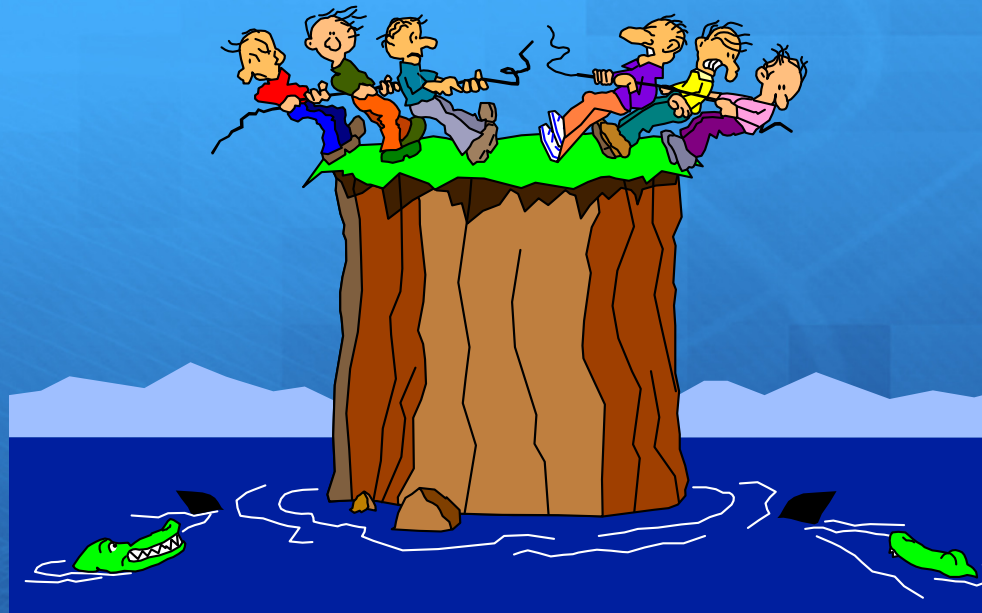


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DMJ Miller & Assoc., Inc.



Risky Business

Severity, Probability, Controls, Oh My!



Risk Assessment: Systematic approach for a work process or activity to:

- Identify hazards
- Evaluate hazards
- Incorporate measures to manage and mitigate the risk.

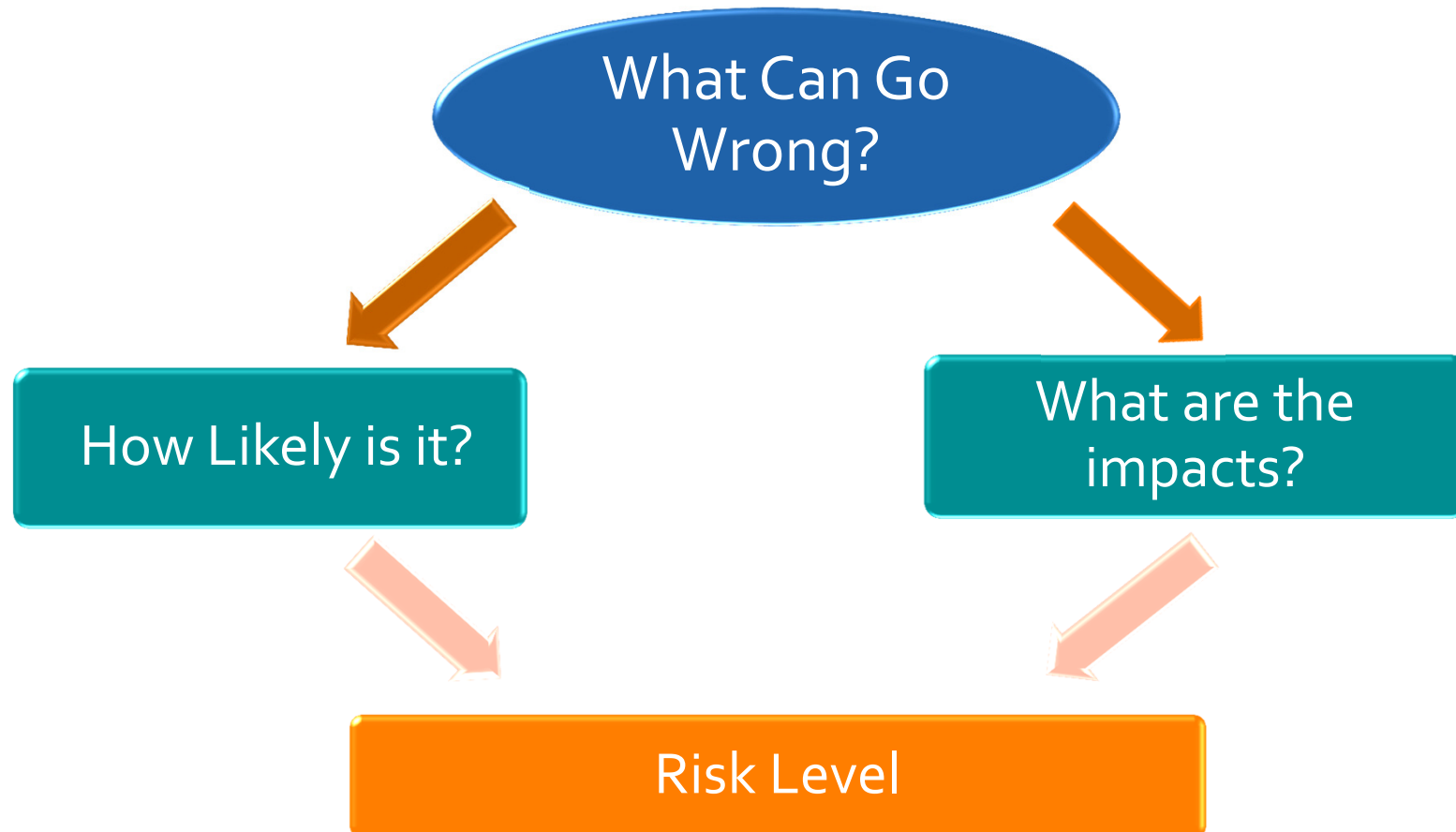
Risk Assessment

Uncertainty is a potential, unpredictable, unmeasurable and uncontrollable outcome.

Risk is a consequence of action taken in spite of uncertainty.

Risk perception is the **subjective** judgment people make about the severity and/or probability of a risk, and may vary person to person.

Identifying and Understanding Risks



Risk Analysis Matrix

Probability of Occurrence

Terms

Almost certain	Frequent
Likely	Probable
Possible	Occasional
Unlikely	Remote
Rare	Improbable

Risk Analysis Matrix

Accident Frequency Categories

Frequency	Category
Extremely unlikely to occur	1
Not expected to occur during the lifetime of the facility	2
Expected to occur no more than once during the lifetime of the facility	3
Expected to occur several times during the lifetime of the facility	4
Expected to occur more than once in a year	5

Risk Analysis Matrix

Probability Level Selection Criteria

Probability Level	Score	Probability of Occurrence (<i>P</i>)
Improbable (Extremely un-Likely)	1	$P < 1/1,000,000$ (0.0001%)
Remote (Unlikely)	2	$1/100,000$ (0.001%) $> P \geq 1/1,000,000$ (0.0001%)
Occasional (Likely)	3	$1/10,000$ (0.01%) $> P \geq 1/100,000$ (0.001%)
Probable (Very Likely)	4	$1/100$ (1%) $> P \geq 1/10,000$ (0.01%)
Frequent (Extremely Likely)	5	$P \geq 1/100$ (1.0%)

Risk Analysis Matrix

Catastrophic	Catastrophic
Major	Critical
Moderate	Serious
Minor	Minor
Insignificant	Negligible

**Severity of Occurrence
Terms**

Risk Analysis Matrix

Accident Consequence Categories

Category	Impact	Production Loss	Facility/Equipment damage (\$M)	Employee/Public Safety	Environment
1	Negligible	< 1 week	< 0.1	No injury or health effect	Release contained within plant boundaries
2	Marginal	1 Wk – 1 Mn	0.1 - 1	Minor injury or health effect	Small release outside plant boundaries
3	Significant	1 Mn – 6 Mn	1 - 10	Serious injury or health effect	Release outside plant boundaries > legal limits
4	Catastrophic	> 6 Month	> 10	Fatality or Serious health effect	Large release outside plant boundaries 10 X the legal limit

Risk Analysis Matrix

Severity Level Selection Criteria

Severity Level	Score	Selection Criteria
Negligible	1	No impact on performance or safety and not noticed by the customer or user, or; Cosmetic impact only with or without annoyance to the user.
Minor	2	Performance impact, up to and including product failure, due to failure of product to meet performance expectations but with no risk to the user
Serious	3	Performance impact, up to and including product failure due to failure of product to meet performance expectations. Moderate injury possible (Temporary / reversible sever symptoms) Specimen from invasive procedure lost.
Critical	4	Performance impact, up to and including product failure due to failure of product to meet performance expectations - serious injury possible (permanent impairment, irreversible, but nor fatal or life-threatening) False positive or clinically significant "over Diagnosis"
Catastrophic	5	Performance impact, up to and including product failure with potential for harm to user due to failure of product to meet performance expectations, Life-Threatening, death could occur. False negative or clinically significant "Under diagnosis"

Risk Analysis Matrix - Accidents

Frequency	Actual number of accidents			
5	2			
4	5	1		
3	15	15	2	
2	56	20	20	1
1	311	40	25	15
	1	2	3	4

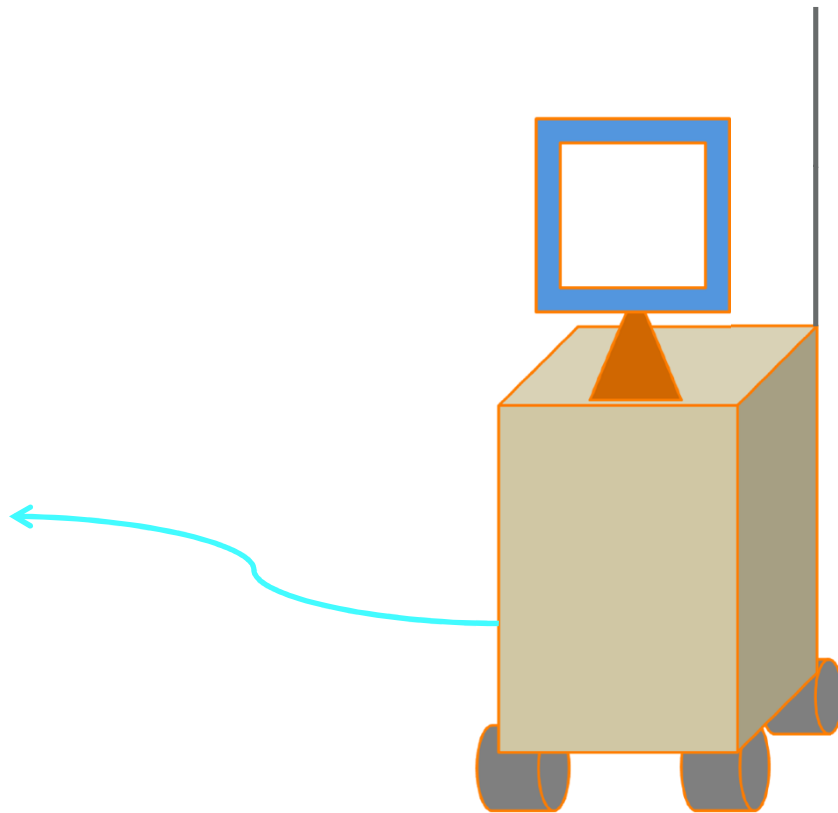
Consequence category
(facility/equipment damage)

Risk Analysis Matrix

Risk Priority

		Severity Level				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability Level		1	2	3	4	5
Improbable	1	1	2	3	4	5
Remote	2	2	4	6	8	10
Occasional	3	3	6	9	12	15
Probable	4	4	8	12	16	20
Frequent	5	5	10	15	20	25

Case Study – Health Hazard Evaluation



Initial risk assessment of Device

Hazard identification

- + Hazards associated with the use of a medical device in intended and reasonably foreseeable misuse conditions
- + Hazards associated with credible and reasonably foreseeable user errors
- + Hazards associated with the use of the device under defect conditions
- + Hazards affecting the patient, user, healthcare provider

Initial risk assessment of Device

Failure Mode and Effects Analyses (FMEA)

- + Design FMEA (DFMEA) The probability of a hazardous situation occurring shall be related to the probability of occurrence of the various design failure modes that result in the occurrence of the hazardous situation.
- + Process FMEA (PFMEA) The probability of a hazardous situation occurring shall be based upon the Process Capability Index (Cp value) of the manufacturing process under review.
- + Clinical FMEA (CFMEA) Identify issues that may cause hazards in a clinical setting.

Initial risk assessment of Device

Mitigation and Control of Risk

- + Iterative process that begins during the Definition phase and continues throughout the product lifecycle.
- + Mitigation Methods
 - Design for inherent safety (Most preferred)
 - Add protective measures to the device or the manufacturing process
 - Provide safety information warnings such as in the device labeling (least preferred)

Initial risk assessment of Device

Risk Level for identified hazard

- + Initial risk level is the risk present before mitigations are implemented. After mitigations are implemented the risk level identified is the Residual Risk Level
- + Risk level is calculated by multiplying the Severity Level and Probability Level of the hazard. This equals the Risk Priority Number (RPN).
 - Severity level and Probability Level are semi-quantitative indicators
 - Categorize the risk associated with the RPN

Risk Management Process

- + Risk Analysis
- + Risk Evaluation
- + Risk Control
 - Residual Risk
- + Residual Risk
- + Medical Benefit Analysis

Normal Surveillance Processes

- Complaints
- Non-conformances
- Investigations
- Literature Review

Post Production Surveillance

- Review
- RE-evaluate

Questions?



References

- + ISO BS EN 14971:2012 (E) Medical devices – Application of risk management to medical devices
- + Les Schnoll, *Ensure Medical Device Safety, A comprehensive risk management process is required*, Standards Outlook, Quality Progress, February 2003, ASQ
- + Nicholas L. Squeglia, *Expert Answers, Minimizing risk*, Quality Progress, January 2010, ASQ