Risk management for medical laboratories as required by ISO15189

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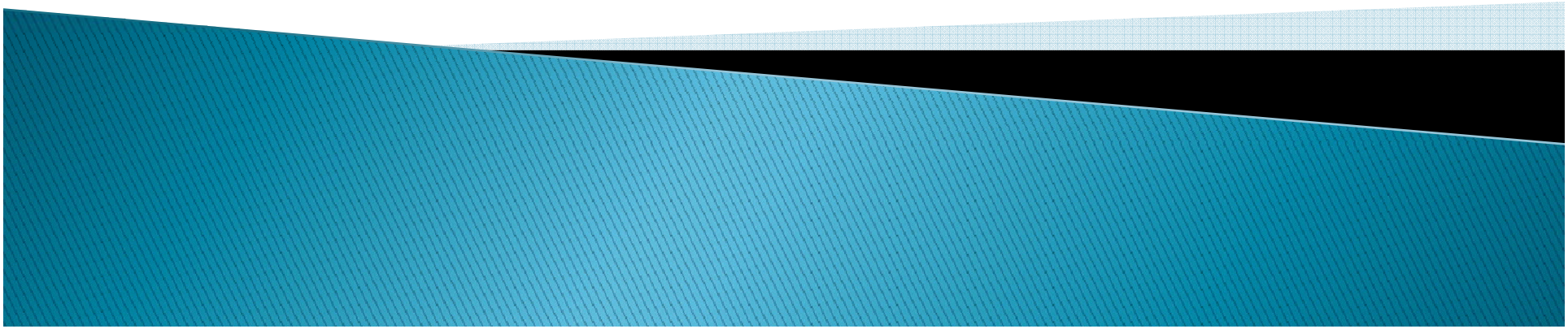
Chair Quality and Regulations EFLM
Teheran, iqc 20 april 2016



Needed for the medical laboratory

ISO 15189 -2012

Medical laboratories – Particular requirements for quality and competence

EN ISO 15189:2003

INTERNATIONAL STANDARD

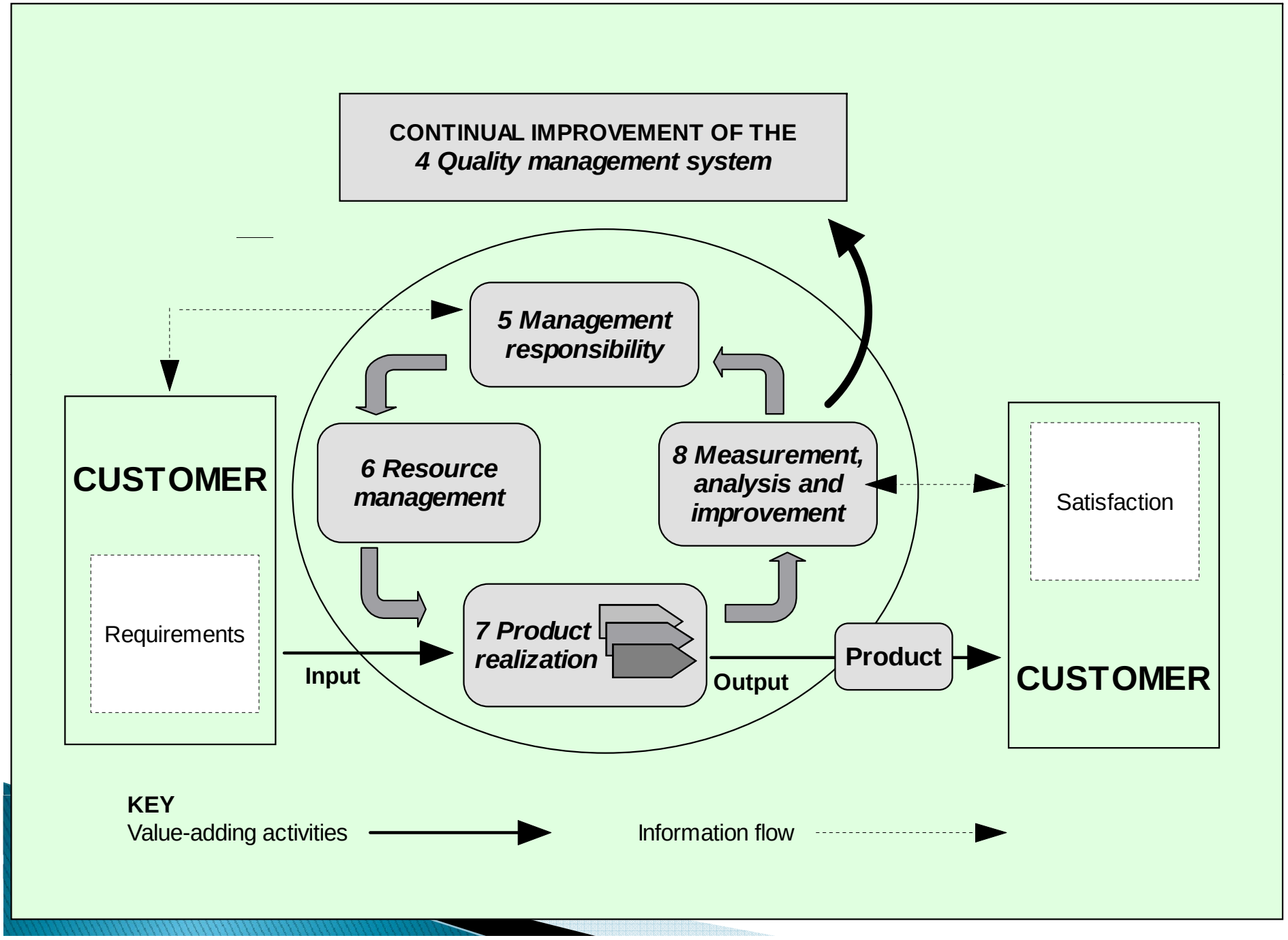
ISO 15189

First edition
2003-02-15

Medical laboratories — Particular requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières concernant la qualité et la compétence

- Written by medical laboratory professionals
- Responsibility of ISO/TC212 WG1
- Requirements for quality and competence
- It has its origins in two ISO Standards …ISO 9001 and ISO 17025


CONTINUAL IMPROVEMENT OF THE
4 Quality management system
5 Management responsibility
6 Resource management
7 Product realization
8 Measurement, analysis and improvement
CUSTOMER
Requirements
Input
Output
Product
Satisfaction
CUSTOMER
KEY
Value-adding activities
Information flow

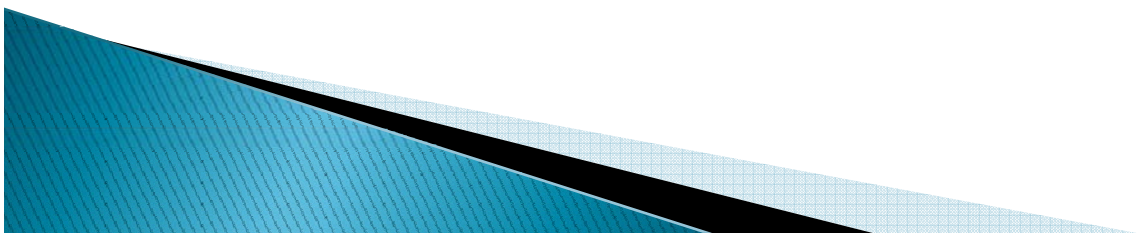
ISO15189

- ISO 15189 **reminds and helps**
- Chapter 4 QMS system
- Chapter 5 Specific (technical) items

- Already in the first edition of 2003 Risk Management was mentioned as shown below, but it got more attention since the 2012 edition, especially from accreditation bodies

4.11 Preventive action

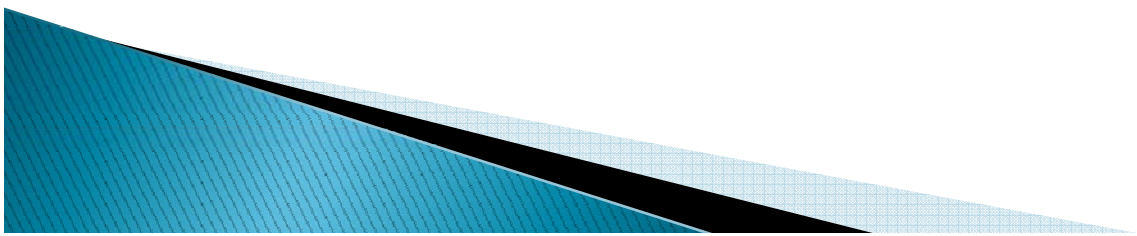
- Note: Preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints … Preventive action might involve analysis of data, including trends and **risk management analysis** and external quality assessment



4.12 Continual improvement

The laboratory shall continually improve the effectiveness of the quality management system.. through the use of management reviews to compare the laboratory's actual performance in its evaluation activities.

Improvement activities shall be directed at areas of highest priority **based on risk assessments**



4.13 Control of records
4.15.2 Review input

4.13

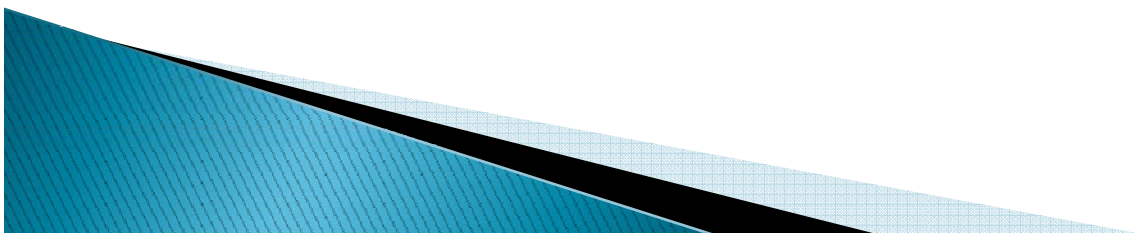
Records shall include at least the following:

n) **Risk management records**

4.15.2

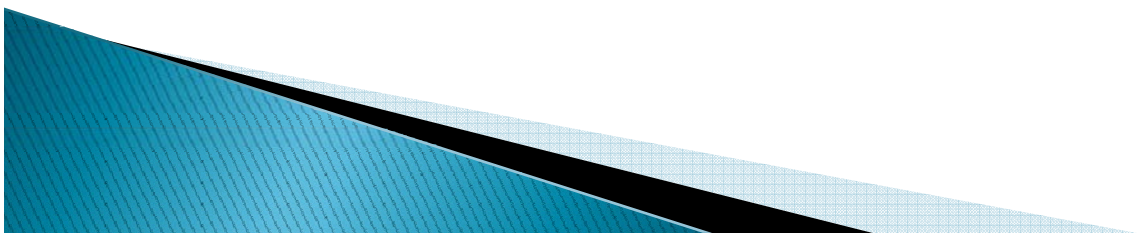
The input to management review shall include information from the results of evaluations of at least the following:

e) **risk management** (see 4.14.6)



4.14.6 Risk management

The laboratory shall ***evaluate*** the **impact of work processes and potential failures** on examination results as they affect **patient safety** and shall ***modify*** processes to ***reduce*** *or* ***eliminate*** the **identified risks** and ***document*** decisions and actions taken



Risk Management standards

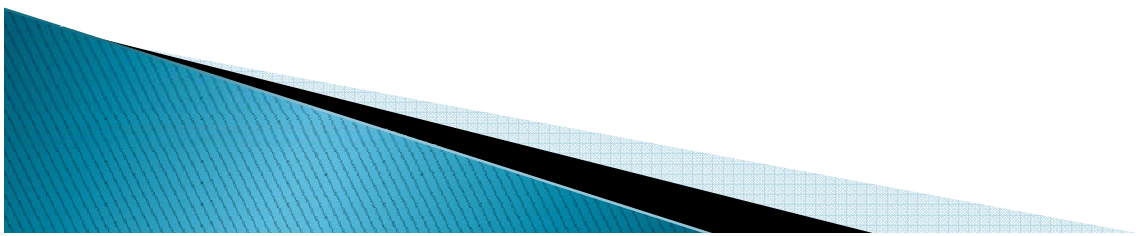
- Basic Standard: ISO31000:2009 Risk management-Principles and guidelines
- IEC/ISO31010:2009 Risk management-Risk assessment techniques
- For medical laboratories TS22367:2008 Medical laboratories- Reduction of error through risk management and continual improvement
- For IVD ISO14971:2007 Medical devices- Application of risk management to medical devices

Continual Improvement

ISO/TS 22367:2008 Medical Laboratories- reduction of error through risk management and continual improvement

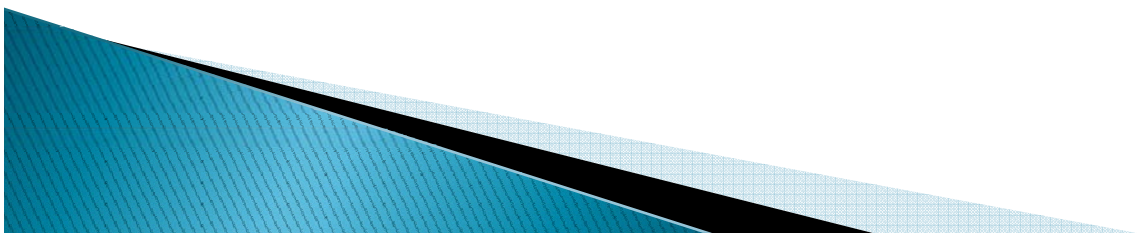
Educates laboratories in

- Learning from a previous mistake (nonconformity)
  - -Not just correction but find the root cause
  - -Look after extensiveness
  - -Find a solution for the root cause (corrective action)
  - -Check if the solution has solved the problem
- But also in prevention of a mistake by setting up risk analysis



TC212 of ISO

- It started a revision with equal attention to root cause analysis as in the original one, and classical risk management. Should give quite a lot of information about the processes and their possible risk
- Now decided to go more in the direction of the ISO14971, the classical risk management approach and thus complement what is already be done by the manufacturers.



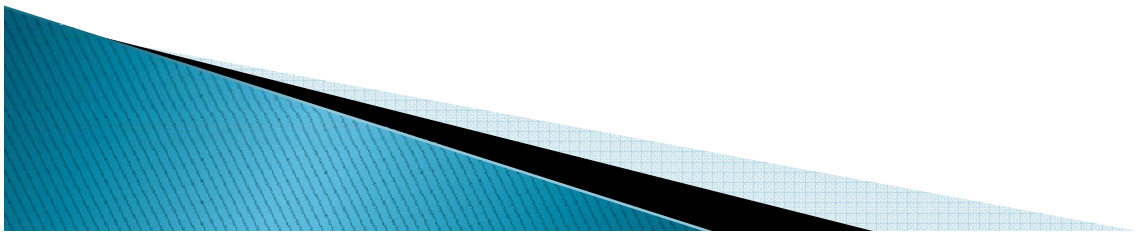
Principles can be broadly used

- For catagorising classification of ivd's in 5 different classes in the draft IVD Regulation of the EU risk is used
- In the draft of a paper on retention time of laboratory documents the principle of "how bad is it if a document is not available anymore" and "what is the frequency that is is needed" are used for the decision

Risk management process

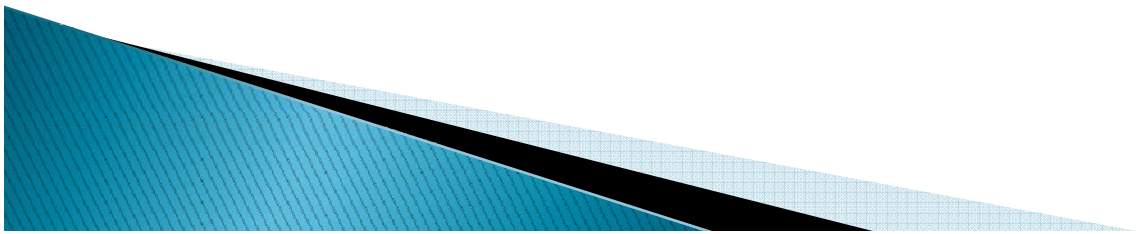
- Risk analysis
- Risk evaluation
- Risk control
- Risk monitoring

Risk analysis and risk evaluation can be considered as risk assessment



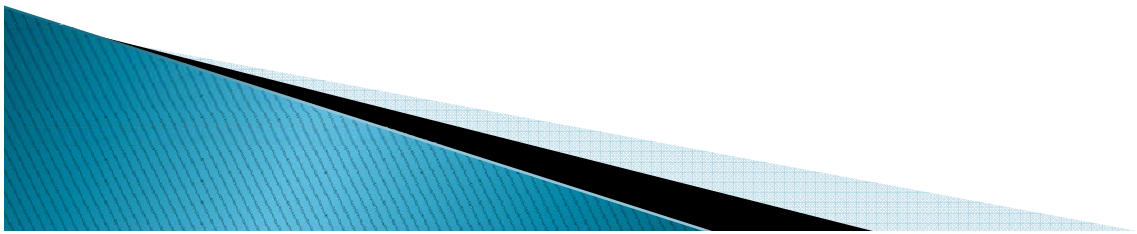
Risk analysis

- Specify intended uses
- Identify safety characteristics
- Identify hazards, hazardous situations, and harms
- Estimate the risks



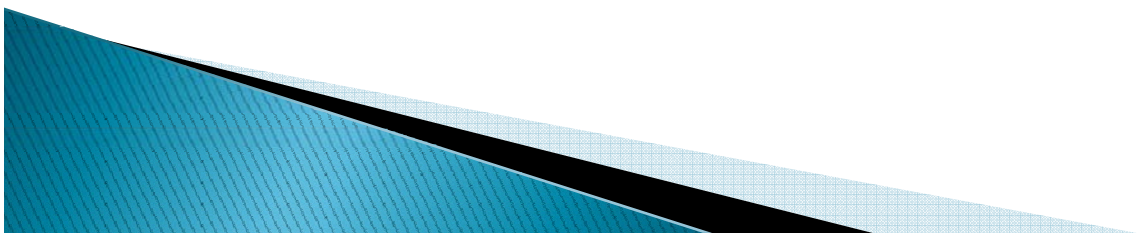
Risk evaluation

- Estimate risk acceptibility
- Perform risk/benefit analysis



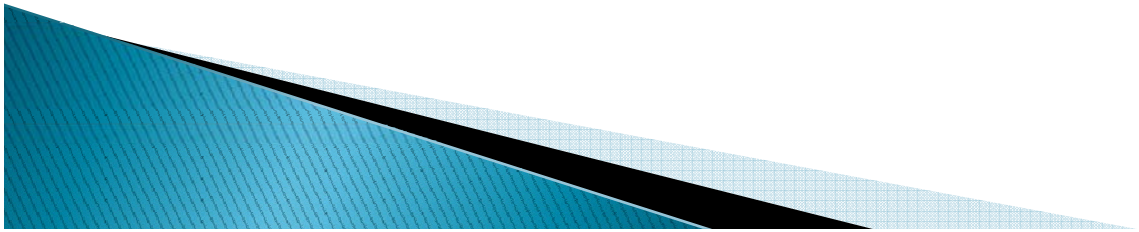
Risk control

- Is risk reduction necessary
- Determine risk control options
- Implement risk control measures
- Verify risk control measures
- Evaluate risk control measures
- New risk from risk control measures



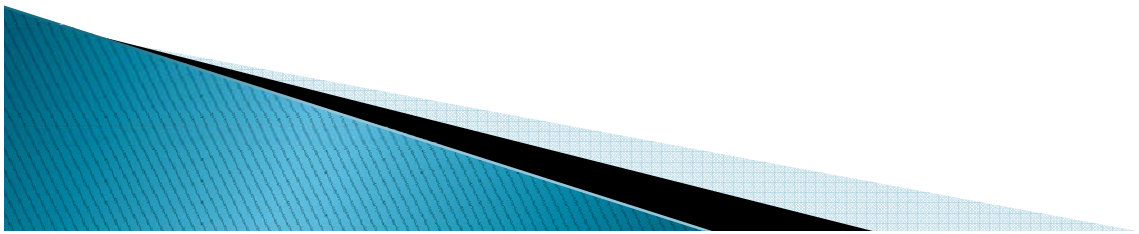
Risk management review

- Verify completeness of risk control
- Evaluate overall residual risk acceptibility
- Approve risk management report

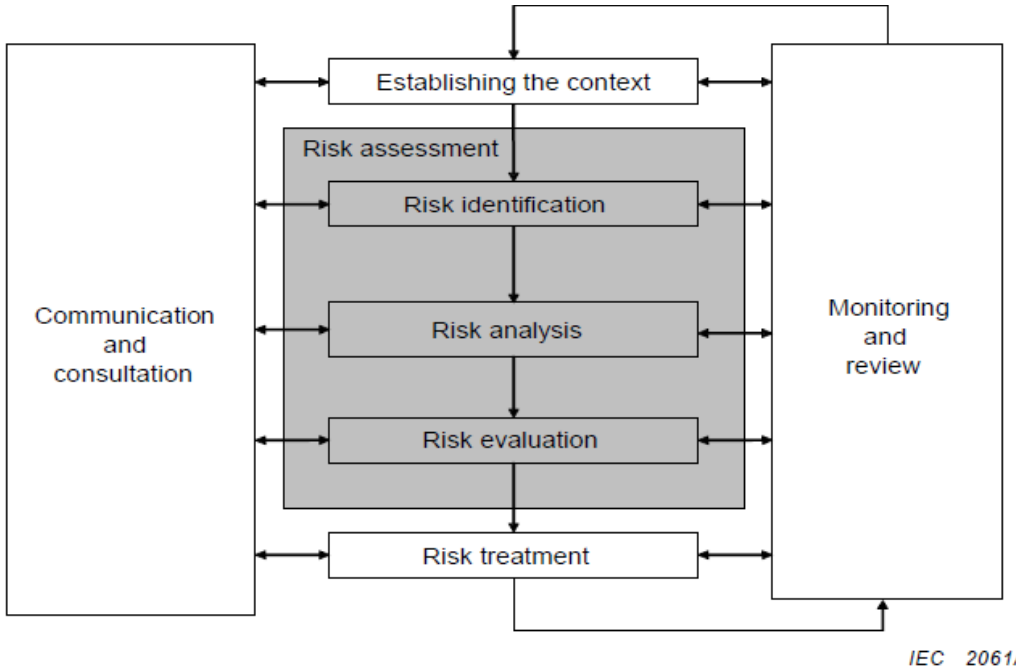


Risk monitoring

- Establish surveillance system
- Monitor internal indicators
- Monitor external indicators
- Address changes in risk profile

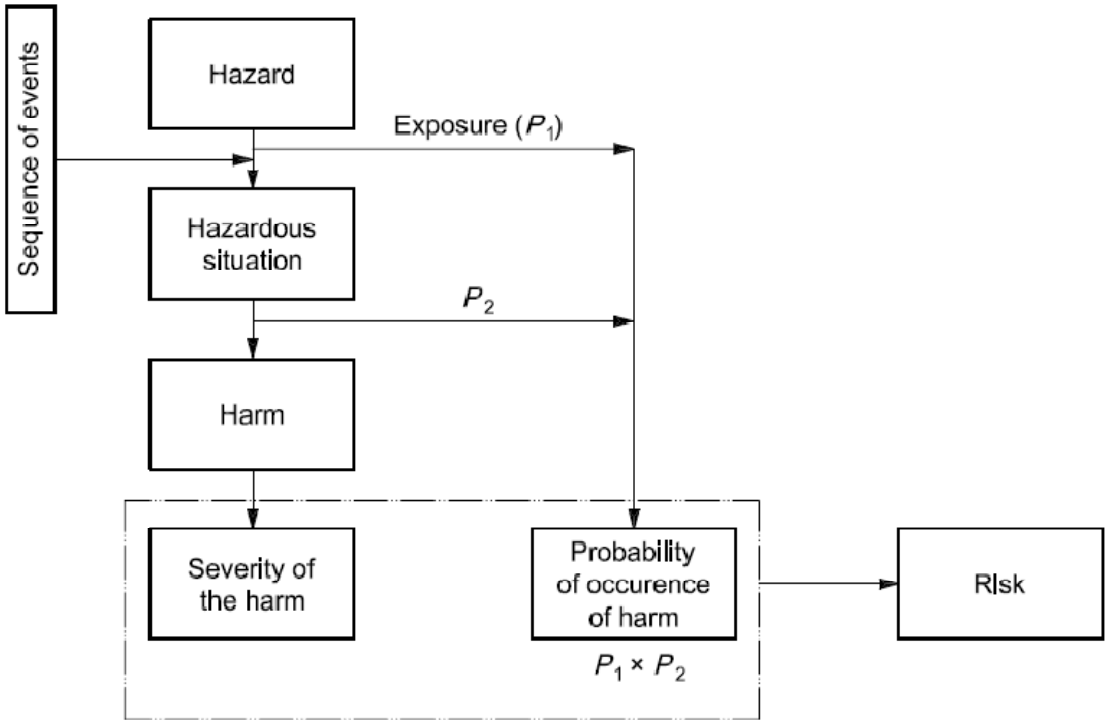


Risk Analysis



re 1 – Contribution of risk assessment to the risk management process

Sequence of events



Failure Mode Effect Analysis(FMEA)

- Especially fit for analysing risks in a process.
- Example is given related to mislabeling of specimens
- Risk priority number (rpn) is product of severity, frequency of occurence, times detection

In this example the scale is 1-10; more often 1-5 is used. As border for acceptance 100 is choosen.

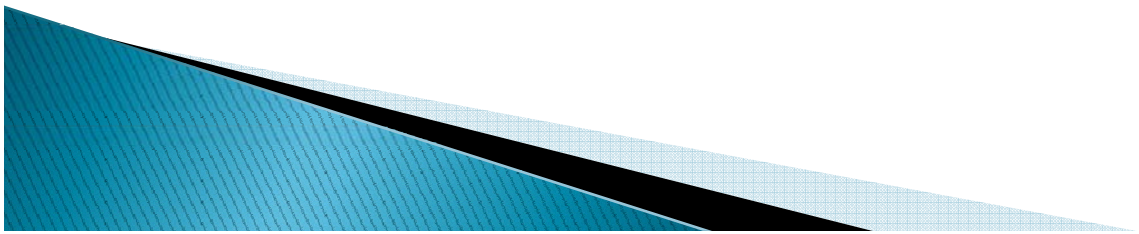
Example labeling

									Action Results				
Process Function (1)	Potential Failure Mode (2)	Potential Effects of Failure (3)	Severity (4)	Potential Causes of Failure (5)	Occurrence (6)	Current Controls (7)	Detection (8)	RPN* (9)	Recommended Action (10)	S (11)	O (12)	D (13)	RPN* (14)
Specimen labelling	Phlebotomist does not check armband	Sample labelled with incorrect name	10	Forgets	1	None	10	100	None				
	Patient armband missing	Sample labelled with incorrect name	10	Computer issues in admitting	3	Ask patient their name	8	240	Resolve admitting issue	10	1	8	80
									New policy: no armband, no phlebotomy	10	3	1	30
									Resolve admitting issue AND new armband policy	10	1	1	10

Risk acceptibility criteria

Needed to state which risk is acceptable

- In accordance with laboratory policy
- Based on regional, nationale safety standards and relevant medical practice standards
- Taken into account state of the art
- Be approved by the laboratory director



FMEA

		Overall Probability of Harm				
		Unlikely (1)	Remote (2)	Occasional (3)	Likely (4)	Frequent (5)
Severity of Harm	Critical (5)					
	Serious (4)					
	Significant (3)					
	Marginal (2)					
	Negligible (1)					

FMEA

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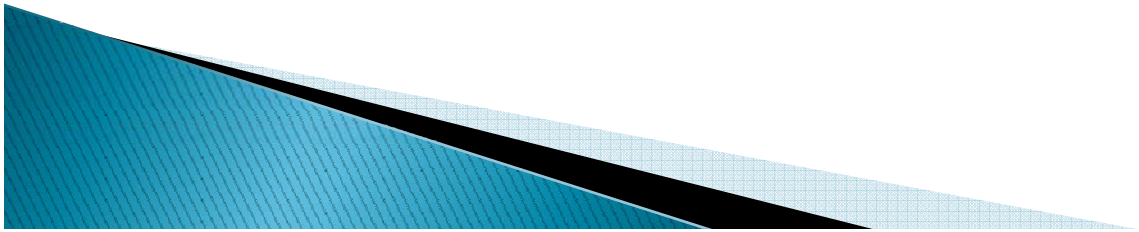
Severity of Harm	Critical (5)					
	Serious (4)					
	Significant (3)					
	Marginal (2)					
	Negligible (1)					

Examples

Nonconformity	Probability	Severity	Risk
Wrong Patient identification	Occasional (3)	Critical (5)	Unacceptable
Wrong Test Result	Occasional (3)	Critical (5)	Unacceptable
Report Delayed (Stat)	Likely (4)	Marginal (2)	Acceptable with risk minimization
Report Delayed (24 hours)	Likely (4)	Marginal (2)	Acceptable with risk minimization
Report Lost	Occasional (3)	Marginal (2)	Acceptable with risk minimization



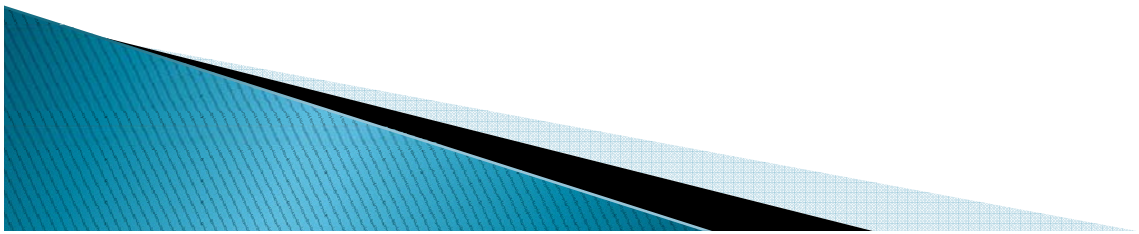
Example

Table G.7 – Risk reduction decisions resulting from FMEA

Nonconformity	Sample collected from wrong patient	Sample collected with incorrect technique	Sample transport incorrect method	Sample transport delayed or late
Preventive or Corrective Action	Implement double identification check	Implement competency assessment check	Implement competency assessment check	Transport Tracking
Severity	Critical (5)	Critical (5)	Marginal (2)	Marginal (2)
Occurrence				
Frequent (5)	Prevent	Prevent	Prevent	Prevent
Likely (4)	Prevent	Prevent	Prevent	Prevent
Occasional (3)	Prevent	Prevent	Monitor	Prevent
Remote (2)	Prevent	Monitor	Monitor	Monitor
Unlikely (1)	Monitor	Monitor	No action	No action

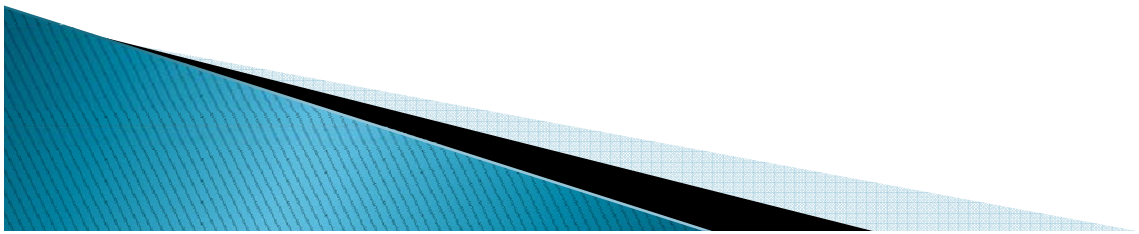
Risk Analysis

- Identify the important processes in your laboratory
- Choose a risk analysis method for instance Failure Mode Effect Analysis (FMEA)
- Choose a process for FMEA and take care for a sufficient detailed process description
- Compose a project group with sufficient knowledge of the process
- Determine for each process step the Risk of Failure (R) and the seriousness of it (S), in relation with the change of early detection. The product RS is the number you use in estimating the risk



Risk analysis

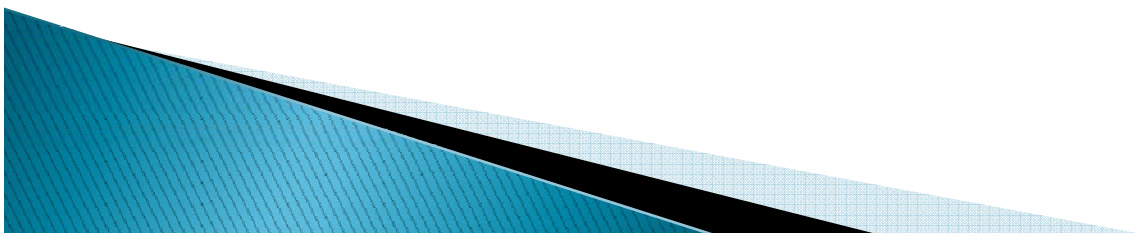
- Identify which Risk is acceptable
- Start with prospective actions to diminish your risk, if possible by changing the process
- Document the changes and check their effect in an assessment
- Do this on a regular base, and when changes occurr



Risk Analysis is needed now

- Make yourself acquaint with one of the possible methods
- Make it one of the processes in your laboratory for continuous improvement

In Europe risk assessment is an obligation for becoming accredited according to ISO15189:2012



TC212 and Risk management

- As indicated work is in progress
- Intended TS (Technical specification) will contain a lot of information
- It is intended to have a lot of appendices on specific items and as well the risky steps in the laboratory processes for the different medical laboratory disciplines.
- For the present moment sufficient information available in the old ISO14971 for ivd's and TS22367

Accreditation according ISO15189 can really improve quality of medical laboratories for patient and doctors