

Risk Management & FMEAs

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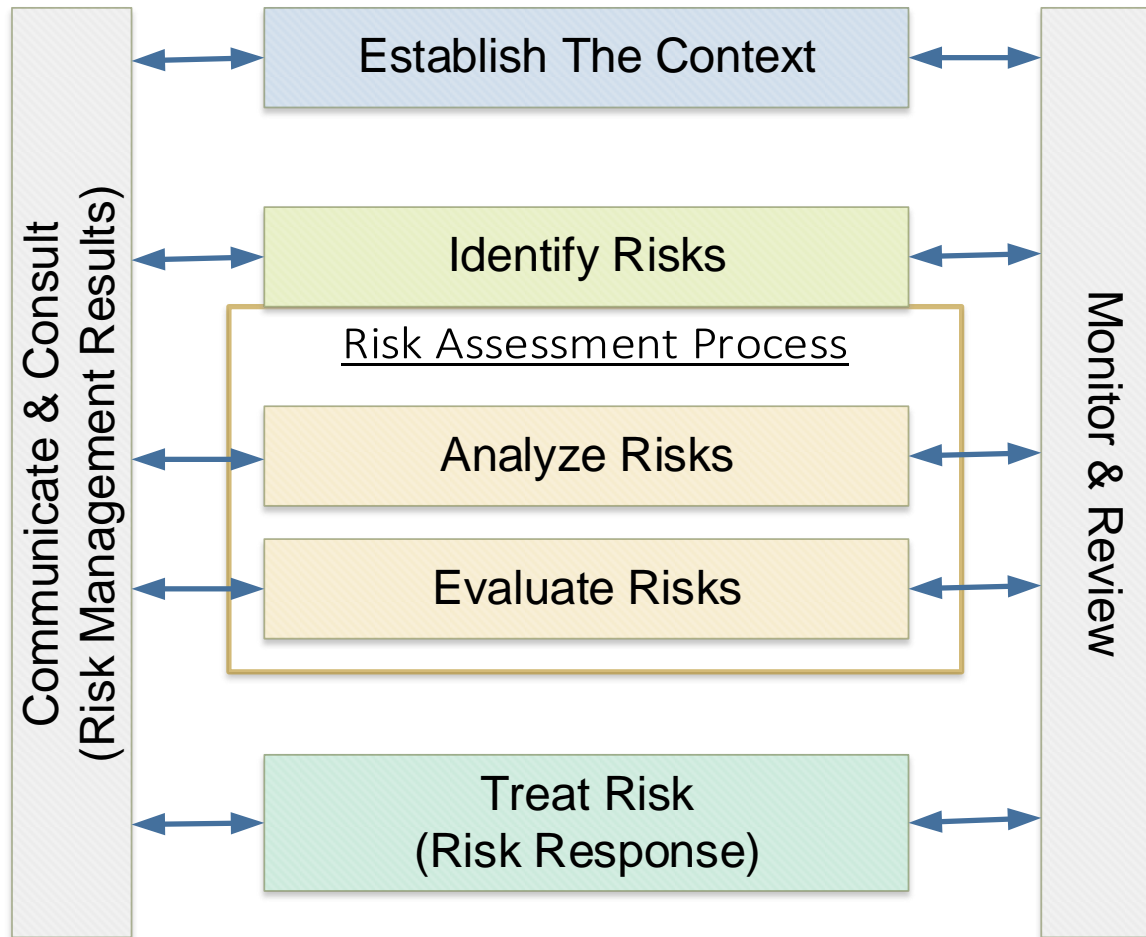
Learning Objectives

- Understand Risk management process elements
- Learn the principles involved in the Risk process
- Know the process FMEAs and how they can be utilized for risk management
- Learn probability and impact scale construction
- Review lessons learned

Content

- Risk Management Process
- Risk Process Principles
- Risk Management Processes & ISO 31000
- Know how FMEAs template can be modified for risk
- Risk Probability and Impact Matrix
- Understand Risk Analysis
- Risk Score & Expected Monetary Value (EMV)
- Document Risk Process

Risk Management Process Elements



Risk Management Process Elements

- **Establish the context:**
 - Set the scope and risk criteria
 - Define the internal and external parameters
 - Set the objectives of the risk management program.
- **Identify risks**
 - Identify the sources of risk
 - Areas of impact with possible risk events
 - Their causes and probable consequences
 - Develop a list or register of risks

Risk Management Process Elements

- **Analyze risks:**
 - Develop an understanding of the nature of the risks
 - Extent, sources, and causes of the risks
 - Consequences and likelihood of the risks also analyzed
- **Evaluate risks:**
 - Compare the risk with the appetite and tolerance set
 - Determine if risk treatment is required

Risk Management Process Elements

- **Treat risks**
 - Select high or unacceptable risks to mitigate or reduce
- **Monitor and review**
 - Review the efficiency, effectiveness, and economics of the risk treatment controls
- **Communication and consult**
 - Trace and communicate results of the risk management framework to ensure continuous improvement, learning, and compliance.

Risk Process Principles

- To create and protect values
- Should be an integral part of all processes
- Should be a part of all decision making
- Should explicitly addresses uncertainty
- Risk processes should be systematic, structured, and timely
- Based on the best available information
- Should be tailored as per needs
- Should take human and cultural factors into account
- Should be transparent and inclusive
- Should be dynamic, iterative, and responsive to change
- facilitate continual improvement

Risk Management

- It is a systematic and proactive approach to control the project by:
 - Understanding uncertainties
 - Minimizing the consequences of adverse events while maximizing the positive events (Results)
- Many processes assume unrealistic degree of certainty
- Risk management addresses the uncertainty in estimates and assumptions

“Risk must be managed systematically and proactively in the new economy” - Jay Patel

Why Do Risk Management?

Near Misses Are a Hit in Disaster Science
WSJ - The Numbers Guy, June 12, 2010
By Carl Bialik

While there never has been an oil spill in the Gulf of Mexico quite as large as the current disaster, there have been other terrible mishaps and, as in every industry, near misses.

These close calls are what Scott Shappell, professor of industrial engineering at Clemson University, looks for when he works with airlines on quantifying their risk from human errors.

"All you hear about are crashes, but it's the near misses that are telling," Prof. Shappell says. "If you only knew how many near misses there are in aviation, you would never fly again."

Near misses can be studied by statisticians to estimate the probability of an event that hasn't occurred before.

Estimating the probability of unlikely disasters has become standard practice for nuclear and space regulators. Such an exercise, experts say, could help companies involved in deep-sea drilling evaluate risks and possibly prevent catastrophes like the Gulf oil spill....

Why Do Risk Management?

Most ISO standards require organizations to identify and assess threats, along with their associated risks

ISO 14001:2006—Environmental management systems: Clause 4.3.1

environmental aspects: "The organization shall establish, implement, and maintain a procedure: To identify the environmental aspects of its activities, products and services within the defined scope of the environmental management system that it can control and those that it can influence, taking into account planned or new developments, or new or modified activities, products or services.

To determine those aspects that have or can have a significant impact on the environment—for example, significant environmental aspects."

ISO 28001:2007—Security management systems for the supply chain: Clause 4.3.1 security risk assessment:"The organization shall establish and maintain

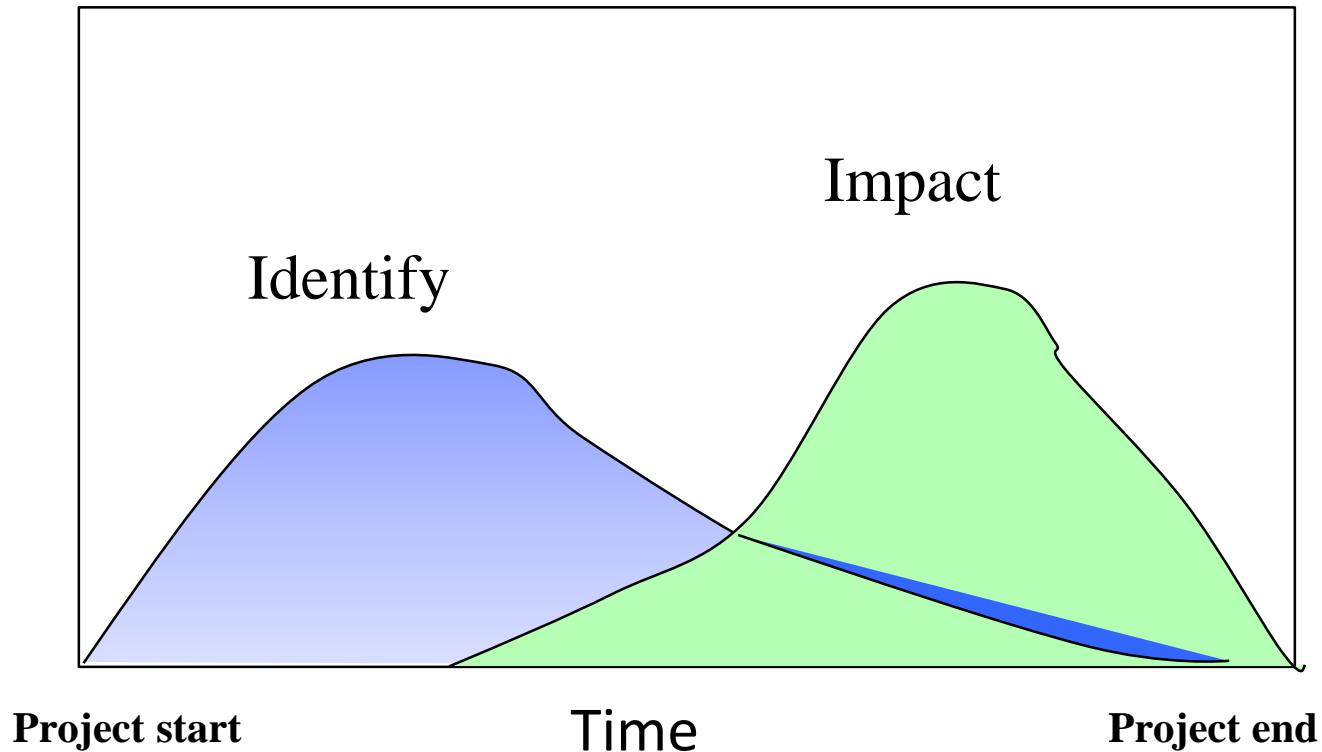
procedures for the ongoing identification and assessment of security threats and security management-related threats and risks, and the identification and implementation of necessary management control measures. Security threats and risk identification, assessment and control methods should, at a minimum, be appropriate to the measure and scale of the operations. This assessment should consider the likelihood of an event and all of its consequences which shall include ..."

Ignoring events with negative impacts will not make them disappear!



How Risk Emerges

Risk management process helps prevent future problems from occurring

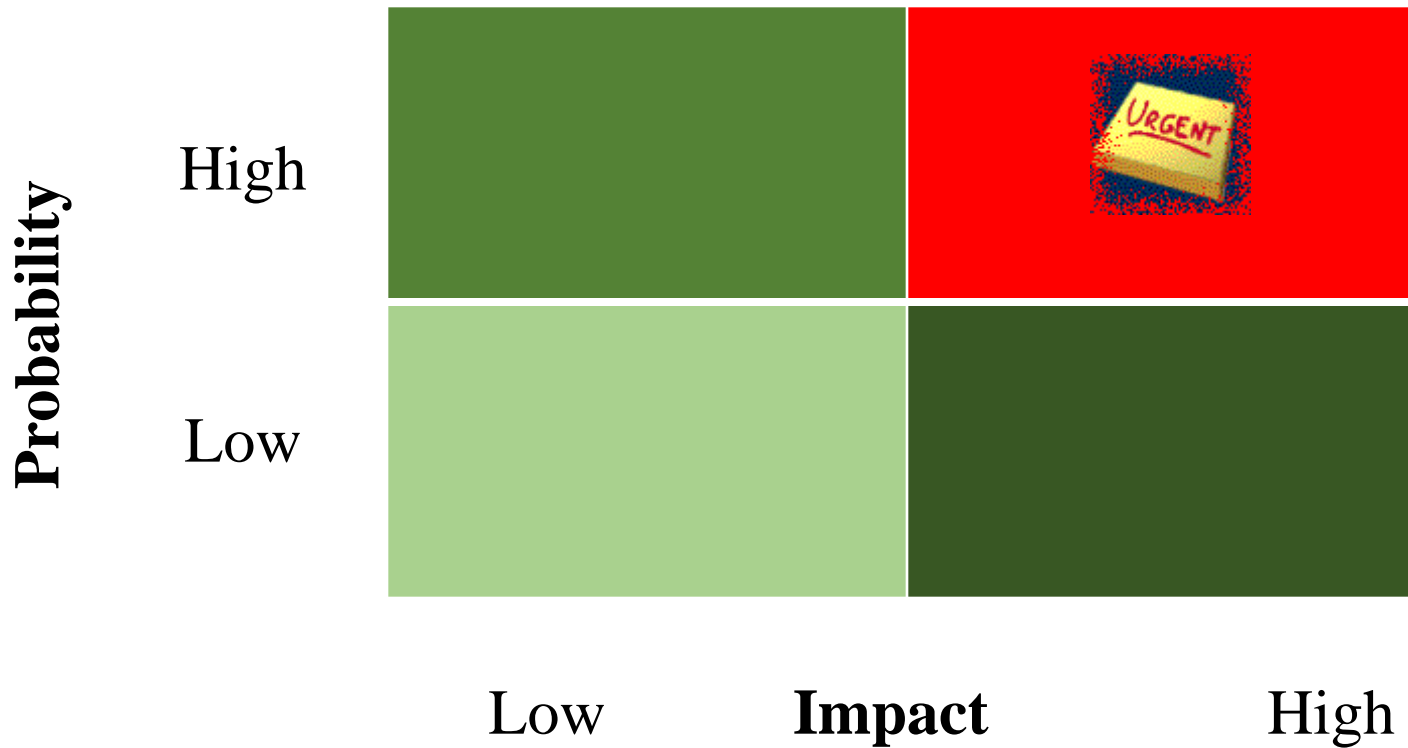


Probability & Impact Scale

<u>Standardize Probability & Impact scale</u>										
Option	Rating									
1	Very Low		Low		Moderate		High		Very High	
2	0.05		0.1		0.2		0.4		0.8	
3	0.1		0.3		0.5		0.7		0.9	
4	1	2	3	4	5	6	7	8	9	10
									<u>FACT</u>	

Risk Severity

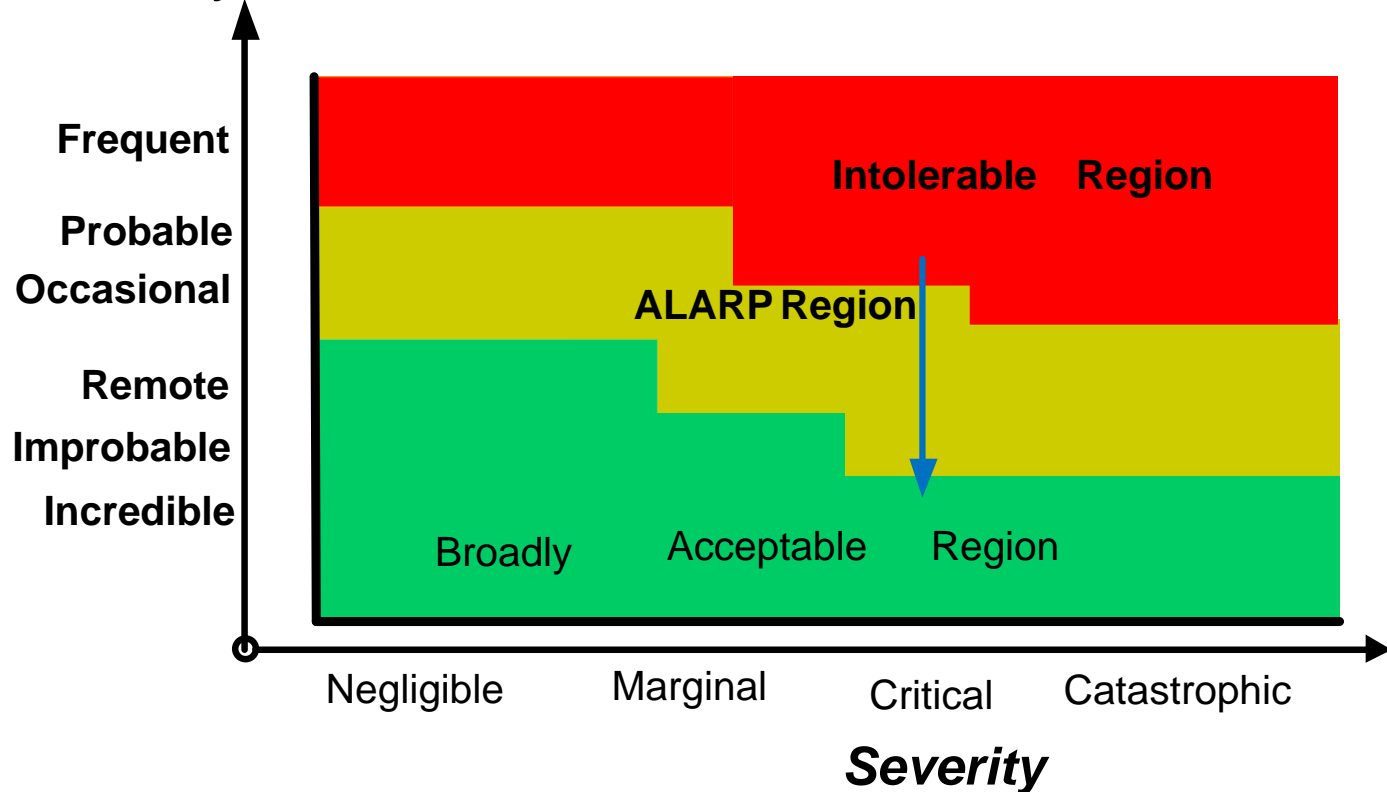
$$\text{Risk Severity} = \text{Probability} * \text{Impact}$$



Probability vs. Severity

Cells of Matrix are populated with calculated risk values ($\text{Severity} * \text{Probability}$)
ALARP = As Low As Reasonably Possible

Probability of Occurrence



Determine Severity & Probability

Choice 1

- Explain risk to five familiar experts or team members
- Ask them to opine on levels using scale, say, 1 to 5
- Discard highest and lowest ratings you receive from above
- Average remaining 3 ratings
- Round off the answer

Choice 2

- Enter risk on spread sheet
- Have five experts rate using the pre-determined scale
- Find the mean
- Round off the answer

The Difference

Qualitative Risk Analysis

- Addresses individual risks descriptively
- Assesses discrete probability of occurrence and impact
- Prioritizes individual risks for subsequent treatment
- Adds to risk register

Quantitative Risk Analysis

- Predicts likely project outcomes based on combined risk effects
- Uses probability distributions to characterize likelihood and impact
- Uses project model (e.g. schedule, cost estimates)
- Requires specialized tools
- Can estimate likelihood of meeting objectives together with confidence intervals
- Identifies risks with greatest effect on project (sensitivity analysis)

Expected Monetary Value (EMV)

- It is the value of a possible outcome, which is calculated by multiplying the value of the outcome by the probability of its occurrence.
- The resultant EMV of a risk can be determined by adding all the EMVs corresponding to different outcomes.
- **EMV = \sum (Impact * probability)** for each activity of WBS elements.

Benefits of Risk Management

- Protects objectives
- Maximizes results of positive events
- Minimizes consequences of adverse events
- Minimizes unpleasant surprises
- Focuses on doing it right the first time
- Proactive not reactive

What You Need Before You Begin

- Organization, QMS, and Process Objectives to consider while identifying risks:
 - How clear are the information and directions?
 - Are the the objectives achievable?
 - What is the degree of difficulty in completing the deliverables?
 - What is the level of authority at QMS level? Adequate or Inadequate?

Risk Management – Stakeholders

- Stakeholders' register to consider while identifying risks:
 - Are all interested parties identified?
 - How clear are their objectives and expectations identified?
 - What is the degree of understanding about their roles?

Risk Management – QMS

- Business processes – consider while identifying risks:
 - What areas are incomplete or hazy?
 - How clear are their objectives and expectations of interested parties addressed?
 - Which work has never been done before?
 - What is the degree of understanding of a process a process owner has?
 - What is the time, cost, and quality commitment required?

Risk Management – Time & Cost

- Time and cost estimates to consider while identifying risks:
 - How and who created the estimates?
 - How clear is the estimator's knowledge?
 - What is the degree of optimism of estimator?
 - What is the level of padding used in estimates?

Risk Management – Communication Plan

- Communication plan to consider while identifying risks:
 - How clearly are the areas identified where communication management is required?
 - How does the plan address the effectiveness of the communication established for the stakeholders' needs?

Risk Management

Example – Purchasing

- Supply Chain to consider while identifying risks:
 - Does it state the method of creating contract?
 - How clearly are the areas identified where specific and careful management is required?
 - How does the plan address the level of expertise required for managing the contracts?
 - How does the plan address the requirement of various terms and conditions to be included in the contract?

Risk Tolerance Areas

- Risk tolerance is usually expressed in terms of:
 - Constraints
 - Scope, time, and quality
 - Resources and customer satisfaction
 - Down time, complaints, and injury incidences
- Determine which areas in which company and their stakeholders are willing to accept the risks

Risk Thresholds

- While accepting risk, “How much is too much” needs to be specified for each risk
 - Example: More than two working days delay in installation of X not acceptable
 - Therefore threshold here is $<$ two working days
- The project manager may keep the information on risk accepted areas, with their thresholds specified, to monitor the overall risks of the project

Risk Management Planning

- Risk Management planning is the process of deciding how to approach and plan the risk management activities for a project
- It is important to plan for risk management
 - Determine right level, type, and visibility
 - Identify and validate stakeholders' risk thresholds
 - Generate the risk management plan

Plan the Work and Work the Plan

FMEAs

- FMEAs are a good way of managing risk management
- FMEAs have been used since 1970 by government, aerospace, and defense industries
- Use only Severity and Probability, no detection for managing risk
- Have a good understanding with risk team and management about mitigating risk score (RPN)
- Mitigate residual risk also, as needed

FMEA Requirements

- Customer defined as the end user (but may include the next operation)
- Responsible person must directly and actively involve representatives from all areas affected
- Should be initiated at the early stage
- Relies less on product or process design changes to overcome weaknesses and more on design characteristics as they relate to the process

FMEA Ground Rules



- Do not consider all conceivable failure modes
- Write failure modes in negative sense
- Develop each column independently
- Use team approach
- Review design/process requirements before start

Tips on FMEA Creation & Use

- Use multi-functional team
- Begin as early as possible; don't wait for all information to get started
- Work on it piecemeal – there is no need to marathon its finish
- Keep in mind that the probability of occurrence tends to be subjective
- Requires final approval

PFMEA Columns



- **Function**

What is the purpose of the process being analyzed?

- **Failure Modes**

How can this process fail to do all the things that it is supposed to do?

- **Effects of Failure**

What do the customers (internal and external) experience as a result of each failure mode?

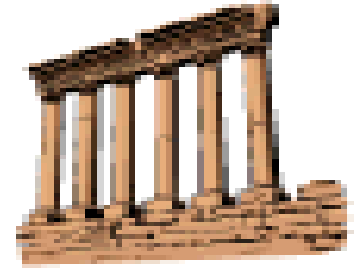
PFMEA Columns



- **Current Process Controls**

What types of controls are in place to assure all failure modes are identified and removed?

PFMEA Columns



- **Risk Priority Number (RPN)**
Product of the Severity (S), Occurrence (O), and Detection (D) rankings
- **Recommended Action(s)**
Actions required to address the failure modes. The actions should be cost effective and have a high degree of permanency
- **Responsibility/Completion Date**
Identify the responsible person and when it will be completed
- **Action Results**
Results of actions

Failure Mode and Effects Analysis

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

Drawing# _____
Revision Date/Level _____

Process Responsibility _____
Key Date _____

FMEA Number _____
Page _____ of _____
Prepared By _____
FMEA Date (orig.) _____
(Rev) _____

Process Function Requirements	Potential Failure Mode	Potential Effects(s) of Failure	S e v e r i t y	C l a s s	Potential Cause(s)/ Mechanism of Failure	O c c u r	C u r r e n t C o n t r o l s	D e t e c t	R P N	Recommended Action	Responsibility & Target Completion Date	Action Results					
												Actions Taken	S e v	O c c u r	D e t e c t	R P N	
<p>What are the functions, features, requirements?</p> <p>What can go wrong? -No Function -Partial Function -Intermittent Function -Unintended Function</p>		<p>What are the effects?</p> <p>How bad is it?</p>			<p>What are the causes?</p>	<p>How Often does it happen</p>	<p>How can this be prevented or detected?</p>	<p>How good is the method of detection?</p>	<p>RPN number provides a priority</p>	<p>What can be done? -Design changes? -Process changes? -Special controls -Changes to standards, procedures, work Instructions?</p>	<p>Assign responsibility and date for actions to be completed</p> <p>List action taken to reduce RPN number</p>						<p>Re-calculate new RPN to demonstrate improvements</p>

Form - FMEA Rev. A

FMEA/Risk Example for Hospital Surgery

Process Function	Potential Failure Mode	Potential Effects of Failure	S E V	Potential Cause(s)/ Mechanism(s) of Failure	O C C	Current Process Controls	D E T	R P N	Recommended Action(s)	Responsibility and Completion Date	Action Results				
											Actions Taken	S E V	O C C	D E T	R P N
The highest value process steps from the C&E matrix.	In what ways might the process potentially fail to meet the process requirements and/or design intent?	What is the effect of each failure mode on the outputs and/or customer requirements? The customer could be the next operation, subsequent operations, another division	How Severe is the effect to the customer?	How can the failure occur? Describe in terms of something that can be corrected or controlled. Be specific. Try identify the causes that directly impacts the failure mode, i.e., root causes.	How often does the cause or failure mode occur?	What are the existing controls and procedures (inspection and test) that either prevent failure mode from occurring or detect the failure should it occur? Should include an SOP number.	How well can you detect cause or FM?	SEV x OCC x DET	What are the actions for reducing the occurrence, or improving detection, or for identifying the root cause if it is unknown? Should have actions only on high RPN's or easy fixes.	Who is responsible for the recommended action?	List the completed actions that are included in the recalculated RPN. Include the implementation date for any changes.	What is the new severity?	What is the new process capability?	Are the detection limits improved?	Recalculate RPN after actions are complete.
Team Scrubs for Surgery	Not Scrubbing Properly	Infection	9	Procedure Violated	5	Training	3	135	Develop test to confirm Scubbing Procedure	XYZ Dec 2006	9	1	1	9	
Team Does "Time Out"	Absenteeism	Surgery Postponed	9	Required Members not present	2	Documentation- Sign-off	1	18							
	Tardiness	Surgery Delayed	5	Employee Related-Special Cause	4	Surgical Dept. Metrics	1	20							
	Poor Participation	Errors may Occur	10	Employee Related-Special Cause	4	Documentation Sign-off	3	120	Verbal Test- To confirm Comprehension		10	2	3	60	
Documentation	Documentation not being done/completed	Violation of Regulations/Surgical	9	Attitude regarding procedures	7	External Audit	1	63	Internal Audit-Penalties Imposed		9	4	1		
Debrief Patient	Missunderstanding	Infection	8	Open stitches	4	Interview before leaving by nurse	2	64							
	Patient does not follow instructions	Infection	8	Open stitches	4	Interview before leaving by nurse	2	64							
								0							
Mark Surgical Area	Marked wrong	Cut off wrong limb	9	Marked wrong before surgery	3	Patient marks limb	1	27							
Perform Surgery	Not following procedures	Patient Dies	10	Rushing	3	Observers submit report	4	120							
	Careless technique	Patient Dies	10	impaired	3	Observers submit report	4	120							
								0							

Risk Analysis

- Risk analysis is the process to assess impact and probability of identified risks
 - Prioritize risks according to potential impact on project objectives
 - All risks not created equal
- Estimate severity and probability that each risk event will occur
- Determine impact (how much at stake) – RPN
- Rank the risks

Evaluating Risk Reduces Uncertainty

Risk Response Planning

- Risk response planning develops the options and actions to enhance opportunities and reduce threats to objectives
- Includes identification and assignment of individuals to take responsibility for each agreed upon risk response
- Uses four major response strategies
 - Avoidance
 - Transference
 - Mitigation
 - Acceptance
- Output is a risk response plan

Risk Monitoring and Control

- Risk monitoring and control keeps track of the identified risks, monitors residual risks, identifies new risks, ensures execution of risk plans, and evaluates effectiveness.
 - Conducts FMEAs reviews
 - Identifies new risks that might result from changes
 - Implements risk response plans if risks occur

An Ongoing Process During Project Execution

Questions?

- Examples
- Questions
- Discussions

Contact Information

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