

Making Risk part of your Quality Management System

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Presentation

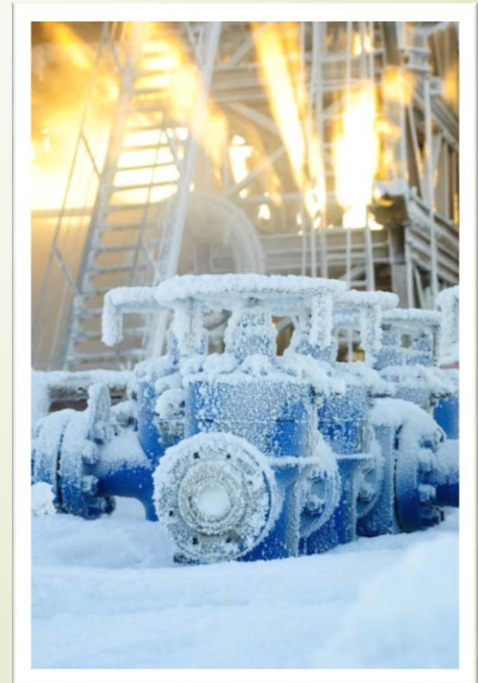
- Risk Assessment
- Contingency Planning
- Management of Change

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Why make Risk part of our QMS?

Industry with Extremes

- High pressure – up to 30,000 PSI
- Corrosive atmosphere
- High concentrations of H₂S gas
- Extreme operating temperatures, -75 °F to +450°F



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Industry with Extremes

Pump Jack near a Dinner



Blowout beside a freeway



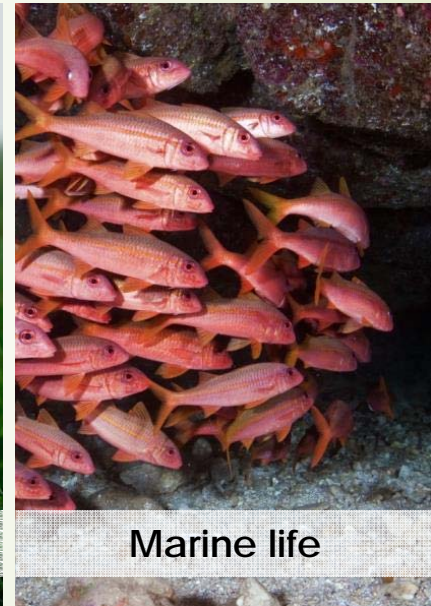
Drilling performed next to a home



Deepwater Horizon, 2010

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Protection of:



What is Risk

- An uncertain event
- In the future
- Has a cause and effect
- Impacts objectives

Risk Impacts

- Scope
- Quality
- Delivery
- Costs

Is Risk Management New?

- ISO 14001: Environmental
- OHSAS 18001/COR Health & Safety
- AS9100 Aerospace
- ISO 13485 Medical Devices
- ISO 31000 Risk Management

API Q1

- Developed to address QMS's for organizations that manufacture products or service for use in the petroleum and natural gas industry.
- Revised in June 2013 to include Risk Assessment and Management as well as Contingency Planning.

Definition of Risk per API Q1

Situation or circumstance that has a likelihood of occurring and a potentially negative consequence.

Risk Assessment Details

Risk Assessment Procedure

Tools, Techniques, Application

Product Delivery

Product Quality

Supplier/Materials

Facility/Equipment

Delivery of NC
Product

Competent
Personnel

If applicable

Records required...

Risk Categories

- Product Delivery
- Product Quality

Product Delivery

- Work Environment
 - Lighting, humidity, temperature, contamination
- Supplier Performance
 - Material/Service availability/supply
- Preventive Maintenance
 - Equipment needed to produce, move and/or store product

Product Quality

- Nonconforming Product
 - Delivery of nonconforming product
- Product Inspection
 - Inspection and testing
- Personnel Competence
 - Availability of competent personnel

Risk Assessment & Management

ISO 31000:2009(E)

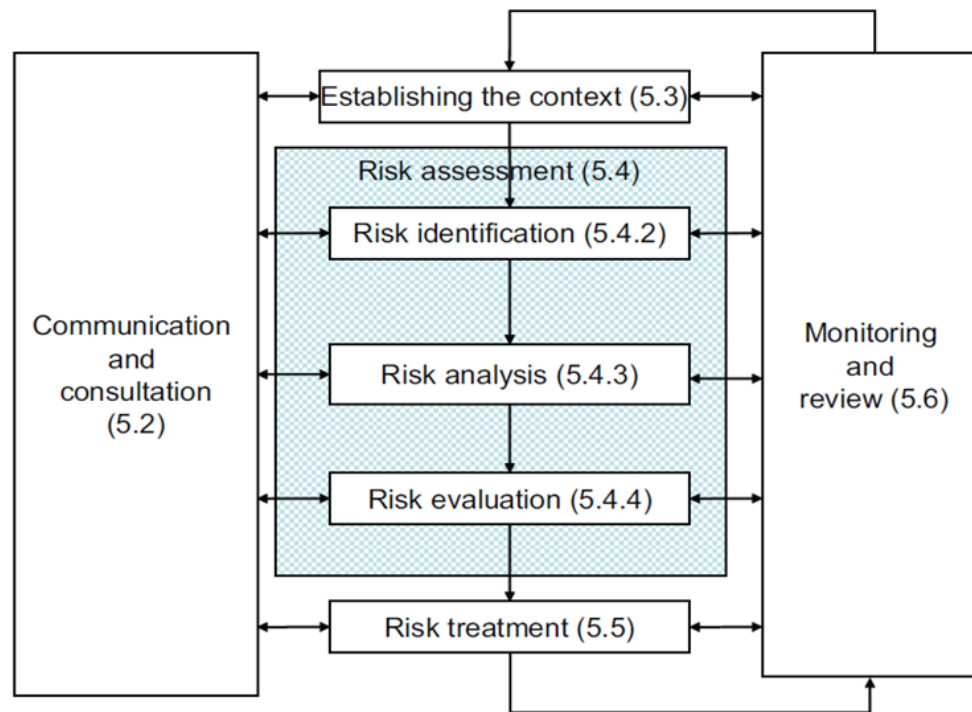


Figure 3 — Risk management process

Source: ISO 31000, Risk management — Principles and guidelines

Risk Management

Design system to:

- Analyze risks prior to performing activities
 - Identification of possible risk events
 - Assessing the likelihood of occurrence
 - Severity of the risk if it does occur
- Define risk control measures in order to reduce or eliminate the risk
 - Applying corrective/preventive and mitigating actions so residual risk can be reduced to an acceptable level.

Risk Mitigation per API Q1

Reducing the severity of a risk when it does occur

Risk Register Example – Having a Party

Risk Category	Risk Name	Risk #	Probability (1-3)	Impact (1-3)	Risk Score	Mitigation	Contingency	Action By	Action When
Guests	The guests find the party boring	1.1	2	2	4	Invite crazy friends, provide sufficient liquor	Bring out the Karaoke	Mack	within 2hrs
Guests	Drunken brawl	1.2	1	3	3	Don't invite crazy friends, don't provide too much liquor	Call 911	Jerry	Now
Nature	Rain	2.1	2	2	4	Have the party indoors	Move the party indoors	Miles	10mins
Nature	Earthquake or fire	2.2	1	3	3	Start the party with instructions on what to do in the event of fire or earthquake	Implement the appropriate natural disaster response plan	Every one	As per plan
Food	Not enough food	3.1	1	2	2	Have a buffet	Order pizza	Joe	30mins
Food	Food is spoiled	3.2	1	3	3	Store the food in deep freezer	Order pizza	Matt	30min

Where to Assess - Operational Risk

- ▶ Production Part Approval Process
- ▶ Manufacturing and on-time Delivery
- ▶ Outsourcing: Supplier performance
- ▶ Nonconforming Report and Planned Deviation (set up - scrap, rework)
- ▶ Incident and Accident Reporting

Where to Assess - Design Risk

- Product/Service Development
- Design Changes
- Aftermarket Activities
- Customer Complaints
- Warranty Work
- Repair Activities

Risk Identification

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Risk Management Techniques

- Qualitative Techniques
 - Brainstorming
 - Assumptions analysis
 - Interviews
 - Checklist
 - Risk registers
 - Risk mapping
 - Probability impact table
 - FMEA: Failure Modes and Effects Analysis
 - other

Risk Management Techniques

- Quantitative Techniques
 - Decision Trees
 - Sensitivity Analysis – What If Analysis
 - Probability Impact Grid
 - Excel Spreadsheet
 - other

5 Why's

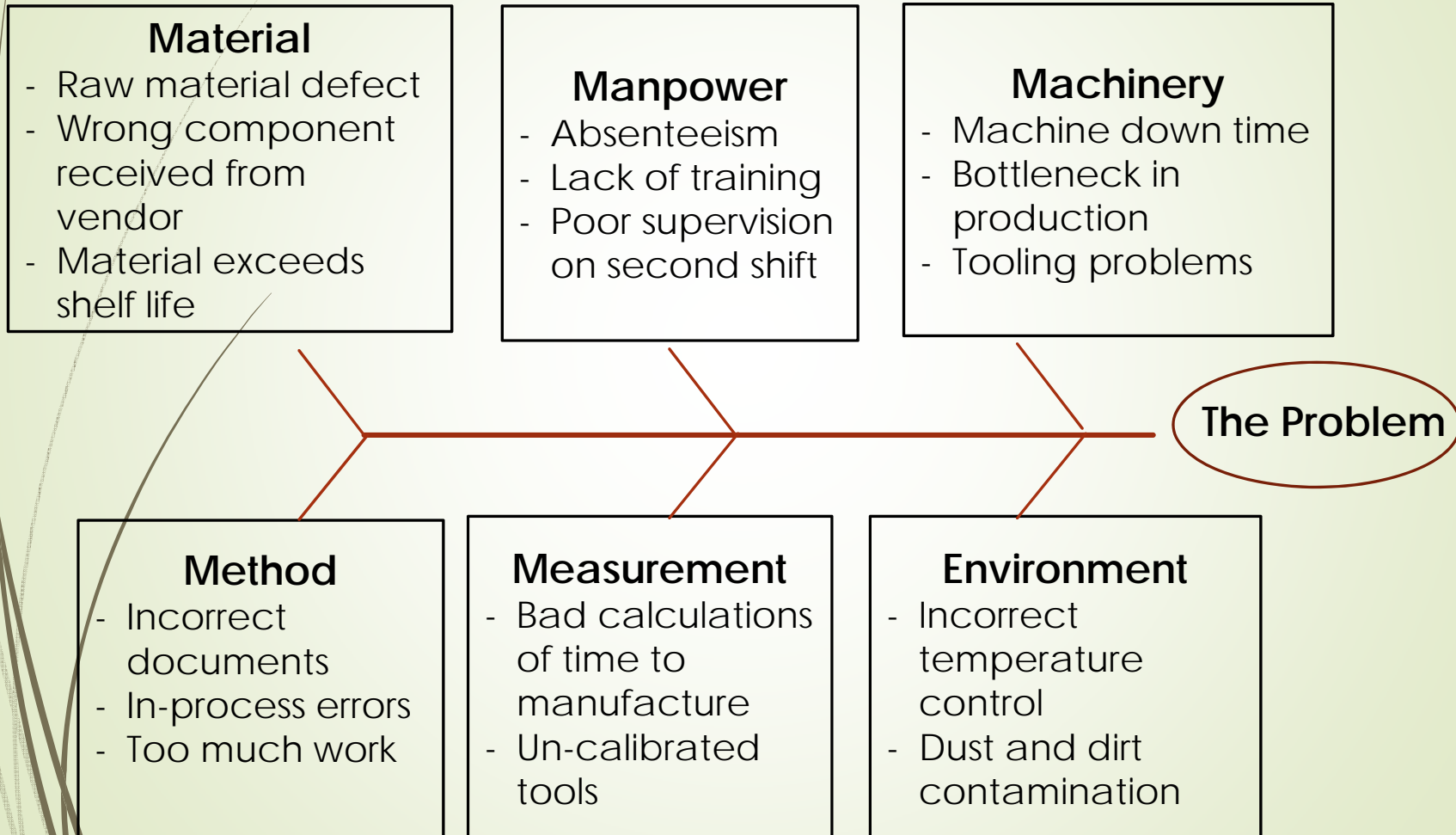
- *5 Whys* is an iterative question-asking technique used to explore the cause-and-effect relationships underlying a particular problem
- Pitfalls Doesn't guide you to ask the right "why" questions.

"If you do not know how to ask the right question, you discover nothing"

- *W. Edwards Deming*

Fish Bone Diagram

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Risk Rating Matrix

	Occurrence				
Severity	1	2	3	4	5
5	LOW	MED	HIGH	EXT	EXT
4	LOW	MED	HIGH	HIGH	EXT
3	LOW	MED	MED	HIGH	HIGH
2	LOW	LOW	MED	MED	MED
1	LOW	LOW	LOW	LOW	LOW

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Score: 0 – 5 = Low

Score: 6 – 10 = Medium

Score: 12 – 16 = High

Score: 20 – 25 = Extreme

Responsibilities

Process Owner

Quality Control

Engineering

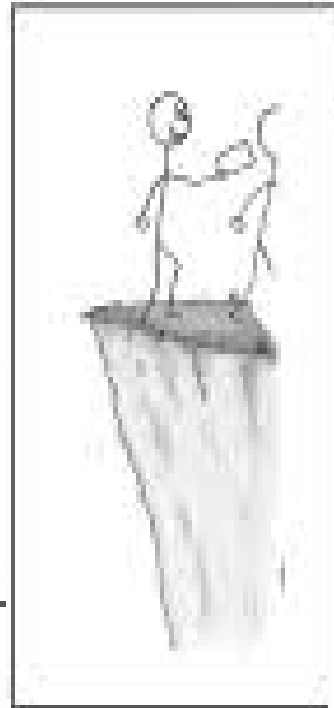
Senior Management



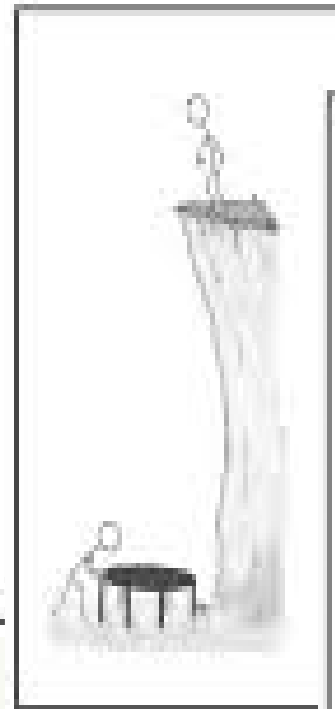
Your Objective



Avoid



Transfer



Mitigate



Accept

Contingency Planning / Risk Treatment

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API Q1 Contingency planning must include as a minimum:

- ▶ Actions required in response to ***significant*** risk scenarios to mitigate effects of disruptive incidents,
- ▶ Identification and assignment of responsibilities and authorities, and
- ▶ Internal and external communication controls.

Contingency Planning / Risk Treatment

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- Systematic approach to identify what can go wrong.
- Not intended to think of every possible contingency, rather it is to encourage you to think about major contingencies and possible responses.

Also known as:

- ❑ Worst-case scenario plan,
- ❑ backup plan, or
- ❑ Disaster recovery plan

Contingency Planning / Risk Treatment

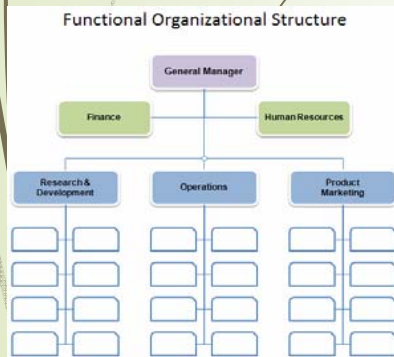
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- ▶ What events may occur that require a response?
- ▶ What disasters might happen during execution of the plan?
- ▶ What scenarios are possible for the situation?
- ▶ What event would cause the greatest disruption of current activities and plans?
- ▶ What happens if costs of the plan are excessive?
- ▶ What happens if delays occur?
- ▶ What if key people leave the organization?
- ▶ What the expected moves of antagonists and competitors?
- ▶ Who or what might impede the implementation of the plan?

Management of Change

If a change has the potential to impact the quality of the product or the integrity of the quality management system.

Organizational Structure



Essential Personnel



Critical Suppliers



Management System Procedures



How Risk Tolerant Are You?

3 Characteristics:

- Risk Adverse: avoidance; easy choices

Facility Management

- Risk Seeker: Start ups; Seeking advantages in a tough economy

Top Management

- Risk Neutral: Risk handled on a case by case basis

Quality Manager

Successful Organizations

- ▶ Not shocked by risk
- ▶ Encourage transparency
- ▶ Open communication of risk

Successful Managers

- Utilization of historical data to identify risk
- Objectively communicate risk to management in a timely manner
- Mitigate risk and increase positive opportunities

“In God We Trust, Everyone else Must Bring Data”

Edwards Deming's

Thank you

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