



Don't Risk it All: How to Tackle Risk in Your Quality Management System



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A Better World Through Accreditation

Topics

- A2LA Introduction
- Intro to Risk
- Examples of Risk
- Risk and 17025
- Records Required?
- Risk Tools and Tips
- Contact Us/Core Values

About A2LA

A2LA is a non-profit, non-governmental, third-party accreditation body, offering internationally recognized accreditation services to testing and calibration laboratories, sampling organizations, inspection bodies, proficiency testing providers, reference material producers, biobanking facilities, and product certifiers.



About A2LA

- Founded in 1978
- Largest U.S. multi-discipline Conformity Assessment Body (CAB) Accreditation system
 - ~3800 CABs (certificates) currently accredited
- Fifth largest system in the world
- Extensive experience working with US Regulators – CPSC, FCC, DoD, DoE, FDA, EPA, etc.



Risky Business





Risk

- Risk is the Effect of Uncertainty on *objectives*
- Every organization has risk
- Attitude vs. Appetite





**Anyone have an example of Risk
in the Lab?**

Example Risks



- Essential Personnel
- Procedures too detailed
- Procedures not detailed enough
- Technician who performs work signs off on results.

17025 and Risk

- The standard discusses risk explicitly in 2 main sections:
 - Section 4.1
 - Section 8.5
- What are CABs supposed to do?
- What are Assessors looking for?



Section 4.1



- “Lab shall identify...”
- “...on an on-going basis...”
- Activities, relationships, or personnel relationships
- May or may not be a risk!

Section 8.5

- “The Laboratory *shall consider* the risks and opportunities...”
- “The Laboratory *shall plan*...”
 - But not really!
- Actions shall be proportional



Records of Risk



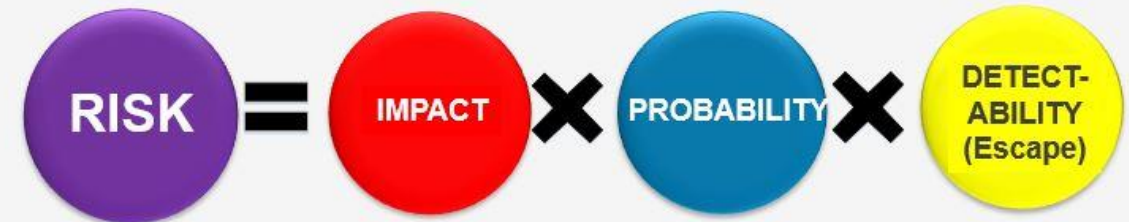
- Management Review
- 8.9.2m “results of risk identification”

Risk Components

- Impact:
 - How bad the outcome is
- Probability of Occurrence:
 - How likely it will happen.
- Detectability:
 - How easy is it to catch



Risk Calculations





Risk Calculations

FREQUENCY OF OCCURRENCE	HAZARD CATEGORIES			
	1 CATASTRO.	2 CRITICAL	3 SERIOUS	4 MINOR
(A) FREQUENT	1A	2A	3A	4A
(B) PROBABLE	1B	2B	3B	4B
(C) OCCASS.	1C	2C	3C	4C
(D) REMOTE	1D	2D	3D	4D
(E) IMPROB.	1E	2E	3E	4E

	UNACCEPTABLE	MEDIUM
	HIGH	LOW

Failure Effect	Potential Failure Cause	Impact	Prob.	Detect	RPN	Rating	Metric
Calibrator Competency	Training	3	3	2	18	NR	95%
	SOP / Process Depth	3	3	3	27	NR	100%
End of Performance Reliability	Intermediate Checks	2	2	2	8	NR	none
	Chemicals	8	5	5	200	2	95%
	Contaminants	8	5	8	320	1	1 week
	Cal Provider	1	2	5	10	NR	100%
Product Recall	Improper Eval	2	2	1	4	NR	85%
	# Pieces affected	8	8	1	64	NR	NA
	# Customers impacted	5	5	5	125	3	NA
	Delayed TAT Evaluation	5	5	5	125	4	NA
OOT Total RPN					901		
Average		4.50	4.00	3.70			



Example Risk Analysis

Risk Register Number	DATE	Identified Risk	Risk Level (Impact X Prob. X Det.)	Mitigation Strategy	Effectiveness
0000001					
0000002					
0000003					



Questions?

Contact Information



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