



ISO 9001:2015 Risk Based Approach

And FMEA Controls and a little Baseball

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ISO Risk Based Approach

5 areas of Risk Treatment in ISO

4.4 Quality Management System and it's Processes

- The organization shall determine the risks and opportunities and plan and implement appropriate actions.

5.1.2 Customer Focus

- Top management shall ensure that the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.



ISO Risk Based Approach

5 areas of Risk Treatment in ISO (cont'd)

6.1 Actions to Address Risks and Opportunities

- When planned for the QMS, the org shall determine the risks and opportunities
- The org shall plan actions to address these risks and opps
- Actions taken shall be proportional to the potential impact

8.5.5 Post-Delivery Activities

- In the determining the extent of post-delivery activities, the org shall consider the risks associated with the products and services.

9.3 Management Review

- MR shall take into consideration the effectiveness of actions taken to address risks and opportunities



ISO Risk Based Approach

Where is Risk Treated now?

SAE AS9101 Revision C					
QUALITY MANAGEMENT SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or Mi	N/A	N/E
7.1 Planning of Product Realization					
7.1.1 Project Management					
As appropriate to the organization and product, the org shall plan and manage product realization in a structured and controlled manner to meet requirements as acceptable risk, within resource and schedule constraints.		X			
7.1.2 Risk Management					
13 Has the organization established a risk management process for managing risk to the achievement of applicable requirements, that include as appropriate:					
a) assignment of responsibilities for risk management		X			
b) definition of risk criteria (e.g. likelihood, consequences, and risk acceptance)					
c) identification, assessment and communication of risks throughout product realizatn		X			
d) identification, implementation, and management of actions to mitigate risks that exceed the definded risk acceptance criteria		X			
e) acceptance of risks remaining after implementation of mitigating actions		X			



ISO Risk Based Approach

Where is Risk Treated now?

SG1	Preparation for risk management is conducted.
SP1.1	Determine risk sources and categories.
SP1.2	Define parameters used to analyze and categorize risks and to control the risk management effort.
SP1.3	Establish and maintain the strategy to be used for risk management.

SG2	Risks are identified and analyzed to determine their relative importance.
SP2.1	Identify and document risks.
SP2.2	Evaluate and categorize each identified risk using defined risk categories and parameters, and determine its relative priority.

SG3	Risks are handled and mitigated as appropriate, to reduce adverse impacts on achieving objectives.
SP3.1	Develop a risk mitigation plan in accordance with the risk management strategy.
SP3.2	Monitor the status of each risk periodically and implement the risk mitigation plan as appropriate.



ISO Risk Based Approach

Normal Risk Computations

Risk = Consequence x Frequency

Frequency is how often the Consequence occurs, not the initial event (i.e. Bad Hubble mirror is the consequence of bad calibration, lack of calibration is not the consequence)

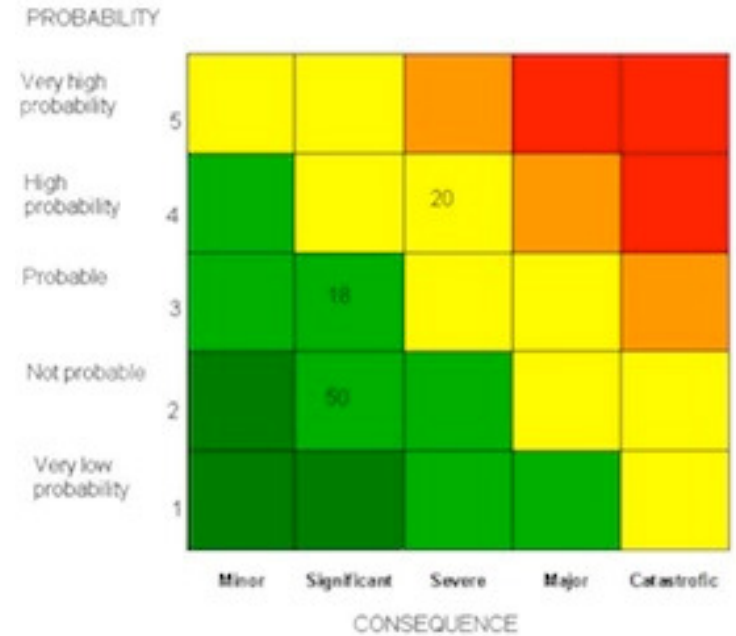
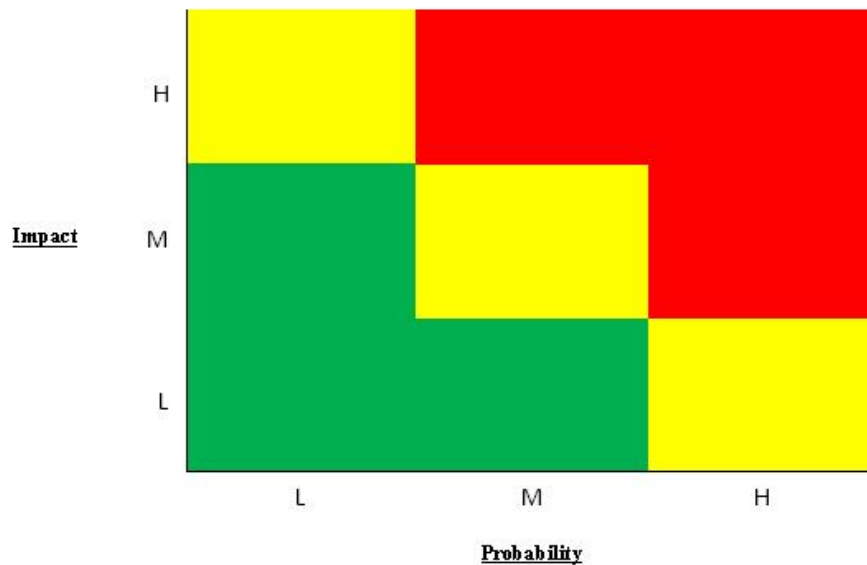




ISO Risk Based Approach

Normal Risk Computations

Risk = Consequence x Frequency





ISO Risk Based Approach

Normal Risk Computations

Risk = Consequence x Frequency

Risk #1							
Risk #2							

5 minute break



FMEA Controls

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FMEA Detection

No	The highest value process steps	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 or the end user.	How Severe is the effect to the customer? (1-10)	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? (1-10)	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? (1-10)	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.
1	Car is hit by stone	Car may get damaged	Can't get to work	10	Stone on roadway is ejected by a tire	2	Road crews maintain highway	10	200	Keep alert for rocks ahead.
2	Car is hit by stone	Car may get damaged	Car can't get to work	10	Stone falls from a dump truck	3	Keep distance from truck	2	60	Change lanes, keep more distance
3	Hose breaks in engine	Car may fail	Cannot get to work	10	Hose line breaks from overheating	2	Go to Jiffy Lube	7	140	Check on a weekly basis by raising hood.

What are the main differences here?



FMEA Detection

Function or Process	Risk or Failure Mode	Impact or Possible Effect	Severity	Cause	Occurrence	S*D	Control	Detection	RPN	Fix
Eligibility	Ineligible land is approved	Ineligible applicant is approved and may result in improper payment	9	Human error in making the decision on whether the land was eligible, i.e. approved contract where there is water	3	27	FSA records and NRCS records. Site Visits. Personal knowledge of the applicant at the local level	6	162	This should be looked at more
Application	Application is accepted after the cutoff date	Non compliance with NRCS application cutoff rules	7	Application date is changed to reflect submission before cutoff date	3	21	Policy states that field office employee is not allowed to back date applications	7	147	Prevent ProTracts from entering applications after the cutoff date unless approved by supervisor



FMEA Detection






- Extends Risk to the prevention or mitigation level
- Shows real differences in Risk
- Can turn low or medium risk into High Risk
- Allows mitigation costs to be planned ahead








Baseball

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AL East Predictions

Rnk	Team	Win	Loss	Expected Win Pct	Sim Win	Sim Loss	Div Pct	WC Pct	Playoff Pct	Playoff Pct (Adj)	WS Win Pct	1 Day Delta	7 Day Delta
?		?	?	?	?	?	?	?	?	?	?	?	?
1	 New York Yankees	32	25	0.508	85.8	76.2	43.10%	21.00%	64.20%	53.80%	7.00%	1.10%	18.80%
2	 Tampa Bay Rays	31	27	0.51	84.3	77.7	26.90%	24.40%	51.20%	39.20%	5.20%	1.20%	12.10%
3	 Boston Red Sox	27	31	0.525	81.7	80.3	15.80%	16.40%	32.10%	24.30%	3.90%	-0.20%	2.30%
4	 Toronto Blue Jays	29	30	0.505	81.1	80.9	11.40%	16.40%	27.80%	19.60%	2.50%	3.80%	13.20%
5	 Baltimore Orioles	26	30	0.479	76.9	85.1	2.80%	5.20%	8.10%	5.30%	0.50%	-1.00%	-1.30%






NL East Predictions

Rnk	Team	Win	Loss	Expected Win Pct	Sim Win	Sim Loss	Div Pct	WC Pct	Playoff Pct	Playoff Pct (Adj)	WS Win Pct	1 Day Delta	7 Day Delta
1	 Washington Nationals	30	27	0.544	87.1	74.9	60.50%	10.50%	71.10%	66.00%	9.00%	-0.50%	-9.40%
2	 New York Mets	31	27	0.514	84.1	77.9	34.70%	12.00%	46.60%	40.50%	3.60%	0.20%	-3.20%
3	 Miami Marlins	24	34	0.499	75.9	86.1	3.10%	2.00%	5.10%	4.10%	0.30%	-0.80%	1.70%
4	 Atlanta Braves	27	30	0.45	74.3	87.7	1.70%	1.00%	2.60%	2.10%	0.10%	-0.10%	-2.20%
5	 Philadelphia Phillies	22	37	0.435	66.6	95.4	0.00%	0.00%	0.10%	0.00%	0.00%	0.00%	0.00%

NL Central Predictions

Rnk	Team	Win	Loss	Expected Win Pct	Sim Win	Sim Loss	Div Pct	WC Pct	Playoff Pct	Playoff Pct (Adj)	WS Win Pct	1 Day Delta	7 Day Delta
1	 St. Louis Cardinals	38	20	0.527	93.2	68.8	72.70%	20.10%	92.70%	82.80%	8.70%	-1.60%	6.40%
2	 Chicago Cubs	30	25	0.528	86.9	75.1	16.70%	43.80%	60.60%	38.90%	4.20%	-1.70%	0.30%
3	 Pittsburgh Pirates	31	26	0.515	85.1	76.9	10.40%	35.30%	45.70%	27.70%	2.60%	-2.90%	7.80%
4	 Cincinnati Reds	25	31	0.475	74.9	87.1	0.20%	2.00%	2.20%	1.10%	0.10%	0.50%	-0.70%
5	 Milwaukee Brewers	21	37	0.478	70.7	91.3	0.00%	0.40%	0.40%	0.20%	0.00%	0.20%	0.00%

NL West Predictions

Rnk	Team	Win	Loss	Expected Win Pct	Sim Win	Sim Loss	Div Pct	WC Pct	Playoff Pct	Playoff Pct (Adj)	WS Win Pct	1 Day Delta	7 Day Delta
1	 Los Angeles Dodgers	33	25	0.571	92.1	69.9	74.80%	15.30%	90.10%	83.20%	16.70%	2.70%	-4.20%
2	 San Francisco Giants	32	26	0.52	85.7	76.3	17.90%	33.10%	51.00%	34.30%	3.30%	0.80%	-6.20%
3	 San Diego Padres	30	29	0.502	82.2	79.8	5.90%	17.70%	23.60%	14.40%	1.10%	1.80%	7.80%
4	 Arizona Diamondbacks	27	30	0.473	76.6	85.4	0.80%	4.10%	4.90%	2.70%	0.10%	0.50%	1.00%
5	 Colorado Rockies	26	30	0.465	75.4	86.6	0.50%	2.60%	3.10%	1.70%	0.10%	1.10%	0.80%