

[Organization logo]

[Organization name]

Commented [170251]: All fields in this document marked by square brackets [] must be filled in.

ADDRESSING RISKS AND OPPORTUNITIES PROCEDURE

Commented [170252]: If you want to find out more about control of risk-based thinking, see:

The Role of Risk Assessment in the QMS
<https://advisera.com/9001academy/blog/2016/06/21/how-to-address-risks-and-opportunities-in-iso-9001/>

Commented [170253]: Adapt to the existing practice in organization.

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Commented [17A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

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1. Purpose, Scope and Users

The purpose of this procedure is the identification of risks and opportunities, the definition of actions to address those risks and opportunities and the evaluation of the effectiveness of the actions taken within the laboratory's activities.

This procedure applies to all laboratory activities both internal and external.

Users of this procedure are the Quality Manager and Laboratory quality management.

2. Reference Documents

- ISO/IEC 17025:2017; Clause 4.1.4, 8.5 (Option A)
- Quality Manual
- ISO 31000

Commented [17A5]: You will find this document in the ISO 17025 Toolkit folder "03_Quality_Manual".

Commented [170256]: ISO 31000 - Risk management – Principles and guidelines is a reference and training tool providing principles, framework and a process for managing and applying risk and opportunities to laboratory activities. It can be used by any organization regardless of its size, activity or sector. Use them while creating a Registry of Key Risk and Opportunities.

3. Risks and Opportunities Treatment

[Job title] should consider the risks and opportunities associated with the laboratory in order to:

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Commented [170257]: Laboratory or quality manager.

Management team must use the results of risk and opportunity assessments to improve the performance of the laboratory, prevent problems and find opportunities.

Commented [170258]: Group of employees that quality or laboratory manager defines to analyze potential risks and opportunities, e.g. top management, CEO, heads of offices etc.

[Redacted]

Commented [170259]: Laboratory or quality manager.

- Identify risks and opportunities associated with laboratory activities.
- Determine risk significance.
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

3.1. Identification of risks and opportunities

When planning the laboratory QMS, [job title] considers internal and external issues relevant to the

Commented [1702510]: Laboratory or quality manager.

[Redacted]

[organization name]

Risks and opportunities are identified and addressed in order to give assurance that the laboratory

employees are responsible for assisting in the identification of potential risks and participating in actions to control them.

[Job title] must integrate risk treatment actions in the decision-making process of existing processes

[Job title] is responsible for identifying risks to impartiality on an ongoing basis and taking action to

- What can happen? How can it happen?
- What kind of damage may occur to the process or product?
- Are general economic conditions stable enough to not influence the organization?

As risks and opportunities are identified, they should be included in the Registry of Key Risks and Opportunities.

3.2. Determining the level of the risk

Depending on the level of effect on laboratory operations, [job title] next defines the levels of the risk significance:

-
-

3.3. Actions to address risks and opportunities

Commented [1702511]: Laboratory or quality manager.

Commented [1702512]: Laboratory or quality manager.

Commented [17A13]: You can use the "14_Complaint_Nonconformity_and_Corrective_Action_Procedure_EN" included in ISO 17025 Toolkit folder "14_Complaint_Nonconformity_and_Corrective_Action".

Commented [1702514]: Laboratory or quality manager.

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Commented [1702516]: Laboratory or quality manager.

[organization name]

[Redacted text]

Commented [1702517]: Laboratory or quality manager.

3.4. Evaluation of the actions for addressing risks and opportunities

[Job title] must, at least annually, review results of actions for risk treatment and opportunities, and

Commented [1702518]: Top management or Laboratory Manager or CEO.

Commented [1702519]: Adapt the period to organization needs.

3.5. Hierarchy of actions for addressing risks

[Redacted text]
management team must establish the following hierarchy in their decision making:

Commented [1702520]: Group of employees defined by the quality or laboratory manager to analyze potential risks and opportunities (e.g. top management, CEO, heads of offices etc.).

- [Redacted bullet point]
- [Redacted bullet point]
- [Redacted bullet point]
- [Redacted bullet point]

4. Managing Records Kept on the Basis of this Document

Commented [1702521]: There are many tools for assessing and evaluating risks and opportunities. As you add new tools, please add them to this table of records.

Records may be stored electronically.

Record name	Code	Storage		Responsibility
		Retention time	Location	
Registry of Key Risks and Opportunities	PR.05.1	Two years	[office]	[job title]

Commented [1702522]: If the record is in electronic form, write the name of the folder on Laboratory or Quality Manager computer.

5. Appendices

- Appendix 1 – Registry of Key Risks and Opportunities