

Risk

All ISO Management standards use the definition shown in ISO Geneva document 'Annex SL'

3.0 – Risk = Effect of uncertainty

Risk and opportunities = Potential adverse effects (threats) and potential beneficial effects (opportunities)

What is required?

Requirement 6.1 of ISO 9001:2015, ISO 14001:2015, and ISO 45001

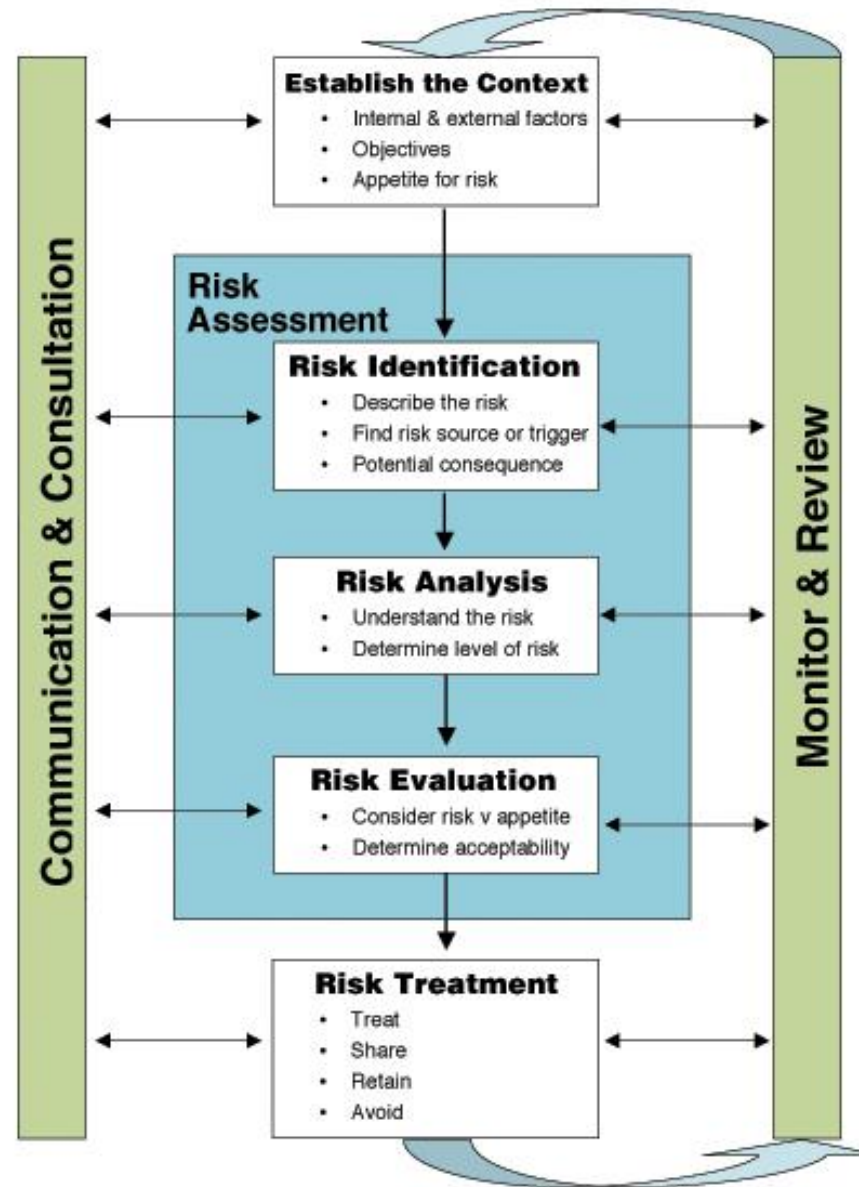
- ❖ Establish, implement and maintain processes.
- ❖ Determine risk and opportunities that need to be addressed related to aspects, compliance and other systems issues.
- ❖ Maintain documented information of its; risks and opportunities that need addressing, and processes needed to have confidence that they are carried out.

Follows the same system logic – risk managed by PDCA

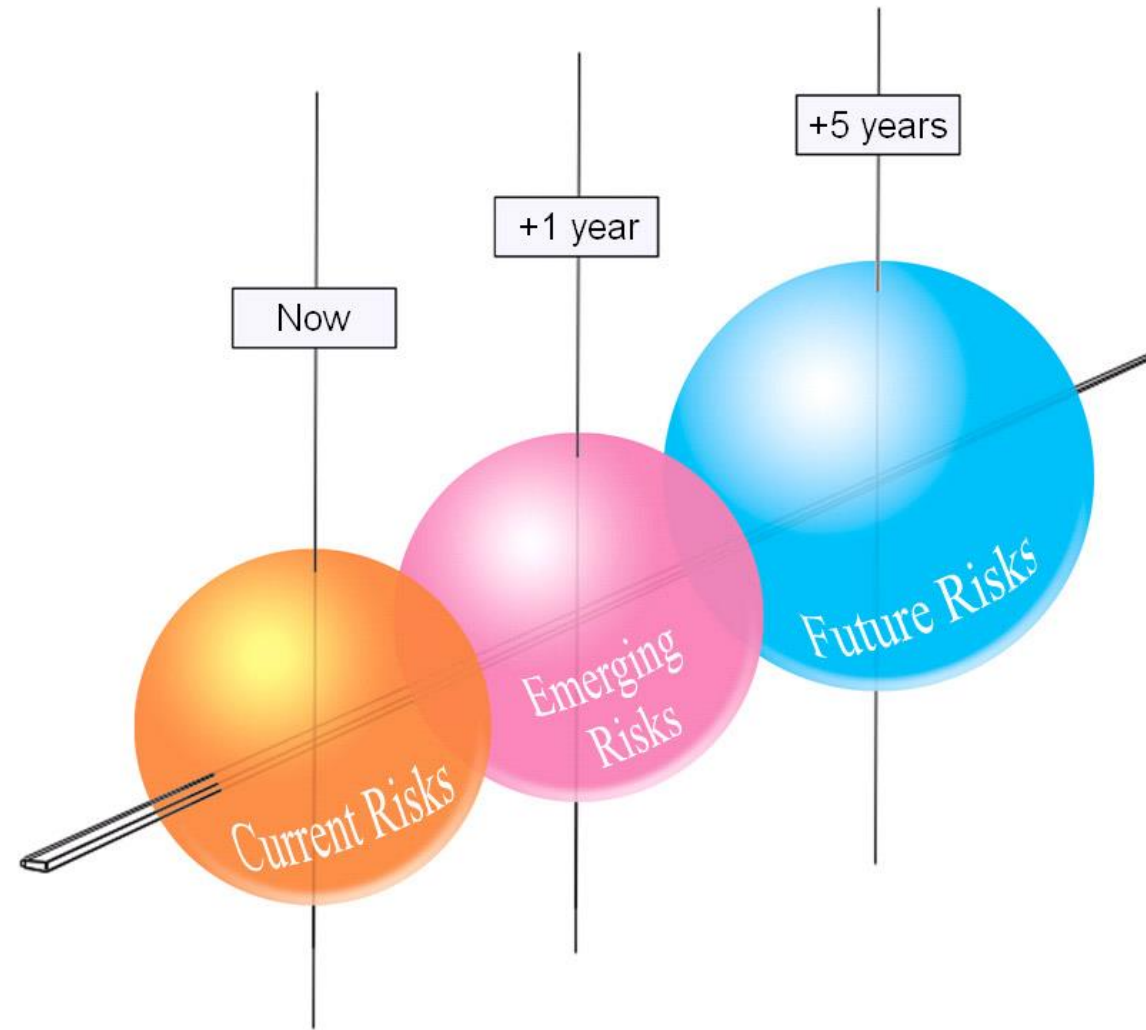


RISK MANAGEMENT PROCESS

Detail of Risk
PDCA cycle



Risk may be considered on 3 levels

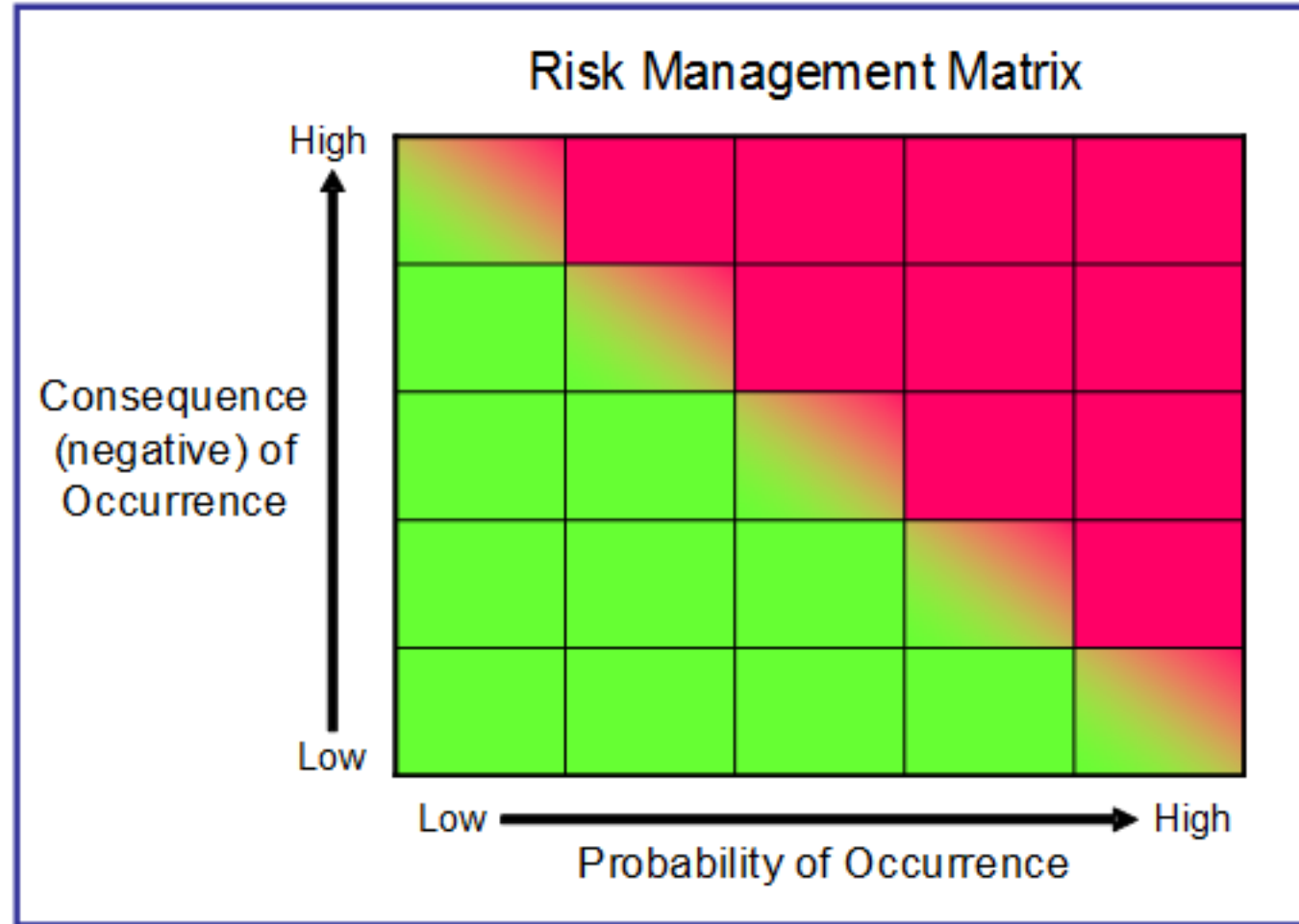


The 3 dimensions of Risk

Risk management uses 3 factors to identify and manage risk...

Severity
Occurrence
Detection

Risk Tools



Risk Tools



Effect	Severity Rank	Criteria
None	1	Improbable no affect on operation
Very Slight	2	Insignificant / negligible effect
Slight	3	Some minor mission impact
Minor	4	Mission continues with difficulty Reduced performance / User Dissatisfied
Moderate	5	Loss of Mission – return to base or minor injury
Severe	6	Loss of Mission – emergency declared or minor to major injuries
High Severity	7	Loss of Mission – damage
Very High Severity	8	Loss of aircraft – crew escapes
Extreme Severity	9	Loss of life and aircraft
Maximum Severity	10	
Occurrence	Rank	Criteria
Extremely Unlikely / Incredible	1	Failure Highly Unlikely > (1×10^{-9})
Remote Likelihood	2	Rare Number of Failures likely > (1×10^{-8})
Very Low Likelihood / Improbable	3	Very Few Failures Likely > (1×10^{-7})
Low Likelihood	4	Few Failures Likely > (1×10^{-6})
Moderately Low Likelihood / Remote	5	Occasional Failures Likely > (1×10^{-5})
Medium Likelihood	6	Medium number of failures Likely > (1×10^{-4})
Moderately High Likelihood / Occasional	7	Moderately high number of Failures likely > (1×10^{-3})
High Likelihood	8	High number of Failures likely > (1×10^{-2})
Very High Likelihood / Probable	9	Very high number of Failures likely > (1×10^{-1})
Extremely Likely / Frequently	10	Failure Almost Certain > ($1 \times 10^{1/2}$)
Detection	Rank	Criteria
Extremely Likely	1	Almost Certain Detection High Probability that failure is detected
Very High Likelihood	2	Detection upon inspection / use
High Likelihood	3	Defect detected visually without usage
Moderately High Likelihood	4	Medium Effectiveness for Detection
Medium Likelihood	5	
Moderately Low Likelihood	6	Detectable during use

Risk – What are our options?



Risk Tools (Based on FMEA)



Then add -

