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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. The cornerstone of preventive action is written and retrievable records of actions taken and follow-up monitoring to determine that preventive actions have been implemented and recorded.

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 initiation of 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 preventive actions.
2. Identify preventive actions to address risks and opportunities during Management Review.
3. Approve preventive actions for implementation.
4. Ensure that preventive actions are identified, action plans are developed, and follow-up is completed.

B. Employees

1. Identify preventive actions and use the Preventive Action form to record, initiate, and perform identified preventive action(s).

C. The Quality System Manager

1. Monitors preventive actions for effectiveness, and timely completion
2. Maintains all records generated during preventive 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. Preventive action plans are part of a proactive process for improvement rather than a reaction to problems or complaints. Preventive action 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.

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.

C. ORA-QMS.008 Preventive Action (ORA-Level)

D. SOP-000235 Quality Event Management (QEM) and Corrective Action/Preventive Action (CAPA) (ORA-Level)

6. Procedure

A. Preventive action plans are part of a proactive process for improvement rather than a reaction to problems or complaints. Risks and opportunities associated with the laboratory activities are considered to prevent or reduce undesired impacts and potential failures in the laboratory activities.

B. 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.

C. The preventive action process consists of:

1. Reviewing potential problems or risks
2. Determining the potential cause of the problems;
3. Developing a course of action
4. Putting the plan into action; and
5. Then ensuring or verifying the action solved the potential problem or is effective over time.

D. 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

E. Preventive action plans are initiated once identified by starting a preventive action form in QMiS.

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

G. Monitoring the information and effectiveness of the preventive 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. Preventive action - This is an endeavor taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation to prevent occurrence.

8. Records

A. Preventive Action form

B. Action plans

C. Management Review

9. Supporting Documents

A. 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

* - 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.

12. Attachments

None