Sections in This Document

1. Purpose

The procedure establishes the process to track and investigate potential nonconformances and address both risks and opportunities to establish a basis for increasing the effectiveness of the management system, achieving improved results, and preventing negative effects in the Office of Regulatory Science (ORS) laboratories quality management system.

2. Scope

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 encompassing the review of risks and initiation of improvement actions to prevent or minimize deviations or potential risks to the quality system.

3. Responsibility

A. Management

1. Evaluates risks and opportunities within the quality system for areas that would merit improvement actions.
2. Identify improvements to address risks and opportunities during Management Review.
3. Approve actions for implementation.

4. Ensure that improvements are identified, action plans are developed, and follow-up is completed.

B. Employees

1. Identify factors that could cause products or processes to deviate from planned results and/or opportunities for improvement.
2. Submit improvement recommendations using the Improvement Form in QMiS

C. The Quality System Manager

1. Monitors improvement actions for effectiveness, and timely completion
2. Maintains all records generated during improvement actions in QMiS, including their investigation(s) and resolution(s).

4. Background

Improvements, potential sources of nonconformities, and potential negative effects on laboratory activities, either technical or concerning the management system, shall be identified, and evaluated. Improvement projects and risk assessments are part of a proactive process for prevention rather than a reaction to nonconformances or complaints. Risk assessment includes the use of sources of information such as processes and work operations which affect the quality system, audit results, and quality records to detect, analyze, reduce the likelihood for potential nonconformances and take advantage of opportunities for improvement.

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 8.5 Actions to Address Risks and Opportunities and Section 8.6 Improvement.

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. Risks and opportunities associated with the laboratory activities are considered to prevent or reduce undesired impacts and potential failures in the laboratory activities.

B. Laboratories shall identify and select opportunities for improvement and implement any necessary actions. These shall be documented with the Improvement form in QMiS.

C. Potential undesired impacts and failures and areas for improvement may be identified using any of the following:

1. Information sources such as processes and work operations that affect quality, audit results, quality records and feedback.
2. Measurable quality objectives and requirements, validation and review processes, audits and management review, feedback, and the quality system and ISO requirements.
3. Proficiency samples, internal quality control samples and QC charts that are monitored for trends or biases.

D. The process consists of:

1. Reviewing opportunities or risks determining their impact on laboratory activities.
2. Plan actions to address these risks and opportunities. Integrate these actions into the management system.
3. Documenting decisions made and implement planned actions; and
4. Evaluate the effectiveness of these actions.

E. Actions taken to address risks shall be proportional to the potential impact on the validity of laboratory results. There are several possible options available such as:

1. Avoiding threats
2. Taking the risk to pursue an opportunity
3. Eliminating the risk source
4. Changing the likelihood or consequence
5. Retaining the risk by informed decision

F. Improvement action plans are initiated by starting an improvement action form in QMiS.

G. The Quality System Manager is responsible for follow-up and ensuring the action plans are completed.

H. Monitoring the information and effectiveness of the improvement action is accomplished by any of the following:

1. control and process charts;
2. performance measurements and training;
3. customer inputs;
4. employee suggestions and inputs;
5. audits and management reviews;
6. and management meetings

7. Glossary/Definitions

A. Non-conformance - This is a non-fulfillment of a specified, or implied, requirement of the Quality Management System or of a quality work product. Fitness-for-use criteria and evaluations determine the significance of a nonconformance.

B. Improvement – Continuous process to enhance performance within the Quality Management System. Quality improvement is anything which causes a beneficial change in quality performance. This is a process to maintain current levels of performance within the QMS, to react to changes in internal and external conditions, and to create new opportunities.

8. Records

A. Improvement form

B. Issue Review form

C. Management Review

D. Complaint_Feedback form

9. Supporting Documents

A. MAN-000034 ORA Laboratory Manual, Volume II, ORA-LAB.4.15 Management Review

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	11/16/05	LMEB	LMEB
1.3	R	12/06/06	LMEB	LMEB
1.4	R	12/31/07	LMEB	LMEB
1.5	R	02/06/12	LMEB	LMEB
1.6	R	03/25/13	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	Updated formatting. Replaced LD, Branch Director, Supervisor with “Managers” in Responsibilities. Added QMiS. Added Management Review to Records. Updated references. Changed flow of procedure & clarified wording. Added ORA CAPA procedure to Reference section. Other revisions as needed to align with recently-revised ISO and AOAC standards.
03	Revised content and changed title from Preventive Action to align with Improvement risk assessment. Term/process for reactive preventive action was removed from current ISO 17025 Standard.

12. Attachments

NONE