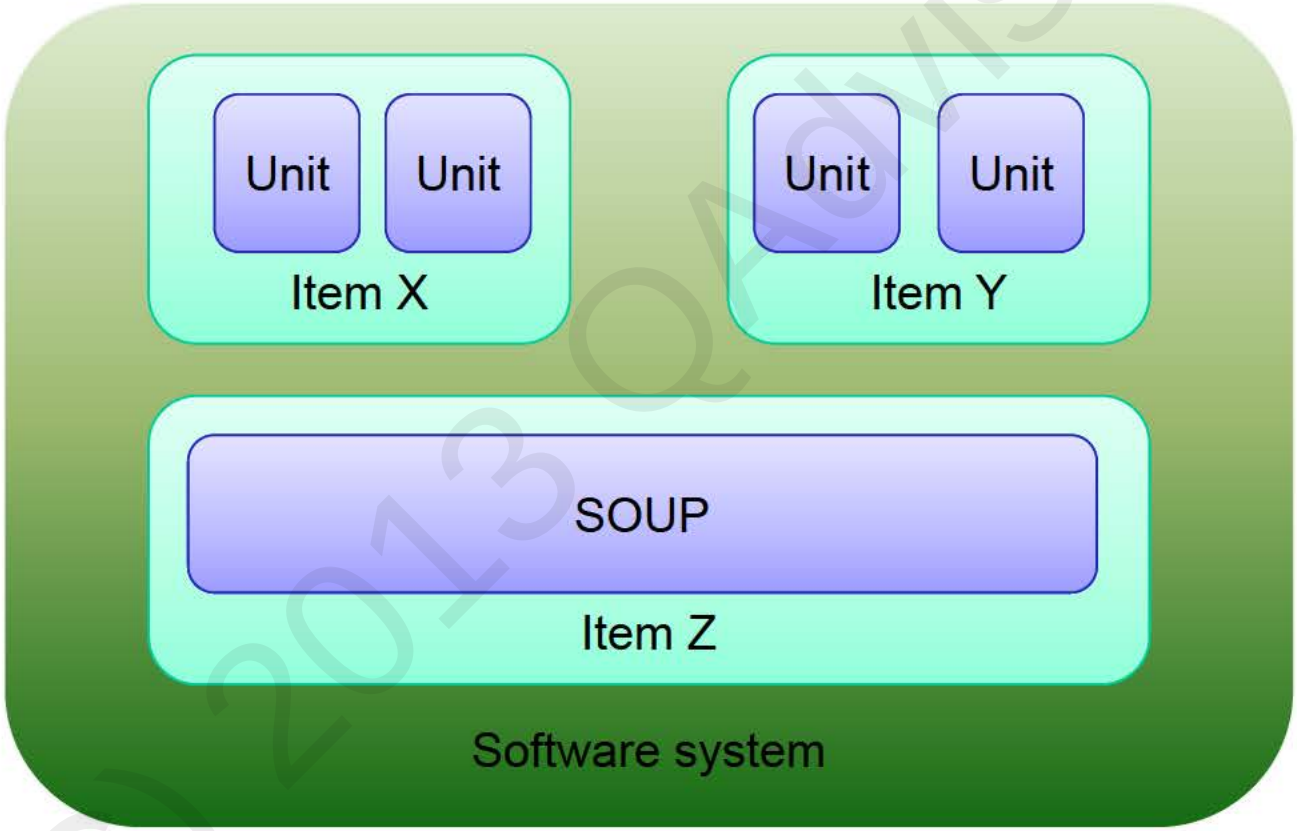
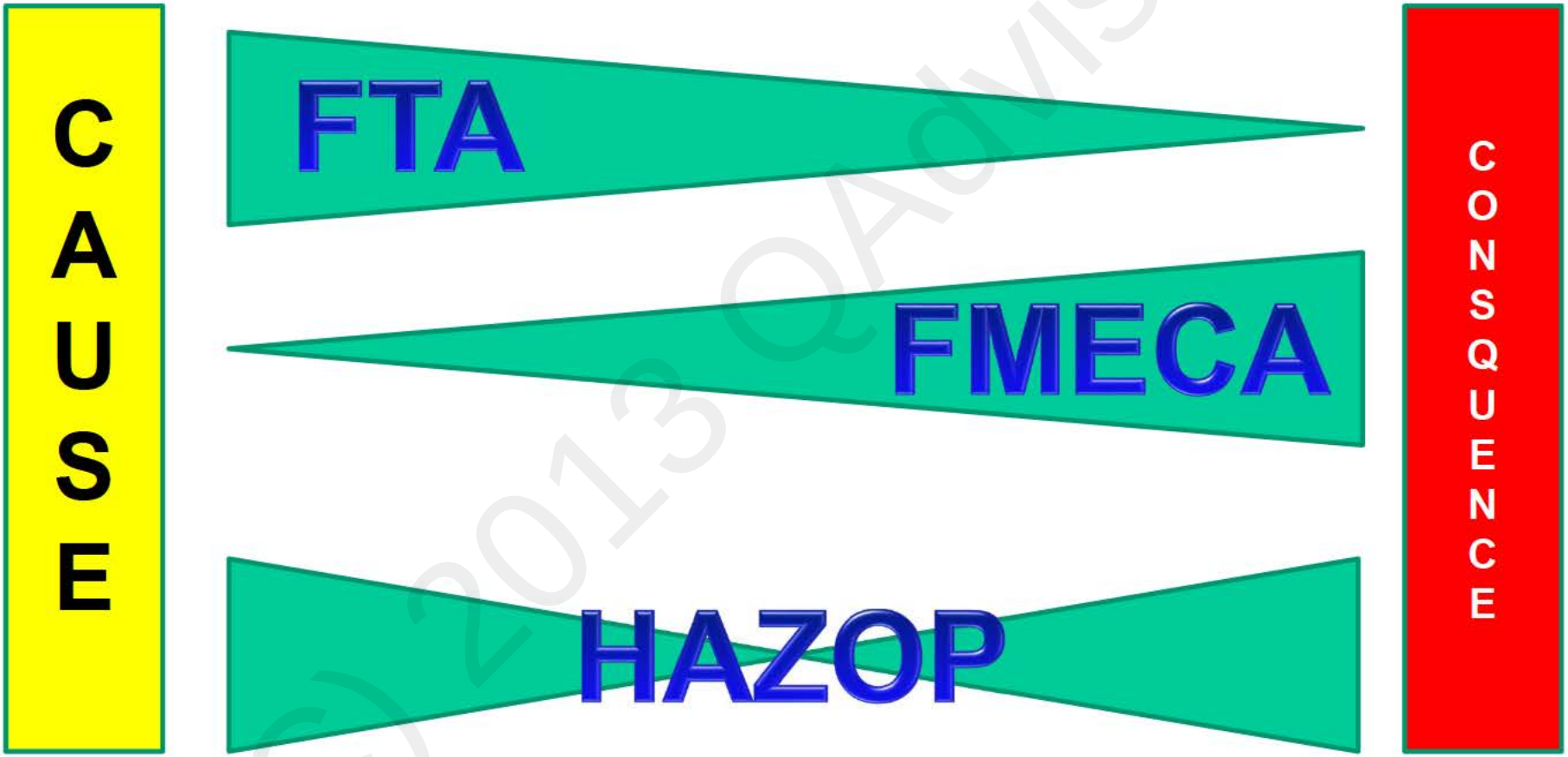
Items and units are the building blocks of a software system



Each manufacturer needs to find his own mix of techniques for Risk Mgmt



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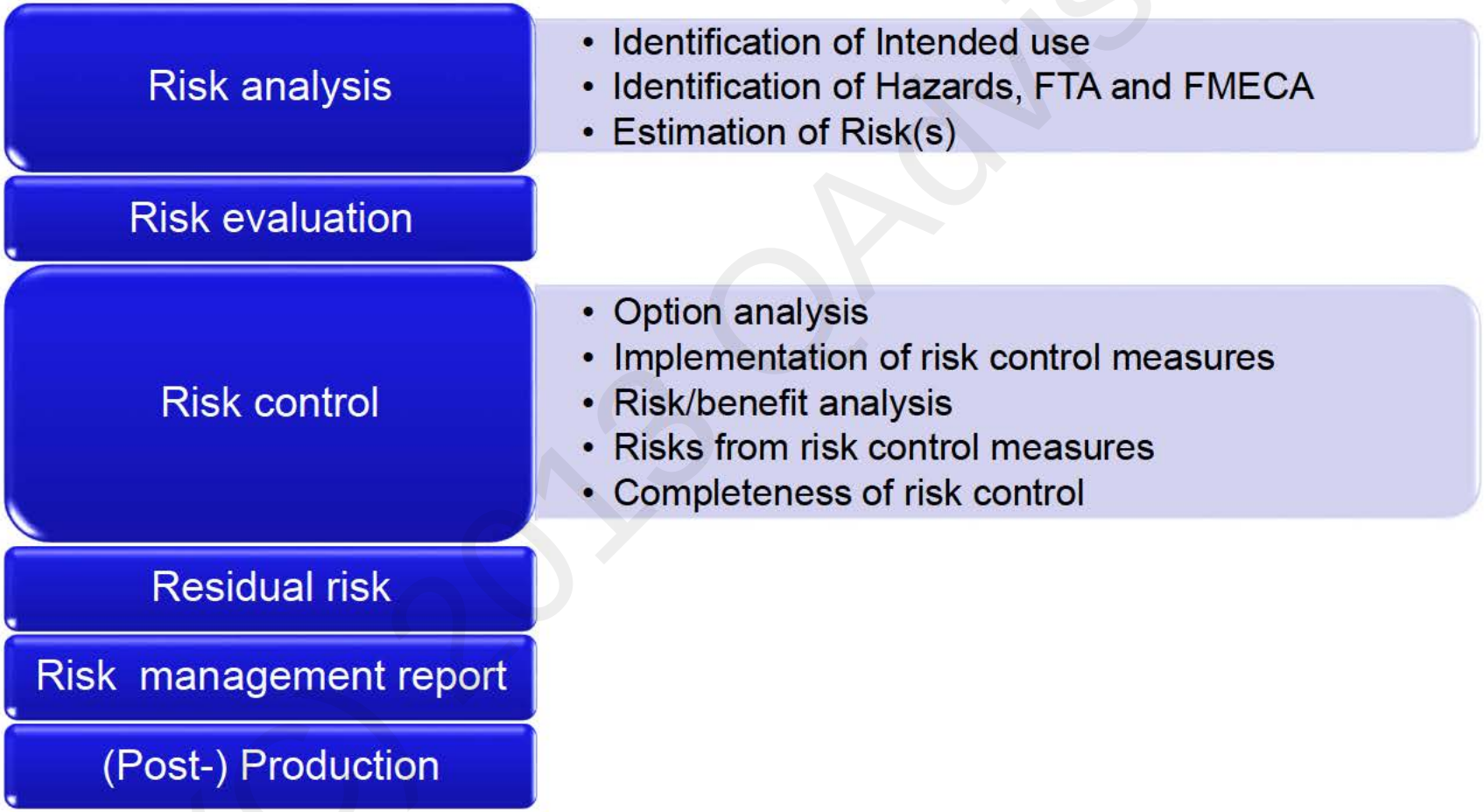
62304 calls for life cycle approach to risk mgmt based on ISO 14971



Risk Control Measures are expected to be expressed as requirements

- Evaluation of new risks due to implementation of RCMs
- Re-evaluation of RM file when appropriate regarding changes in requirements
- Update of system requirements when appropriate

Defining a safe architecture is one of the major tasks in the SW RM process

Safe architecture

- Proper partitioning
- Testable
- Predictable behavior
- ”Flight recorder”
  - On lab
  - In field

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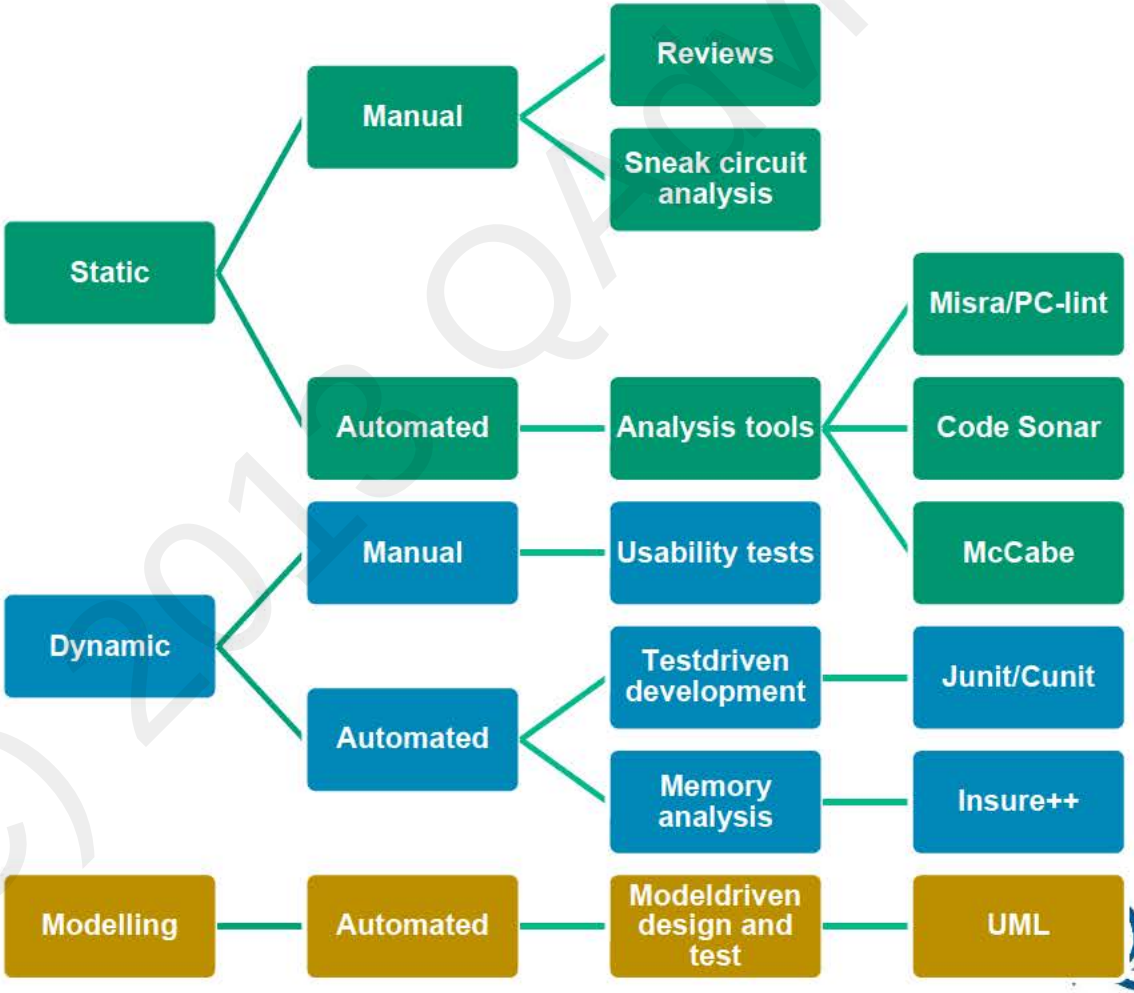
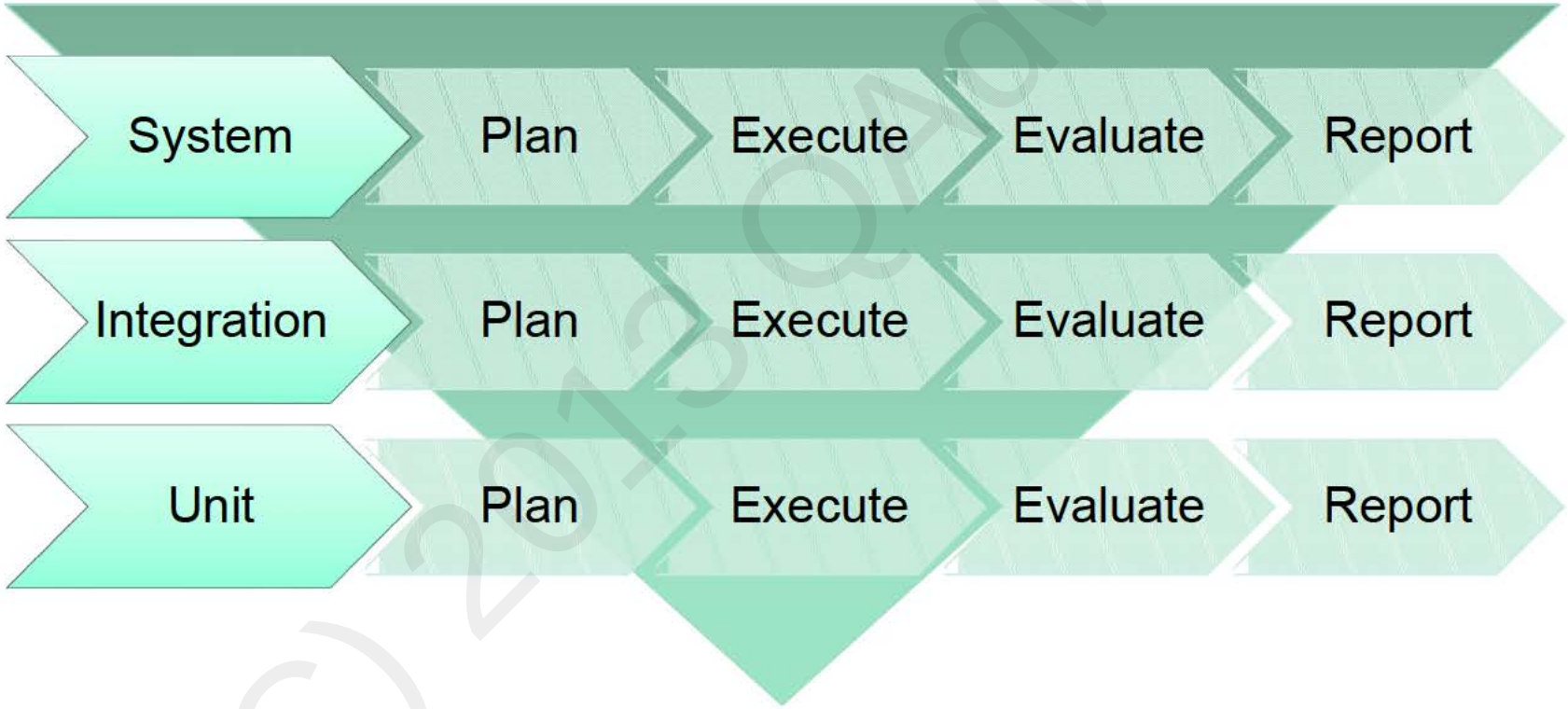
Assurance of RCMs can be done with a number of techniques



Verification activities are expected to be planned upfront and fully executed



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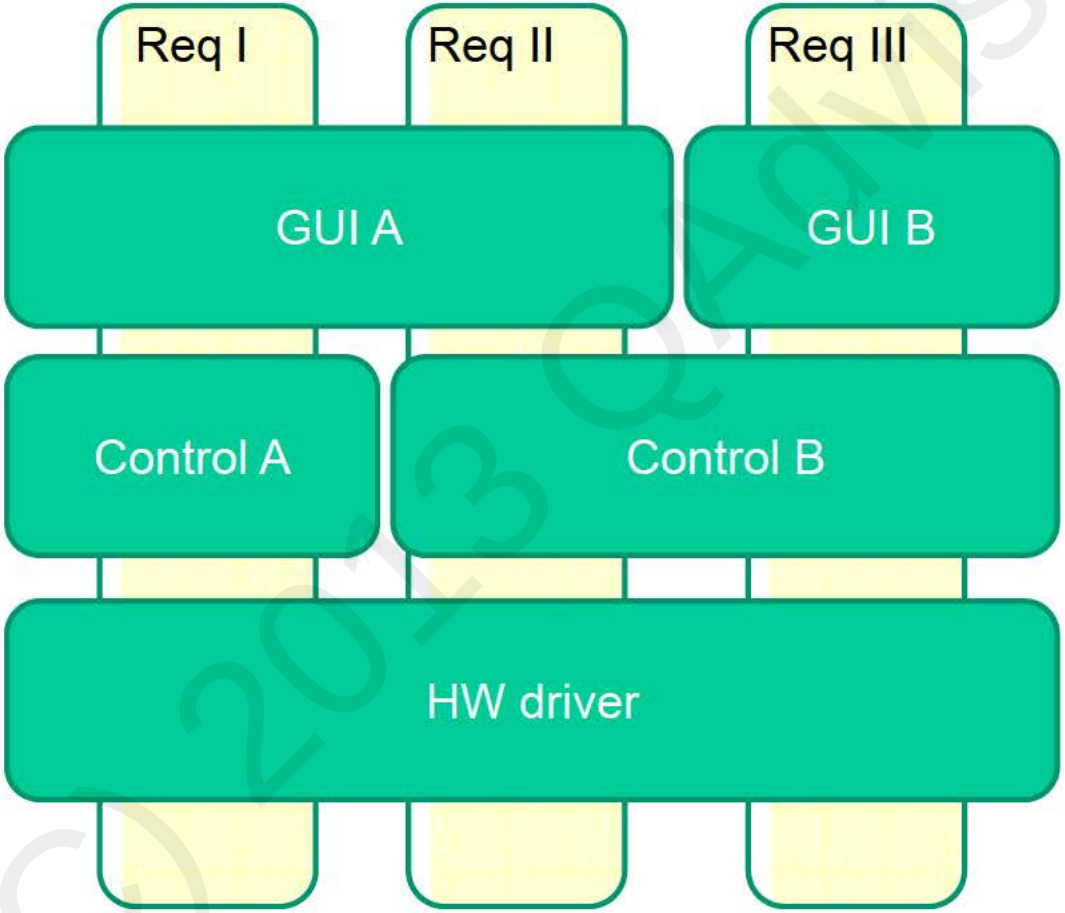
Two views to consider Functional reqs - architecture



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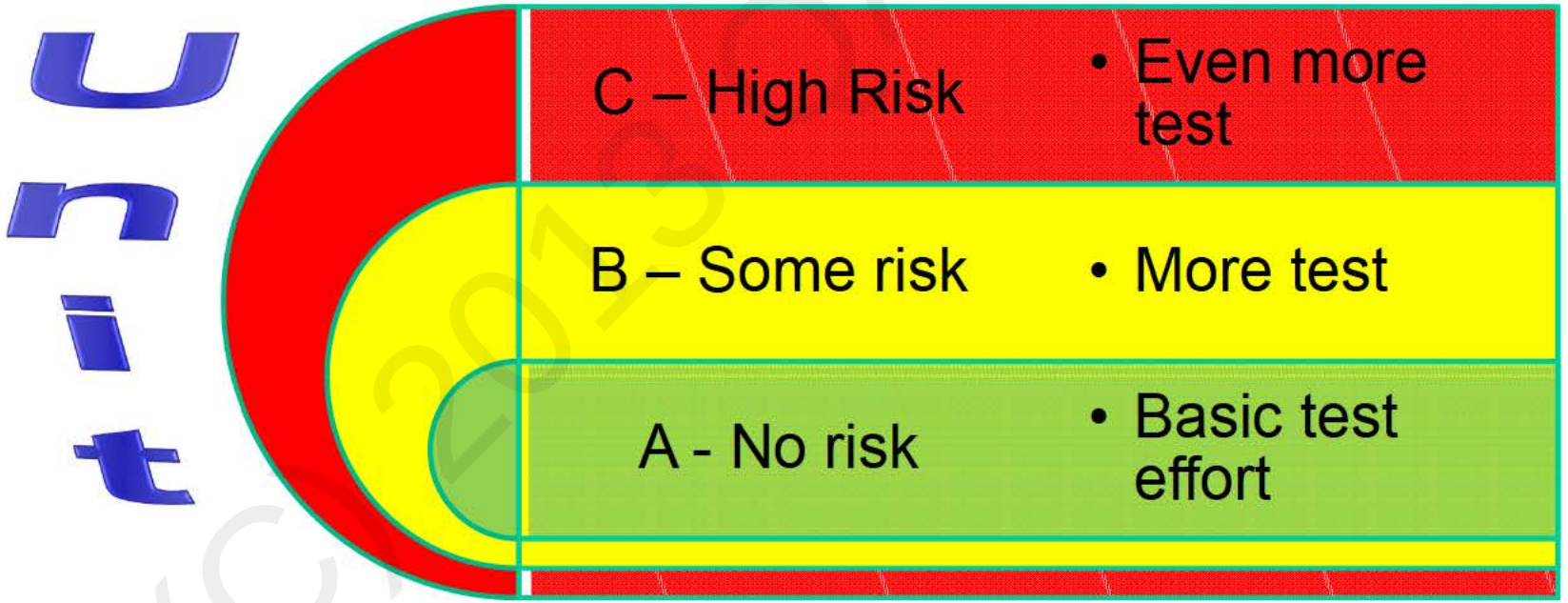
Risk driven Item/Unit verification is an explicit expectation in 62304

- To do more test for risk related units
- Some guidance on how to implement this



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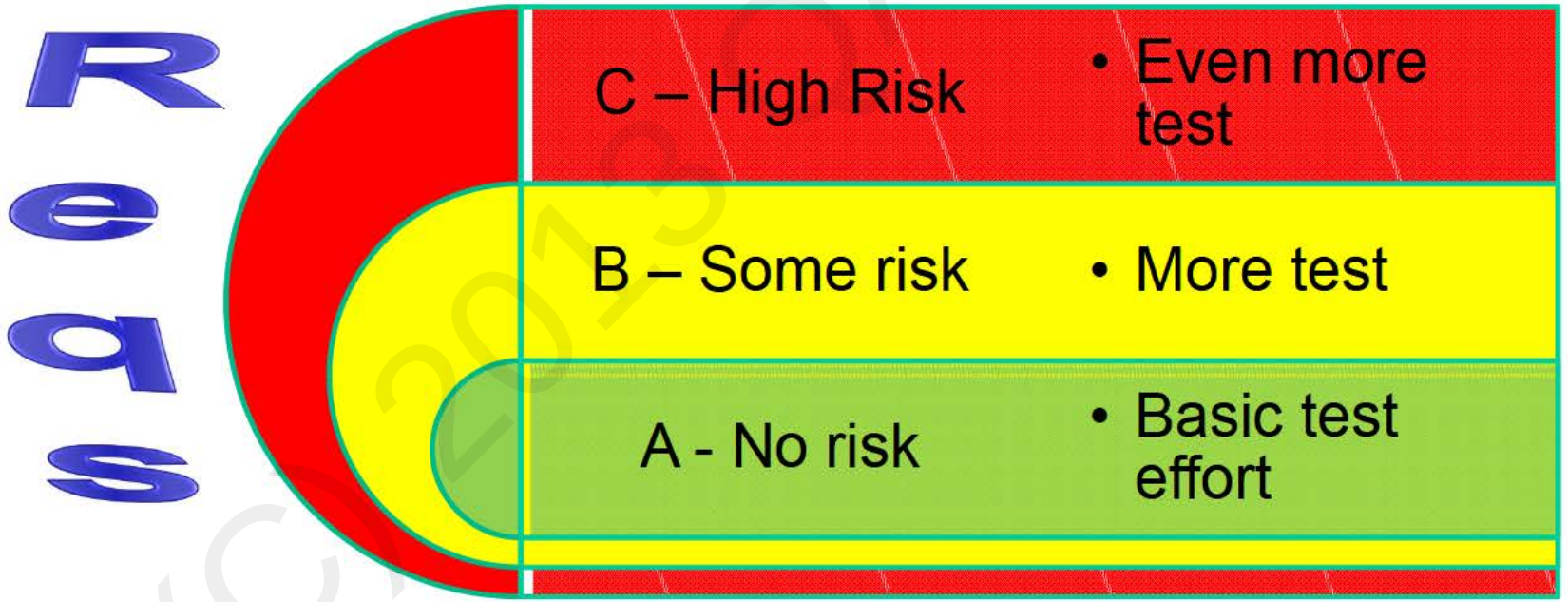
Risk driven requirement verification is an underlying expectation in 62304

- To do more test for risk related features
- Significant freedom on how to implement this



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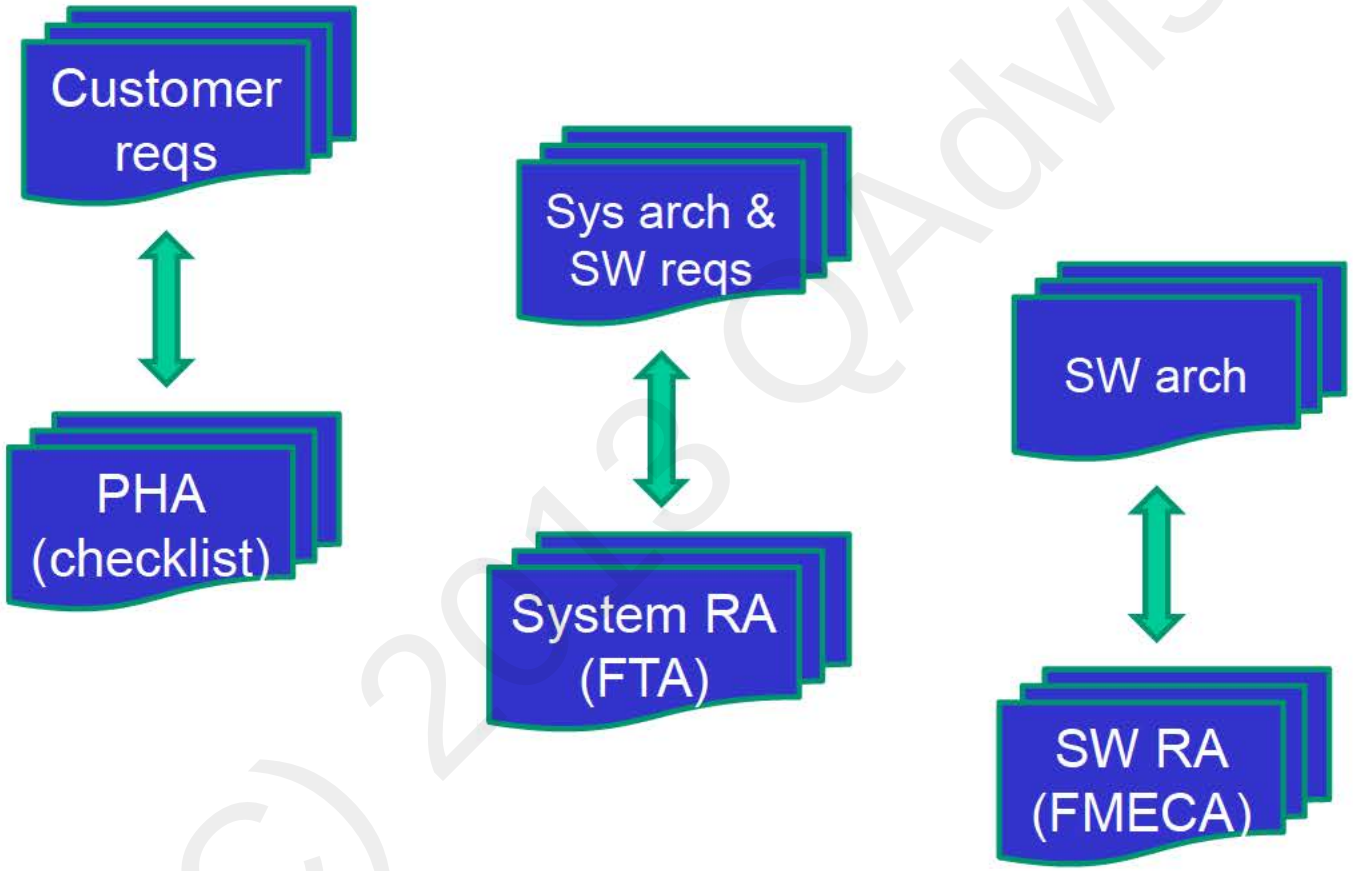
Example on how Risk Analysis activities can relate to key documents



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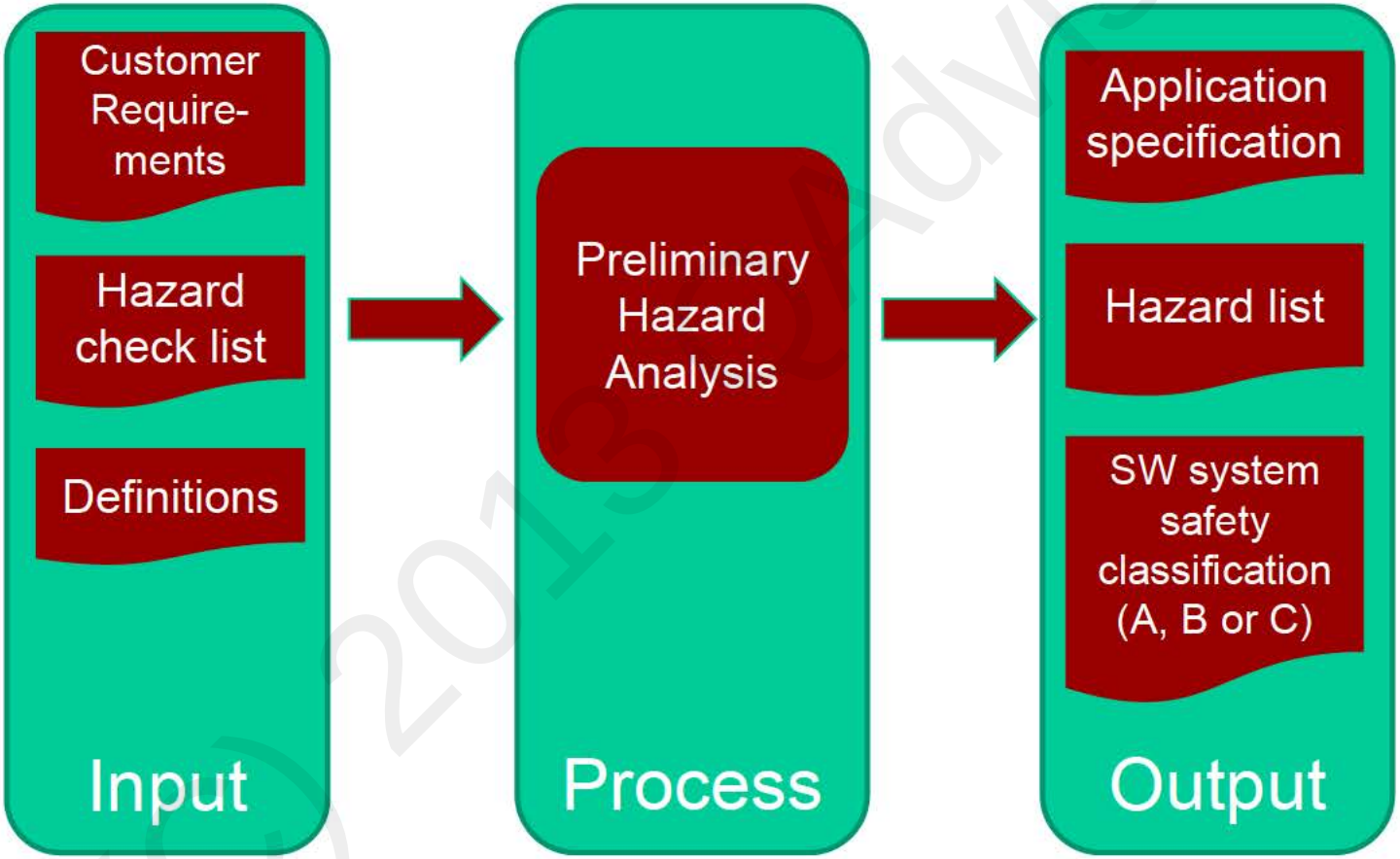
Example of an IPO diagram for Preliminary Hazard Analysis



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It is very difficult to find probability for a SW failure

Risk analysis

Risk evaluation

Risk control

Residual risk

Risk management report

(Post-) Production

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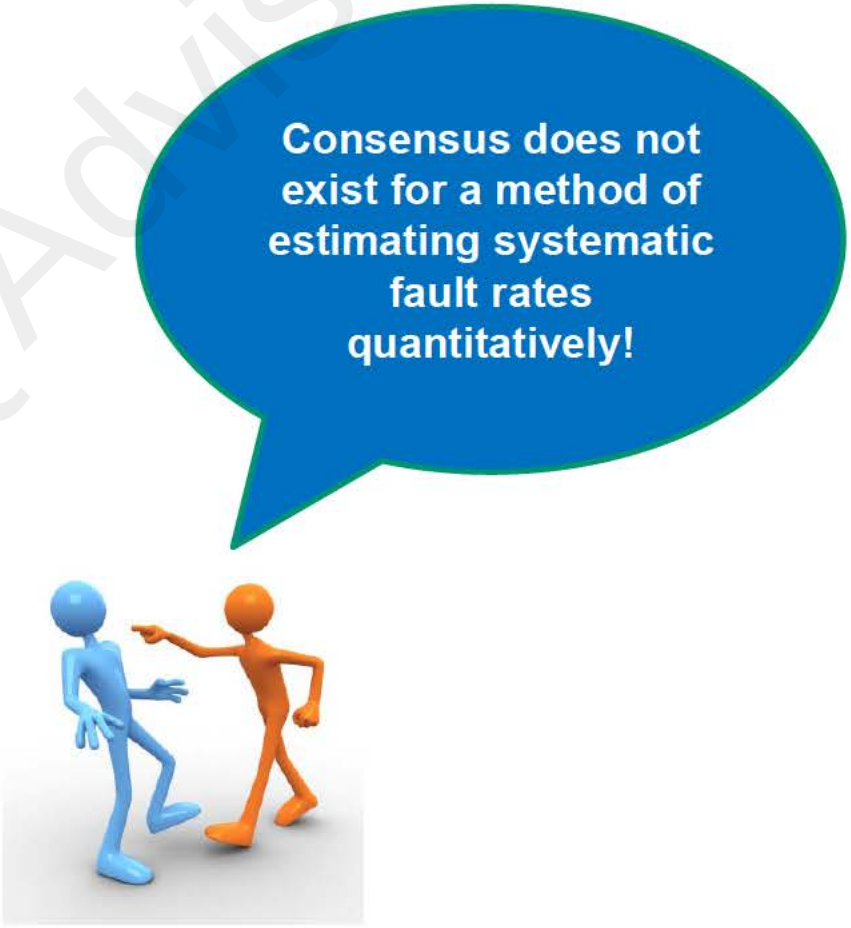
Software fails systematically

Random failures

- Ionizing radiation
- Wear out, fatigue

Systematic failures

- Software
- Incorrectly rated fuse



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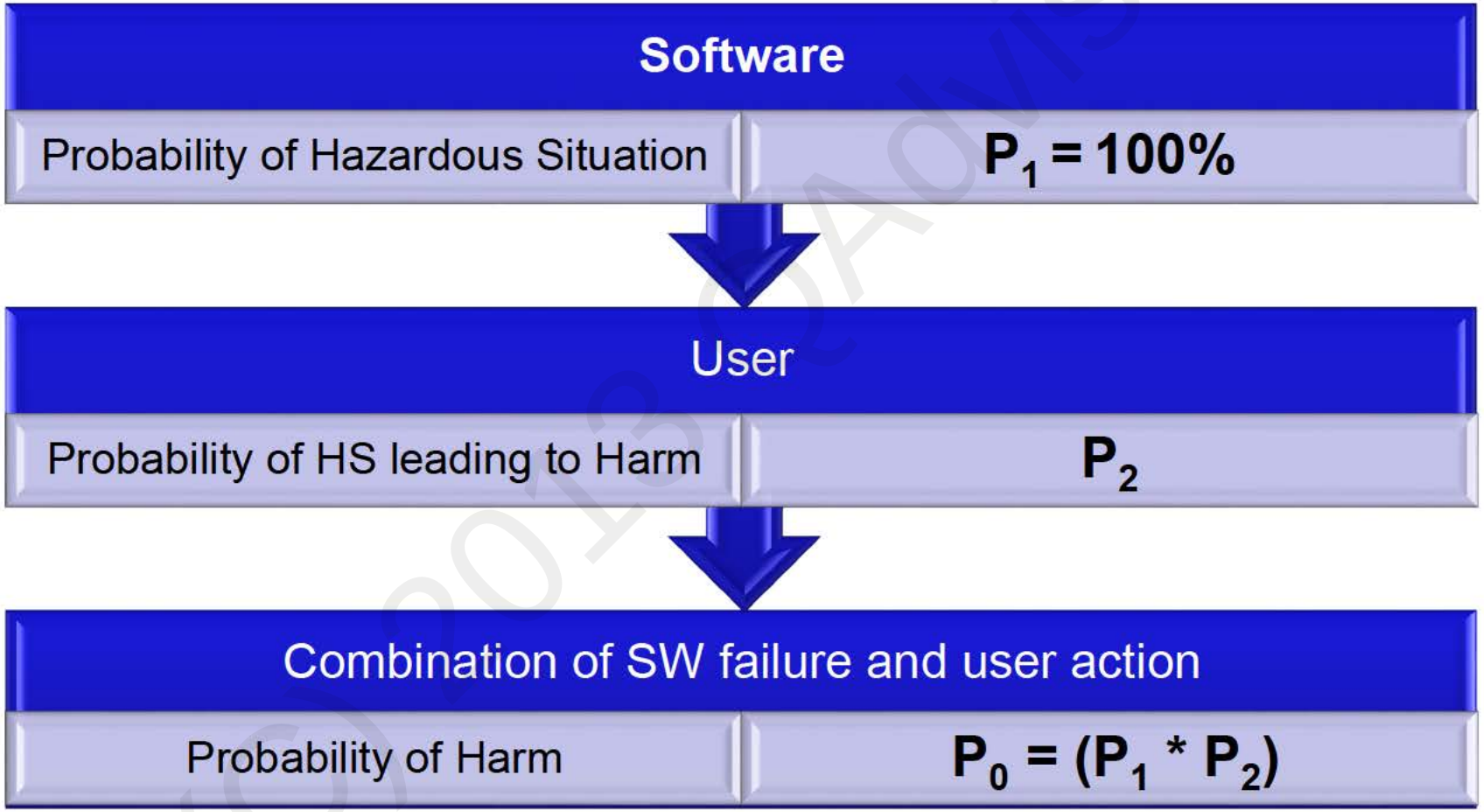
Probability of SW to fail is expected to be 100%



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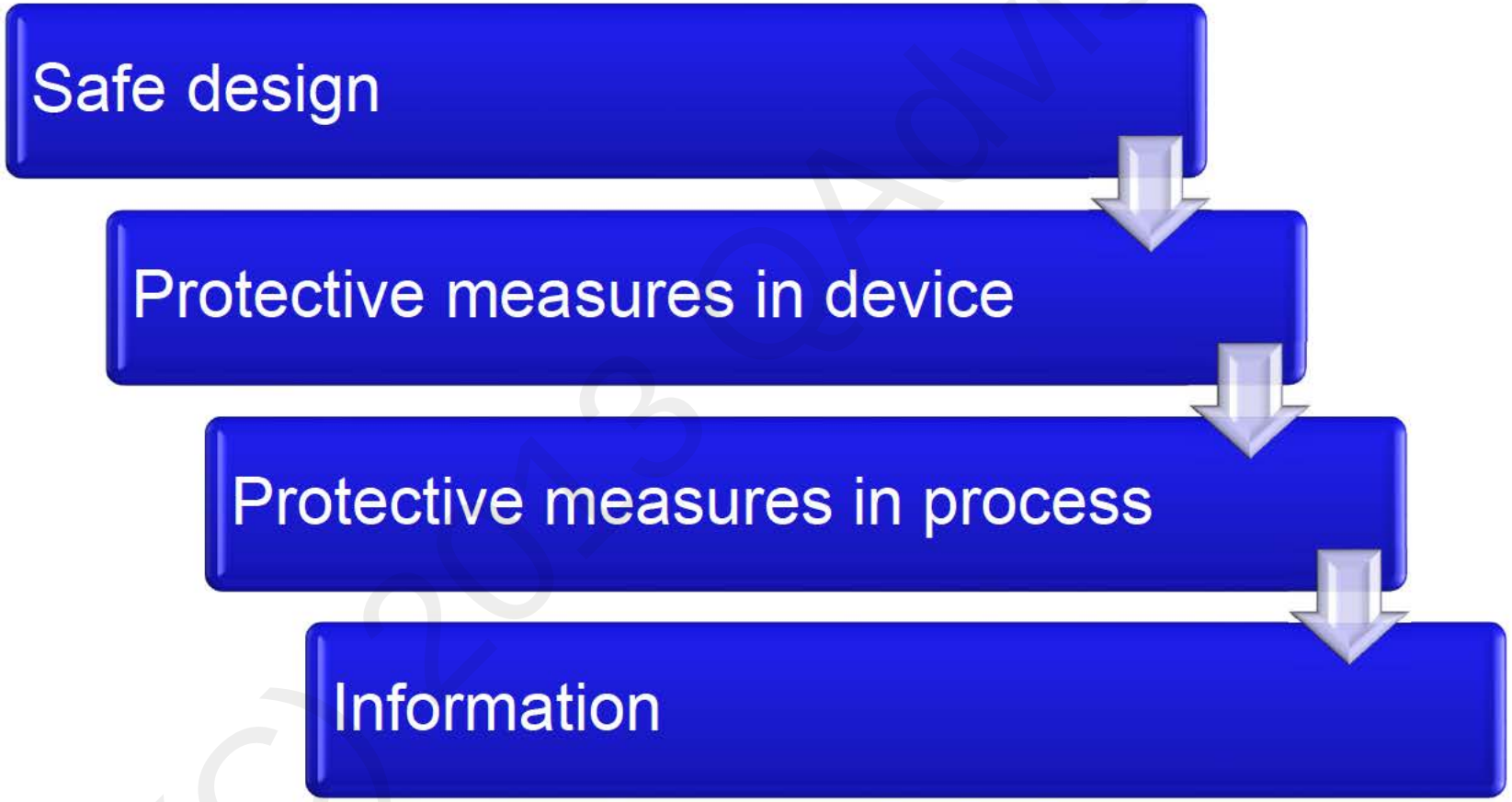
The key message in 62304 is to do software engineering for safety



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Risk based V&V strategy can utilize the resources efficiently

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Example of a risk based requirement test strategy

Req class Verification	A	B	C
Scripted (Req Based)	M	M	M
Independent Review	O	M	M
Exploratory	O	O	M

- M = Mandatory O = Optional
- Risk control measures included in reqs

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

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Example of risk based Item/Unit test strategy

Unit Verification	In Item A	In Item B	In Item C
Rule check	M	M	M
Basic unit test	O	M	M
Review	O	M	M
100% Code coverage	O	O	M
Independent review	O	O	M

- M = Mandatory
- O = Optional

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

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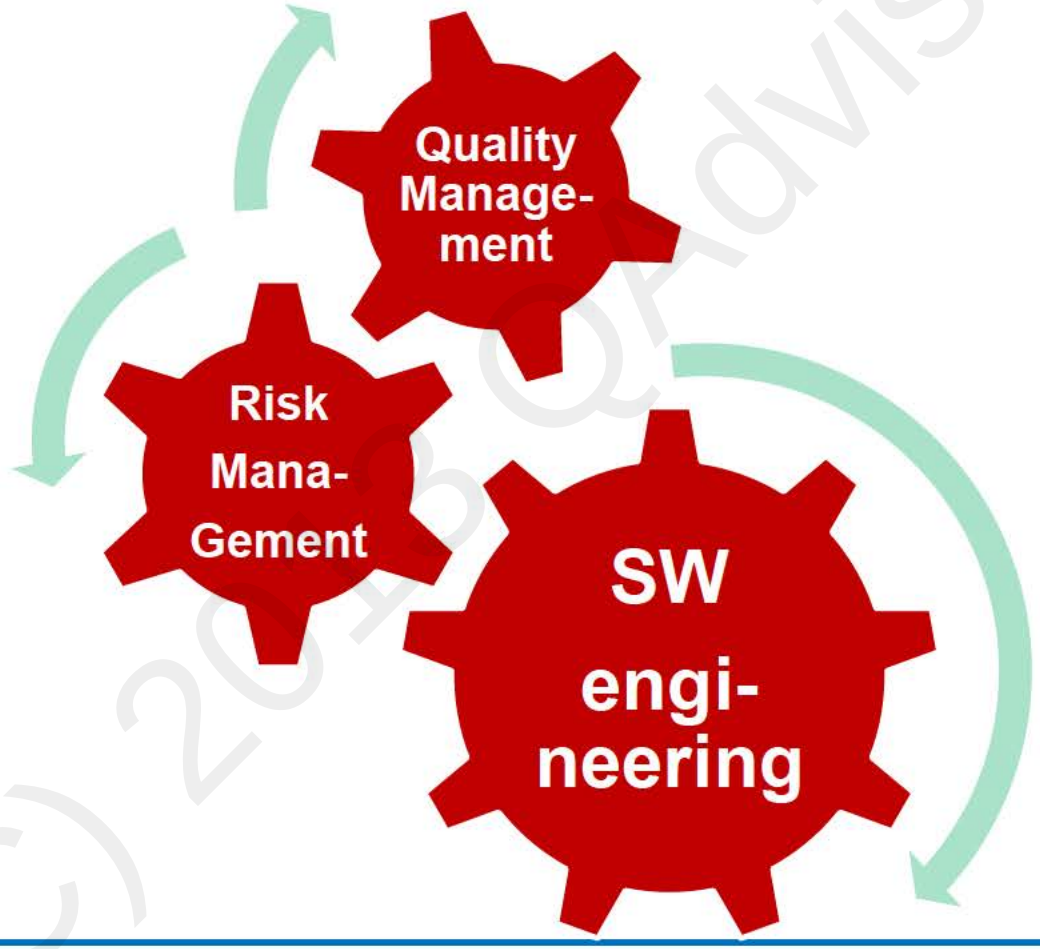
Software risk management can be time consuming and hard

Good software engineering is the key to successful risk management



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A good starting point is to document what already is done

The MANUFACTURER shall document TRACEABILITY of software HAZARDS as appropriate:

a) from the hazardous situation to the SOFTWARE ITEM;
b) from the SOFTWARE ITEM to the specific software cause;
c) from the software cause to the RISK CONTROL measure; and
d) from the RISK CONTROL measure to the VERIFICATION of the RISK CONTROL measure.

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Building a solid V&V process can enable productivity

Synergus can contribute with consulting within:

- Auditing and reviews
- Mentoring
- Risk manager role
- SQA role (Software Quality Assurance)
- Process development and documentation
- Product documentation
- Implementation of supporting IT-tools