RISK MANAGEMENT IN MEDICAL LABORATORIES

Overview of Risk Management

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ISO 15189:2022 Introduction

"A clinical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results"

Key concepts to be aware of

- This version is patient-focused
- The standard is risk-based
- The standard is a minimum requirement not a maximum
- The expectation is that laboratories should seek to be the best they can, not just reach the minimum set out by the standard
- This standard does not prevent you from doing things that are optional or no longer required

Key ISO Standards

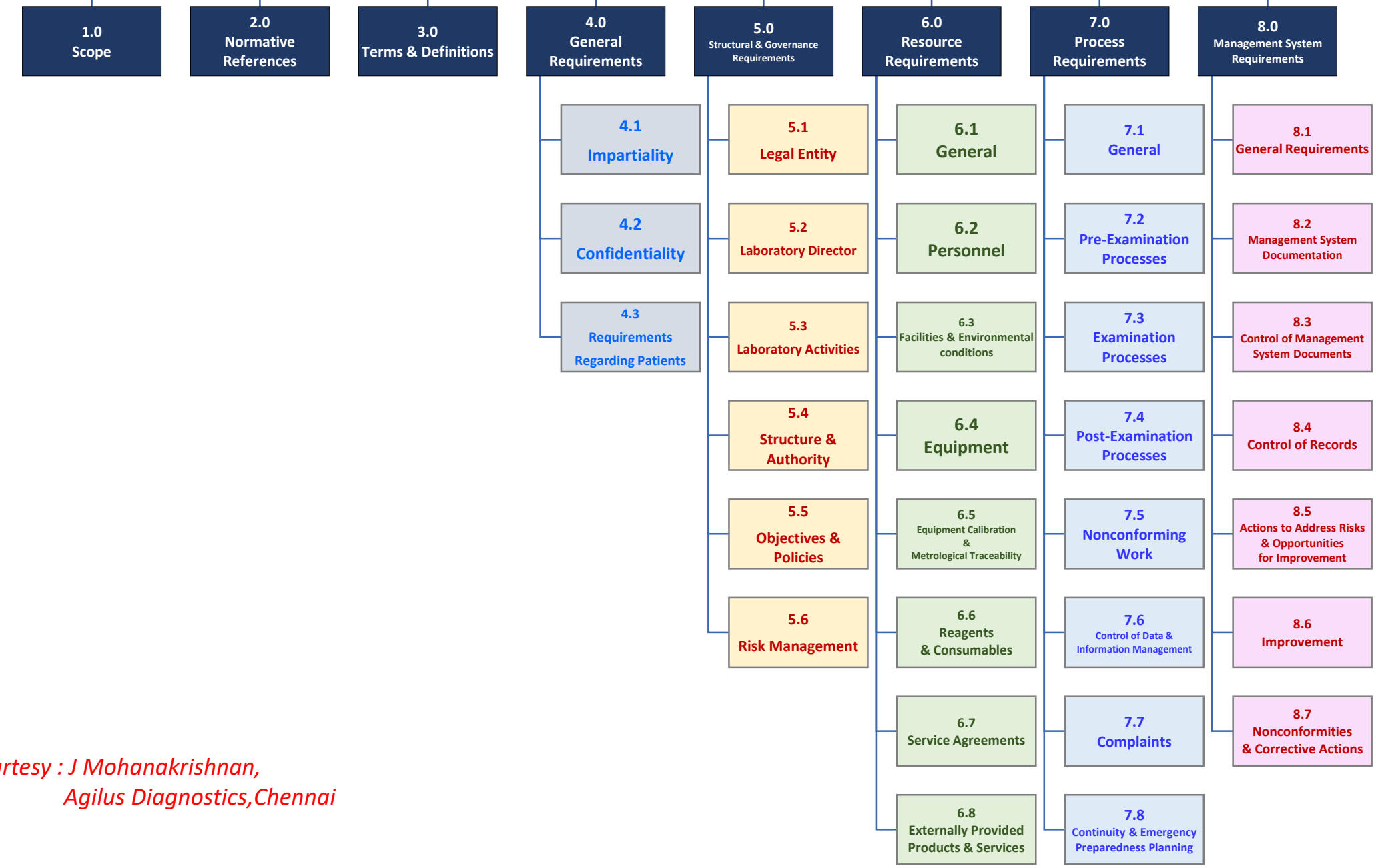
- ISO 9001 – Quality management systems
- **ISO 17025 – Testing and calibration laboratories**
- **ISO 15189 – Medical laboratories**
- **ISO 22367 – Risk management**
- **ISO 15190 – Laboratory safety**
- **ISO 20658 – Sample collection and transport**
- **ISO 22870 – Point-of-care testing (POCT)**
- ISO 17043 – Proficiency testing / External quality assessment
- ISO 19011 – Internal audit
- ISO 17011 – For accrediting bodies

Content Overview of ISO 15189:2022 Standard

- The standard is divided into 8 major sections plus annexes (A-C)
  1. Scope
  2. Normative references
  3. Terms and definitions
  4. **General requirements**
  5. **Structural and governance requirements**
  6. **Resource requirements**
  7. **Process requirements**
  8. **Management system requirements**

- Sections 1, 2 and 3 are for guidance only and are not auditable
- The 'meat' of ISO 15189 resides in the *requirements* sections (5 total)
  - Laboratories must effectively satisfy these requirements to be accredited

ISO 15189:2022



Courtesy : J Mohanakrishnan,
Agilus Diagnostics,Chennai

ISO15189 supporting documents

- ISO 22870:2016 *Point of care testing (POCT) – Requirements for quality and competence*
- ISO15190:2019 (new) *Medical laboratories – Requirements for safety*
- ISO 22367:2019 (new) *Medical laboratories – Application of risk management to medical laboratories*
- ISO/TS 20658:2017 *Medical laboratories – Requirements for collection, transport, receipt and handling of samples*
- ISO/TS 20914:2019 *Medical laboratories – Practical guidance for the estimation of measurement uncertainty*
- ISO 35001:2019 *Biorisk management for laboratories and other related organisations*
- Documents developed in other WGs may also be relevant to specific laboratories e.g. molecular diagnostics

General risk concepts

- Clause 5.5.2 covers the requirements of the laboratory director
- Clause 5.6 is the main risk clause
- Clause 7.1 looks at preanalytical risk
- Clause 7.5 covers risk and non-conformance
- Clause 7.8 covers the requirements for risk to patients and services in contingency planning
- Clause 8.1.1 risk and opportunities for continuous improvement
- Clause 8.5 identification of risk
- Clause 8.6.1 looks for areas with the highest degree of risk
- Clause 8.7 risk and corrective action
- Clause 8.8.3.2 risk and audit
- Clause 8.9 risk and management review

Risk and risk management permeate this standard,
the general and specific references to risk have been identified,
but risk and risk to the patient should be considered throughout this document

Specific risk concepts

- Clause 6.3.2 facility controls
- Clause 6.5.2 risk and calibration
- Clause 7.2.4.1 risk and primary sample collection
- Clause 7.2.4.3 risk and consent
- Clause 7.2.5 sample transport
- Clause 7.2.6.2 sample acceptance
- Clause 7.3.5 biological reference intervals
- Clause 7.3.7.2 internal quality control
- Clause 7.4.1.4 results
- Clause 7.4.1.5 automation of results

Overview of Risk Management

"Most of the evil in this world is done by people with good intentions." – T.S. Eliot

- Process mapping
- Risk identification
- Evaluation
- Reduction
- Analysis and
- Mitigation

Concept of Risk is not New

- Gamblers and investors
- Finance
- Manufacturing
- Service industry
- Transportation
- Airlines
- Insurance

They all try to mitigate

Concept of Risk is not New

- Gamblers and investors
- Finance
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It is new to us

Healthcare (1970s)

Patient safety programs (2000)

Medical laboratories (2003)

NC, Risk, Error and Harm

NC - an opportunity for improvement

Risk - possibilities of causing harm

Error - already occurred and

Harm- is the final outcome.

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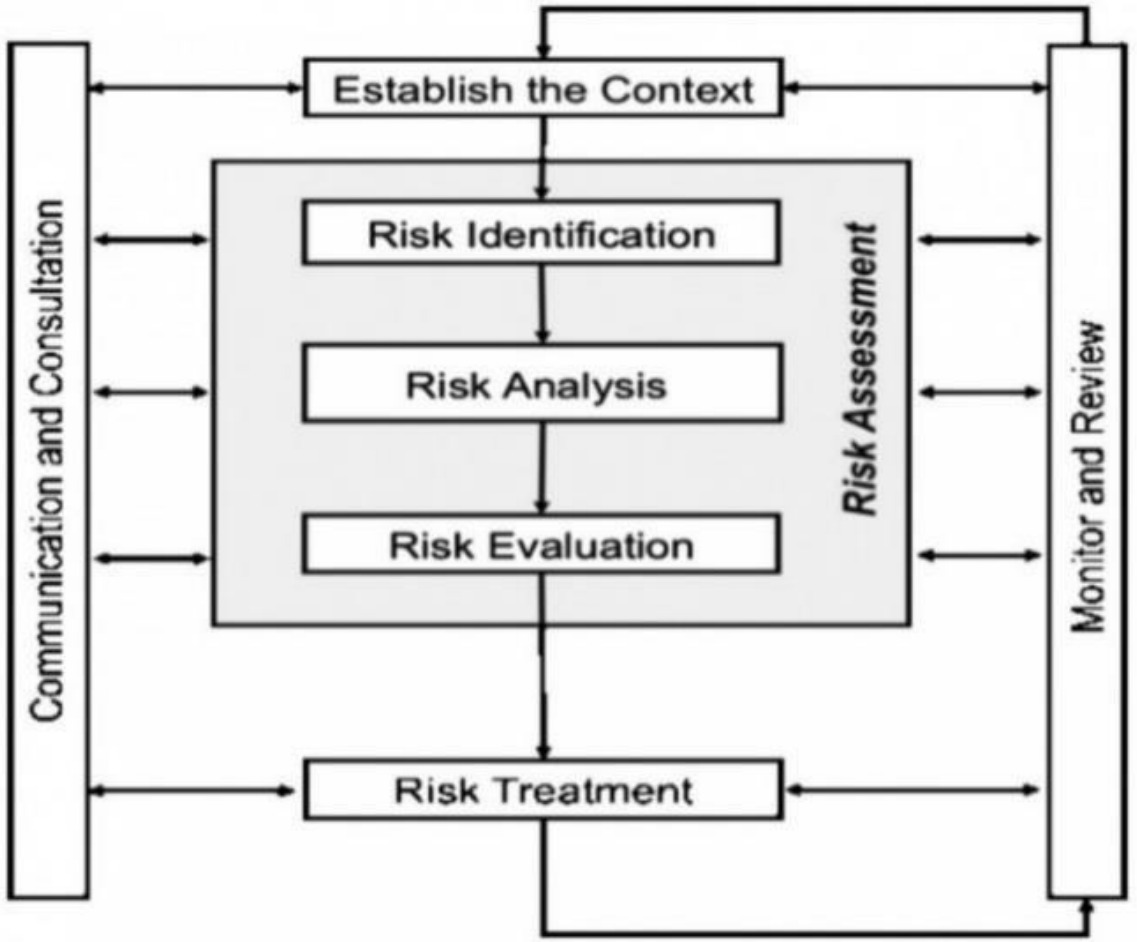
Risk Management Process



Laboratory is involved in Measurements which has to be Traceable

- Measurement has to be accurate.
- Measurement has to be precise.
- Measurement has to be specific.
- Measurement must be reliable.
- Measurement need to be dependable.
- Measurement has to be **traceable.**

If measurements are not traceable

Results in risk

Risk Management

Risk: Chance of something happening that will impact the objectives
Riscare: to dare (latin)
Risk is the effect of uncertainty on objectives (ISO 31000:2009 Risk management – Principles and guidelines)

ISO 14971: Medical Devices – Application of Risk Management to Medical Devices

CLSI EP18-A2 Risk management techniques to identify and control error sources

CLSI EP23-A (2011) Laboratory QC based on risk management

Risk Management

Harm: Physical injury or damage to health of people

Hazard: Potential source of harm

Mitigate, mitigate and mitigate…

Sten Westgard (2005)

- Put simple, risk is the possibility of suffering harm
- Risk is omnipresent in healthcare

more so in diagnostic services

- *Risk management* ***is the art*** of
  - ➢ figuring out the possible outcomes
  - ➢ planning for these outcomes

Risk mitigation is science

If **quality** asks

“How do we do the right things right?”,

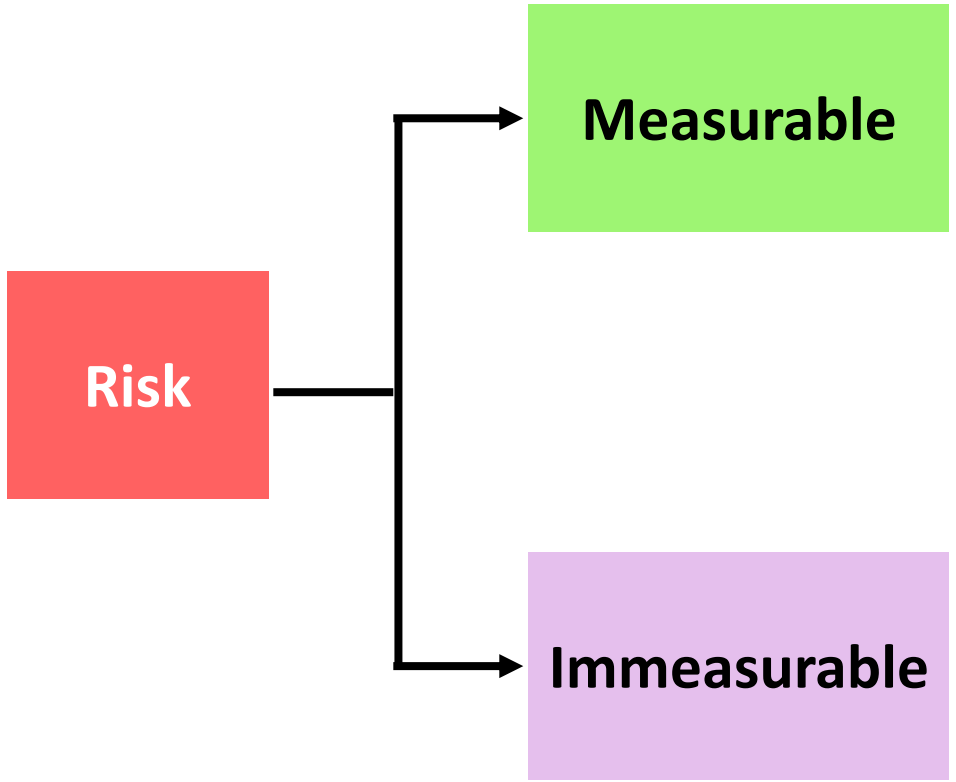
Risk management asks

“What can go wrong and what can we do about it?”

…….Mitigate and mitigate……

Risk

- **One can never completely predict a cause** or outcome (result).
- **Risk is not a fixed measurement**. Small causes may have big effects (down streaming).
- **Greater the interval between cause and effect,** the **less likely the relationship is recognized.**
- Reduce element of surprise by **increasing information.**



Risk and the Medical Laboratory

- **Clinical decisions** are made on the results of analysis.
- Poor information leads to adverse outcomes.
- Variables are many – some controllable, others difficult to control and still others that we cannot foresee.
- Laboratory is often seen as the source of the problem regardless of contributing events.

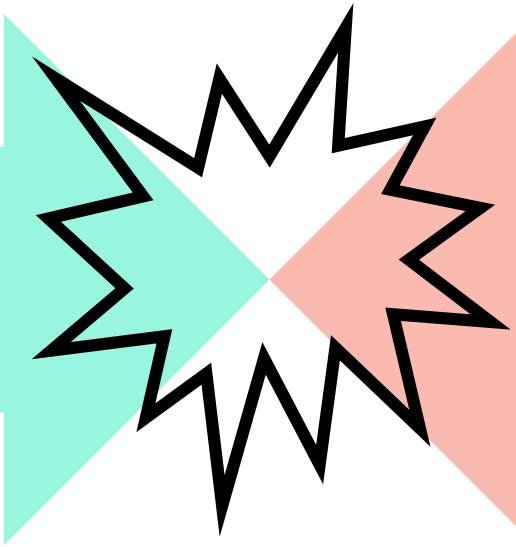
Medical Laboratory Standards on Quality and Risk

Quality Management Framework
ISO 15189:2012
Medical Laboratories: Requirements for quality and competence

ISO 22367: 2008
Medical laboratories: Reduction of error through risk management and continual improvement.

Quality Management Framework

Quality
Competence
Continual Improvement
Prevention



Risk Management Framework

Analysis and Calculation
Risk Reduction

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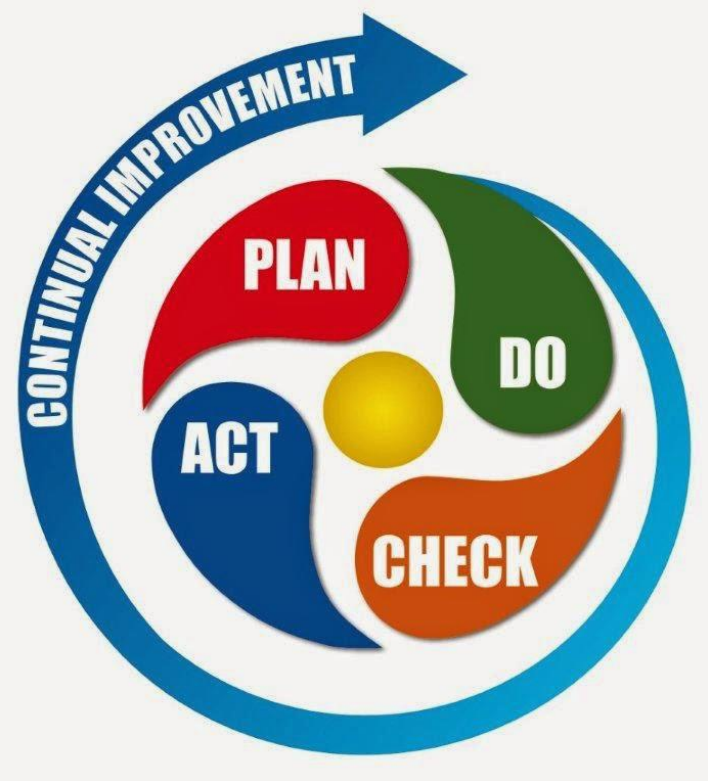
Deming Cycle



Plan for Risk

Identify Risk

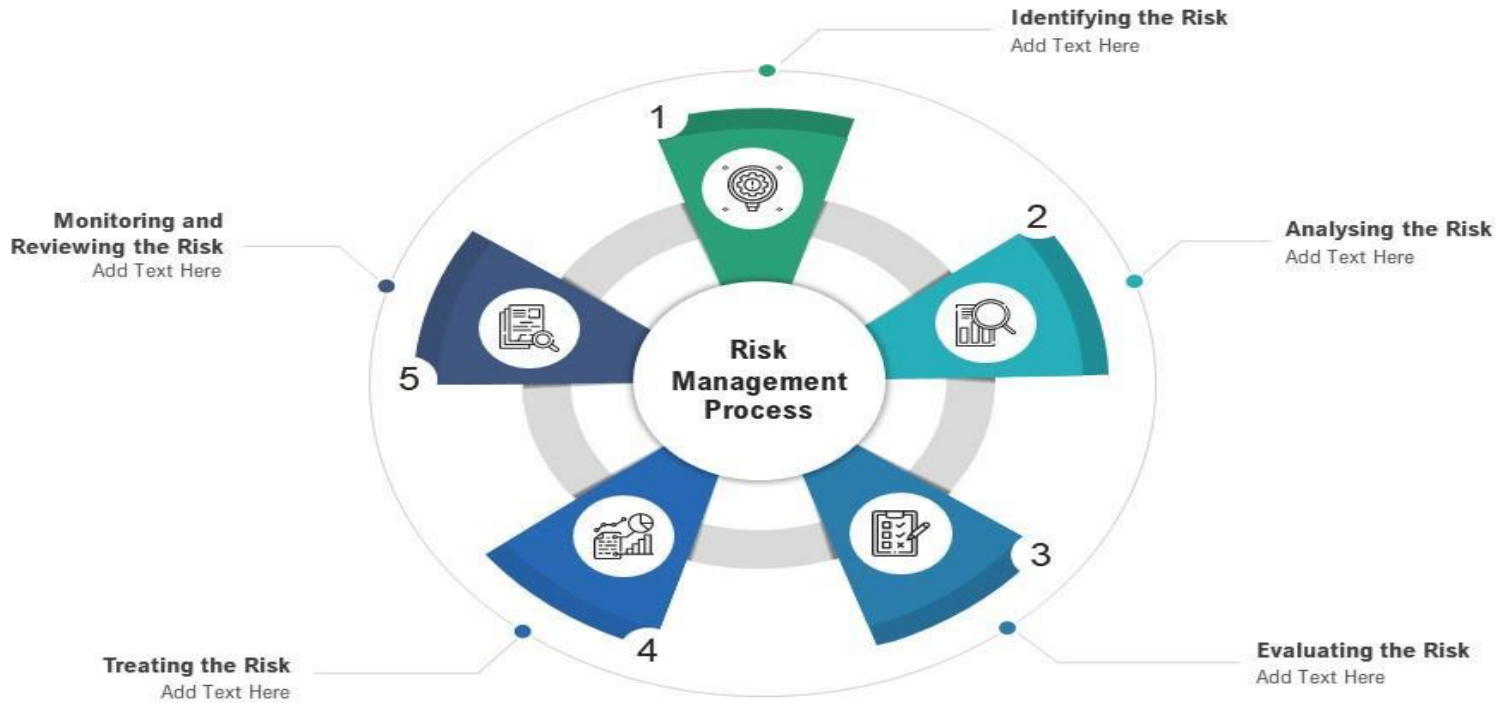
Examine for Impact

Mitigation strategies

Monitor and control outcome

Risk Management Process

Five Stage Cycle of Risk Management Process



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Decision Making

- High risk does not necessarily mean “avoid”
- Low risk does not necessarily mean “forget about it”

Risk level sets the responsibility matrix for RISK DECISION MAKING

What impacts RISK DECISION making?

Risk Mitigation

Risk mitigation involves **taking action to reduce an organization's exposure to potential risks and reduce the likelihood that those risks will happen again**. ... Risk mitigation is one of the steps in risk management, which includes identifying the risk, analyzing the risk, and mitigating the risk.

Identification------analysis-------**mitigation**

Risk Mitigation

… IS POSSIBLE

Any Questions

Thank You!