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EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Risk Management

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Principles of Risk Management

Risk management is essential for informed decision-making within all organisations.

A new concept…?

Risk management processes have been around for many years both within the healthcare and pharmaceutical industries. The definition of “risk” was first introduced into an ISO standard in 1990.

Why might we introduce risk management into our organisation?

- Requirement from a new or updated standard/regulation
- Increased spend due to unplanned events
- Lack of risk based decisions leading to patient safety risk
- Only use of reactive risk assessments- “fire fighting approach”

15189:2022 Updates

The newly updated ISO15189 standard has increased the emphasis on risk management and is aligned with ISO 22367- Medical laboratories – Application of risk management to medical laboratories. More specifically the standard focuses on **patient risk.**

In comparison to the 2012 edition where risk is stated **12** times, the new ISO 15189 standard states the term "risk" **85 times** over a 70 page document.

"The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories.
This document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. Benefits of this approach include: increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment."
- ISO15189:2022

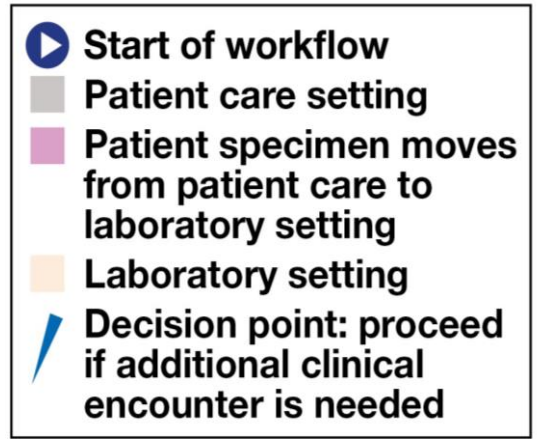

Fourth edition
2022-12

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

Total Testing Process

Path of Workflow
Assessing quality = considering every step of our testing process



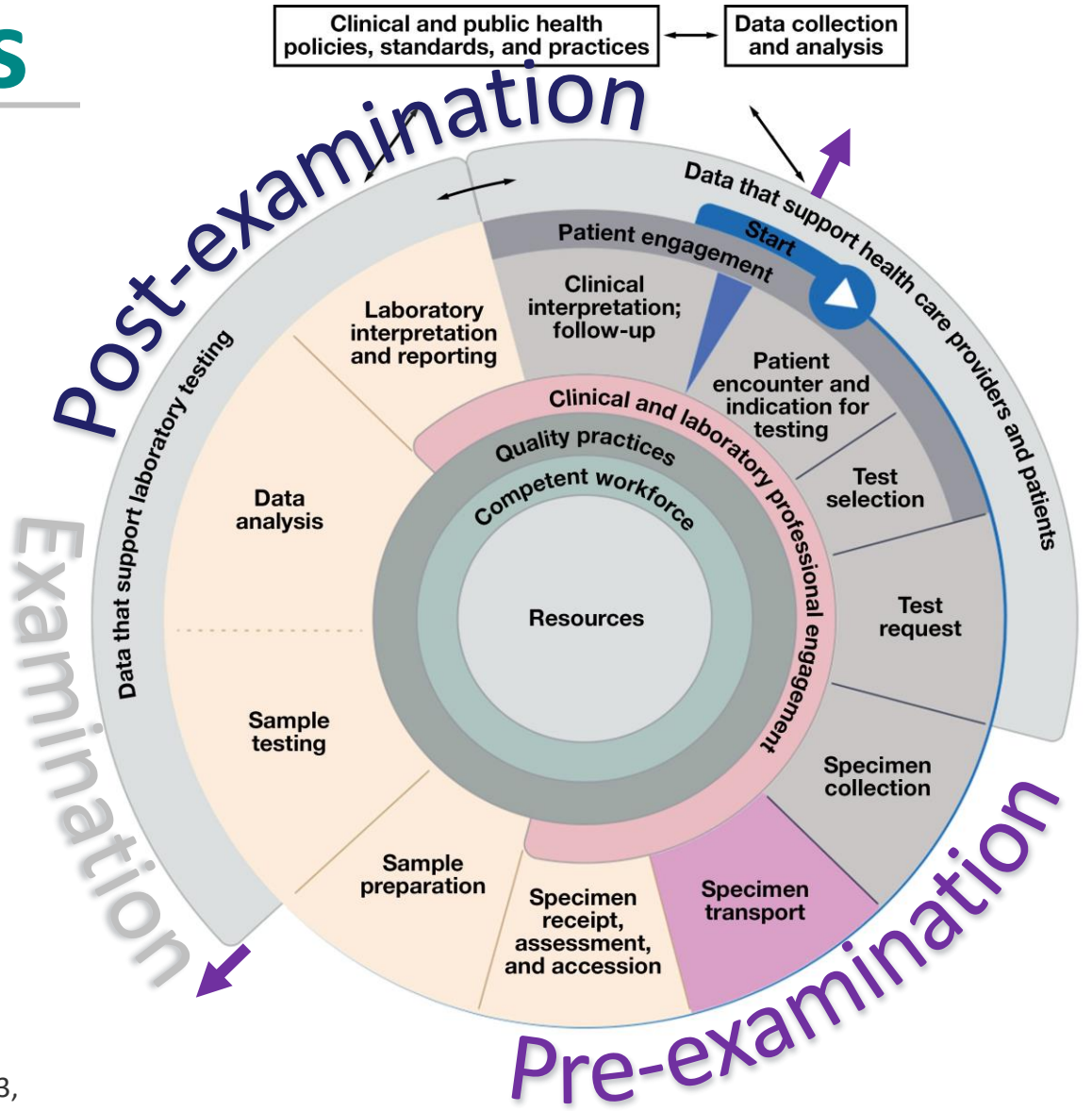


Image adapted from: Am J Clin Pathol, Vol 160(2), August 2023, Pg 124–129. https://doi.org/10.1093/ajcp/aqad038

(Quality) Management System Requirements

Establish, document, implement and maintain a management system

To include:

- responsibilities
- objectives and policies
- documented information
- actions to address risks and opportunities for improvement
- continual improvement
- corrective actions
- evaluations and internal audits
- management reviews

Underpinned by Risk Management

ISO15189:2022 5.4.2, 8.0

Risk Management: ISO15189:2022

Risk based
Patient focused
Continuous improvement
Less prescriptive

NOTE: clinical decision making can be used as a factor when performing risk assessments

QMS: Risk management

Quality management **duties**

- Implement, maintenance, improve the QMS
- Identify deviations from QMS or lab procedures
- Act to prevent or minimize deviations
- Report to management on QMS performance and improvement needs
- Ensure effectiveness of lab activities

Risk management

- Establish, implement, maintain processes for:
  - Identifying risks of harm to patients
  - Identifying opportunities for improved patient care
  - Developing actions to address risks and opportunities for improvement
- Lab director responsibility to ensure effectiveness and modification when ineffective

ISO 15189:2022 5.4.2, 5.6; ISO22367

Risk Management

RISK: the frequency with which a hazard occurs AND the severity of harm that may result when a hazard occurs

Acceptability and/or control of risks

In **design** of systems (initially) and in **monitoring** (when problems occur)

Recognition that controlling an identified risk may cause or worsen other associated risks (unintended consequences)

Evaluation of residual risk

Balance of perceived benefit against residual risk that still presents significant hazard

CLSI QMS01, CLSI EP18, ISO15189:2022, ISO22367:2020

Risk Definitions

Risk Management	Risk management is the identification, evaluation, and prioritization of risks. It is the practice of using processes, methods, and tools for managing these risks.
Harm	Damage to patient health, including the damage that can occur from loss of product quality or availability
Hazard	The potential source of harm
Risk	The combination of the probability of occurrence of harm and severity of that harm
Risk Assessment	A systemic process of organising information to support a risk decision to be made within risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Risk Assessment Definitions

Risk Identification: What might go wrong? This step identifies hazards based on historical data, theoretical analysis, informed opinions or concerns of stakeholders

Risk Analysis : What is the likelihood (probability) it will go wrong? This step is the estimation of risk associated with the identified hazards. Links the likelihood of occurrence and severity of harm. Often this stage is data driven- ensure data is reliable and accessible!

Risk Evaluation: What are the consequences (severity)?

Risk Management Basics

Plan for risk
Identify risk and its impacts
Develop risk-handling strategies
Monitor for risk control

Image: https://www.itprotoday.com/compliance-and-risk-management/what-it-risk-management

Risk Management: Overall process

Conduct a risk assessment using established tools

- Failure Modes and Effects Analysis (FMEA), process mapping, fault tree analysis

Prioritize risk based on effect and probability

Mitigation plan

- Insert process controls: example – critical POC glucose results
- Nonconformity process

Monitor

- Customer complaints, non-compliance events, quality indicators, audit findings

Types of Risk Assessments

There are many types of risk assessment tools available to use.

OUTCOME FOCUSED TOOLS

- Severity outcome grid/risk assessment matrix
- SWOT analysis assessments.

PRECISION FOCUSED TOOLS

- Failure mode studies
  - Failure mode effects analysis (FMEA)
    - Process that produces a list of *potential* failure modes across testing phases for a given process
  - Failure reporting and corrective action system (FRACAS)
    - Process to capture *failures*, apply control measures (corrective actions), prevent future failure
  - Hazard and operability study (HAZOP)
- Computer simulations (eg – Monte Carlo models)

Comparing tools

OUTCOME FOCUSED TOOLS

- Severity outcome grid/risk assessment matrix
  - High level, not detailed
  - Incomplete information
- Helpful for decision making
- Helpful where risk is concerning but there are low levels of information and control

PRECISION FOCUSED TOOLS

- Failure mode studies
  - Thorough
  - Systematic
  - Lengthy
  - Detailed
- Most useful when there are high levels of information and control

Use the products of these tools to prioritize risk based on effect and probability

CLSI EP18-A2

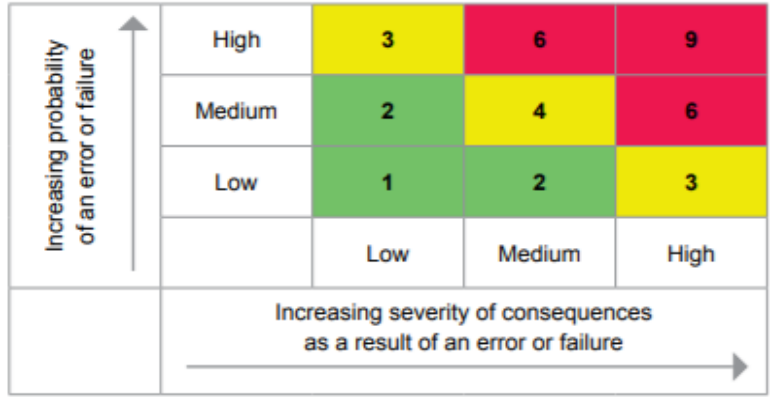
Conducting a risk assessment

OUTCOME FOCUSED TOOLS - Severity outcome grid/risk assessment matrix**:** This technique works by assigning values to probability of occurrence and the severity of the outcome to give a two-dimensional view. Often used for more basic risk assessments.

Consider only 2 major issues about possible / negative outcomes

How bad could the outcome be?

How frequently could the outcome occur?



For each identified risk the probability (likelihood) and severity (impact) are multiplied to give a risk score, with 1 as the lowest and 9 as the highest score in the simplest model

Once scored, the risks can be ranked and a risk score assigned to each identified undesirable event.

The weightings for severity and frequency can be modified to give a different spread of risk depending on the application and focus required.

Risk assessment matrix

PROBABILITY LEVELS			
Description	**Level**	**Specific Individual Item**	**Fleet or Inventory**
Frequent	**A**	Likely to occur often in the life of an item.	Continuously experienced.
Probable	**B**	Will occur several times in the life of an item.	Will occur frequently.
Occasional	**C**	Likely to occur sometime in the life of an item.	Will occur several times.
Remote	**D**	Unlikely, but possible to occur in the life of an item.	Unlikely, but can reasonably be expected to occur.
Improbable	**E**	So unlikely, it can be assumed occurrence may not be experienced in the life of an item.	Unlikely to occur, but possible.
Eliminated	**F**	Incapable of occurence. This level is used when potential hazards are identified and later eliminated.	Incapable of occurence. This level is used when potential hazards are identified and later eliminated.

Risk assessment matrix

SEVERITY CATEGORIES		
Description	**Severity Category**	**Mishap Result Criteria**
Catastrophic	**1**	Could result in one or more of the following: death, permanent total disability, irreversible significant environmental impact, or monetary loss equal to or exceeding $10M.
Critical	**2**	Could result in one or more of the following: permanent partial disability,injuries or occupational illness that may result in hospitalization of at least three personnel, reversible significant environmental impact, or monetary loss equal to or exceeding $1M but less than $10M.
Marginal	**3**	Could result in one or more of the following: injury or occupational illness resulting in one or more lost work day(s), reversible moderate environmental impact, or monetary loss equal to or exceeding $100K but less than $1M.
Negligible	**4**	Could result in one or more of the following: injury or occupational illness not resulting in a lost work day, minimal environmental impact, or monetary loss less than $100K.

Risk assessment matrix

RISK ASSESSMENT MATRIX				
SEVERITY / PROBABILITY	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequent (A)	High	High	Serious	Medium
Probable (B)	High	High	Serious	Medium
Occasional (C)	High	Serious	Medium	Low
Remote (D)	Serious	Medium	Medium	Low
Improbable (E)	Medium	Medium	Medium	Low
Eliminated (F)	Eliminated			

MIL-STD-882D

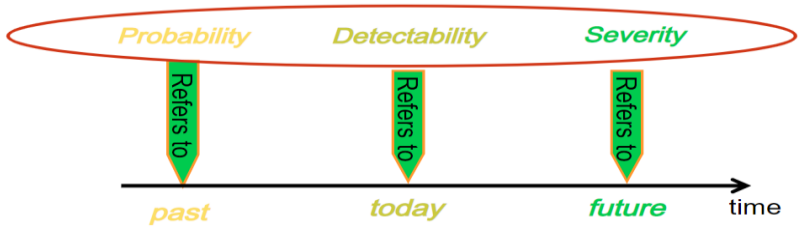
Conducting a risk assessment

PRECISION FOCUSED TOOLS - Failure Mode Effect Analysis (FMEA):
Prevention tool used to assess, manage and reduce risk associated with failure or potential failure of products, processes, services and other systems

- Identifies the points of potential failure for a given process or product
- Provides structured and sensitive scoring with a Risk Priority Number (RPN) to make high risks visible
- Requires significant information for input into the tool

The probability x severity x detectability is used to calculate the RPN:

1. Examine each step of the process
2. Consider every way process could fail
3. Alternatives for each possible failure (monitoring, new process)
4. Implement process with safeguards in place



FMEA Risk Assessment Scoring 1- 5

Category	Score	Severity (S)
Remote	1	No impact on patient health or product quality
Low	2	Minor impact on patient health or product quality
Moderate	3	Moderate impact on patient health or product quality
High	4	Major impact on patient health or product quality
Very High	5	Serious adverse impact on patient health or product quality

Category	Score	Probability of Occurrence (O)
Remote	1	Seldom fails
Low	2	Fails infrequently
Moderate	3	Fails periodically
High	4	Fails frequently
Very High	5	Always fails

Category	Score	Detectability (D)
Remote	1	Failure is obvious and readily detected
Low	2	Failure is frequently detected
Moderate	3	Failures might be undetected
High	4	Multiple failures may be undetected
Very High	5	Failure almost always escapes detection

FMEA example

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Table 3 Initial FMEA analysis with highest risk failure modes (before action plan)

Failure mode	Potential Effect	SI	Potential Cause	OI	Control measure	DI	RPN	Action taken
Transcription error (Wrong entry of result)	Useless result	5	Inefficient staff	5	Efficient staff training	4	100	Staff training was given
Malfunction of reagent	Useless result	5	Contamination	3	IQC before sample analysis	5	75	IQC before and after run
Malfunction of calibrator	Calibration failure	4	NC storage temperature	3	Visual check of calibrator	4	48	Continuous Temperature monitoring of refrigerator
Samples taken in wrong tubes	Wrong result	3	Inefficient staff	4	Efficient staff training	3	36	Staff training was given
Sample misplaced in laboratory	Delayed reports	3	Inefficient staff	3	Efficient staff training	4	36	Staff training was given

Scale 1-5	RPN
Severity x Occurrence x Detection	< 10
	≥ 10 - ≤ 30
	> 30

SI: Severity index

OI: Occurrence index

DI: Detection index

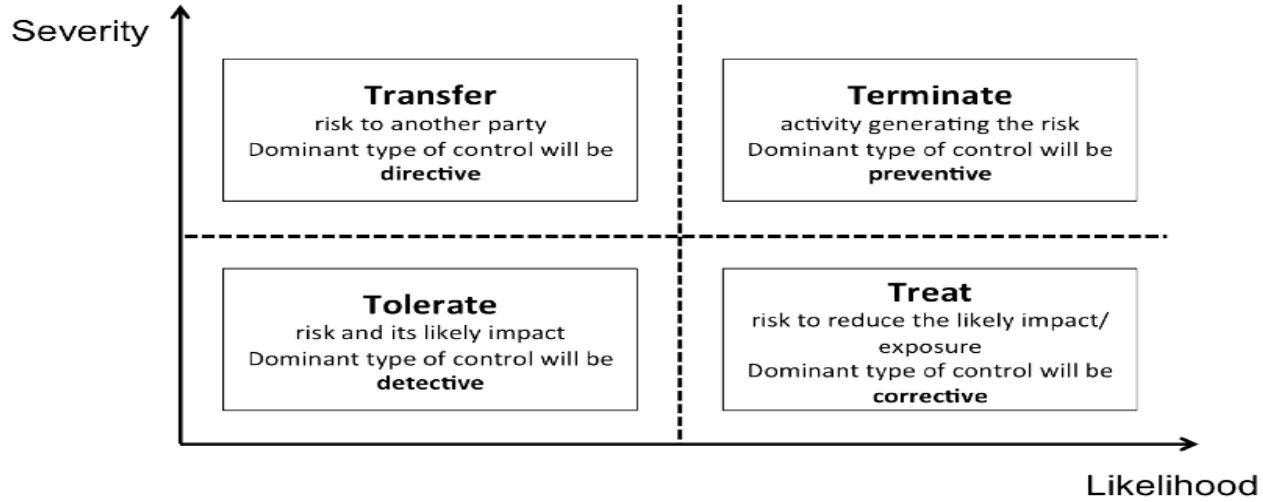
Sadariya, B.R., & Sudhakar, B. (2018). Application of failure mode and effects analysis to minimize quality failures in clinical biochemistry laboratory. International Journal of Clinical Biochemistry and Research.

Risk Control

Risk control includes decision making to reduce and/or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used for risk control should be proportional to the significance of the risk

Risk control should focus on the following questions:

1) Is the risk above an acceptable level?
2) What can be done to reduce or eliminate risks?
3) What is the appropriate balance among benefits, risk and resources?
4) Are new risks introduced as a result of the identified risks being controlled?



FMEA for POCT glucose (after control measures)

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Failure Mode	Type and Potential effect	SI	OI	Control Measure	DI	RPN
	what could go wrong ? (failure type)			what procedures have I implemented to mitigate risk ?(detection)		
identifying the wrong patient	• wrong patient WRONG TREATMENT	5	3	positive patient identifiers. name, date of birth electronic ID via CRN/ NHS no.	1	15
taking an inappropriate sample	• sample contaminated: by food / drink alcohol wipe by interstitial fluid • patient dehydrated or in peripheral shutdown WRONG RESULT	5	2	user understands pre-analytical effects competence assessed	1	10
Incorrect testing procedure	• incorrect sample volume • incorrect reagents / strips contaminated or stored at incorrect temperature or humidity. • Device faulty WRONG RESULT	5	3	user trained and assessed as competent electronic operator lock out IQC check of reagent strips and device – QC lock out if outside limits Temperature indicators on reagent boxes. Electronic recording of strip information / errors	1	15
Incorrect recording of result	• transcription error – poor light/ busy WRONG RESULT	5	4	electronic transfer of data to clinical portal/ patient notes audit trail of date / time / operator	1	20
Wrong interpretation	• drug interferences galactose/ maltose / haematocrit effects dehydrated/ shut down WRONG RESULT	5	2	user trained in limitations of procedure user aware of pre-analytical effects	1	10
Not acting on the result	NOT ACTING ON A HYPO AND HYPERGLYCAEMIC RESULT – WRONG MANAGEMENT	5	4	user trained on critical ranges and alerts appropriate personnel.	1	20

Reducing the risk score in FMEA

Once mitigating actions have been completed, the risk assessment should be re-reviewed and the RPN score recalculated to ensure the risk is acceptable.

If the RPN remains high, further actions may be required, or the decision may be made to either accept the residual risk based on risk to patient or to not accept the risk and a decision taken to suspend a test/platform if considering unsafe.

Establish controls, mitigation actions and avoidance initiatives which aim to reduce severity and/or impact of risk.

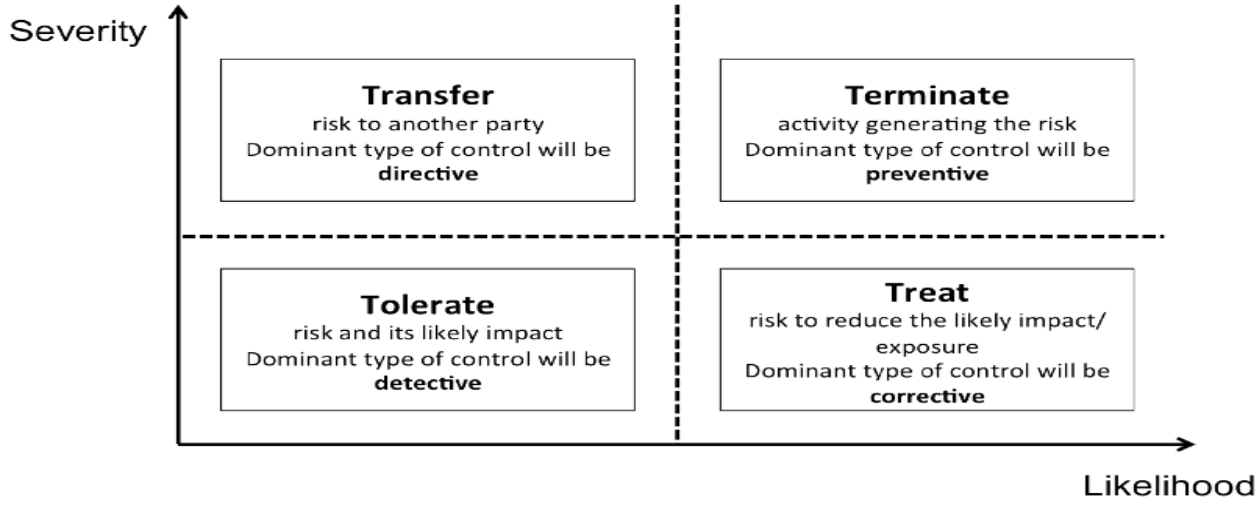


Figure 10: Risk treatment matrix[119]

Risk Management: Overall process

Conduct a risk assessment using established tools
- Failure Modes and Effects Analysis (FMEA), process mapping, fault tree analysis

Prioritize risk based on effect and probability

Mitigation plan
- **Insert process controls**
- **Nonconformity process**

Monitor
- Customer complaints, non-compliance events, quality indicators, audit findings

Process management and control

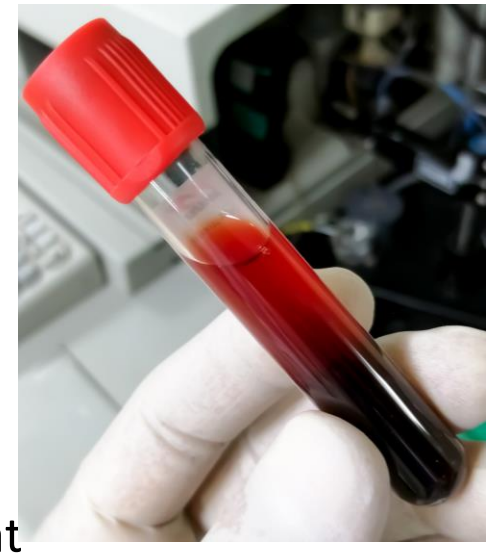
Process management/control

- Identify process controls for pre-examination, examination and post-examination activities in addition to all QSE activities
  - For examination activities these are usually IQC
  - Other examples: verify patient ID, link aliquots to the original specimen, reading back critical values

Goal of process controls:

- **Prevent** possibility of performing the process activities incorrectly (eg – automation)
- **Minimize** the likelihood of performing the process activities incorrectly (eg – verify patient ID)
- Increase the likelihood of **detecting** incorrect performance (eg – IQC)

Pre-examination risk management



RISK: Improper venipuncture can result in hemolysis
IMPACT: Specimen result is incorrect due to hemolysis interference
Process control to implement: Screen incoming samples for hemolysis on the automated analyzers by spectrophotometry. Automatically reject specimens exceeding defined hemolysis thresholds for each assay. (**detection**)
Process change to implement: Use of slightly larger bore venipuncture needles that demonstrate no increase in pain for patients but reduce hemolysis. (**minimize**)
Preventive measures to implement: Laboratory to participate in annual training of nurses to provide proper venipuncture training and reinforce consequences of poor technique (**prevention)**

Post-examination risk management

RISK: Updates to laboratory information system do not update appropriately to electronic medical record system
IMPACT: Clinicians and patients may not see patient results, results displayed improperly, or with wrong associated information leading to misdiagnosis or treatment.
Process control to implement: Following any laboratory information system update the electronic medical record system will be assessed for accurate reflection of laboratory results and associated information. (**detection**)

Examination risk management: IQC

Developed by a Motorola employee in 1980's
Measure: process capability relative to quality requirements
    E.g. - # defects per million results (products)
Six Sigma approach
    Problem solving
    Continuous improvement (DMAIC)
    Quantitative statistical process control

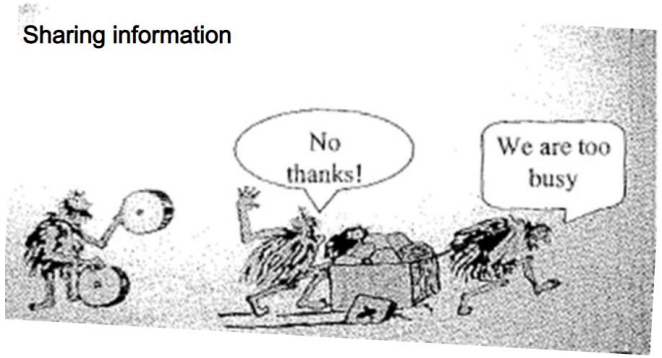
Image: https://www.6sigma.us/six-sigma-articles/six-sigma-business-analytics-lean-six-sigma-analytics/

Risk Review

The Risk management process should be revisited at defined intervals and actively evaluated in response to events/new information. Without a planned review, the risk process may gradually become more out of date, and may cease to be valid or useful. As a result, new risks and variables will not be identified and controlled.

Benefits of risk management

- Positive Contribution to patient protection
- Evaluate changes
- Encourages transparency- Supports science-based decision making- identifying risks can be positive! Do things that matter to the patient/product quality
- Facilitates Communication- an aid to convince stakeholders with trust
- Encourages a preventative approach- Proactive control of risks and uncertainty & benefit of knowledge transfer by team approach
- Better understanding of risk-based decisions
- Acceptance of residual risks are well documented



How should risk assessments be documented?

Ideally completed risk assessments should be stored and maintained within the organisations quality management system (QMS) or similar. This way much like a controlled document, the assessment can be given an agreed review date and be approved by stakeholders.

If risk assessments are being completed to support a recent non-conformance, it may be attached to that non-conformance record as evidence.

A risk assessment report may be created to go alongside the risk assessment. (an example can be provided)

If integrated within the QMS, any mitigating actions may be raised as individual actions within the QMS and given an owner and target date.

It is really up to the organisation to decide how their risk assessments will be stored and documented as long as they are readily available, up to date and are being tracked/reviewed on an agreed basis.

Creating a Risk Culture within an organisation

Risk Management is a lifecycle approach, and requires vigilant management of risks, supported by:

- Strong organisational culture- maturity
- Critical thinking skills
- Robust data
- Trained and experienced staff – with excellent product and process knowledge

When starting to create a risk culture within an organisation it's important to consider how the organisation currently operates:

An organisations "risk maturity" level may change:

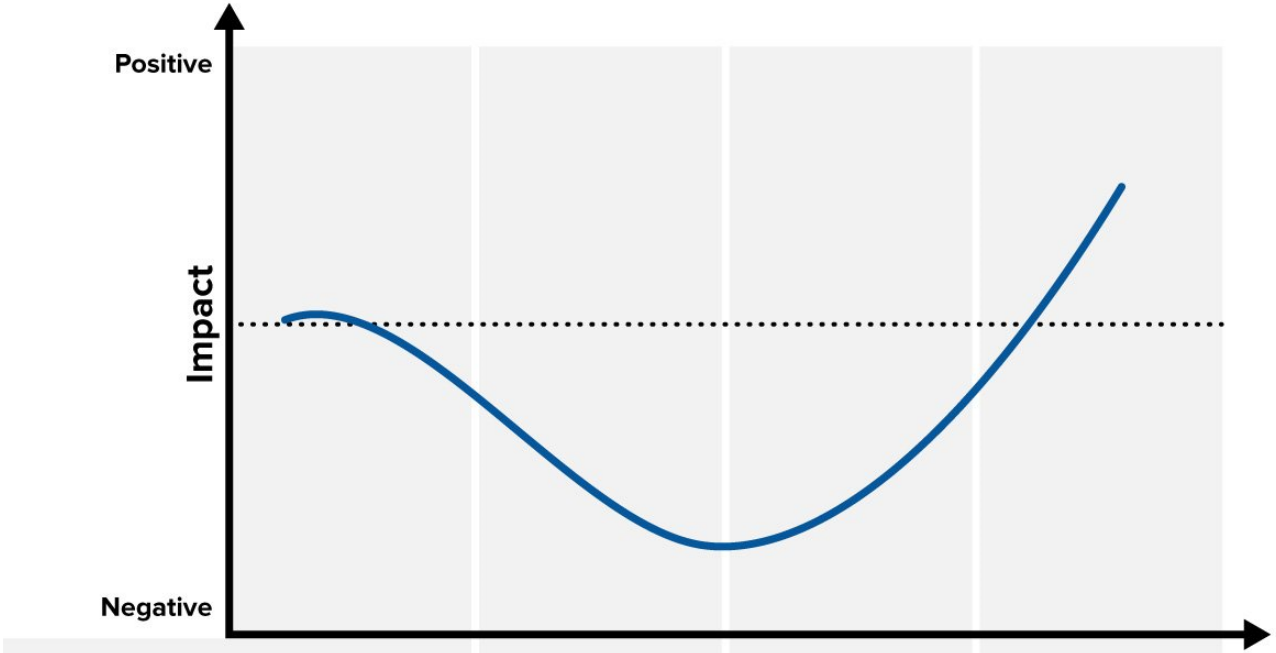
- Key members of staff leave the business (knowledge gap)
- Loss of data
- Loss of communication to key stakeholders
- Lack of senior management support in reducing organisational risks

Risk Maturity Level	Risk Processes	Attitude	Behaviour	Skills and Knowledge
Skepticism	No formal processes	"Accidents will happen"	'Fear of blame' culture	Unconscious incompetence
Awareness	Isolated use of stand-alone processes	Suspended belief	Reactive, 'fire fighting'	Conscious incompetence
Understanding and application	Extended use of combined processes	Passive acceptance	Compliance thinking	Conscious competence
Embedding and integration	Risk management embedded in the business	Active engagement	Risk-based decision making	Unconscious competence
Robust risk management	Frequent risk review and improvement	Champion	Innovative and appropriate risk management	Expert

How does your organisation manage risk?

- Do you have up to date process flows?
- Do you report non conformances/deviations effectively?
- Do you trend and turn your data into knowledge? Is this knowledge accessible?
- Do you have organisations objectives?
- Do you conduct internal audits?
- Regulatory and cultural environment?
- Do you have a Risk Management SOP/systems?
- Do you have effective communication mechanisms?
- Are staff appropriately trained in risk management?
- Do you monitor risks?
- How are your risk mitigating actions captured? Do the actions have owners and appropriate target dates?
- Do you have a risk register?

The Change Curve



Stage	1	2	3	4
State	Status Quo	Disruption	Exploration	Rebuilding
Reaction	Shock, Denial	Anger, Fear	Acceptance	Commitment

And of course with implementation of new systems such as risk management comes acceptance of change by staff within the organisation.

With good forward planning, robust systems, staff training and support from management, changes can be implemented effectively.

Risk Assessment Process/Systems

ISO15189:2022 Section 5.6 a)- *laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with it's examinations and activities, and develop actions to address both risks and opportunities for improvement.*

It also states that although the standard requires that the laboratory identifies and addresses risks, there is no requirement for any particular risk management method. Laboratories can use ISO 22367 and ISO3501 for guidance.

However- in order to create a strong risk culture and ensure staff are able to access guidance for both conducting and reporting/reviewing risk assessments, it would be very difficult to do this without appropriate systems in place. Something to think about…

Risk Register Example

You may wish to introduce a organisational/department risk register to capture risks and ongoing mitigating actions.

Date raised	Risk description	Severity	Mitigating action	Progress of actions	Status
01 Dec 2023	Equipment maintenance planned for equipment X on 21 Dec 23	High – no equipment available to run glucose testing on this day	Order back up equipment/device to ensure no disruption to service and risk to patient	PO placed for back up equipment/device	Open

THINGS TO REMEMBER:

- Always try to work as a team when conducting new risk assessments- knowledge is power and risk assessments can be subjective when performed in silo
- Set out clear objectives and agree scoring before initiation of the risk assessment
- Ensure risk scoring is based on good data and there is appropriate evidence of this
- Risk management is a life cycle- risk assessments should be reviewed on an agreed date based of the level of risk and formality of that risk assessment. If new risks arise then the risk assessment should be reviewed soon after.
- Seek approval of the risk assessment by management and ensure the risks are well documented and communicated
- There may be instances where the decision is taken to accept residual risks. Ensure these are well documented/justified and have management approval.
- Keep the **safety of the patient** at the forefront of your mind throughout the process!

Any Questions?