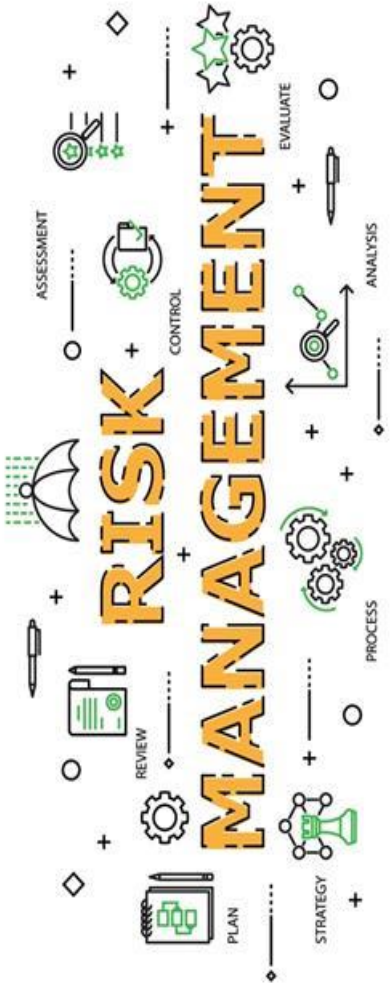
Risk Based Assessments

Changing the focus from compliance based
to risk based assessments



ISO 31000

- **Managing risk is part of governance and leadership, and is fundamental to how the organisation is managed at all levels.** It contributes to the improvement of management systems.
- Managing risk is part of all activities associated with an organisation and includes interaction with **stakeholders**.
- Managing risk considers the **external and internal context** of the organisation, including **human behaviour and cultural factors**.
- By definition, “risk” is a measure of the **severity of the impact** of a potential error, multiplied by the **probability of how likely** it is that the error will occur and the ability to **detect the error** if it should re - occur.

NPAAC & Risk Based Assessments

- NPAAC applies a risk based approach to the pathology accreditation framework.
- Focus on areas of **high potential risk** and on the **prevention** of harm to patients.
- Medical Pathology Services must **identify** key risks to patient safety, **collect data** and **monitor** the performance of the Medical Pathology Service in managing these risks.
- The risk management framework must include, or form part of, a Quality Management system.
- RMPS - *Appendix A Risk Assessment – Risk Points,*

Risk Based Assessments

NPAAC – RMPS *Risk Point – App A*	Scenario examples	Risk points to consider	Discussion: Compliance vs Risk to patient
Pre-analytical Patient identification Specimen integrity Specimen traceability & transportation	You are observing a collector taking blood, and noted that patient identification was done incorrectly. The waiting area is busy and a number of patients are waiting on the collector. You ask the facility representative what they have in place for monitoring correct patient identification, but it seems they rely mostly on complaints coming back and a 3year refresher training. You also know, that studies have shown that the majority of lab errors occur during the pre & post analytical phase.	*Severity (Impact on patient)* High - Has potential for high impact on patient *Probability of occurrence* High - based on industry studies *System in place to detect errors* High - limited evidence that system in place is robust enough to detect or monitor errors	Do you see this as a once off, collector probably nervous due to the number of patients waiting? Do you just mention this in passing to the collector? OR discuss with LA?

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NPAAC – RMPS *Risk Point – App A*	Scenario examples	Risk points to consider	Discussion: Compliance vs Risk to patient
Competency of staff: **Demonstrated ability** to perform a task successfully and efficiently. Ability to escalate critical results/ events	You are assessing a laboratory and noted that the ongoing competency evaluation of one of the bench scientists have not been performed in the last 12 months, as required by the laboratory's own procedures. You also note that this scientist have participated in QAP, with no discordant results and no issues with IQC.	*Severity (Impact on patient)* High - Has potential for high impact on patient *Probability of occurrence* Low - evidence confirmed that no other instances were noted *System in place to detect errors* Low - evidence confirmed that there are no issues with QA	Consider what the impact of this scenario could be on the patient?

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NPAAC – RMPS *Risk Point – App A*	Scenario examples	Risk points to consider	Discussion: Compliance vs Risk to patient
Competency of staff: (Continuing)	You are assessing a laboratory and noted that ongoing competency evaluation occurs haphazardly. You also noted a number of QAP discordant results and IQC failures.	*Severity (Impact on patient)* High - Has potential for high impact on patient *Probability of occurrence* High - evidence confirmed numerous instances *System in place to detect errors* High - evidence confirmed numerous fails	

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NPAAC – RMPS *Risk Point – App A*	Scenario examples	Risk points to consider	Discussion: Compliance vs Risk to patient
Specimen analysis, incl. equipment and reagents/ consumables	You are assessing the core laboratory and noted that the temperature log form (reagent fridge) requires the Lab Man to sign-off at the end of each month; however this has not been done for 3 out of the preceding 12 months. You also note, that the fridge is fairly stable, a few outliers have been noted over the last 12 months and staff have noted (at each occurrence) any corrective action they have taken due to the outliers.	*Severity (Impact on patient)* Low - Limited impact on patient *Probability of occurrence* Medium – evidence confirmed a few instances *System in place to detect errors* Low - evidence confirmed that fridge is in control and outliers have been actioned	