Sections in This Document

1. Purpose

To provide guidelines when any aspect of testing, or the results of this work, do not conform with laboratory procedures or specified requirements.

2. Scope

This procedure applies to the Office of Regulatory Science (ORS) laboratories and laboratory work products. This procedure directly concerns the laboratory's quality assurance program.

3. Responsibility

The ORS laboratory designates the responsibilities and authorities for the management of nonconforming work within the ORS laboratory's quality documents with actions (including halting of work and withholding of test reports, as necessary) defined and taken when nonconforming work is identified. These actions are based upon the risk levels established by the laboratory.

The laboratory quality documents will include designation of authority for resumption of work if halted.

4. Background

If properly executed, quality control parameters can monitor the various aspects of data quality on a routine basis. In instances where performance falls outside acceptable limits, the data produced can be questioned and, after investigation, a determination made as to its validity. The laboratory's internal quality assurance program is the principal recourse available for ensuring that only a quality product is released. Quality control parameters and quality assurance elements are defined in the laboratory's quality management program. These identified quality control parameters are the critical elements that would cause a nonconforming product if not met.

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 7.10

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-000133 Control of Non-Conforming Processes, Services, or Products (ORA-Level)

6. Procedure

Identification of nonconforming work or problems with the management system or with testing activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control (QC), instrument calibration, checking of consumable materials, staff observations or supervision, test report checking, management reviews, and internal or external audits.

A. Identified nonconformances with any procedure, process, quality control parameter or customer requirement are recorded in QMiS (ORA's Quality Management information System). This process involves documenting the nonconformance, evaluation of the significance or impact the nonconforming work has on the quality system, technical operations, and data reported, and any remedial actions taken.

B. When the evaluation (based upon the significance of the nonconforming work) indicates that it could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures outlined in ORA-LAB.4.11 shall be promptly followed.

C. Corrections will be performed immediately, together with any decisions about the acceptability of the nonconforming work.

D. Dispositions or actions taken on a nonconforming work product are based upon an impact analysis on previous results and include one of the following:

   1. Rework – action taken on nonconforming product so that it will fulfill the specified requirements;
   2. Redone – action taken to re-collect sample or reanalyze (redo) sample to bring the product into conformance;
   3. Use as is – approving the use of nonconforming product without rework or redoing, a disclaimer is made that the product was accepted and the quality requirements that the product did not meet are specified; and
   4. Unable to use – action taken if unable to resolve the problem. The receiver is notified that the data cannot be reported.

E. Data, reports, and actions are not released until the problem is resolved and verified by management. The sample may need to be reanalyzed or re-collected or the inspection redone. If unable to resolve the problem, the receiver is notified that the laboratory data cannot be reported or accepted; with disclaimers made that the product did not meet quality standards.

F. When a non-conformance has been identified and the validity of previously-reported data is in question, a corrective action with investigation will be opened, the customer is notified, and if possible, the product brought into limits by rework or reanalysis to confirm the validity of what was reported.

G. If in error, a corrected report will then be sent to the customer. The corrected report must be identified as an amended or corrected report.

H. A customer supplied product (sample) which is lost, damaged or otherwise unsuitable will be annotated in the web application, such as Field Accomplishment and Compliance Tracking System (FACTS) or Laboratory Information Management System (LIMS), and reported to the customer verbally or electronically.

7. Glossary/Definitions

Nonconformance – This is a departure of a quality characteristic from its intended level or state that occurs with enough severity to cause an associated product or service to not meet a specification or requirement.

8. Records

A. QMiS Nonconformance or Corrective Action records.

B. Records of communications with the customer

9. Supporting Documents

A. ORA Laboratory Manual, Volume II, ORA-LAB.4.11 Corrective Action

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.3	R	02/06/12	LMEB	LMEB
1.4	R	05/08/14	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB
* - D: Draft, I: Initial, R: Revision				

11. Change History

Revision #	Change
02	Added Background. Moved process order for smoother flow. Changed Responsibility wording from “laboratories “ensure” to “designate”; added document/record actions are part of entire process. Referenced OQMS-level SOP. Other revisions as needed to align with recently-revised ISO and AOAC standards.

12. Attachments

None