ENVIRONMENT

Risk Analysis and the ISO 17025 Laboratory

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TOPICS

- Define what is risk?
- What are the ISO 17025 requirements of risk?
- What is Risk Management?
- Essentials of Risk Management
- Types of Risk Management
  - ✓ Qualitative
  - ✓ Quantitative
  - ✓ SWOT (not SWAT)
- The Basics

"DON'T PANIC!"

- Douglas Adams, *Hitchhikers Guide to the Galaxy*

RISK DEFINITION

- Merriam Webster Risk

  1 : possibility of loss or injury : peril.

  2 : someone or something that creates or suggests a hazard.

  3: the chance of loss or the perils to the subject matter of an insurance contract also : the degree of probability of such loss.

- ISO 31000 Risk - ‘effect of uncertainty on objectives’ a positive or negative deviation from the expected.

ISO 17025 AND RISK

ISO 17025 references the word ‘risk’ 31 times

- Impartiality
- Decision Rules with Statements of Conformity
- Non-conforming Work
- Risks and Opportunities
- Improvements
- Corrective actions
- Management Review

RISK VS PREVENTATIVE ACTIONS

- ISO 31000 Risk - ‘effect of uncertainty on objectives’ a positive or negative deviation from the expected.

- Preventative action - Action to eliminate the cause of a potential nonconformity or other potential undesirable situation.

- ISO moved away from preventative actions to risk to allow the management system to holistically identify, evaluate and plan for positive and negative risks to their laboratory objectives and activities.

RISKS AND OPPORTUNITIES REQUIREMENTS

8.5.1 The laboratory shall *consider the risks and opportunities* associated with the laboratory activities…

a) give assurance that *the management system achieves its intended results*;

b) enhance opportunities to *achieve the purpose and objectives of the laboratory*;

c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) achieve improvement

RISKS AND OPPORTUNITIES REQUIREMENTS

8.5.2 The laboratory *shall plan*:

a) actions to address these risks and opportunities;

b) how to:

- *integrate and implement these actions* into its management system;
- *evaluate the effectiveness* of these actions.

HOW TO "CONSIDER" RISK??

- ISO 17025 does not;
  - ✓Dictate how to consider risk
  - ✓Dictate tell you how to plan
- Risk Management is the process for considering and planning for risk
- Google search "Definition of Risk Management"
  - ✓About 1,360,000,000 results (0.74 seconds)

- Where do you begin? ?

RISK MANAGEMENT

- Risk Management protects and creates value.
  - ✓ Coordinated activities to direct and control management of the laboratory in regards to risk.
- ISO 31000 provides a solid starting point for Risk Management
- Perform Risk Assessment
  - ✓ Identify Risks - What are the risks? Positive and Negative!
  - ✓ Risk Analysis – Potential, likelihood, possibility of the risk?
  - ✓ Evaluation of Risk – Prioritization or ranking of risks
  - ✓ Risk Treatment – actions to be “integrated” and “implemented” with regards to risks identified.

WHAT ARE THE LABORATORY OBJECTIVES?

- Provide a high quality, defensible and reliable data product with the best in class customer service.
- What are your laboratory objectives?
  - ✓ Highest data quality for our customers
  - ✓ Quickest turn around time for data and EDDs
  - ✓ Best in class customer service
  - ✓ Improve final report TAT
  - ✓ Lower per analysis cost

WHAT ARE THE LABORATORY ACTIVITIES?

What your laboratory does…..

- Sample Receiving
- Metals Preparation and Analysis
- Wet Chemistry/General Chemistry Preparation and Analysis
- Semi-volatile Preparation and Analysis – GC/MS, GC/FID, UPLC, etc.
- Volatile Preparation and Analysis - GC/MS, GC/FID, etc.
- Producing Electronic Data Deliverables (EDDs)
- Issuing final reports

RISK IDENTIFICATION

Step 1: Identify laboratory objectives

Step 2: Develop balanced representation for departments, groups or management team

- All facets of the laboratory
- All levels of experience

Step 3: Brainstorm Risks

- Identify risks to the department – employee retirements, instrument age, type and number,
- Identify opportunities – employee openings for internal candidates, improved sample throughput,
- Perform the same analysis at the laboratory level during Management Review

TYPES OF RISK MANAGEMENT

Three basic approaches to risk management

1. Qualitative
   - Probability vs Impact Matrix
   - Develop risk exposure from the matrix
   - Allows for comparable rating to identified risks
2. Quantitative
   - Input information of all facets of your risk(s) into a model to determine a numeric output expressing uncertainty and different probability levels.
   - Excel based approaches with ordinal assigned values for probability and impact,
   - Monte Carlo and Primerva risk analyses
3. SWOT analysis

TYPES OF RISK ANALYSIS AND EVALUATION

Qualitative

Bill's Laboratory and Analytical Services				
Department	**Risk Identification**	**Probability**	**Impact**	**Overall Score**
Metals	ICP needs replacing will not hold calibration	**High**	**High**	**High**
	1 Staff of 5 retiring 2021	**High**	Moderate	Moderate
GC/MS	Pump units have no back-up	Low	**High**	Moderate
	CRM availability problems for specialty analyses	Moderate	Moderate	Moderate
Organic Prep Lab	Hood Certification Vendor may lose accreditation need to find replacement prior to March 2021	Low	Low	Low

TYPES OF RISK ANALYSIS

Quantitative

- Set ordinal values for Probability and Impact
- Scale of 1 to 5
  - 1 – least probability and impact
  - 5 – highest probability and impact

- Overall Risk Profile is determined by Probability x Impact

TYPES OF RISK ANALYSIS AND EVALUATION

Ted's Laboratory and Analytical Services				
Department	**Risk Identification**	**Probability**	**Impact**	**Overall Score**
Metals	ICP needs replacing	**5**	**5**	**25**
	1 Staff of 5 retiring 2021	5	3	15
GC/MS	Pump units have no back-up	1	**5**	5
	CRM availability problems	3	3	9
Organic Prep Lab	Hood Certification Vendor may lose accreditation need to find replacement prior to March 2021	1	1	**1**

IMPLEMENT YOUR PLAN OF ACTION

1. What is your risk management approach?
   - Avoidance – eliminate, withdraw, not be involved with risk
   - Reduction – optimize, mitigate, reduce your risk profile
   - Sharing – transfer or outsource, develop strategic partnerships
   - Retention – accept the risk, budget for the risk, anticipate the impact
2. What are the metrics you are going to use to monitor?
   - Lower number of data quality errors
   - Instrument up time
   - Improved customer satisfaction
   - Revenue increase/decrease
3. Metrics need to reflect the action plan.

SWOT ANALYSIS

SWOT – Strengths, Weaknesses, Opportunities and Threat Analysis

- Internal Perspective
  - ✓ Strengths – What are the strengths of the department or laboratory?
  - ✓ Weaknesses – Where do the weaknesses exist in the department or laboratory?
- External Perspective
  - ✓ Opportunities – What are the sales potentials, client partnerships, or regulatory changes available?
  - ✓ Threats – What are the external threats? Competition, regulatory changes, project closures?
- Not always true in these distinctions

SWOT ANALYSIS

- Each category follow the same approach
  - Identify elements for each group.
  - Use qualitative or quantitative analysis
  - Evaluate and Prioritize Risk
- Develop Action Plans for your top number of risks
- Implement!
- Monitor the impact of your improvement!

WHO IS RESPONSIBLE FOR RISK MANAGEMENT?

- Responsibility is an element of the Management Review process
  - ✓ ISO 17025 Section 8.9.2 m) results of risk identification
- Ideally all employees should be involved in the identification, development and implementation of risk management.
- Ownership and buy-in come from participation - an essential piece to a successful implementation and management of risk.

IN SUMMARY....

"DON'T PANIC!"

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REMEMBER….

- There are resources available and are easily found.
- If you have a 3rd party accreditor – they will have consultants to help you.
- Evaluate the complexity needed for your laboratory.
  - Not all laboratories are the same.
- Fit the risk management program to your laboratory needs.
- Keep in mind the basics….

THE BASICS

- Determine our laboratory's objectives and activities.
- Develop your risks and opportunities to achieve your laboratory's objectives.
- Identify your risks
- Analyze and evaluate your risks
- Develop your action plan with metrics that allow you to monitor your action plan.
- Implement and Monitor your action plan.
- Document all of the above!!!! PLEASE!

QUESTIONS???

Thank you!

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