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Failure mode and effects analysis (FMEA) as a tool for risk management and quality improvement of the EQA schemes

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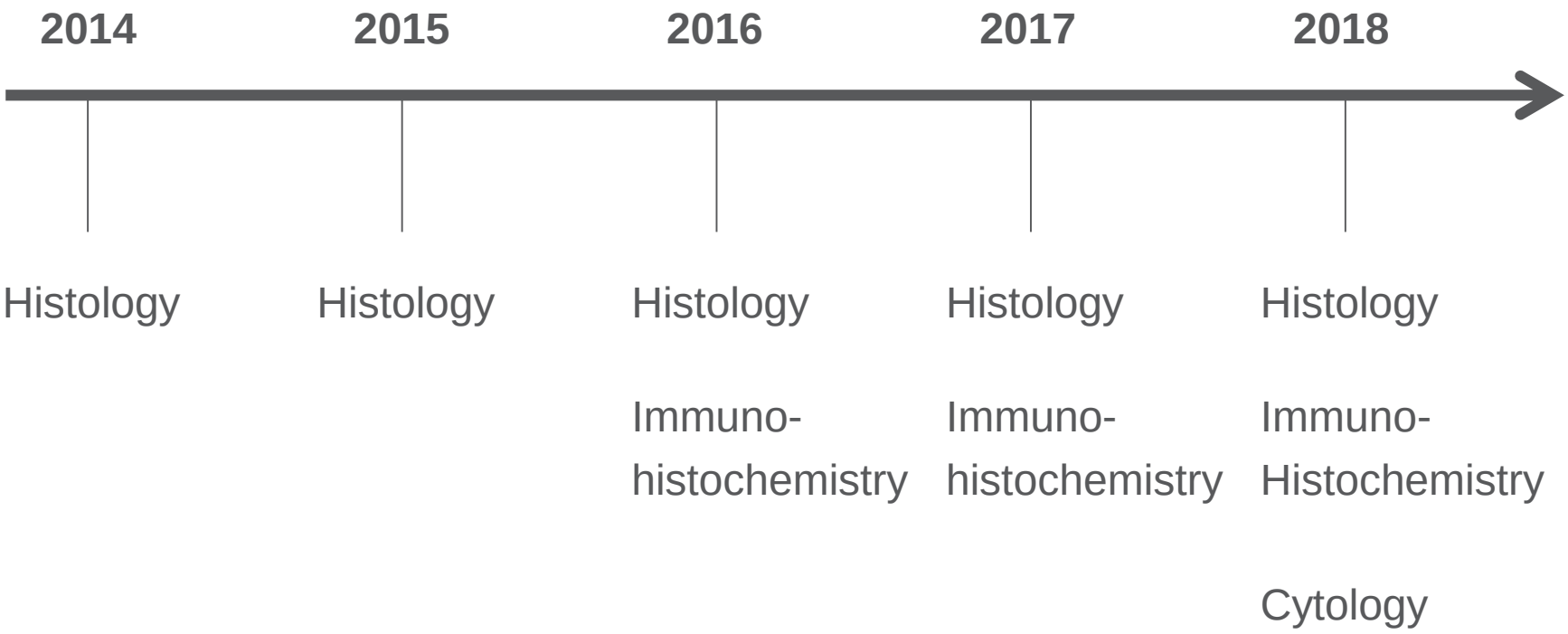
Belgian EQA program for pathology



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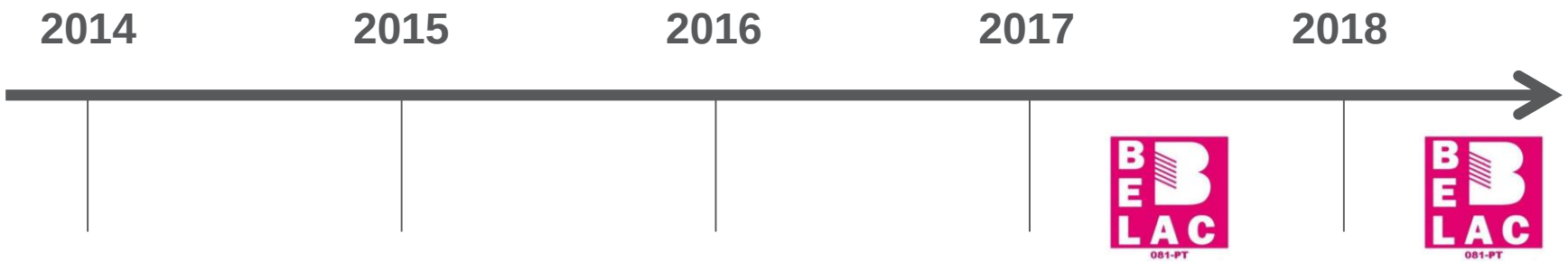
Belgian EQA program for pathology



2014	2015	2016	2017	2018
Histology	Histology	Histology	Histology	Histology
		Immuno-histochemistry	Immuno-histochemistry	*Immuno-histochemistry*
				Cytology

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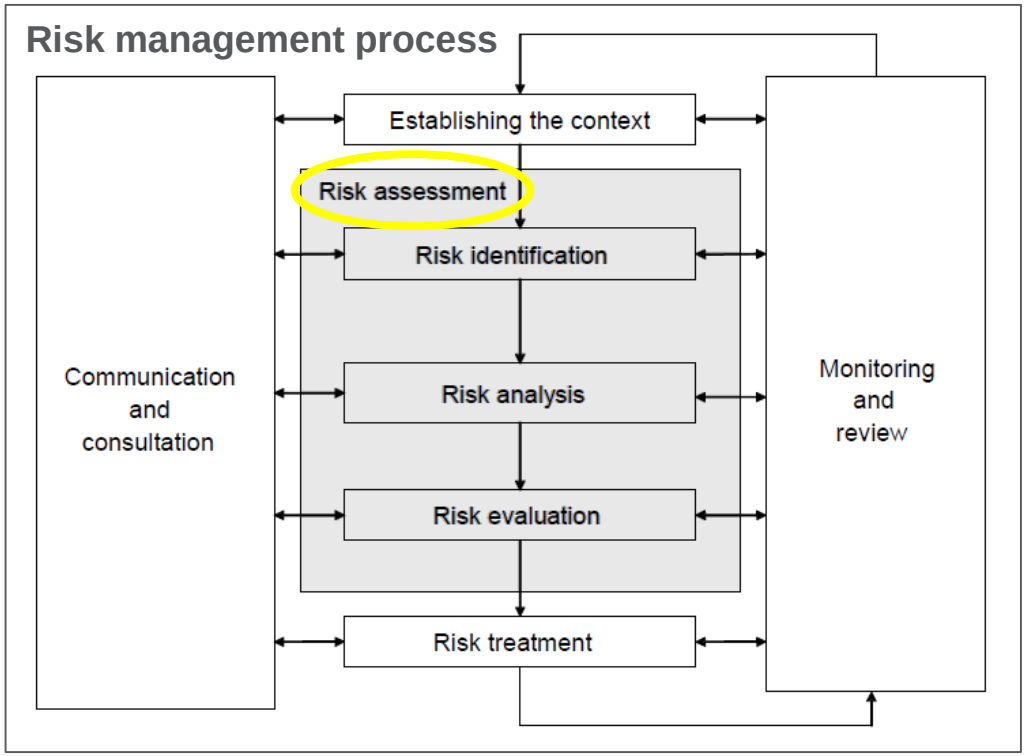
Contribution of risk assessment to the risk management process

Risk assessment attempts to answer the following questions :



- what can happen? (risk identification)
- why? (cause)
- what are the consequences?
- what is the probability of the future consequence?
- are there any factors that reduce the consequence or the probability of the risk?

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Failure Mode and Effects Analysis (FMEA)

- **Failure Mode and Effects Analysis (FMEA)** is a technique used to identify the ways in which the process can fail to fulfil its design intent.
- FMEA identifies :
  - ► potential failure modes
  - ► the effects these failures may have on the process
  - ► the mechanisms of failure
  - ► how to avoid the failure and/or reduce the effect on the process
- Once failure modes have been identified, corrective actions can be defined and implemented for the more significant failure modes

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FMEA - Round 1

Process step	Potential failure mode	Round 1 : Initial state						
		Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN
What is the step?	Manner in which the process could fail or go wrong	Consequences on other processes, customers,…		Causes of the step to go wrong (how could the failure mode occur?)		Activities that exist to prevent the failure mode from occurring or detecting it should it occur		

SEV = Severity, OCC = Occurrence, DET = Detection, RPN = Risk Priority Number
Source : www.isixsigma.com

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FMEA - Round 1

Process step	Potential failure mode	Round 1 : Initial state						
		Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN
What is the step?	Manner in which the process could fail or go wrong	Consequences on other processes, customers,…	Ranking 1 → 10	Causes of the step to go wrong (how could the failure mode occur?)	Ranking 1 → 10	Activities that exist to prevent the failure mode from occurring or detecting it should it occur	Ranking 1 → 10	

SEV = Severity, OCC = Occurrence, DET = Detection, RPN = Risk Priority Number
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Ranking definitions

Ranking		Severity	Occurrence	Detection
1 → 10		How severe is the effect?	How frequently is the cause likely to occur?	How probable/difficult is detection of the failure mode?
1	Very low	No effect	Eliminated	Almost certainly detected by process control
2				
3	Low			
4				
5	Medium			
6				
7	High			
8				
9	Very high	High level of impact	Inevitable failure	Cannot be detected (no control)
10				

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FMEA - Round 1

Process step	Potential failure mode	Round 1 : Initial state						
		Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN
What is the step?	Manner in which the process could fail or go wrong		**How severe is the effect?**		**How frequently is the cause likely to occur?**		**How probable/ difficult is detection of the failure mode?**	**Overall risk score**
			Ranking 1 → 10		Ranking 1 → 10		Ranking 1 → 10	**SEV × OCC × DET**

SEV = Severity, OCC = Occurrence, DET = Detection, RPN = Risk Priority Number
Source : www.isixsigma.com

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Risk Priority Number (RPN)

- **The risk priority number (RPN)** is the product of the rankings for :

RPN =	SEV	x	OCC	x	DET
	↓		↓		↓
	Conseq.		Causes		Controls

- Classify each identified failure mode according to its criticality
- High RPN's are flags to take action to reduce the calculated risk
- High severity ratings should be given special attention, regardless of RPN

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FMEA - Round 2

Potential failure mode	Round 1 : Initial state							Actions taken	Round 2 : New state (re-evaluation)			
	Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN		SEV	OCC	DET	RPN
								Actions for reducing occurrence of the cause or for improving its detection	can not be changed			

SEV = Severity, OCC = Occurrence, DET = Detection, RPN = Risk Priority Number
Source : www.isixsigma.com

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FMEA applied to the EQA process

- Retrospective evaluation of each step of the process of the EQA for pathology, in particular for the immunohistochemistry program
- Determined the failure modes and rated them for Severity, Occurrence and Detection
- Calculated the RPN for each failure mode
- Provided corrective actions on high RPNs (≥50) and highest severity ratings
- Applied these corrective actions to the following EQA immunohistochemistry
- Recalculated the RPN to assess their effectiveness in reducing errors

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FMEA applied to the EQA process : round 1

Process step	Potential failure mode	Round 1 : Initial state						
		Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN
Quality of the EQA samples	N = 8							RPN ≥50 N = 1
Logistics	N = 11							RPN ≥50 N = 2
Evaluation of the results	N = 3							RPN ≥50 N = 1
Reports	N = 3							
Other	N = 2							RPN ≥50 N = 2
Total	**27**							Median RPN = 15

RPN ≥50 N = 6

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FMEA applied to the EQA process : round 1

Process step	Potential failure mode	Round 1 : Initial state						
		Potential failure effect	SEV	Potential cause of failure	OCC	Current process controls	DET	RPN
Quality of the EQA samples	Poor sample selection	No evaluation possible	**8**	Human error	4	1) Sample is chosen on the basis of the available scientific information 2) Sample is released by supplier after being checked by a pathologist (HE & IHC stain)	4	**128**
Logistics	Participant results lost or delayed in the mail	Delay on the results	**5**	Cause with participant or error in the mail	2	1) The deadline is stated on the answer form and in the instructions letter 2) An e-mail is sent to remind the deadline	10	**100**
Evaluation of the results	Reviewer recognizes his own result	Influincing the results	**7**	Human error	5	1) The coordinator is present during the evaluation 2) A result is only accepted after consensus between all evaluators	5	**175**

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FMEA applied to the EQA process : round 2

Process step	Potential failure mode	Round 1 : Initial state				Actions taken	Round 2 : New state (re-evaluation)			
		SEV	OCC	DET	RPN		SEV	OCC	DET	RPN
Quality of the EQA samples	Poor sample selection	8	4	4	**128**	The samples are additionally checked by an expert committee	8	(1)	(1)	**8**
Logistics	Participant results lost or delayed in the mail	5	2	10	**100**	A traceable shipment is provided to each participant so that the shipment can be tracked by us	5	2	(2)	**20**
Evaluation of the results	Reviewer recognizes his own result	7	5	5	**175**	For additional anonimization, the slides are identified by means of a random number only known by the coordinator	7	(1)	5	**35**

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Summary

- Performed a risk assessment (FMEA) on the processes which directly affect the quality of the EQA schemes for pathology
- Determined 27 failure modes and their RPN's
- Defined and implemented corrective actions for the more significant failure modes (high RPN and high severity)
  - ► reduce the identified risks
  - ► optimize the process
  - ► achieve quality improvement of the EQA

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Sources and reference documents

- **ISO 31000:2018 //** Risk management – Guidelines

  ► provides a common approach to managing any type of risk faced by organizations; guidelines are not industry or sector specific
- **ISO 31010:2009 //** Risk management – Risk assessment techniques

  ► provides guidance on selection and utilization of risk assessment techniques (supporting standard for ISO 31000)
- **ISO 60812:2006 //** Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)

  ► describes FMEA and gives guidance as to how it may be applied

Table A.1 – Applicability of tools used for risk assessment

Tools and techniques	Risk assessment process					See Annex
	Risk Identification	Risk analysis			Risk evaluation	
		Consequence	Probability	Level of risk		
Brainstorming	SA[1)]	NA[2)]	NA	NA	NA	B 01
Structured or semi-structured interviews	SA	NA	NA	NA	NA	B 02
Delphi	SA	NA	NA	NA	NA	B 03
Check-lists	SA	NA	NA	NA	NA	B 04
Primary hazard analysis	SA	NA	NA	NA	NA	B 05
Hazard and operability studies (HAZOP)	SA	SA	A[3)]	A	A	B 06
Hazard Analysis and Critical Control Points (HACCP)	SA	SA	NA	NA	SA	B 07
Environmental risk assessment	SA	SA	SA	SA	SA	B 08
Structure « What if? » (SWIFT)	SA	SA	SA	SA	SA	B 09
Scenario analysis	SA	SA	A	A	A	B 10
Business impact analysis	A	SA	A	A	A	B 11
Root cause analysis	NA	SA	SA	SA	SA	B 12
Failure mode effect analysis	SA	SA	SA	SA	SA	B 13
Fault tree analysis	A	NA	SA	A	A	B 14
Event tree analysis	A	SA	A	A	NA	B 15