

ANALYSIS



PLAN



PROCESS

IMPLEMENTING

RISK

BASED THINKING
IN ISO 9001 : 2015

REVIEW



EVALUATE



CONTROL



ASSESSMENT



BY PRANEET SURTI

RISK-DEFINITION

ISO 9001:2015 defines risk as **THE EFFECT OF UNCERTAINTY ON AN EXPECTED RESULT.**

Or

an uncertain event or condition which if happens affects mission objective.

- An effect is a deviation from the expected – it can be **POSITIVE** or **NEGATIVE**.
- Risk is about what could happen and what the effect of this happening might be.

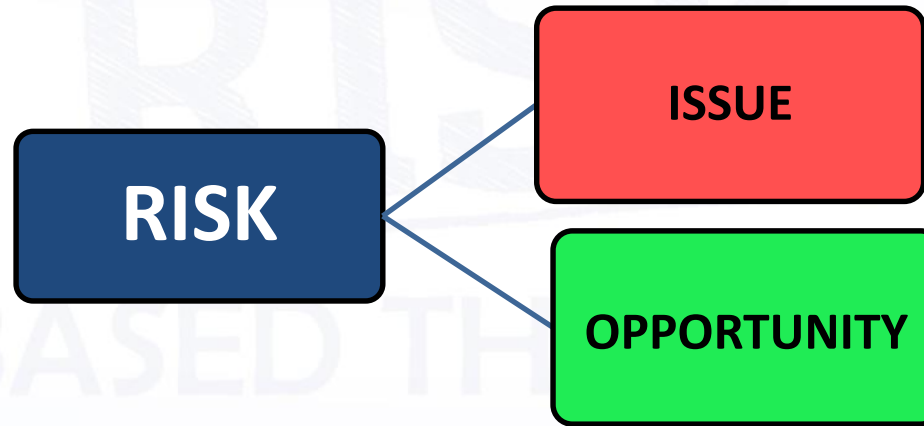
Intensity of the Risk is based upon two parameters

- **Severity** (This is the Seriousness of the harm)
- **Probability of Occurrence** (This is the Probability that the harm will occur)



OUTCOMES OF RISK

- **POSITIVE RISK** (Opportunity)
- **NEGATIVE RISK** (Issue)



Opportunity can lead to adaptation of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customer's needs.



WHAT IS RISK-BASED THINKING

- Risk-based thinking is something we all do automatically and often sub-consciously
- The concept of risk has always been implicit in ISO 9001, the 2015 revision makes it more explicit and builds it into the whole management system
- Risk-based thinking makes preventive action part of the routine
- Risk is often thought of only in the negative sense. Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk



WHAT IS RISK-BASED THINKING

PREVENTIVE ACTION

Clause 8.5.3

ISO 9001:2008

*Organization shall take action to eliminate the causes of **POTENTIAL NONCONFORMITIES** in order to prevent their **OCCURRENCE**.*



IMPLEMENTING RISK BASED THINKING IN ISO 9001:2015

RISK APPROACH IN ISO 9001:2015 QUALITY MANAGEMENT SYSTEM



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RISK APPROACH IN ISO 9001:2015

- **Clause 4 (Context)** the organization is required to **DETERMINE THE RISKS WHICH MAY AFFECT THIS CONTEXT**. The organization is also required to determine its QMS processes and to **ADDRESS** its risks and opportunities

Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating risk source, changing likelihood or consequences, sharing risk or retaining risk by informed decision

- **Clause 5 (Leadership)** top management are required to commit to ensuring Clause 4 is followed. Top management is required to

- **PROMOTE AWARENESS OF RISK-BASED THINKING**

PLAN – DETERMINE AND ADDRESS RISKS AND OPPORTUNITIES



RISK APPROACH IN ISO 9001:2015

- **Clause 6 (Planning)** The organization is required to **IDENTIFY RISKS AND OPPORTUNITIES RELATED TO QMS** performance and **TAKE APPROPRIATE ACTIONS** to address them
- **Clause 7 (Support)** the organization is required to **DETERMINE AND PROVIDE NECESSARY RESOURCES** (risk is implicit whenever “suitable” or “appropriate” is mentioned)



RISK APPROACH IN ISO 9001:2015

- **Clause 8 (Operation)** the organization is required to manage its operational processes (risk is implicit whenever “suitable” or “appropriate” is mentioned) in design, development & processes . **THE ORGANIZATION IS REQUIRED TO IMPLEMENT PROCESSES TO ADDRESS RISKS AND OPPORTUNITIES**
 - INCLUDING ALL THE PROCESSES AS DEFINED IN THE SYSTEM
- **Clause 9 (Performance evaluation)** the organization is required to **MONITOR, MEASURE, ANALYZE AND EVALUATE THE RISKS AND OPPORTUNITIES.**



RISK APPROACH IN ISO 9001:2015

- **Clause 10 (Improvement)** the organization is required to correct, prevent or reduce undesired effects and improve the QMS and **UPDATE RISKS AND OPPORTUNITIES.**
 - **CONSIDERING RISK AS A LIVE DOCUMENTED INFORMATION**

IMPLEMENTING
RISK
BASED THINKING
IN ISO 9001 : 2015

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RISK REQUIREMENTS AS PER ISO 9001:2015

- Create a R.B.T culture *Clause 5.1.1*
- Address Risks & Opportunities *Clause 4.4.1*



Cover all segments for risk based thinking

- Internal Issues (Strength & Weakness) *Clause 6.1.1*
- External Issues (Opportunities & Threats) *Clause 6.1.1*
 - *Political, Economic, Social & Technological Clause 6.1.1*
- Associated with Quality Policy *Clause 6.1.1*
- Associated with Quality Objectives *Clause 6.1.1*
- Associated with the Processes [Defects, Delays, Accidents, Waste, Mistakes, Design] *Clause 5.1.1*
- Non Confirming End Product/ Service/Complaints *Clause 5.1.2*
- Customer Satisfaction *Clause 5.1.2*
- Other interested parties *Clause 6.1.1*
- Change in the System



RISK REQUIREMENTS AS PER ISO 9001:2015

- Take actions to address risks *Clause 6.1.2*
- Monitor the Risk & Action Taken *Clause 9.1.3*
- Evaluate Effectiveness *Clause 9.1.3*
- Retain Documented Information *Clause 9.1.1*
- Update the record whenever required
Clause 10.2.1
- Include risk as an agenda in MRM *Clause 9.3.2*

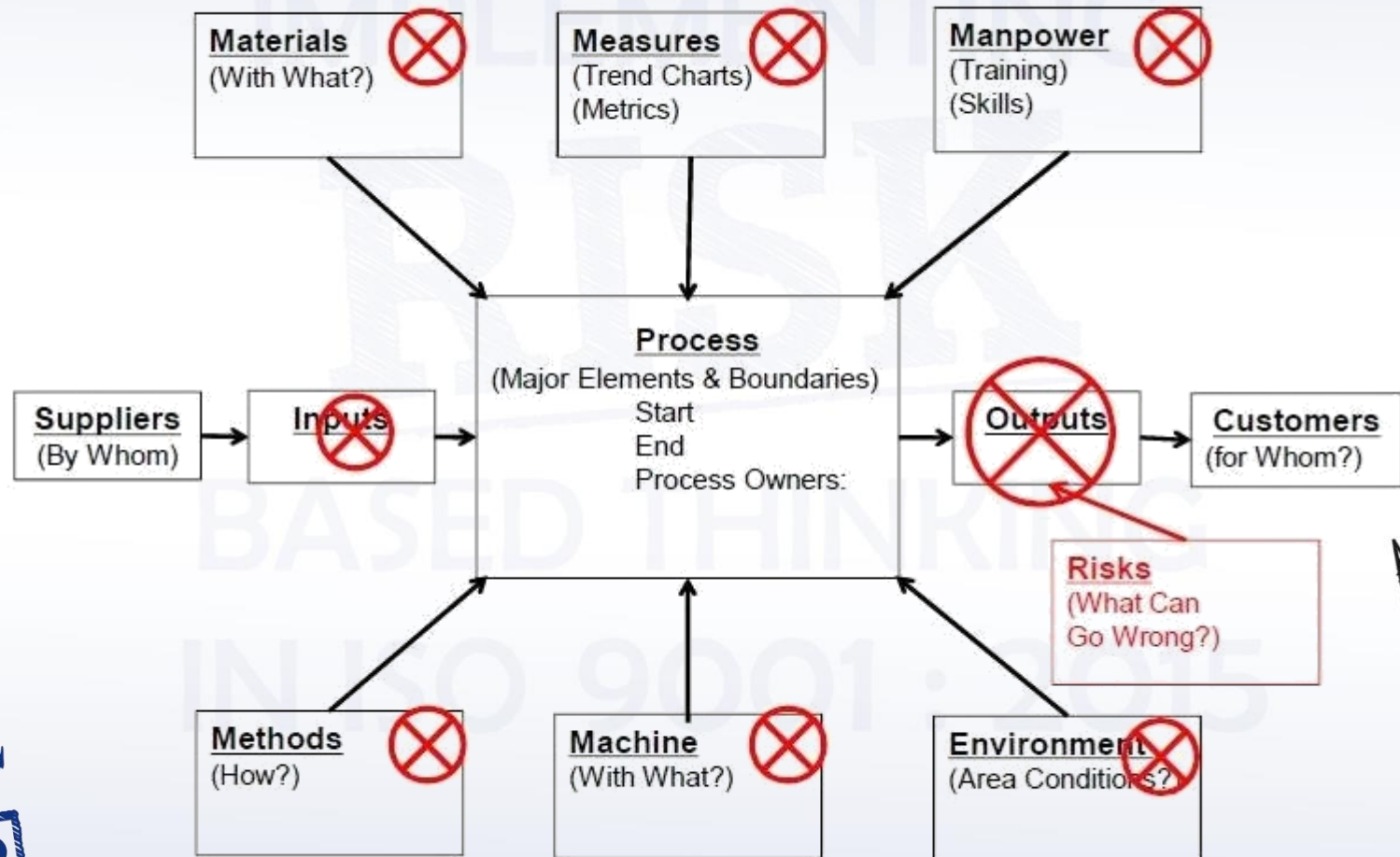


IDENTIFYING RISKS & OPPORTUNITIES



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RISKS ASSOCIATED IN A SYSTEM



PLAN



STRENGTHS- INTERNAL FACTOR

- What advantages does your organization have?
 - Infrastructure, Machines, Resources
 - Goodwill in Market
 - Less Competitors
 - Experienced
- What do you do better than anyone else?
- What do people in your market see as your strengths?



WEAKNESS - INTERNAL FACTOR

- What could you improve?

Past experience, Suggestions, Complaints, OFIs & New machinery / methods

- What should you avoid?

Delays, Scrap, Waste, Defects, Repetitive Problems

- What are people in your market likely to see as weaknesses?

Analysis, surveys

- What generates the most customer dissatisfaction and complaints?



EXTERNAL FACTOR



PESTEL

Political, Economic, Social, Technological, Environmental & Legal

- **POLITICAL FACTORS** are basically how the government intervenes in the economy. Specifically, political factors have areas including tax policy, labor law, environmental law, trade restrictions, tariffs, and political stability.
- **ECONOMIC FACTORS** include economic growth, interest rates, exchange rates, and the inflation rate.
- **SOCIAL FACTORS** include the cultural aspects, Customs, Festivals, Lifestyle, Area, Locality
- **TECHNOLOGICAL FACTORS** include technological aspects like New Process Adaption, R&D activity, automation, technology incentives and the rate of technological change.
- **ENVIRONMENTAL FACTORS** include ecological and environmental aspects such as weather, climate, and climate change.
- **LEGAL FACTORS** include the statutory and regulatory compliances associated with the system



OPPORTUNITIES – EXTERNAL FACTOR

- Where can you apply your strengths?
- How are your customers and their needs changing?
- Launching New Products
- Addressing New Customers
- What interesting trends are you aware of?



Useful opportunities can come from such things

- Changes in technology, adaptation of new practices and markets on both a broad and narrow scale.
- Changes in government policy related to your field.
- Changes in social patterns, population profiles, lifestyle changes, and so on.
- Local events/ Festivals.



THREATS – EXTERNAL FACTOR

- What obstacles do you face?
- What are your competitors doing?
- Are quality standards or specifications for your job, products or services changing?
- Is changing technology threatening your position?
- Is new competition coming?
- Is new technology making your product obsolete?



ASSOCIATED RISKS WITHIN A MANUFACTURING INDUSTRY

- Associated with Vision of Company
- Associated with Scope
- Associated with Quality Policy & Objectives
- Associated with the Processes
 - HR
 - Marketing
 - Purchase
 - Production & Planning
 - Quality
 - Dispatch/After Sales
 - Dispatch
 - Security
 - Logistics
 - Civil/ Canteen/Automobile
- Non Confirming End Product/ Service
- Customer Satisfaction



ASSOCIATED RISKS WITHIN A MANUFACTURING INDUSTRY

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RISK ANALYSIS TRAIL

1. OBJECTIVE SETTING

What are we trying to do ? Understanding SCOPE, CONTEXT & ENVIRONMENT

2. RISK IDENTIFICATION

What uncertainties hinders/ helps our objectives?

3. RISK ASSESSMENT

How do we prioritize them ? What is acceptable & What is Not acceptable ?

- Likelihood
- Severity

4. ADDRESSING THE RISK WITH AN ACTION PLAN

What should we do ?

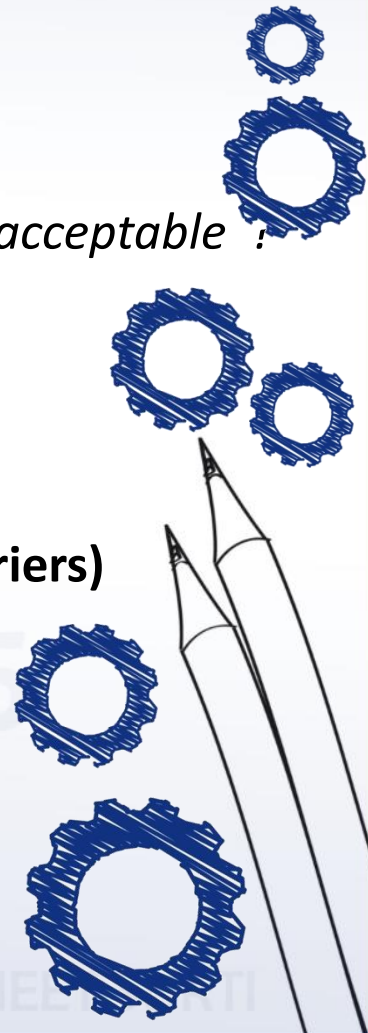
- how can we avoid or eliminate the risk? (**preventive barriers**)
- how can we mitigate the risk? (**mitigative barriers**)

5. EFFECTIVENESS

Did it worked ?

6. CONTINUAL IMPROVEMENT

What changed ? What did we learnt ? Are there any similar risks ?



RISK ASSESSMENT TOOLS

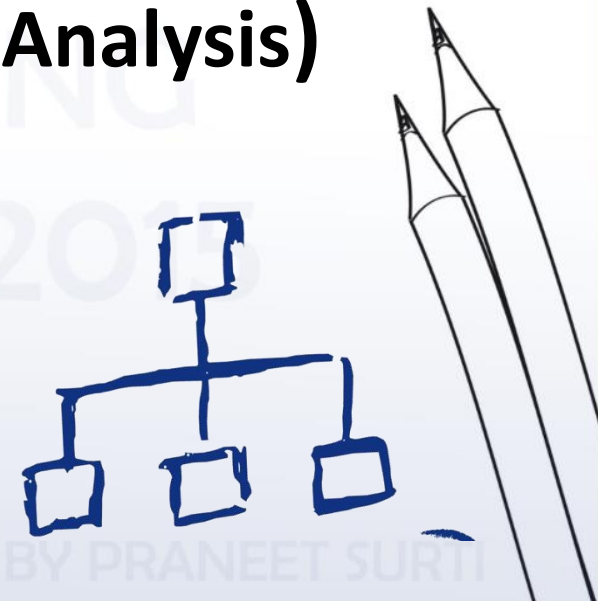


PRA (Preliminary Risk Assessment)

Basic Model

FMEA (Failure Mode Effects Analysis)

Technical Risk



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PRA (PRELIMINARY RISK ASSESSMENT) RISK REGISTER

- Most easiest way to access risk
- Narrative PRA can apply to risk at change management



PRA (PRELIMINARY RISK ASSESSMENT) RISK REGISTER

- The risk register or risk log becomes essential as it records identified risks, their severity, probability of occurrence , and the actions steps to be taken.
- It can be a simple document, spreadsheet, or a database system, but the most effective format is a table.
- A table presents a great deal of information in just a few pages.



RISK REGISTER COMPONENTS



There is no standard list of components that should be included in the risk register. Some of the most widely used components are

- **Dates:** As the register is a living document, it is important to record the date that risks are identified or modified. Optional dates to include are the target and completion dates.
- **Description of the Risk:** A phrase that describes the risk.
- **Causes of Risk:** Predictive cause of the risk to occur or happen



RISK REGISTER COMPONENTS

- **Likelihood of Occurrence:** Provides an assessment on how likely it is that this risk will occur.
- **Severity of Effect:** Provides an assessment of the impact that the occurrence of this risk would have on the project
- **Countermeasures/ Additional Controls:** Actions to be taken to prevent, reduce, or transfer the risk. This may include production of contingency plans.



RISK REGISTER COMPONENTS

- **Owner:** The individual responsible for ensuring that risks are appropriately engaged with countermeasures undertaken.
- **Effectiveness / Status:** Indicates whether this is a current risk or if risk can no longer arise and impact the project. Example classifications are: C-current or E-ended.



Other columns such as quantitative value can also be added if appropriate.

PRELIMINARY RISK ANALYSIS - TEMPLATE

Date	Risk Description	Potential Causes	Harm/Consequence	L	S	Risk Score [L x S] Likelihood x Severity	Possible Additional Controls	Owner	Effectiveness

Severity of Harm		Probability of Occurrence	
S-5	Catastrophic	O-5	Frequent
S-4	Critical	O-4	Probable
S-3	Serious	O-3	Occasional
S-2	Minor	O-2	Remote
S-1	Negligible	O-1	Improbable



HEAT DIAGRAM FOR RISK ASSESSMENT



SEVERITY

LIKELIHOOD

	Very Low	Low	Medium	High	Very High
Very High					
High				EXTREMELY	
Medium		HIGH		HIGH	
Low	MODERATE				
Very Low					

FMEA

FAILURE MODE EFFECTS ANALYSIS

A modified model of the previously discussed model used in different segments of manufacturing and service industries



Widely used for

- ***Design***
- ***Product***
- ***Process***
- ***System***
- ***Equipment***



FMEA - TEMPLATE

PROCESS FMEA													FORM NO.				
													ISSUE NO.				
													REV. NO.				
DRG. REV. NO.		A	CUSTOMER		SUPPLIER CODE			VEHICLE		DOC. NO.							
PART NAME	PERFORATED INNER PIPE				PART NO.					DATE (ORG.)							
ASSY. NAME					ASSY. NO.					REV. NO. DATE							
CFT	NAME OF TEAM					PROCESS RESPONSIBILITY				HEAD PRODUCTION							
OPN. NO.	PROCESS FUNCTION REQUIREMENT	POTENTIAL FAILURE MODE	POTENTIAL EFFECT (S) OF FAILURE	S E V	C L A S S	POTENTIAL CAUSE (S)	O C C	CURRENT PROCESS CONTROLS		D E T	R P N	RECOMMENDED ACTIONS	RESP/ TARGET DATE	ACTION RESULTS			
						MECHANISM (S) OF FAILURE		PREVENTION	DETECTION					ACTION TAKEN	S E V	O C C	DET
4/6	TIG WELDING	Sheet not coincide in arc shape	a) Fitment not ok.	4		1.Variation in rollers height	4	Before each set up ensure for same rollers height.	1 st pc approval and Patrol inspection	4	64						
			b) Assembly problem			2. Length offset		Controlling of length offset in previous operation.									
			c) Poor appearance			3. Component feeding Improper		Operator training.									
		Welding Missing	a) Weak welding	4		1. Improper welding parameters.	4	Before each set up ensure for welding parameters.	1 st pc approval and Patrol inspection	3	48						
			b) Assembly problem														
		c) Poor performance / Functional problem															
d) Poor appearance																	
Pin Holes	a) Weak welding	4		1. Improper welding parameters.	4	Before each set up ensure for welding parameters.	1 st pc approval and Patrol inspection	3	48								
	b) Assembly problem																
c) Poor performance / Functional problem																	
d) Poor appearance																	
Over Burning of component	a) Weak welding	4		1. Improper welding parameter	4	Before each set up ensure for welding parameters.	1 st pc approval and Patrol inspection	4	64								
	b) Assembly problem																
c) Poor performance / Functional problem																	
d) Poor appearance																	
Less Penetration	a) Weak welding	4		1. Improper welding parameter	5	Before each set up ensure for welding parameters.	1 st pc approval and Patrol inspection	4	80								

FMEA RATING CRITERIA - RPN



Rating High 10 ↑ Low 1	Severity	Occurrence	Detection
	Hazardous without warning	Very high and almost inevitable	Cannot detect or detection with very low probability
	Loss of primary function	High repeated failures	Remote or low chance of detection
	Loss of secondary function	Moderate failures	Low detection probability
	Minor defect	Occasional failures	Moderate detection probability
	No effect	Failure unlikely	Almost certain detection

RISK PRIORITY NUMBER:

The Risk Priority Number, or RPN, is a numeric assessment of risk assigned to a process, or steps in a process, as part of Failure Modes and Effects Analysis

$$\text{RPN} = \text{Severity} \times \text{Occurrence} \times \text{Detection}$$



BOW TIE METHOD

IMPLEMENTING

RISK

Just a glance at further Scope of Precise Risk Based Assessment



BY PRANEET SURTI

KEY POINTS TO REMEMBER

- Risk Based Thinking = Proactive Preventative Action
- Risk is an input to Management Review
- Risk Based Thinking is everybody's business!
 - Risk Based Thinking is not just the responsibility of management
 - Risk Based Thinking must become an integral part of the organizational culture



KEY POINTS TO REMEMBER



- Risk Based Thinking has to be demonstrated during audits; a risk register is documented information that validates an organization has done Risk Based Thinking.
- Risk Based Thinking is an element in the continual improvement process that is focused on prevention
- Risk-based thinking ensures greater knowledge and preparedness



BENEFITS OF RISK BASED THINKING



- Builds a strong knowledge base
- Establishes a proactive culture of improvement
- Assures consistency of quality of goods or services
- Improves customer confidence and satisfaction



About the Trainer



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