

Risk-based Thinking for Laboratories

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QMS Department

A new version of ISO 17025 – *General requirements for the competence of testing and calibration laboratories* – was published on November 2017 by the International Organization for Standardization (ISO). All laboratories will need to transition to the new version within a 3-year period.



The main changes in the 2017 version are:

- The **scope** has been revised to cover testing, calibration and sampling associated with subsequent calibration and testing.
- The **process approach** now matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies).
- The standard has now a **stronger focus on information technologies** and incorporates the use of computer systems, electronic records and the production of electronic results and reports.
- A new chapter introduces the concept of **risk-based thinking**.

Laboratories transitioning to the new version should have a plan to address risks and opportunities. This is done to prevent, or reduce, undesired impacts and potential failures in the laboratory activities. Labs prepare the Risks and Opportunities Management procedure and finalize it. This procedure defines steps of actions to address risks and opportunities on a structured approach for understanding and managing risk and opportunities to:

- 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.

For an effective implementation, each related staff member should be trained on the procedure based on a scheduled plan. Paying attention to the defaults and definitions is important.

Risks and Opportunities Management process consist of:

1. Plan Risk management
2. Identify Risks
3. Perform Qualitative Risk Analysis
4. Plan Risks Responses
5. Monitor and Control Risks

The key factors in a successful Risk management execution are commitment and support from top management, communication, teamworking, organizational culture and structure, information technology and training. Identifying risks and opportunities is the key component of this process and it can affect the other phases.

Risk-based thinking provides great opportunities for improvement for testing and calibration laboratories.

