IMPLEMENTATION OF RISK MANAGEMENT IN MEDICAL LABORATORY

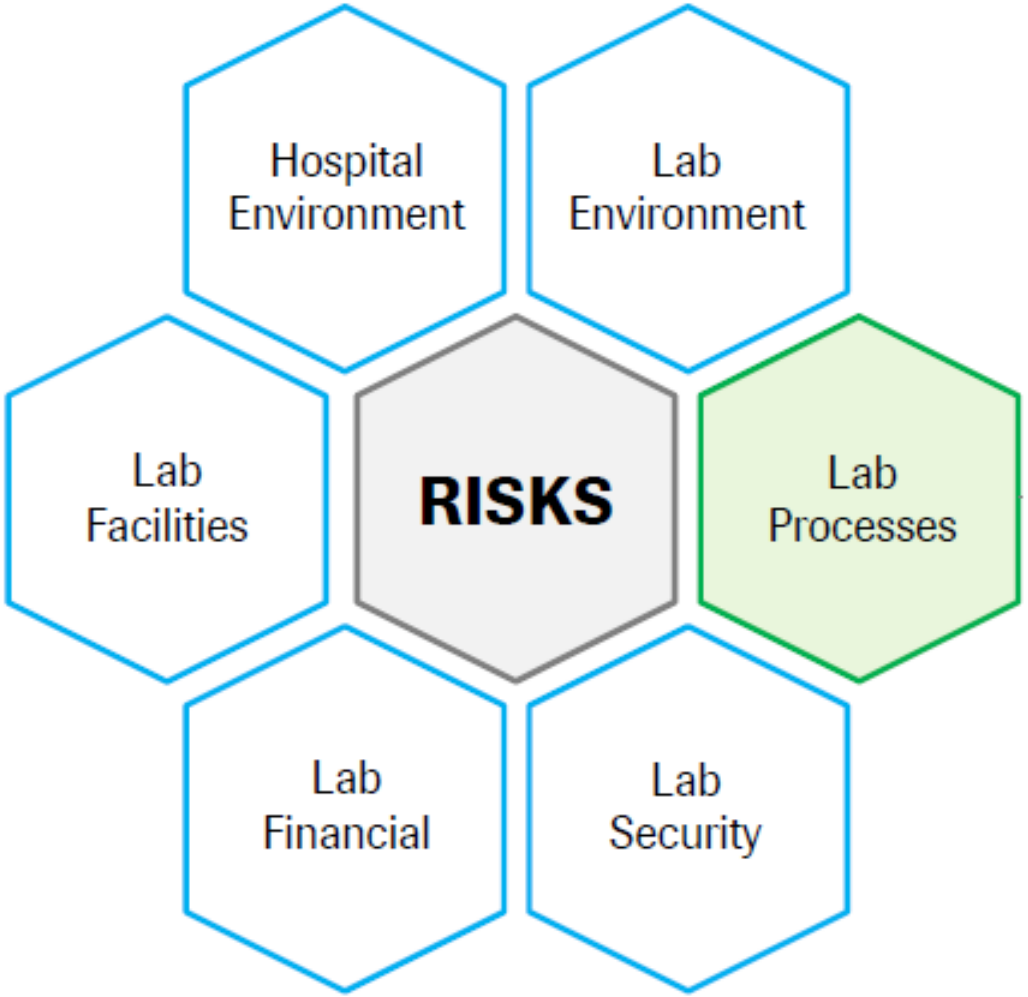
Introduction

- Potential non-conformity

  Potential non-compliance of any aspect of testing work (including test results) to the laboratory’s quality management system (QMS), or the agreed requirements of the clients.

Introduction

Laboratory related risks;



When to do Risk Assessment ?

- New processes start-up
- Changing of work practices, procedures or the work environment
- Purchasing new or used equipment or using new method
- Planning to improve productivity or reduce costs
- Responding to workplace incidents (even if they have caused no injury)
- Responding to concerns raised by staff, health and safety representatives, regulations for specific hazards or internal and external auditor.

Implementation requirements

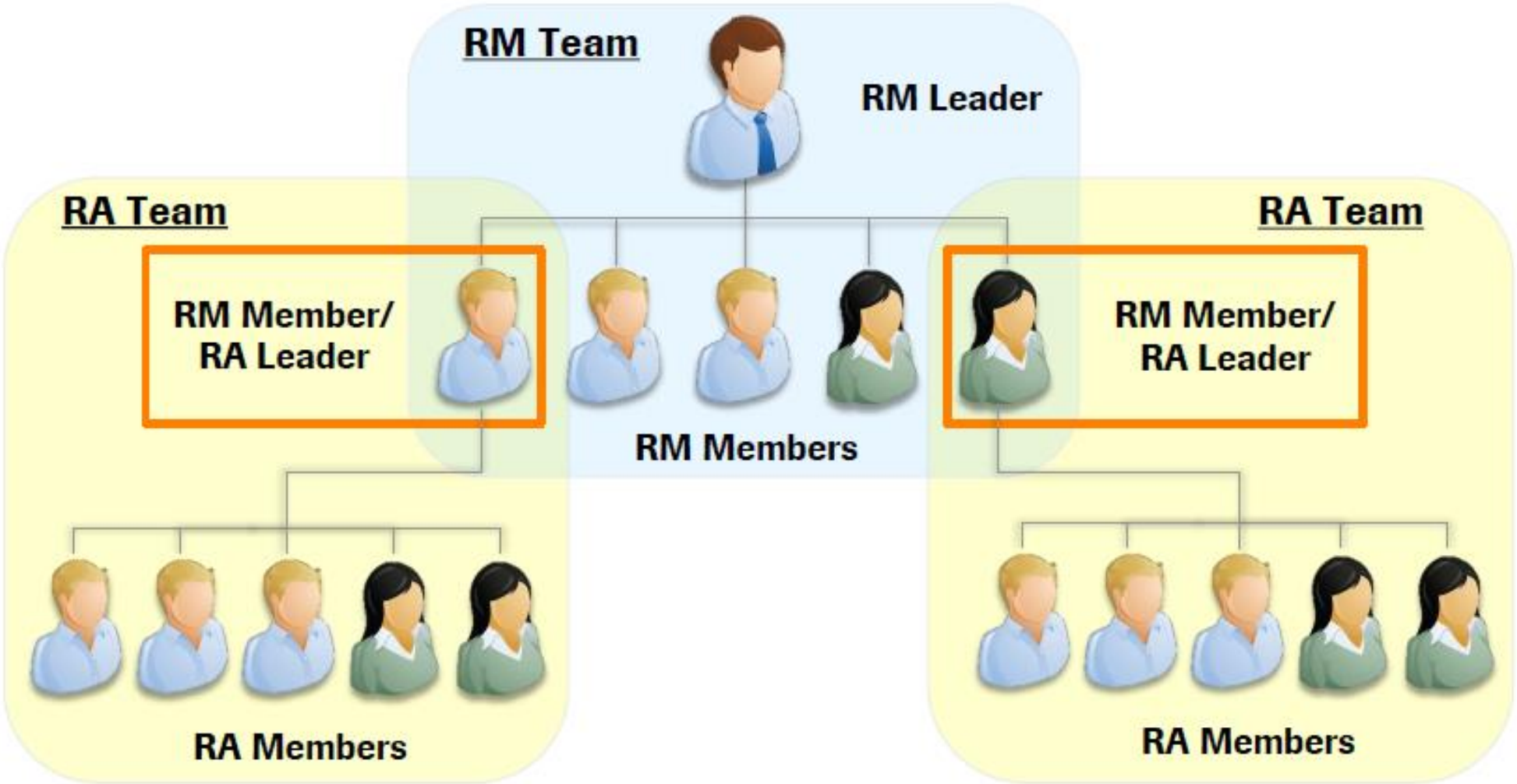
Risk Management Team

References;

(CONTROL OF NON-CONFORMITY, CORRECTIVE ACTION AND PREVENTIVE ACTION)

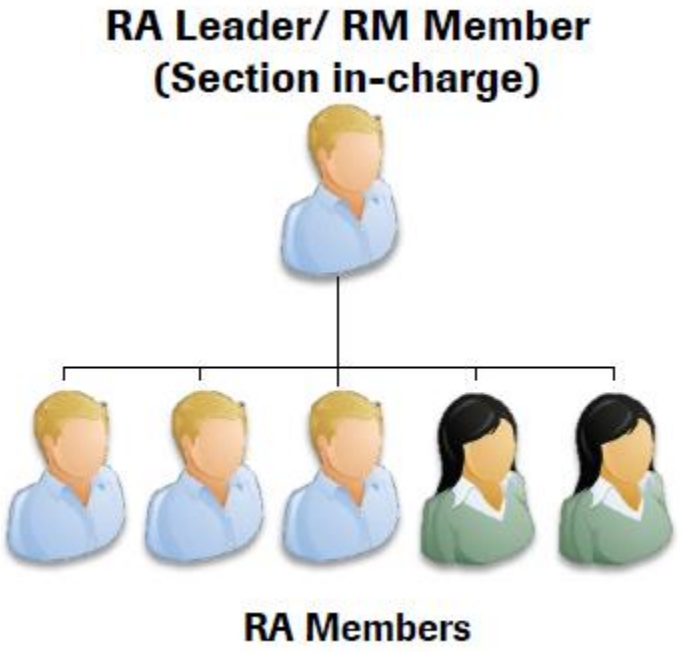
Tools and Templates – e.g. Risk Assessment Form, Risk Management Communication Plan, Gantt Chart, etc.

RISK MANAGEMENT TEAM



Note: RM Member is not necessary a RA Leader

Roles and Responsibility of Risk Assessment Team



- Good understanding and familiar with respective lab section's processes
- Understand how risk assessment is carried out
- Attend RM training course
- Conduct RA in assigned lab section and area
  - Determine if risks can bring harm beyond their work area
  - List down all lab processes in their area for risk identification and assessment
  - Implement control measure

Tools – risk assessment form

Appendix 4

Part 2 of 3

RISK ASSESSMENT FORM

Department/Section:		Leader/Job Title:	RA Leader:	Approved by: (Signature)	Reference Number:
Process:		Members:			
Process/Activity/Location:					
Original Assesment Date:				Name:	
Last Review Date:				Designation:	
Next Review Date:				Date:	

Risk Identification				Risk Evaluation				Risk Control					
S/N	Process Step	Risk	Possible non-conformities	Existing Risk Control	S	P	RPN	Additional Risk Control Measures	S	P	RPN	In-Charge Name: Due Date:	Remarks
1													
2													
3													
4													
5													
6													

Tool – Gantt Chart

Risk Management Part 1: Gantt Chart

Part 1 of 3

Department:		Leader:		Approved by: (Signature)	Reference Number:
Process:		Member 1:			
Process/Activity Location:		Member 2:			
Original Assesment Date:		Member 3:		Name:	
Last Review Date:		Member 4:		Designation:	
Next Review Date:		Member 5:		Date:	

No	Task List	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Preparation												
1.1	Form Risk Management team												
1.2	Establish Risk Management policy												
1.3	Identify scope of lab process												
2	Risk Assessment												
2.1	Identify process steps and associated risks												
2.2	Identify types of non conformities												
2.3	Identify existing control measures and RPN												
2.4	Determine additional control measures and improved RPN												
2.5	Assign responsibility and timeline												
3	Documentation and Review												
3.1	Obtain employer/management approval												
3.2	Implement control measures (conduct training if necessary)												
3.3	Communicate the risks identified and their controls												
3.4	Conduct first Risk Assessment audit												
3.5	Establish agenda/frequency of Risk Assessment report review												

Individual:

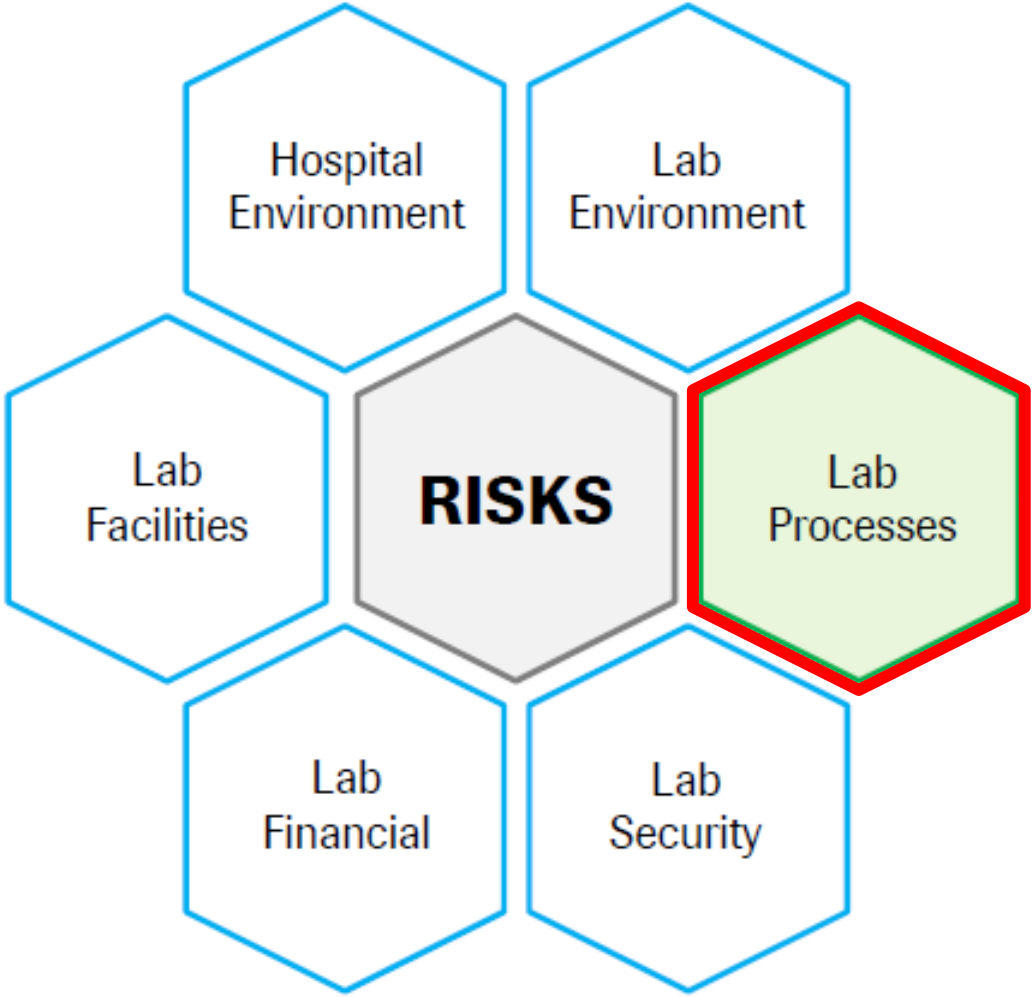
A4 Gantt Chart

Group:

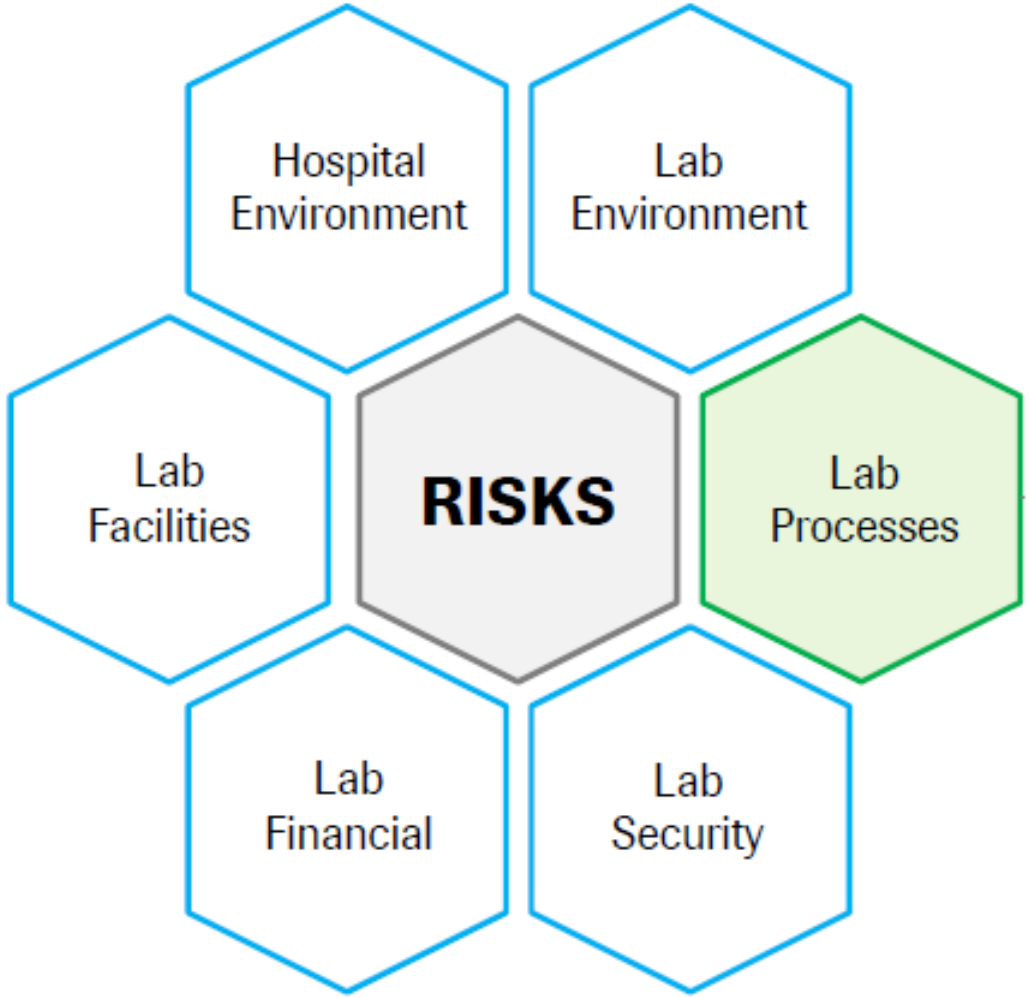
A3 Gantt Chart

STEP-by-STEP Implementation

Step 1: IDENTIFY SCOPE



Step 1: IDENTIFY SCOPE



i. Section;

- Pre-analytical
- Analytical
- Post-analytical

ii. Unit;

- Histopathology
- Cytopathology

Identify Process Steps

Process Steps are…

A **series of steps** that encompasses the **pre-analytic, analytic** and **post-analytic phases** specific to the handling of **sample, reagents, equipment, instruments, calibrators, controls, result presentation** and **result documentation**.

Laboratory Process Step

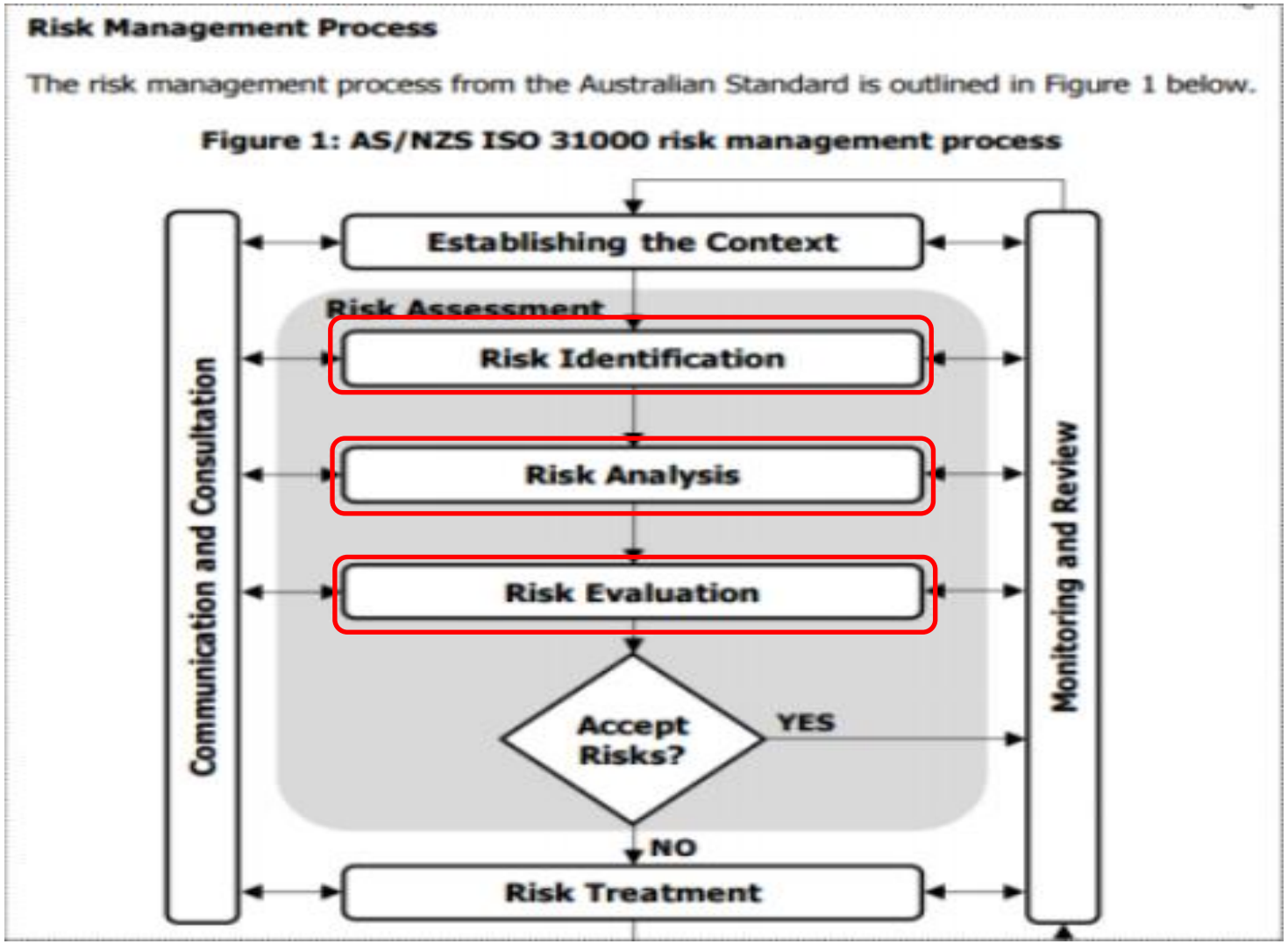
LABORATORY PROCESS STEPS

Instruments	Reagents	Controls	Calibrators	Sample	Report
Install Instruments	Obtain Reagents	Obtain Controls	Obtain Calibrators	Collect Sample	Report Transcription
Maintain Instruments	Store Reagents	Store Controls	Store Calibrators	Transport Sample	Report Text Selection
Setup Instruments	Prepare Reagents	Prepare Controls	Prepare Calibrators	Prepare Sample	Report Generation
Calibrate Instruments	Calibrate Reagents	Transfer Controls		Transfer Sample	Report Transmission
		Examine/Test Controls		Examine/Test Sample	
				Archive Sample	

Step 2: RISK ASSESSMENT

Step 2: RISK ASSESSMENT

- Risk Identification
- Risk Analysis
- Risk Evaluation



Risk Identification

LABORATORY PROCESS STEPS

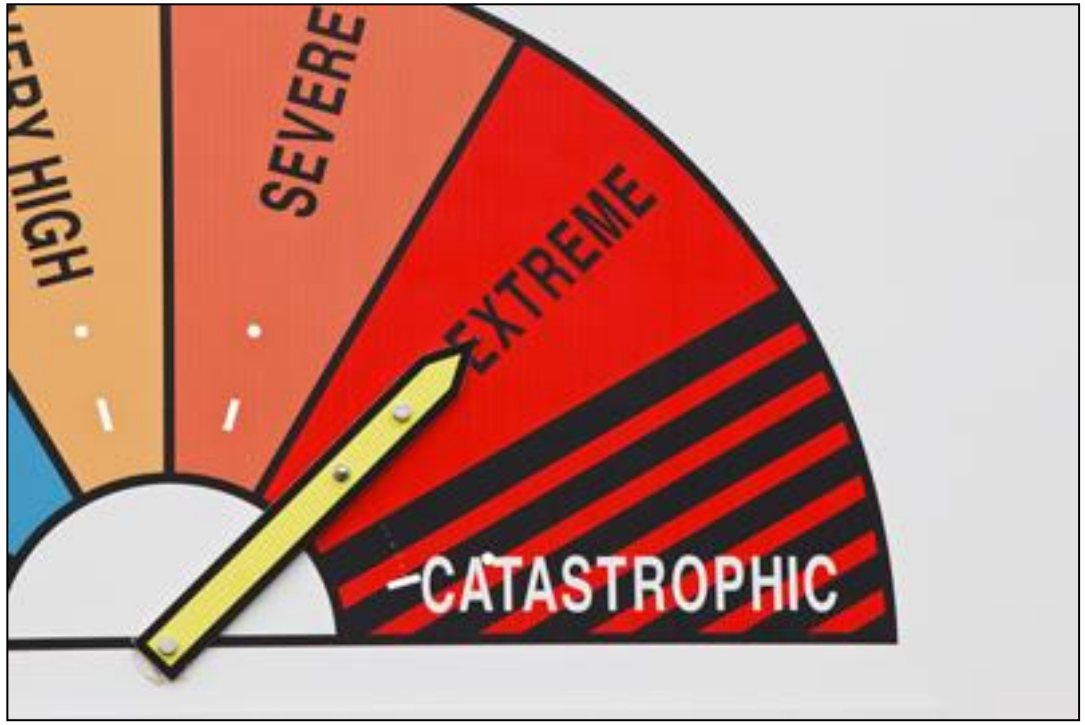
Instruments	Reagents	Controls	Calibrators	Sample	Report
Install Instruments	Obtain Reagents	Obtain Controls	Obtain Calibrators	Collect Sample	Report Transcription
Maintain Instruments	Sto Reag			nsp	Report Text Selection
Setup Instruments	Prep Reag			pare mple	Report Generation
Calibrate Instruments	Calib Reag			nsfer mple	Report Transmission
				ne/Test ample	
				Archive Sample	

Think of the associated harm that can occur in the process step.

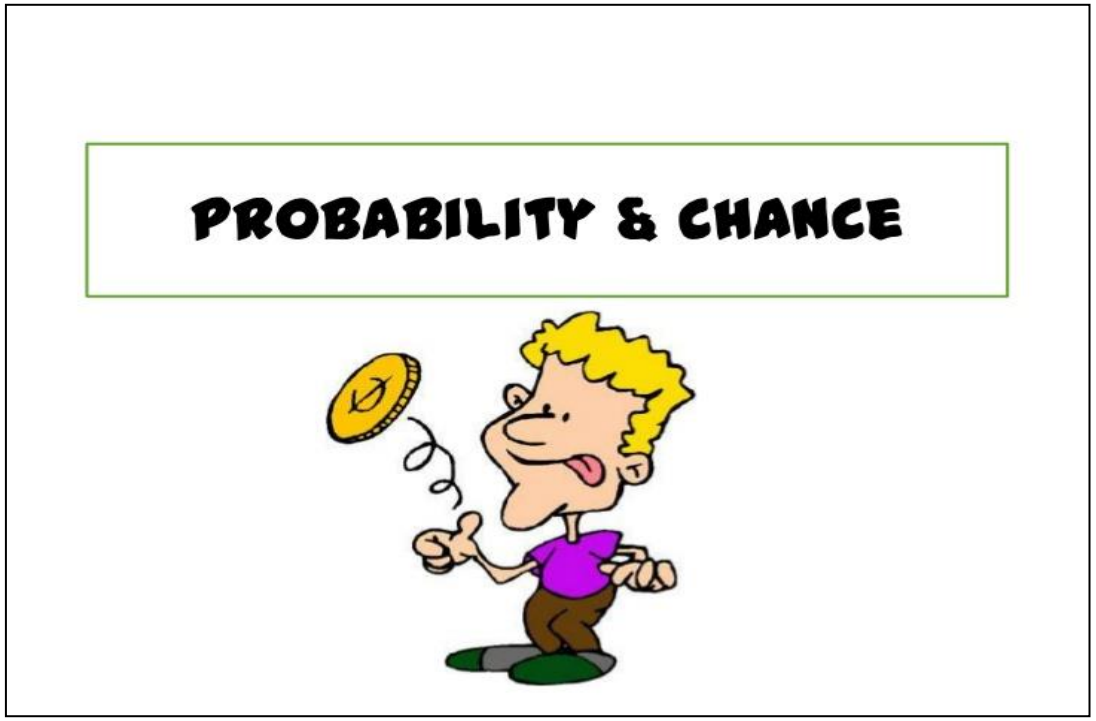
E.g Transcription error

Risk Analysis

Determine the **SEVERITY** and **PROBABILITY** of the risk.



SEVERITY



PROBABILITY

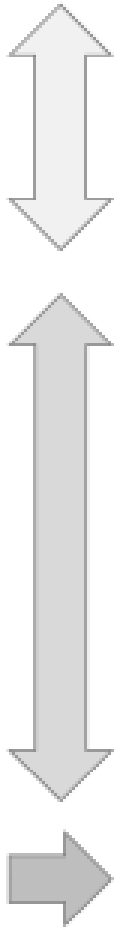
Risk Severity

Possible outcome	Severity	Score
Patient's death	Catastrophic	5
Permanent impairment or life-threatening injury	Critical	4
Injury or impairment requiring professional medical attention	Serious	3
Injury or impairment NOT requiring professional medical attention	Minor	2
Inconvenience or temporary discomfort	Negligible	1

(Reference: ISO 14971:2007, Table 0.3)

Risk Severity

Interpretation	Types of Non-Conformities
Laboratory	Delayed Report
	Incorrect Report
Physician	Delayed Diagnosis
	Incorrect Diagnosis
	Delayed Therapy
	Incorrect Therapy
Patient	**Harm**



Consequence of risk is contained within the laboratory

Consequence of risk is a result of Physician's action or decision

Consequence of risk impacts patient

Risk Severity

Interpretation	Types of Non-Conformities	Severity Score
Laboratory	Delayed Report	1 or 2
	Incorrect Report	2 or 3
Physician	Delayed Diagnosis	3
	Incorrect Diagnosis	3 or 4
	Delayed Therapy	3 or 4
	Incorrect Therapy	4
Patient	**Harm**	4 or 5

Risk Probability

Score	Severity Level	Examples of Probability Range
5	Almost certain	Occurs once a week
4	Likely	Occurs once a month
3	Possible	Occurs once every six months
2	Unlikely	Occurs once every year
1	Remote	No occurrence for more than a year

Risk Evaluation

- Evaluate if the RISK is **acceptable** or **not acceptable.**
- Based on **Risk Prioritization Number (RPN)**

Risk Priority Number (RPN) is…

The product of **severity scoring (S)** and **probability of occurrence (P)**.

It is viewed as a **relative measure** of the **design risk**.

RPN = SEVERITY X PROBABLITY

Severity scoring

('S' column)

Probability of occurrence

('P' column)

Ranking of risk (risk matrix)

('RPN' column)

erity Table (Ref ISO 14971:2007, Table D

Score	Severity Level	Possible Description
5	Catastrophic	Result in patient death
4	Critical	Results in permanent impairment or life-threatening injury
3	Serious	Results in injury or impairment requiring professional medical intervention
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
1	Negligible	Inconvenience or temporary discomfort

Probability Table (Ref Hospital Selayang Incident Report, Part 3)

Score	Severity Level	Examples of Probability Range
5	Almost certain	Occurs once a week
4	Likely	Occurs once a month
3	Possible	Occurs once every six months
2	Unlikely	Occurs once every year
1	Remote	No occurance for more than a year

k Prioritisation Number (RPN) = Severity x Probability

(Ref Department of Occupational Safety and Health, Ministry of Human Resources, Malaysia)

PROBABILITY	SEVERITY: Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
Almost certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Remote (1)	1	2	3	4	5

Risk Evaluation

- Example:

	Severity	Score
	Catastrophic	5
e-threatening injury	Critical	4
g professional medical	Serious	3
quiring professional medical	Minor	2
discomfort	Negligible	1

RISK PROBABILITY

Score	Severity Level	Examples of Probabi
5	Almost certain	Occurs once a week
4	Likely	Occurs once a month
3	Possible	Occurs once every six months
2	Unlikely	Occurs once every year
1	Remote	No occurrence for more than a yea

RPN :4 x 5 = 20

RPN Table/ Risk Assessment Matrix

		SEVERITY				
		Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
PROBABILITY	Almost certain (5)	5	10	15	20	25
	Likely (4)	4	8	12	16	20
	Possible (3)	3	6	9	12	25
	Unlikely (2)	2	4	6	8	10
	Remote (1)	1	2	3	4	5

The higher the score, the unacceptable the risk is.

Risk Evaluation

Risk evaluation based on RPN

Action Table (Ref: Department of Occupational Safety and Health, Ministry of Human Resources, Malaysia)

Color	RPN	Risks	Action
	15 - 25	High	A **HIGH risk** requires **immediate action** to control the hazard as detailed in the hierarchy of control. Actions taken must be documented on the risk assessment form including date for completion.
	5 - 12	Medium	A **MEDIUM risk** requires a **planned approach** to controlling the hazard and applies temporary measure if required. Actions taken must be documented on the risk assessment form including date for completion.
	1 - 4	Low	A risk identified as **LOW** may be considered as acceptable and further reduction may not be necessary. However, if the risk can be resolved quickly and efficiently, control measures should be implemented and recorded.

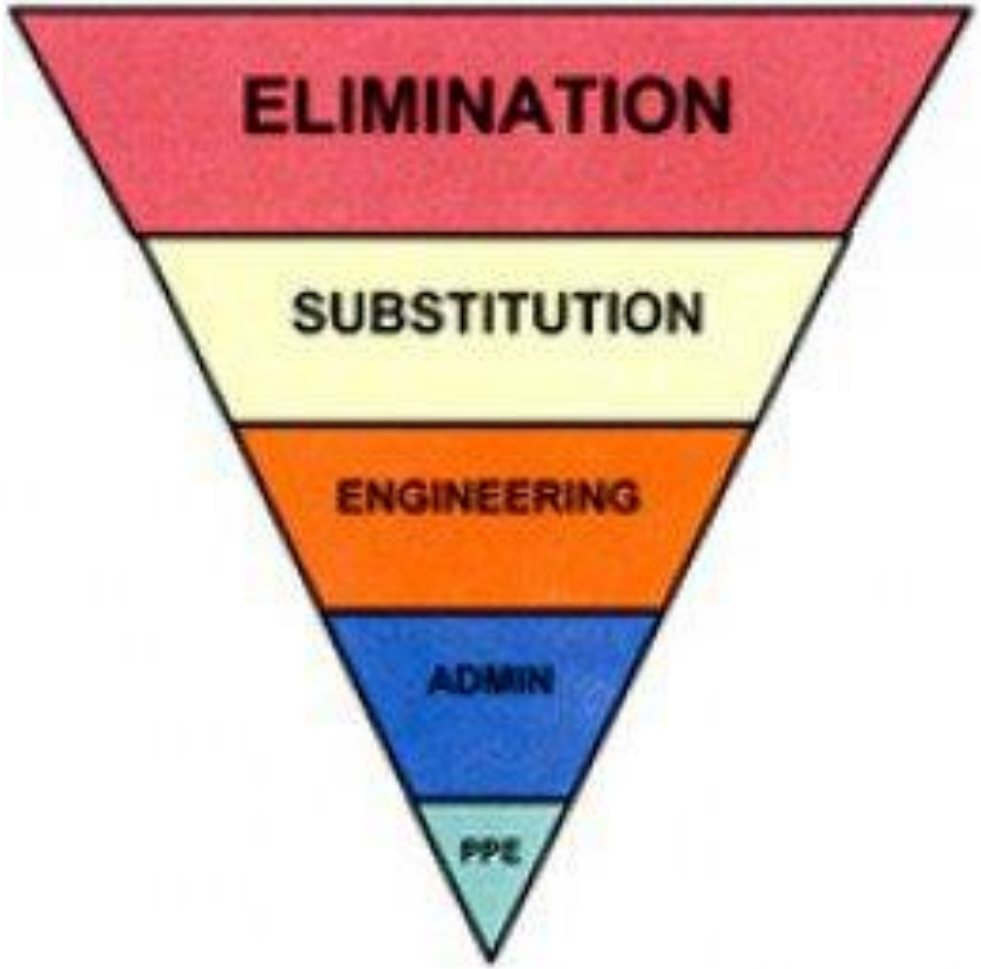
Step 3: RISK TREATMENT

Risk **can never be** eliminated completely

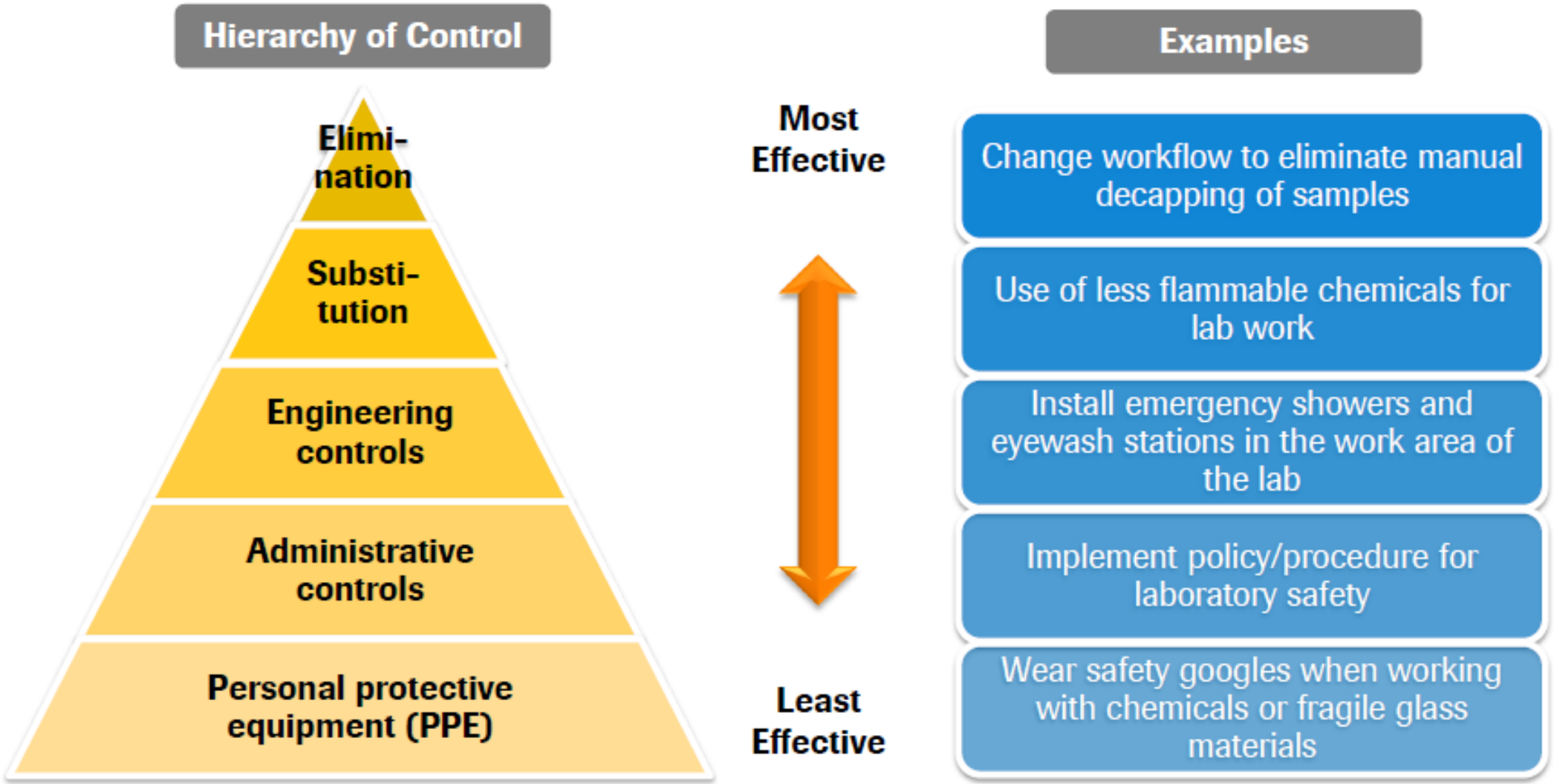
Risk Management aims to **reduce** and **control** risk to a clinically **acceptable level**

Prevention > Cure

Step 3: RISK TREATMENT



Step 3: RISK TREATMENT



Step 3: RISK TREATMENT

(Measures to reduce/minimize or eliminate the risk).

1. Know the existing control measure.
2. Think of the additional control measure.
3. Assign the most appropriate personnel to carry out the control measure
4. Communicate the planned control measure to all staffs.

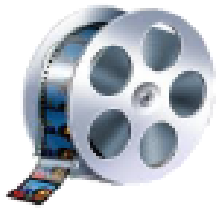
   e.g by CME, memo, notice board announcement, whatsapp, email, etc.
5. Determine the timeline.
6. Implement the control measure.

Examples of communication channels…

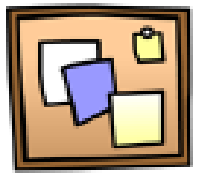
Roll call/ briefing before the start of specific processes

Monthly staff meeting/ lab section meeting

Emails and text messages



Recorded video of risk control measures/ meetings



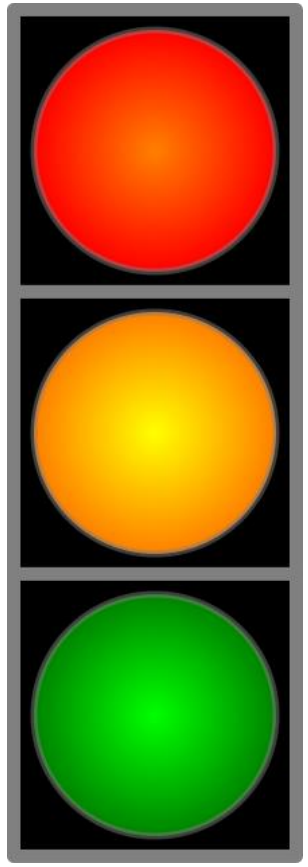
Notice board/ communication log book

Step 4: REVIEW CONTROL MEASURES

- Assess RPN score **BEFORE** and **AFTER** implementation of control measures

How do we assess the effectiveness of the control measure ?

CURRENT RPN



REVISED RPN

Ideal value: should be within low risk zone **(GREEN)**
Acceptable: improved to medium **(YELLOW)**

Ideal value: should be within low risk zone **(GREEN)**
Acceptable: No change

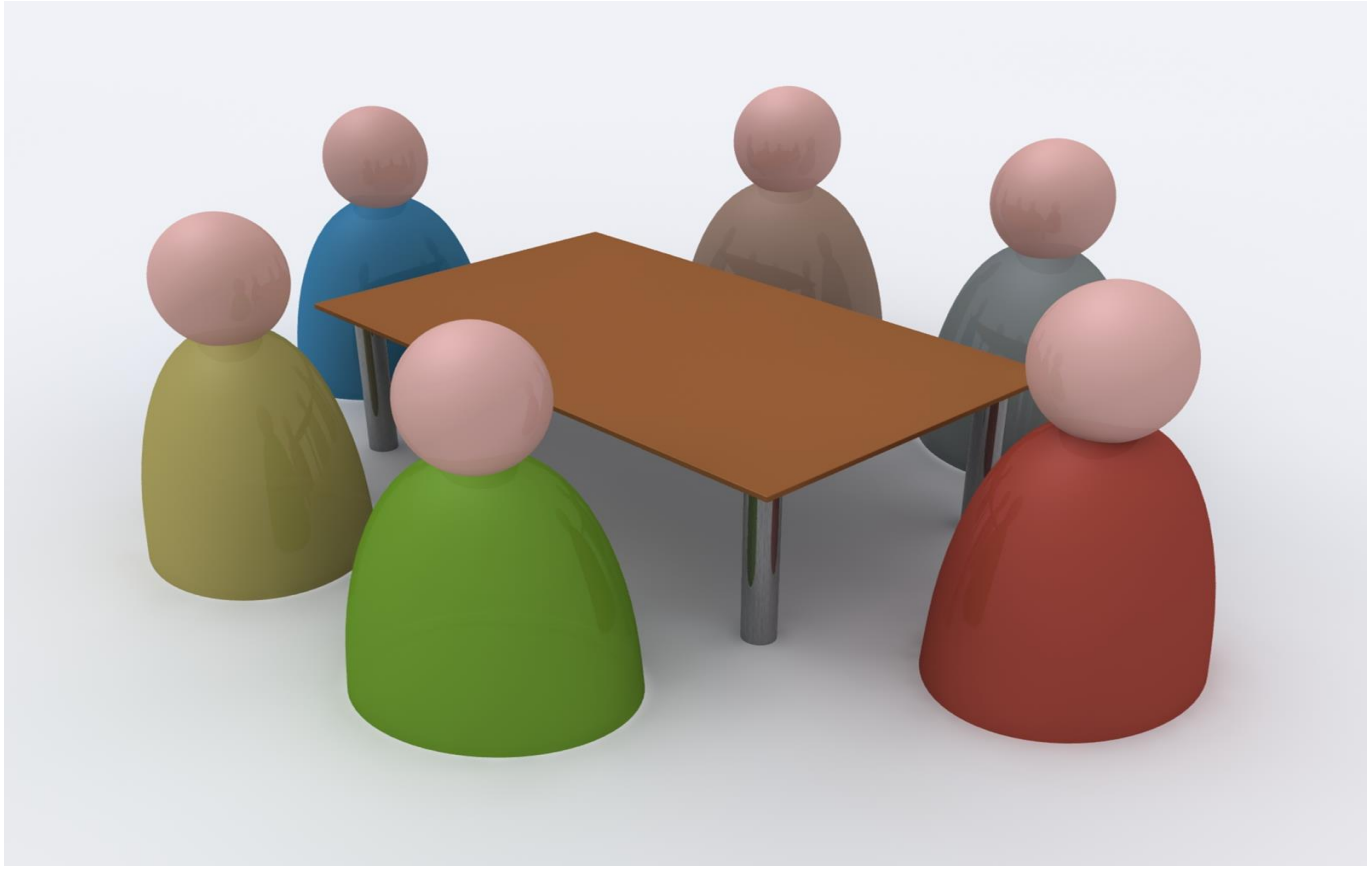
Ideal value: should be within low risk zone **(GREEN)**
Acceptable: No change

Step 5: RECORD & DOCUMENTATION

RA records

- **Ensure RA records** are **readily available** upon request
- **Keep** all RA records for **at least 3 years**

PRESENTATION IN MRM



THANK YOU