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Risk Management
&
Quality Systems

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Overview

- ISO 17025 (2017 version) adds risk components.
- Rethink your quality system and express it with new risk-based language in your processes and procedures.
- Use common sense solutions for incorporating risk analysis, planning and decision making to enhance and bolster your existing quality management system.
- Risk analysis and risk mitigation strategies can help businesses improve performance by minimizing the impact of the cost of failure on profitability.
- Quality Risk management can be part of a labs *Business Continuity Plans*.

Expect New Audit Questions

For example:

- **What actions does the lab take to address risks and opportunities? How are risks minimized?**
- **When a statement of conformity to a specification is provided in reports, does the laboratory document the decision rule employed?**
- **Do you have objective evidence of compliance?**

Risk Management

Elements of risk management emphasized in ISO 17025:2017

- **Risk to impartiality**
- **Risk to confidentiality**
- **Risk when reporting statements of conformity**
- **Risk due to nonconforming work**

Good News:

- **These are not really new**
- **Simple changes to your QA Manual can emphasize these areas more strongly using the language in the new ISO standard**

Risk To Impartiality

New to ISO 17025, but a familiar concept

- Impartiality means that we take an unbiased and evenhanded approach to our work

For example:

- We ensure that our work product is not adversely affected by financial pressures
- We take measures in ethics training to avoid personal or organizational conflicts of interest

Directives On Impartiality

QA Manual

Roles and Responsibilities, Section: "Each person carries out his/her daily tasks **impartially** and in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs."

Ethics and Data Integrity, Section:

- "Present services in a confidential, honest and forthright manner"
- "Provide procedures and guidance to ensure the **impartiality** and confidentiality."

Objective Evidence: Signed ethics agreements

When / Where Do We Identify Risks To Impartiality

- **Annual Management Review**
- **QA Manual Section on Management review "Evaluation of overall risk, including risks to impartiality, confidentiality…."**

Objective Evidence:

- Completed Management Review and incorporate risks to business continuity, using a risk analysis matrix for prioritization.
- If significant risks are found they are included in the resulting improvement plan.

Risk When Reporting Statement of Conformity

- Risk must be assessed when making statement of conformity to a standard or specification, except when the decision rule is prescribed by the customer, regulations or normative document (an authoritative document describing the correct way to do something).

For example

- When reporting to a state that a drinking water sample result exceeds the MCL, the uncertainty associated with the test result is not normally required.
- How does your laboratory report this? What is the risk of being wrong?
  - **When a client requests a reanalysis, how do you report differing results? What's your risk to impartiality?**

Risk of QA Impartiality

- Operations has profitability, growth and cost control pressure; with primary focus on stockholder satisfaction.
- Client Service has pressure to meet client's needs to drive repeat business; Sales are incentive-driven and primarily focused on the delivery of services to meet client needs.
- Quality Assurance has compliance pressures to meet regulatory and program requirements, accreditation standards, ethical conduct and business risk mitigation; with primary focus on regulations and compliance.
- Each of these three business drivers are critical to the success of the company. If any one of the three drivers is overly emphasized to the extent that it minimizes the others, the business can get out of balance and potentially destabilize a company.

Risk of QA Impartiality

- It is important that the quality assurance function has independence and can act impartially to ensure that the functional drivers are stabilized and the business is balanced.
- Quality direct reporting line to the top of the organization establishes the legitimate authority to ensure that a clear message of integrity, compliance, and quality will be in balance and aligned with profitability, growth and meeting client needs, without compromising or minimizing business opportunity and growth.
- Profitability, clients service, innovation and quality are all important for success and growth. Without quality's transparent representation in the executive level of the organization, other business drivers could be overemphasized and increase business risk.
- Below are a few examples, could these happen in your business?

Scenarios

- Sitting on a data error when reports need to be recalled. But, decided not to because it could impact profits. Not notifying clients of errors in data could lead to poor environmental decision impacting heath of the environment and society at large.
- Understaffing quality assurance resources for cost reasons or hiring less experienced staff intentionally. Leading to a poorly operated quality system and non-compliance situations. A risk of accreditation loss, poor data quality or ethical breaches.
- Corner cutting, lack of regulatory compliance.
- Hiring inexperienced QA staff to save money. Resulting in weak systems, poor corrective action, and ultimately non-compliance situations.
- Lack of investing in or having poor training systems. Leading to poor data quality or lack of data defensibility.

Risk Analysis

Analyse and prioritize your risks and opportunities

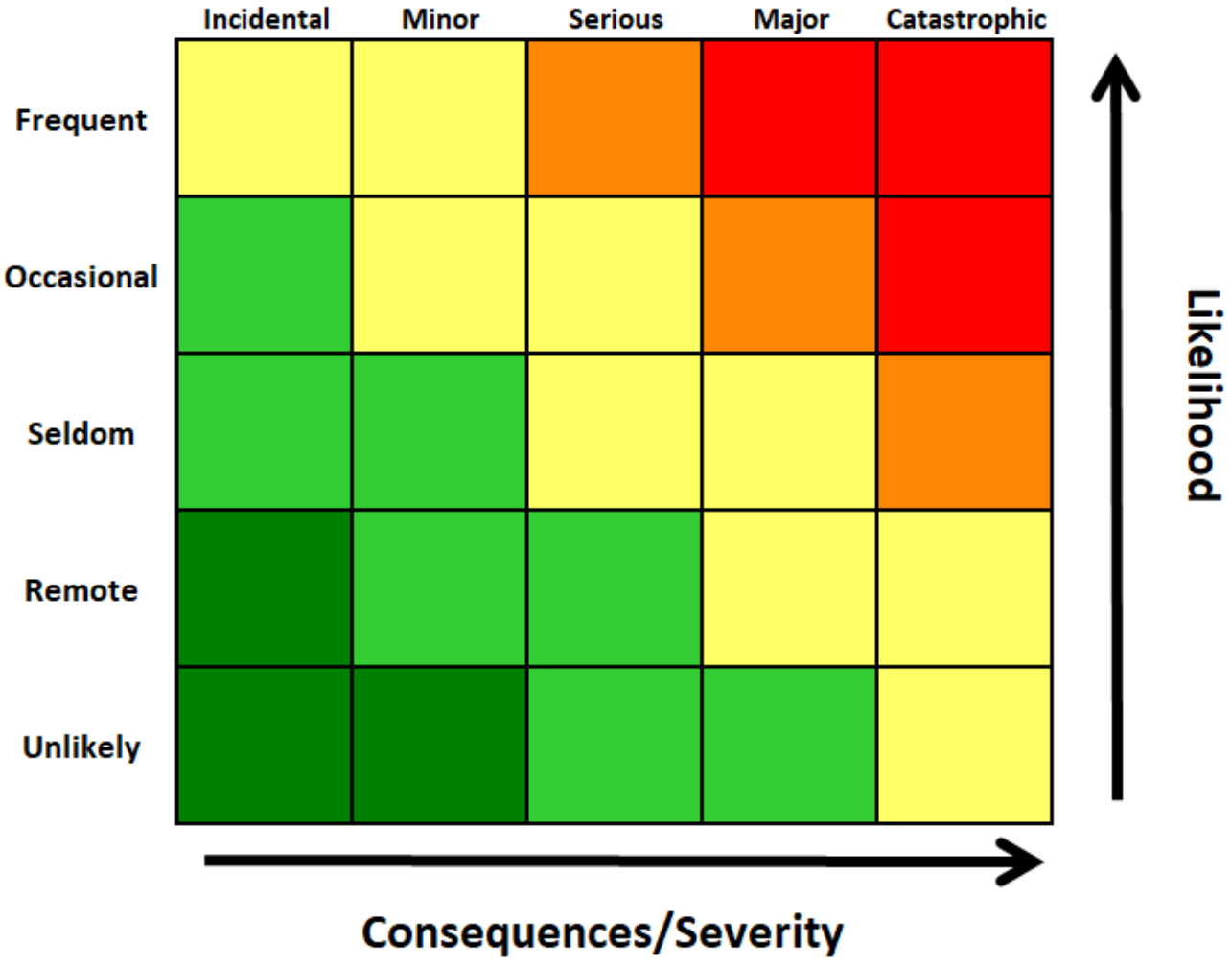
What is acceptable, what is unacceptable? What advantages or disadvantages are there to one approach over another?

Examples to consider:

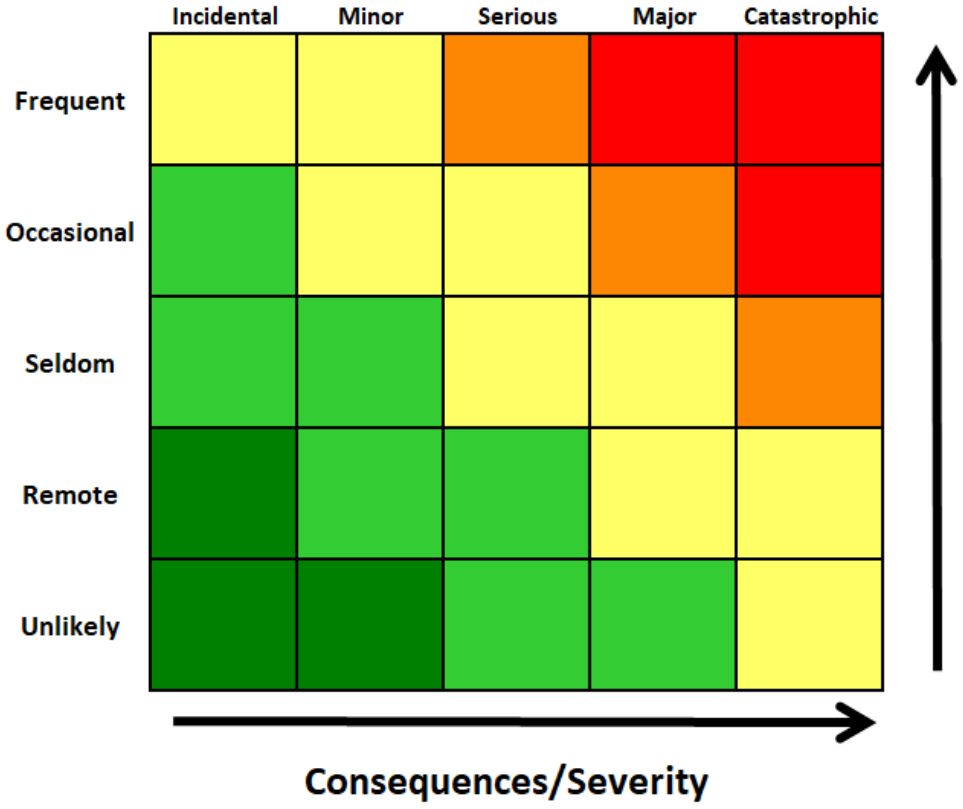
- Systemic Ethics Violations
- Repeat PT Failures leading to accreditation loss
- Audit failures and repeat findings leading to accreditation loss
- Data Errors resulting in report recalls
- Holding time failures leading to client dissatisfaction
- Unacceptable QC
- Breach of client confidentiality
- Lack of data or Quality System impartiality
- Poor or insufficient staff training

Risk Analysis Matrix





Risk Analysis Matrix - Prioritization



1. Systemic Ethics Violation
2. Repeat PT Failure leading to accreditation loss
3. Audit failure and repeat findings leading to accreditation loss
4. Data Error resulting in report recalls
5. Holding time failures leading to client dissatisfaction
6. Unacceptable QC
7. Breach of client confidentiality
8. Lack of impartiality in your Quality System
    - When a client requests a reanalysis, how do you report differing results?

Quality Key Performance Indicators (KPIs)

- To Manage risk, you need to know how you are doing.
- Are risks increasing, decreasing or stabilized?
- If you don’t measure it, you can’t manage it!

- Perform a risk analysis and prioritize (measure) those that will significantly impact your business.
- Nobody can tell you how much risk you have to take, it is an individual business decision

Example KPIs – what can these measure?

- Internal audit findings - open / closed
- Method and analysts audits performed
- Repeat audit findings (internal and external)
- PT cumulative score results by lab department and lab whole
- PT repeat analyte failures within 4 consecutive studies
- Corrective actions past due
- SOPs revision status
- Ethics training for new hires and annual refresher training
- MDLs/MDLVs Status
- Annual management systems review completion and goals status
- Method certification losses
- Holding time failures

Summary

- Risk is not new to quality systems thinking
- Risk management can be a tool for evaluating how resources will be prioritized and directed
- Unplanned risks can impact your business sustainability/continuity
- Do you have the cost of failure in your risk plan?
- Develop a risk assessment and business continuity plan (BCP)
- Be prepared to discuss management activities having to do with risk and opportunities
- Conduct or at least have scheduled a Management Systems Review using new checklist with risk/opportunity elements
- Establish quality system KPIs for tracking and managing risk



Questions?