ISO/IEC 17025:2017

Its all about Risk Management*

*and opportunities

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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 in ISO/IEC 17025:2017

• Foreword,
• Introduction,
• Clauses 4.1.4 and 4.1.5 on impartiality,
• Clause 7.8.6.1 risk in terms of DRs used in reports,
• Clause 7.10.1 related to management of NCW,
• Clause 8.5.1 consider risk associated with lab activities
• Clause 8.5.2 on actions implemented to address risks
• Clause 8.5.3 on proportional to potential impact on results
• Clause 8.7 on corrective action & updating risk
• Clause 8.9 on inputs on risk identification in management reviews.
Risk Management

- Requires the laboratory to plan and implement actions to address risks and opportunities.
  - Establishes 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
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 and Impartiality

• Some impartiality risk sources:
  - Ownership
  - Governance
  - Management
  - Personnel
  - Shared Resources
  - Finance
  - Contracts
  - Lobbying
  - Marketing
  - Commissions
  - Volunteering
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
Risk Exposure

Risk Exposure = Risk \times Impact

Risk Reduction = Risk \times Mitigation \times Contingency
Risk Management

• Minimize **EXPOSURE**

Ideal: Exposure = 0
Risk Tools

Risk Score \(=\) Severity \(\times\) Probability \(\times\) Detectability
<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>Adulterated/mislabeled supply/reagent resulting in false or incorrect results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single/unreliable source causing delays in testing</td>
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<td></td>
<td></td>
<td>Back orders infrequent, periodically impacting TAT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minor supply disturbances, no impact on TAT</td>
</tr>
<tr>
<td></td>
<td>Sample Handling</td>
<td>Loss of sample or sample damaged, lab unable to analyze</td>
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<tr>
<td></td>
<td></td>
<td>Sample compromised and test results adversely affected</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initial Analysis affected but retesting possible</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No negative impact of financial results</td>
</tr>
<tr>
<td></td>
<td>Data Integrity</td>
<td>Loss or alteration of data without traceability back to source</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of data with probable chance of recovery</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of data but easily recovered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modification of data without change in underlying value</td>
</tr>
<tr>
<td>Business</td>
<td>Financial Profit</td>
<td>Serious loss harming financial stability of company</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Missed profit opportunities</td>
</tr>
<tr>
<td></td>
<td>Continuity</td>
<td>Entire lab site closed due to disaster</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Server/Computer systems breakdown</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Department shutdown, due to equipment breakdown or loss of personnel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Routine employee turnover or equipment/software updates</td>
</tr>
<tr>
<td></td>
<td>Customer Service</td>
<td>Loss of business or customer trust</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unsatisfied customer, possible customer complaint</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stress or uncomfortable situation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Normal customer request and feedback</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>
</tbody>
</table>
# Risk Detectability

<table>
<thead>
<tr>
<th>Detectability Score</th>
<th>Level of Detection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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-existental</td>
<td>There are no controls in place</td>
</tr>
</tbody>
</table>
## Risk Rating

Risk Score = (Probability) x (Severity) x (Detectability)

<table>
<thead>
<tr>
<th>Risk Rating</th>
<th>Calculated Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimal</td>
</tr>
<tr>
<td></td>
<td>≤ 32</td>
</tr>
<tr>
<td></td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td>&gt;32 and &lt;128</td>
</tr>
<tr>
<td></td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td>&gt;128 and &lt;288</td>
</tr>
<tr>
<td></td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>≥ 288</td>
</tr>
</tbody>
</table>
3.7 Decision Rule

- Documented rule that describes how measurement uncertainty is accounted in statements of compliance with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement
- Used for the clause regarding “statement of conformity”
Decision Rules (RISK)

• **17025:2005 clause 5.10.4.2**
  - “statements of compliance . . . MU into account.”

• **17025:2017 clause 7.1.1.3**
  - “Customer requires . . . conformity . . . the decision rule shall be clearly defined . . . and communicated”

• **17025:2017 clause 7.8.6**
  - Document DR applied
  - Take into account the associated risk
  - Apply the DR
Decision Rules

Upper Limit

Lower Limit

Data Point

Uncertainty
7.8.6 Reporting statements of conformity
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 Rule Defined and Agreed To
    - No
      - Decision Rules not required

No
Summary

• **Changes in 17025 focus on risk mitigation:**
  • Emphasis on Impartiality and Confidentiality
  • But maps well to 2005 version

• **Decision rule are a special form of risk:**
  • Conformity to a specification
  • Per customer agreement
Questions / Comments