



Search Less, Know More

The essential tool for regulatory,
compliance, & quality professionals

www.govzilla.com
help@govzilla.com
(844) 332-3320

Deploying Risk-Based Thinking Within Management Systems

Presented by:
Ernest Blanchard
Technical Operations Manager, SGS, N.A, Inc.

Introduction

Risk Defined

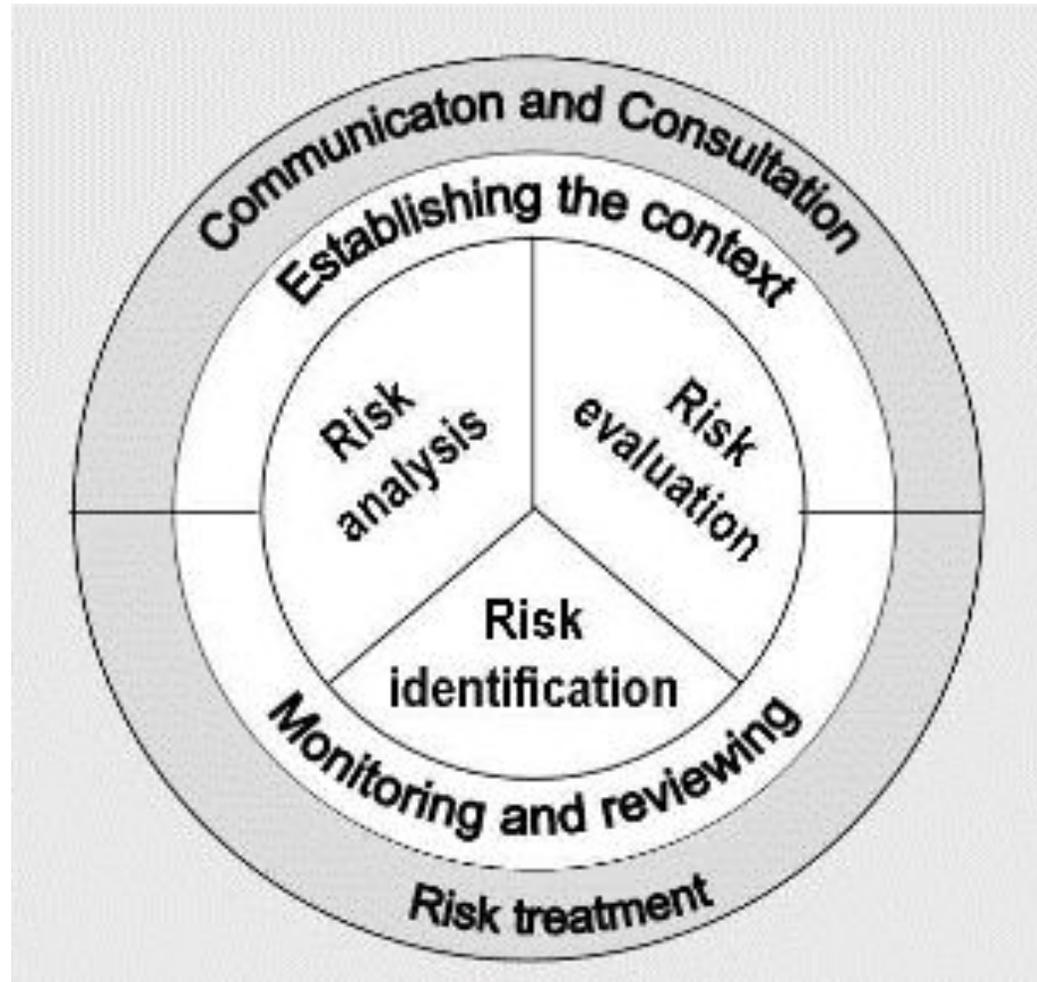
- ▶ Risk (per ISO 31000:2018)
- ▶ Risk-based thinking (per ISO 9001:2015)
- ▶ Risk Management



Risk-Based Thinking Defined

- ▶ Risk-based thinking is a systematic organic process of integrating risk management thinking at all levels of the organization continuously.

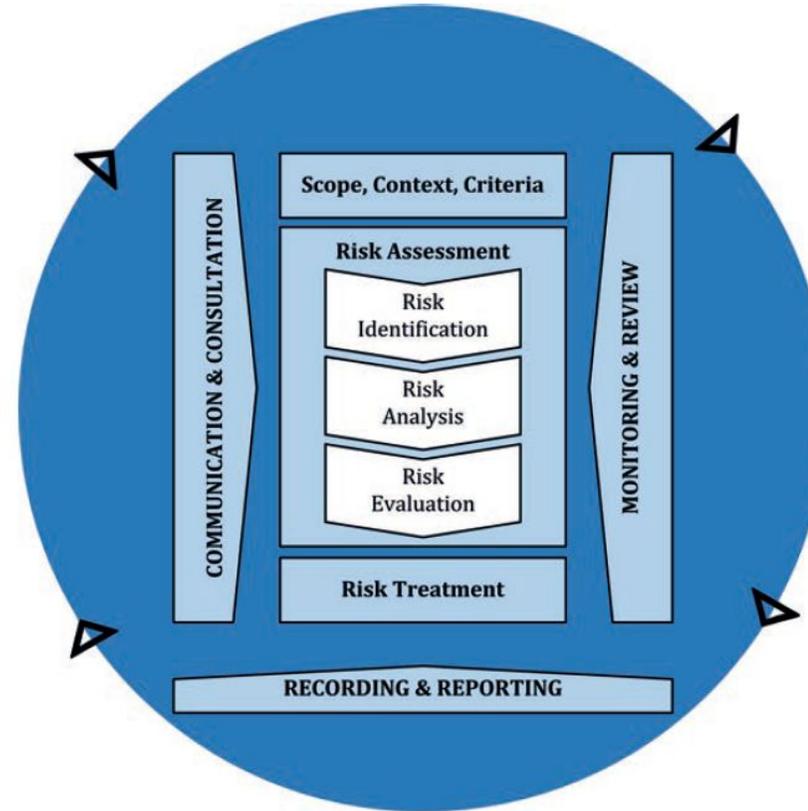
Risk Management Framework



Risk Assessment

Risk Management

- ▶ Strongly mirrors 6.1
- ▶ Iterative process
- ▶ Communication is key



ISO 31000:2018 clause 6.1

ISO 9001:2015 - Leadership

Leadership

- ▶ Promoting the use of the process approach and risk-based thinking (clause 5.1.1d)
- ▶ Risk-based thinking is essential (0.3.3)



ISO 9001:2015 - Planning

Determine risk and opportunities

- ▶ Based upon context & stakeholder needs
- ▶ Plan
 - ▶ Actions
 - ▶ How to implement & integrate into QMS
 - ▶ Evaluate the effectiveness



Promoting Risk-Based Thinking

- ▶ No required framework/methodology
- ▶ Risk assessment is foundational
- ▶ Sharing results with the organization is key first step



Tools for Risk Assessment

RISK MATRIX

		CONSEQUENCES				
		Marginal	Minor	Moderate	Major	Severe
LIKELIHOOD	Almost Certain	MEDIUM	HIGH	HIGH	CRITICAL	CRITICAL
	Likely	MEDIUM	MEDIUM	HIGH	HIGH	CRITICAL
	Possible	LOW	MEDIUM	MEDIUM	HIGH	CRITICAL
	Unlikely	LOW	MEDIUM	MEDIUM	MEDIUM	HIGH
	Rare	LOW	LOW	MEDIUM	MEDIUM	HIGH

STRATpro

Simple Risk Matrix

Likelihood	Consequences		
	Minor	Moderate	Major
Likely			
Possible			
Unlikely			

Risk Treatment Key

<p>Intolerable Risk Level. Immediate action required</p>
<p>Tolerable Risk Level. Risks must be reduced so far as is practicable.</p>
<p>Broadly Acceptable Risk Level. Monitor and further reduce where practicable.</p>

Tools for Risk Assessment

Risk Assessment Template

Risk Assessment

Potential Hazard	Who is at risk?	Existing Control Measures	Risk Rating	Preventative Measures	Responsibilities

Risk Assessment Log

Potential Hazard	Stakeholders	Controls	Severity	Occurrence	Consequences	Risk Rating
Pandemic	Organization	Business Contingency Plan	Severe	1	5	5
Product Recall	Customers/Regulatory Bodies	Product Recall Process/Regs.	Major	2	4	8
Unplanned Downtime	Production Dept./Operations	Capacity Plans/Spare Parts on-hand	Moderate	3	4	12
Employee Turnover	Operations/Planning	Employee Empowerment Program	Major	4	4	16

Tools for Risk Assessment

Plant manager:

Risk register:

- Customer satisfaction
- Business continuity
- Program launch
- Production transfer



Risk N°	Process	Name of the Risk	KPI	Risk Category	Risk Criticality	Impact	Im	Occ	Risk Rating
1	Quality	Quality (ext)	GFP/YOCA/SORTING HOURS	N/A	Cautionary	Operational	3	3	9
2	Quality	Quality (ext)	PPM/TRP	N/A	Acceptable	Operational	1	2	2
3	Quality	VAVE Changes	Internal rework/Scrap	N/A	Cautionary	Operational	3	4	12
4	HSE	Safety	First aide/Loss-time	N/A	Acceptable	Legal	4	1	4
5	Equipment	Breakdown-Prod. Equipment	DMC Downtime	N/A	Cautionary	Operational	3	4	12
6	Equipment	Specific: Trailer breakdown (JIT delivery)	Follow up of subcontractor	N/A	Acceptable	Operational	3	3	9
7	Equipment	Breakdown- Shipping System	DMC Downtime	N/A	Critical	Operational	3	5	15
8	Production	OEM delivery	Hourly OEM buffer	N/A	Cautionary	Operational	3	3	9
9	Production	5S	5S Audit	N/A	Acceptable	Operational	2	3	6
10	Logistics	JMI inventory	JMI Inventory	N/A	Acceptable	Operational	2	2	4
11	Logistics	Cycle Count	Cycle Count accuracy	N/A	Acceptable	Operational	2	2	4
12	Logistics	Obsoletes	Obs inventory	N/A	Acceptable	Operational	2	2	4
13	Logistics	Logistics Performance	Customer Score Card	N/A	Acceptable	Operational	3	2	6
14	Finance	Budget ver. Forecast	Budget Attainment	N/A	Cautionary	Operational	3	3	9
15	Finance	OT ver. Sales	Daily OT	N/A	Cautionary	Operational	3	3	9
16	HR	Hourly Employee Turnover	Hourly Turn-over	N/A	Cautionary	Operational	4	3	12
17	HR	Salaried Employee Turnover	Salaried Turn-over	N/A	Critical	Operational	4	4	16
18	Plant	Business Opportunities	Ramp-down plan	N/A	Critical	Operational	4	5	20
19									0
20									0



Review

Leadership

- ▶ Promoting the use of the process approach and risk-based thinking (clause 5.1.1d)
- ▶ Risk-based thinking is essential (0.3.3)

Promoting Risk-Based Thinking

Communication & Consultation

Recording & Reporting

Monitoring & Review



Conclusion

Risk-Based Thinking is essential

- ▶ Communicate, communicate, communicate
- ▶ Leverage the PDCA cycle
- ▶ All levels and functions within an organization need to be involved

References

Committee of Sponsoring Organizations of the Treadway Commission. (2017). *Enterprise Risk Management - Integrating with Strategy and Performance*. (Item Number. 10.6405). Retrieved from <https://bookstore.theiia.org/enterprise-risk-management-integrating-with-strategy-and-performance>

International Organization for Standardization. (2015). *Quality management systems – requirements* (ISO Standard No. 9001).

International Organization for Standardization. (2015). *Quality management systems – Fundamentals and vocabulary* (ISO Standard No. 9000).

International Organization for Standardization. (2018). *Risk management — Principles and guidelines*. (ISO Standard No. 31001).

Questions

