Sections in This Document

1. Purpose

To provide guidance in the process of identifying, evaluating, recording, investigating, correcting the causes of, and determining the disposition of nonconforming processes, services, and work products (hereafter referred to as nonconformances). The cornerstone of corrective actions is written and retrievable records of actions taken and follow-up monitoring to determine that corrective actions have been performed, documented, and found to be effective.

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.

3. Responsibility

A. Managers:

1. Take action to control and correct nonconformances when they occur.
2. Ensure that corrective actions are performed, implemented, and communicated.
3. Review corrective actions that have been taken and approve or recommend if further corrective actions are needed.
4. Complete appropriate sections of nonconformance and corrective action records in the Quality Management information System (QMiS).

B. Employees:

1. Initiate and/or participate in the completion of corrective actions.
2. Complete appropriate sections of the nonconformance and corrective action records in QMiS.

C. The Quality System Manager (QSM):

1. Monitors the quality system for systematic problems.
2. Facilitates the corrective action process.
3. Initiates corrective actions in QMiS when needed, i.e. as a result of complaints/feedback, nonconformances, audit results, management review, or other findings.
4. Monitors corrections and corrective actions for trends, effectiveness, and timely completion.
5. Maintains all records generated during corrections, corrective actions and their investigation(s), including objective evidence of actions taken, in QMiS.

4. Background

Nonconformances can occur at various places within the quality system and technical operations. Examples include customer complaints, unacceptable quality control samples, instrument and sample problems, environmental problems that affect results, purchased materials for laboratory use, staff observations, management reviews and audits. Processes, services, and/or

products considered to be nonconforming may be identified in the following ways:

- Incoming product from suppliers
- Services provided by external sources (i.e. service contractors)
- Processes producing unacceptable results or products.
- Internal or External Quality Audits.

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 8.7.

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

6. Procedure

6.1. Review of Nonconformity

A. When a nonconformity occurs, the laboratory must take action to control and correct it with actions appropriate to the effects of the nonconformities encountered.

B. A review of the consequences of the nonconformity is performed to determine if a Correction or Corrective Action is warranted.

6.2. Correction

A. If a minor nonconformance is detected where a product was not affected but absolute compliance to a statement of intent or clause of a standard was not met on basis of objective evidence, it can be recorded as a correction only with rectification actions recorded and closed.

B. An obvious trend in a repeated minor nonconformance can escalate it to a corrective action.

6.3. Root Cause & Corrective Action

A. Once a nonconformance that impacts a lab's product, processes, or service is detected an evaluation of the need for action to eliminate the cause(s) will be performed.

B. The laboratory determines if similar nonconformities exist or could potentially occur.

C. An investigation to determine the root cause(s) of the problem will be initiated in order to determine an effective corrective action.

D. Often the root cause is not obvious, therefore careful analysis of all potential causes of the problem is required. Areas to investigate can include:

1. Customer requirements
2. The samples or sample specifications
3. Methods and/or procedures
4. Staff skills and training
5. Consumables and/or vendors used
6. Equipment and its calibration

E. Once the root cause has been determined potential corrective actions shall be identified.

1. Decide what can be done to prevent the problem from recurring.
2. Determine how the solution will be implemented.
3. Define who will be responsible for implementation.
4. Evaluate the risks of implementing the solution.

F. The corrective action(s) most likely to eliminate the problem and to prevent a recurrence shall be selected for implementation.

G. Changes required as a result of the investigation shall be recorded and implemented (i.e. procedure revisions, training, resumption of work where it was stopped due to the nonconformance, etc.).

H. The QSM closes the corrective action when there is objective evidence that the actions are completed and effective.

6.4. Monitoring for Effectiveness

A. Corrective actions that are implemented must be monitored to determine if they are and/or continue to be effective.

B. The QSM can keep a completed action report open for a specified time to monitor effectiveness, and then close the issue once it has been determined to be effective.

C. Once an action report has been closed its effectiveness can still be determined with an audit in the area affected by the original nonconformance.

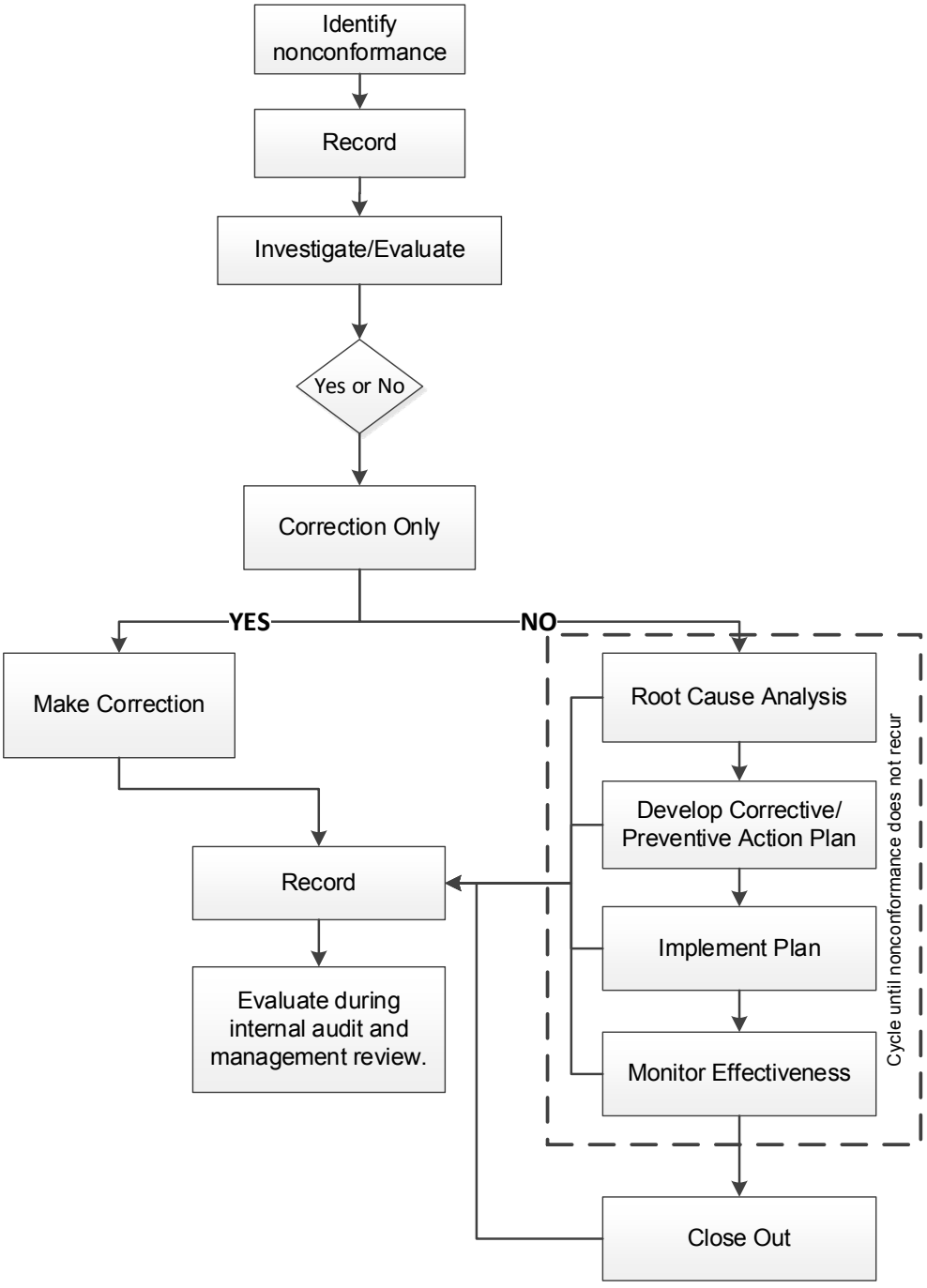
D. In the event a corrective action is found to be ineffective a new nonconformance report will be initiated with a different root cause investigation to determine why the first corrective action was not effective, if the true root cause was determined, and to evaluate and identify the best corrective action to implement and record.

E. This additional corrective action must also under go monitoring to determine its effectiveness

6.5. Recording Correction(s) and Corrective Action(s)

Record nonconformance, investigation, correction, corrective action information in QMiS and according to local laboratory procedures. Instructions for using QMiS can be found within QMiS and local laboratory procedures.

1.1 Process Map



7. Glossary/Definitions

A. Correction - action taken to render the work product acceptable for use by eliminating the detected nonconformity.

B. Corrective Action - The steps taken to eliminate the root cause(s) identified by a root cause analysis.

C. Deficiency – an alternate term used to describe a non-conformance.

D. Nonconformance – A non-fulfillment of a specified or implied requirement of the quality management system or of a quality work product.

E. Observation – a perceived or detected abnormality or anomaly that is not out of conformance to a specified or implied requirement; yet could possibly become a non-conformance if not acted upon or can be improved upon.

F. Preventive Action: Steps to mitigate or remove the underlying cause of a nonconformance.

G. QMiS – ORA's Quality Management information System software. This is where corrective actions are recorded. (Refer to 9. Supporting documents for guidance on initiating, processing, and completing a nonconformance form in QMiS).

H. Root Cause(s) – The underlying reason (i.e. cause) that results in a nonconformance.

I. Root Cause Analysis – A systematic method of problem solving that identifies the root cause(s) of non-conformances.

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8. Records

A. Correction and Corrective Action Reports

B. Notes created during Root Cause investigation(s)

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9. Supporting Documents

A. QMiS User Manual

B. ORA Laboratory Manual, Volume II, ORA-LAB.4.9 Control of Nonconforming Work

C. ORA Laboratory Manual, Volume II, ORA-LAB.4.12 Preventive Action

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D. ORA Laboratory Manual, Volume II, ORA-LAB.4.14 Audits

E. 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
1.4	R	12/31/07	LMEB	LMEB
1.5	R	02/06/12	LMEB	LMEB
1.6	R	09/29/14	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB
* - D: Draft, I: Initial, R: Revision				

11. Change History

Revision #	Change
1.4	In Document
1.5	In Document
1.6	In Document
2.0	Complete revision to streamline process to align with actual process(es) in ORS.; removed 1st – 3rd level managers & replaced with authorities to be determined at the laboratory level for initiation/implementation. Changed “document” to record where appropriate. Added use of QMiS form. Updated flow chart. Added ORA CAPA procedure to Reference section. Other revisions as needed to align with recently-revised ISO and AOAC standards.

12. Attachments

None