Sections in This Document

1. Purpose

Management performs, as a minimum, annual reviews to determine the fitness and effectiveness of the quality system in achieving the stated quality objectives. This procedure establishes the method by which management reviews are performed within the ORS Laboratories.

2. Scope

This procedure applies to the management review (MR) process conducted on a routine basis by ORS laboratory management. This procedure applies to the Office of Regulatory Science (ORS) laboratories and laboratory work products and processes. This procedure directly concerns the laboratory's quality assurance program.

3. Responsibility

A. Laboratory Director:

1. Conducts management review.
2. Assigns action items, plans, and approves system changes.
3. Designates personnel to assist in the management review activities.

B. Laboratory Management:

1. Provides information and reports for review.
2. Assists in the management review activities as designated.
3. Ensures action items and plans issued are completed and identified system changes are implemented in their respective areas.

C. Quality System Manager (QSM):

1. Coordinates and collects the information for the management review.
2. Documents action items and plans.
3. Monitors implementation of system changes.
4. Assembles and maintains management review records.

4. Background

Management reviews ensure the quality management system's continuing suitability, adequacy, and effectiveness. The reviews are led by the senior manager and include evaluating the performance of the management system and assessing opportunities for improvement and the need for changes, including the quality policy and objectives. Actions and plans are established to implement improvements to the management system and its related processes.

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 8.9.

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals. An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

6. Procedure

A. A periodic review of the quality management system (QMS) is performed according to ORA procedures. This review examines the QMS and determines if it meets the conditions set by the agency and the standards. The review will serve as a guide in making future determinations towards the effectiveness and direction of the quality

system. The quality system may need to be modified due to changes that have or are expected to take place in the organization, facilities, staffing, equipment, activities, or workload.

B. The Quality System Manager gathers the information needed for the management review and provides it to the Laboratory Director and other management review participants.

C. The management review addresses the inputs of the management system and includes but is not limited to the following elements:

1. Changes in internal and external issues that are relevant to the laboratory.
2. Fulfilment of objectives.
3. Suitability of policies and procedures.
4. Status of actions from previous management reviews.
5. Outcome of recent internal audits.
6. Corrective actions.
7. Assessments by external bodies.
8. Changes in the volume and type of the work or in the range of laboratory activities.
9. Adequacy of resources. (Are there enough materials and/or resources (people) to meet the needs for processes in place or for changes in processes or activities?)
10. Customer and personnel feedback.
11. Complaints and effectiveness of their resolution.
11. Effectiveness of any implemented improvements.
12. Outcomes of risk identification.
13. Outcomes of the assurance of the validity of results.

    Note: This review shall include a review of proficiency test results.

14. Other relevant factors, such as monitoring activities and training program adequacy.
15. Responses to agency mandates/requirements which may be communicated via a memo or email to management by the ACRA.

D. Management reports the findings of the management review and actions according to ORA procedures. The outputs from the

management review shall record all decisions and actions related to at least:

1. The effectiveness of the management system and its processes. (i.e., How effective were you in meeting your objectives and goals? What actions can be taken to be effective in addressing risk and opportunities for improvement? Are there systemic issues or common themes that run through various instances?)
2. Recommendations for improvement of the laboratory activities related to the quality system.
3. Provision of required resources.
4. Revised or new SMART objectives and targets for the upcoming year.

   NOTE: A SMART objective is one that is specific, measurable, achievable, relevant, and time-bound providing the details for how the laboratory will achieve a goal. They should be aligned with the ORA/ORS Strategic Plan where possible.

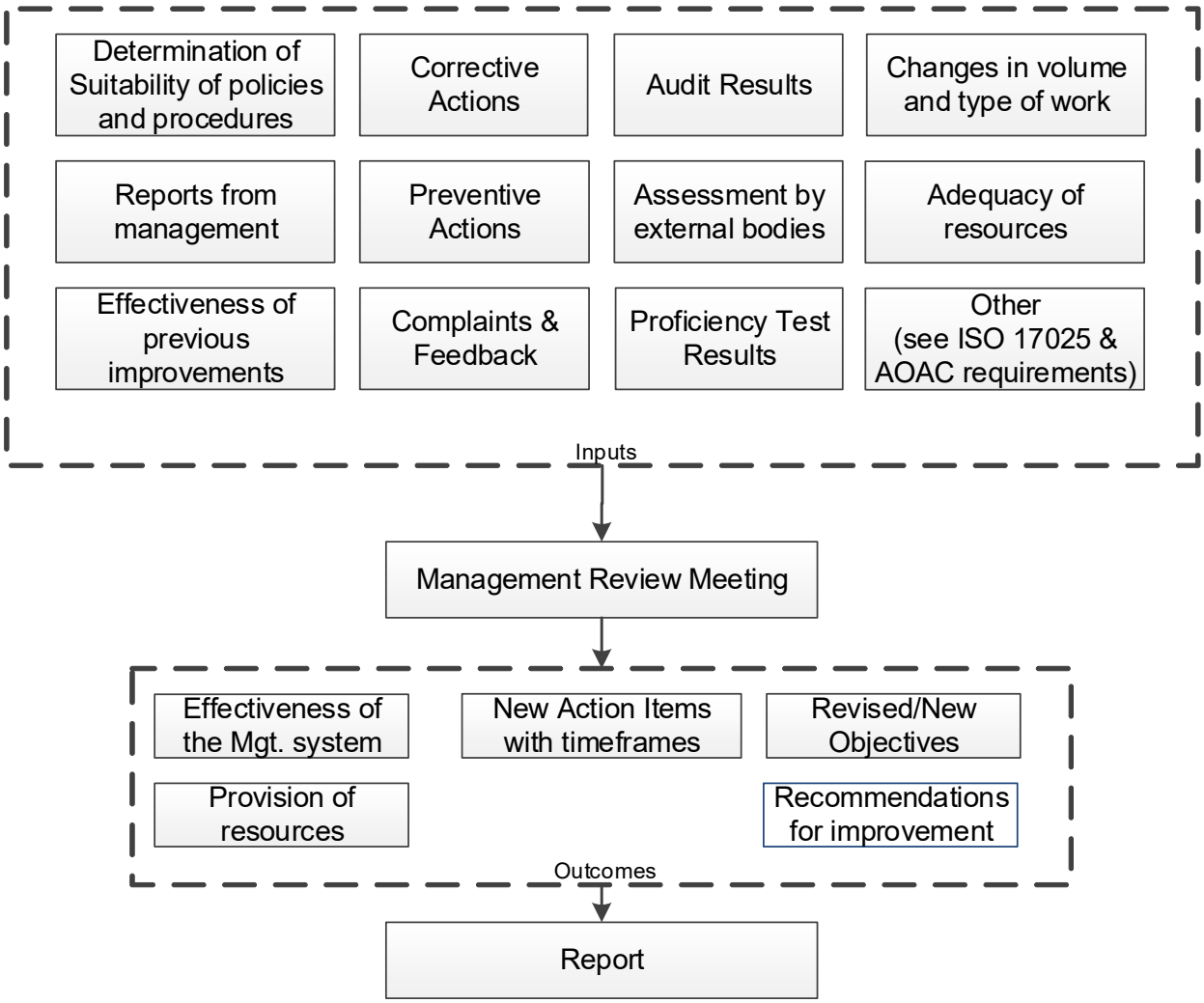
E. Improvements, if any, are identified, implemented, and monitored.

F. If needed, a corrective action is initiated for identified nonconformances in accordance with MAN-000033 ORA-LAB.4.11 Corrective Action Procedure.

G. Management ensures actions are carried out within established timeframes.

H. Action items and plans are closed when the results of the investigation are implemented or are judged as having no added value to the quality system.

Figure 1. Process Map



7. Glossary/Definitions

A. **ACRA** – Associate Commissioner for Regulatory Affairs

B. **Effectiveness** – Effectiveness results when system requirements are routinely met.

C. **Management review** – Management review is the evaluation of the quality system by management to determine its effectiveness, suitability, and future direction.

D. **Requirement** – A requirement is a declared, implied, or routine need or expectation.

E. **Suitability** – Suitability is the property of a system with attributes that address the requirements of the Quality Management System.

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8. Records

A. Management Review Report

C. Action items and plans

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9. Supporting Documents

A. MAN-000028 ORA Laboratory Manual, Volume II, ORA-LAB.4.8 *Complaints and Feedback*

B. MAN-000030 ORA Laboratory Manual, Volume II, ORA-LAB.4.11 *Corrective Action*

C. SOP-000418 Management Review

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10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	12/31/07	LMEB	LMEB
1.3	R	02/06/12	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB
03	R	Refer to QMiS	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Revisions made to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were made.
03	Added SMART requirement to align with ORA requirement. Added input/output suggestions to consider.

12. **Attachments**

None