ISO/IEC 17025:2017

It's all about Risk Management*

*and opportunities

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Don’t Panic it is just a RISK!
**17025:2017**

*Risk emerges in evaluating laboratory competence:*

- Establishes a basis for **increasing the effectiveness** of the management system, achieving improved results and preventing negative effects

- The **laboratory is responsible** for deciding which **risks and opportunities** need to be addressed

- Now requires the laboratory to **plan and implement actions** to address risks and opportunities

- From being mentioned once in the previous standard (4.11.3) **risk** is **now mentioned 30 times** in the document and is found in multiple clauses
From the Foreword of ISO/IEC 17025:2017:

- “...risk-based thinking...has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

- “greater flexibility ...in the requirements for processes, procedures, documented information and organizational responsibilities...”
Risk Management

- Requires the laboratory to **plan and implement actions** to address risks and opportunities. And works in
  - Establishing a basis for increasing the effectiveness of the quality management system,
  - Achieving improved results and
  - Preventing negative effects.

- The laboratory is **responsible for deciding** which risks and opportunities need to be addressed
Risk/Opportunity-Based Thinking

- Risks are the **effect of uncertainty**
- Uncertainties are **unique** to each organization
- **Opportunities are favorable** situations
- Risks and Opportunities increase operational effectiveness
Risk-Based Thinking

or When ISO Did the Thinking

- **ISO/IEC 17025:2005**
  - Quality Manual
  - Policies (many)
  - Procedures (33+)
  - Job Descriptions
  - Top Management
  - Quality Manager
  - Technical Manager

  - Risk Managed by ISO

- **ISO/IEC 17025:2017**
  - Documented Information
  - Policies (1-3) maybe
  - Procedures (13+)
  - Responsibilities and Authorities
  - Management
  - Competency

  - Risk Management by the Lab!
Risk mentions in ISO/IEC 17025:2017

- Foreword & Introduction,
- Impartiality,
- Decision Rules
- Management of NCW,
- Lab activities,
- Actions to address risks,
- Proportionality,
- CorAct & updating risk
- Inputs on risk ID.
Impartiality

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.
Impartiality Risks

Some impartiality risk sources:
- Ownership
- Governance
- Management
- Personnel
- Shared Resources
- Finance
- Contracts
- Lobbying
- Marketing
- Commissions
- Volunteering
Decision Rules

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.
Decision Rules:
- Customer Request for Pass/Fail
- Lab needs to estimate MU
- No instruction on how to apply MU from method or specification
- Lab creates decision rule

Records of:
- Decision rule
- Communication to customer
- Customer agreement with rule
Decision Rules

- Upper Limit
- Lower Limit

Data Point

Uncertainty
Did Customer Request a Pass/Fail Statement?

- Yes:
  - Does Uncertainty Come Into Consideration?
    - Yes:
      - Do Customer or Method Tell Lab How to Incorporate Uncertainty?
        - Yes:
          - Decision Rule Defined and Agreed To
        - No:
          - Decision Rules not required
    - No:
      - Decision Rules not required

- No:
  - Decision Rules not required
Nonconforming work

7.10.1(b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
Risks in the Lab

- Using new test methods
- Using new equipment
- Hiring / Firing personnel
- Frequency of QC checks
- Frequency of monitoring
- Defining Competence
- Detail in Purchasing Docs
- Keeping or Deleting Procedures
- Detail in Procedures
- Internal vs External Calibrations
- Calibration Intervals
- Service Acceptance Criteria
- Subcontractor Use
- Decision Rules
- Acting on Non-Conformities
- Resolving Complaints
- Corrective Action Implementation and Monitoring
Corrective Action

8.7.1 When a nonconformity occurs, the laboratory shall: e) **update risks and opportunities** determined during planning, if necessary;
Management Review

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

m) results of risk identification;
Risks and Opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance the QMS achieves its intended results;
b) enhance opportunities to achieve the purpose / objectives of the lab;
c) prevent, reduce, undesired impacts / potential failures in lab activities;
d) achieve improvement.
8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.
Risk-Based Approach

An Ounce of Prevention...
Risk

Opportunity

- Effect of uncertainty on objectives ISO 31000 [2.1]
Risks and Opportunities

- NOT an encouragement to race to the bottom

- IS an encouragement to be more aware when making business decisions, taking advantage of opportunities to grow / become better

- Does the risk lead to better competence, impartiality, or consistency?

- Is the lab willing to mitigate residual negative effects?
Risks, Opportunities & Objectives

Examples of Opportunities

- Expand the scope of laboratory activities
- Address new customers
- Use new technology

Examples of Associated Risk

- Expansion too fast resulting in lack of competent personnel
- Too many new customers leaving inability to handle workload impartially
- Cost / complexity of new technology causes problems with timely processing of work

DO THE ACTIONS YOU ARE PLANNING HELP THE LABORATORY ACHIEVE ITS DEFINED OBJECTIVES?
A few Risk Management Tools

- **Qualitative**
- **Quantitative**
- **FMEA**
- **Fishbone**
- **SWOT**
- **Brainstorming**

**COST / RESOURCES TO IMPLEMENT**

**SEVERITY or CRITICALITY OF RISK**
Risk Management

- Minimize **EXPOSURE**

EXPOSURE = RISK

Ideal: Exposure = 0
Brainstorming
Brainstorm

Pros
- Promotes creativity
- Allows for multiple perspectives
- Low risk of conflicts (crazy ideas encouraged!)
- Easier to identify correlations
- Visual tool

Cons
- Difficult to moderate w/o stifling creativity
- Quick entry into rabbit holes
- Participants have to describe how the suggestions tie into the objectives
- Not the end; supports most other strategic tools!
Aims to identify the key internal and external factors seen as important to achieving an objective. Brainstorming...

SWOT analysis groups into two main categories:

**Internal factors** - strengths and weaknesses internal to the organization

**External factors** - opportunities and threats presented by the environment external to the organization
Fishbone

Fishbone Diagram Example

1. Develop problem statement
2. Begin to categorize
3. List contributing factors
4. Ask why for each factor
5. Look for deeper causes
6. Test for root causes
"Failure modes" the ways in which something might fail. "Effects analysis" studying the consequences of those failures.
Risk Tools: Risk Register

Risk Score = Severity #1 \times Probability #2 \times Detectability #3
<table>
<thead>
<tr>
<th>Category</th>
<th>Sub-Category</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab</td>
<td>Procurement (quality critical supplies)</td>
<td>High 8</td>
</tr>
<tr>
<td></td>
<td>Adulterated/mislabeled supply/reagent resulting in false or incorrect results</td>
<td>Medium 6</td>
</tr>
<tr>
<td></td>
<td>Single/unreliable source causing delays in testing</td>
<td>Low 4</td>
</tr>
<tr>
<td></td>
<td>Back orders infrequent, periodically impacting TAT</td>
<td>Negligible 2</td>
</tr>
<tr>
<td></td>
<td>Minor supply disturbances, no impact on TAT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sample Handling</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss of sample or sample damaged, lab unable to analyze</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sample compromised and test results adversely affected</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initial Analysis affected but retesting possible</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No negative impact of financial results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data Integrity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss or alteration of data without traceability back to source</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss of data with probable chance of recovery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss of data but easily recovered</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Modification of data without change in underlying value</td>
<td></td>
</tr>
<tr>
<td>Business</td>
<td>Financial Profit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serious loss harming financial stability of company</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Missed profit opportunities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Limited profit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Business</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customer Service</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss of business or customer trust</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unsatisfied customer, possible customer complaint</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stress or uncomfortable situation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal customer request and feedback</td>
<td></td>
</tr>
</tbody>
</table>
## Risk Probability

<table>
<thead>
<tr>
<th>Probability Score</th>
<th>Description</th>
<th>Frequency of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Remote (could happened but extremely improbable)</td>
<td>Once every 3 years or greater</td>
</tr>
<tr>
<td>4</td>
<td>Possible (known to occur occasionally but unlikely)</td>
<td>Once every 1-2 years</td>
</tr>
<tr>
<td>6</td>
<td>Probable (known to occur)</td>
<td>Once a month</td>
</tr>
<tr>
<td>8</td>
<td>Expected (occurs often)</td>
<td>Once a week or more</td>
</tr>
<tr>
<td>Detectability Score</td>
<td>Level of Detection</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>2</td>
<td>High</td>
<td>The current controls have a high probability of detecting the risk outcome promptly if it occurs</td>
</tr>
<tr>
<td>4</td>
<td>Moderate</td>
<td>Control systems in place could detect the defect or its effects but potentially after an extended period of time</td>
</tr>
<tr>
<td>6</td>
<td>Low</td>
<td>Control Systems in place have a low probability of detecting the defect or its effects</td>
</tr>
<tr>
<td>8</td>
<td>Non-existent</td>
<td>There are no controls in place</td>
</tr>
</tbody>
</table>
## Risk Rating

### Calculated Risk Category

<table>
<thead>
<tr>
<th>Risk Rating</th>
<th>Minimal</th>
<th>Minor</th>
<th>Major</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \leq 32 )</td>
<td>( &gt;32 \text{ and } &lt;128 )</td>
<td>( &gt;128 \text{ and } &lt;288 )</td>
<td>( \geq 288 )</td>
</tr>
</tbody>
</table>

Risk Score = (Probability) x (Severity) x (Detectability)
THIS MORNING I SPENT AN HOUR ON THE BIKE.

TOMORROW I INTEND TO START PEDALING.
Scenarios Class Exercise

- **Scenario:** AAFCO’s Quality Assurance/Quality Control Guidelines notes that “the State PROGRAM utilize valid and defensible laboratory testing data to ensure their mission in protecting animal and public health and enforcing feed regulations if the State PROGRAM utilizes REGULATORY TESTING LABORATORY(IES)” per AFRPS Chapter 10 that:
  - 10.3.5.1: Are accredited by a recognized AB to ISO/IEC 17025:2005, or
  - 10.3.5.2: Implement and comply with AAFCO QA/QC Control guidelines, or
  - 10.3.5.3: Implement and comply with the ISO/IEC 17025:2005.


**Instruction:** Determine if the scenario presented is a non-conformance, or simply presents some level of risk to the lab. Identify the issue, risk and **brainstorm** on mitigation efforts. Be cautious and do not assume anything that is not stated in the scenario!
Scenarios

- **Assignment**: Each table Group Discussion

- **Timing**: up to 5 min per scenario (25 minutes)
  - Each table will be assigned a set of five scenarios
  - Same set will be assigned to three (or more) tables to each work out collectively per table
  - We will compare each tables' solutions)

- **Instruction**
  - Determine if the scenario presented is a non-conformance, or simply presents some level of risk to the lab.
  - Identify the issue and associated level of risk
  - What would be the appropriate Risk Assessment tool to use?
  - Mitigation steps?
Risk Scenario No. 1

- **Risk:** Supplies
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

**Scenario:** In order to slow expenses our lab is moving to a more “Just in Time deliver approach. What is the risk of under or over ordering needed analytical supplies in regards to limited budget, but necessary work?
**Risk Scenario No. 2**

- **Risk:** CO alarm response
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** CO alarms in our building had been recently installed that were not tied into the building alarms. Instructions were to pull the fire alarm to evacuate the building if they went off. We realized no one knew what they actually sounded like.
Risk Scenario No. 3

- **Risk:** Requalifying test methods and equipment after move to new building
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** We will be moving to a new location sometime in 2020. Our new lab will be located about one hour away from our current location and will have a mix of new and current analytical instruments and need to be able to begin testing as soon as possible.
Risk Scenario No. 4

- **Risk:** Operation interruptions prevent adhering to sampling agreement
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** There are occasions where sporadic interruptions in laboratory operations prevent us from performing Test material sampling as outlined in the sampling agreement.
Risk Scenario No. 5

- **Risk:** Deliberate introduction of deleterious substance to the test sample
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** A firm has accused our laboratory of contaminating the sample with the deleterious substance. The firm has done an open records request for all procedures relating to quality control, sample storage, sample handling, sample receipt, the SOP for the analyte in question and all documents relating to certificates of analysis, certificates of sterility, and environmental control and monitoring and cleaning in the lab.
Risk Scenario No. 6

- **Risk:** Testing SOPs do not address infrequent situations
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** Our testing SOPs currently in use only address common occurrences and do not have the specific necessary information to address what to do in low prevalence situations.
Risk Scenario No. 7

- **Risk:** Testing SOPs do not address infrequent situations
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** There are tests currently being performed in our laboratory that do not yet have documented and approved associated Work Instructions.
Risk Scenario No. 8

- **Risk:** Staff who are qualified for only part of a method
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** Competency assessments of multiple staff in our lab show that we have analysts that are qualified and approved and authorized as being "competent with assistance". There are various interpretations as to what this means.
Risk Scenario No. 9

- **Risk:** Lack of available resources top recruit and retain key personnel
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** Early retirement has been accepted by several professionally qualified scientists in the laboratory, including a number of emergency response critical positions (ie: BT, FERN personnel). However there is a lack of resources available to retain and recruit qualified personnel for the lab.
Risk Scenario No. 10

- **Risk:** CAPA process does not include a global trending look-back
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** The current CAPA process in our laboratory does not include a global trending look-back in order to determine if similar nonconformities or opportunities for improvement exist, or could potentially occur.
Risk Scenario No. 11

- **Risk**: Receipt of small gifts from vendors and community
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario**: From time to time, the lab receives small tokens of appreciation from vendor or the community as a way to advertise their business or to say thank you for being a customer. Past items have mainly been food items, coupons.
Risk Scenario No. 12

- **Risk:** Broken, unfixable Retsch test sample miller
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** Our Retsch Mill used for much of our sample preparation has broken and can no longer be used or repaired and a replacement unit was not in our capital equipment budget.
Risk Scenario No. 13

- **Risk:** External documents are not incorporated into lab’s Quality System
- **Scenario:** During our lab’s previous accreditation assessment, the assessor suggested that we should show evidence of approval to use external documents such as their policies and the ISO/IEC 17025:2017 standard however we feel that we cannot be in compliance with clause 8.3.2 (management system documents) of the 17025 standard.

- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?
Risk Scenario No. 14

- **Risk**: Personnel Department and laboratory Training
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario**: When questioned about training and records, the Laboratory Director replied that the lab’s procedure required that the Personnel Department administer or provide all training and update all training records.
Risk Scenario No. 15

- **Risk:** Method R&D and validation records
- Identify the Risk assessment tool to use:
- How much risk is there?
- Mitigation steps?

- **Scenario:** Because of the nature of its work, several of the test methods in use in the lab had been developed in-house from methods published in technical journals. Records of the development and validation of these test methods were only maintained as hard copies in the laboratory's technical library.
Summary

- Changes in 17025 focus on risk mitigation:
  - More emphasis on Impartiality and Confidentiality
  - But maps well to 2005 version
  - Risk is mentioned in many areas
- For every risk there is an opportunity
- Many ways to evaluate risk
- Use the most appropriate tool
Questions / Comments
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