[Organization logo]

[Organization name]

MANAGEMENT REVIEW PROCEDURE

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Change History

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 to ensure systematic and periodic review of Quality Management System (QMS) by laboratory [Top Management] in order to evaluate possibilities for improvement and needs for changes, including the effectiveness of the management system and its processes, improvement of laboratory activities and provision of required resources.

This procedure is applied to all processes within the laboratory QMS.

Users of this document are [members of laboratory top and mid-level management] of [organization name].

Commented [170255]: For laboratories that are part of larger organizations, Annex B, the parent organization's management review must make reference to the laboratory's participation in their management review.

2. Reference Documents

- ISO/IEC 17025:2017 standard, clause 8.9
- Quality Manual

Commented [17A6]: You will find this document in the ISO 17025 Toolkit folder "03_Quality_Manual".

3. Conducting Management Review

The laboratory's top management, together with mid-level management and laboratory supervisors, conduct the management review meetings at planned intervals.

3.1. Management review methods

The management review meetings can be conducted in the following ways:

- Meetings with previously written agendas.
- ~~Phone or internet conference call meetings.~~
- ~~Partial reviews on different levels within organization reporting to the top laboratory manager, who will conduct a final review with the gathered information.~~

3.2. Periodic management review

[Job title] organizes the meeting with top and mid-level management. Other members of staff must be invited to participate in this review as appropriate.

Commented [170257]: The quality manager or person in a role or designated by Quality manager.

~~Management review meetings are planned and scheduled on a periodic basis with the period between meetings being no longer than twelve months.~~

~~The objective of the review must be to ensure continued QMS:~~

1. Suitability – *Having policies, procedures and properties that are right for the specific purpose*.
2. ~~Adequacy – sufficient to satisfy a requirement or meet a need. A quality management system should be capable of satisfying applicable requirements, including those specified by the organization, the customer, and any applicable standards and/or regulations.~~

3. Effectiveness – *Capable of accomplishing the purpose for producing the intended or expected result.* A quality management system should enable the organization to meet its own needs, those of the customer and those of other interested parties including the ISO/IEC 17025 standard.

4. Impartiality – Responsibility for the impartiality of laboratory activities and not allowing commercial, financial and other pressures to compromise impartiality.

5. Confidentiality – Protection of laboratory customers' confidential information and proprietary rights.

3.3. Review Input

As a minimum, the following information and data are presented during the management review meeting organized by [job title]:

- **Changes in internal and external issues that are relevant to the laboratory:**

  The laboratory management must consider changes in the external and internal context of the organization, determine if there were some changes, and plan further actions to address those changes.

- **Fulfilment of objectives:**

  Quality objectives established through the review period are systematically evaluated to assess progress.

  - Objectives that have been achieved may either be upgraded to a higher performance level or closed out to free resources for improvement in another area.
  - When objectives are not achieved on time, the review investigates and determines cause for failing to achieve the objective.
  - Depending on the nature of the objective and cause for failure to achieve it, top management may decide to drop the objective, reduce its scope or limit, reassign responsibilities and/or allocate additional resources, or extend the due date for achieving the objective.
  - Any decisions regarding quality objectives are recorded in the minutes of the review.
  - New objectives are established where it is necessary to improve performance in order to fulfil the quality policy or other organizational goals or aspirations.
  - New objectives are documented in the minutes of the review.

- **Suitability of policies and procedures:**

  The management team assembled for the management review meetings must determine if the current policies and procedures applicable to the laboratory quality management system (QMS) are still current, relevant and suitable. Recommendations for change should be part of the management review outputs.

- **Status of actions from previous management reviews:**

[Job title] reports on the status of action items from previous meetings. Items that are not completed are carried on as continuing actions and are recorded as such in the minutes.

- **Outcome of recent internal audits:**

  [Job title] presents results of internal audits. This includes summaries of results for the cycle, frequencies of audit findings against particular elements of the quality system, and discussion of particularly important findings.

- **Corrective actions:**

  [Job title] reports on the status and trends of corrective actions. Corrective Actions that are not completed are carried on as continuing actions and are recorded as such in the minutes. The effectiveness of corrective actions must be discussed and activities to evaluate their long-term validation and effectiveness must be reviewed.

- **Assessments by external bodies:**

  [Job title] presents results of external quality system audits and other assessments by external bodies. External bodies include Customers, Government and other Regulatory bodies. This includes summaries of particular elements of the quality system, and discussion of particularly important findings.

- **Changes in the volume and type of the work or in the range of laboratory activities including:**
  - Types of tests or calibrations added or deleted.
  - Test or calibration cycle time increases or decreases.
  - Changes in test methods directed by regulatory agencies.
  - Changes in sampling arrangements made with customers.
  - Changes in the volume of work received compared to planned operations.
  - Increases or decreases of nonconforming work identified through inspections or audits.

- **Customer and personnel feedback, both positive and negative, including:**

  - Customer satisfaction results
  - Suggestions for collecting customer satisfaction information
  - The perception of customer satisfaction and any planned improvements.
  - Results of customer visits/audits.

[Job title] presents summaries of customer feedback and, including analysis of trends for particular categories, customer satisfaction data and trends.

- **Customer formal and informal complaints, including:**

  - Customer complaints.
  - Corrective actions resulting from customer complaints.
  - Changes made to the QMS as a result of customer complaints.

Comments (right margin):

Commented [1702510]: Laboratory or Quality manager.

Commented [1702511]: Laboratory or Quality manager.

Commented [1702512]: Laboratory or Quality manager.

Commented [1702513]: Quality manager; Top management.

Commented [1702514]: Part of the Quality Manager's tasks and responsibilities is to perform corrective actions on changes that can affect the laboratory QMS.

Commented [1702515]: Sales manager, person in marketing and/or customer service.

[Job title] presents summaries of complaints, including analysis of trends for particular

> **Commented [1702516]:** Quality manager or person designated by quality manager.

- **Effectiveness of any implemented improvements:**

[Job title] presents data that demonstrates progress toward achieving continual improvement goals, and reviews current and completed improvement projects to the top management.

> **Commented [1702517]:** Quality manager or person designated by quality manager.

[Job title] must review the performance of external providers, including suppliers and

> **Commented [1702518]:** Quality manager or person designated by quality manager.

- **Results of risk identification:**

Laboratory top management must review all individual risks identified within the QMS and

- **Outcomes of the assurance of the validity of results:**

[Job title] collects and analyzes appropriate data to evaluate the effectiveness of the control of quality requirements, which may include:

> **Commented [1702519]:** Quality manager or person designated by quality manager.

must also decide on past, current and future training needs and resources. Recommendations from these discussions become management review meeting outputs.

3.4. Review Output

- The effectiveness of the management system, its processes, and intended results.

- Improvement of laboratory activities related to fulfillment of the ISO/IEC 17025 standard.
- ~~Implement any action needed for change.~~
- ~~Resource needs for the current period and the future.~~

[Job title] documents the following in the Management Review Record:

> **Commented [1702520]:** Quality manager or management review team leader.

- Action items that address the effectiveness of the management system and its processes.
- ~~Action items that address laboratory activities related to fulfillment of ISO/IEC 17025 requirements.~~
- ~~Action items that address the provision of required resources.~~
- Action items that address the need for change.

~~Upon complete review of all inputs and generation of the outputs, laboratory top management will determine the continuous suitability, adequacy and effectiveness of the management system.~~

4. Managing Records Kept on the Basis of this Document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Management Review Record	PR.19.1	Indefinitely	[office of [job title]]	Quality Manager

> **Commented [1702521]:** If the record is in electronic form, write the name of the folder on [job title]'s computer.

5. Appendices

- Appendix 1 – Management Review Record