Sections Included in this Document and Document History

1. Purpose

To establish a procedure and to assign responsibilities for identification, documentation and disposition of non-conforming work products.

2. Scope

This procedure applies to the Office of Regulatory Affairs (ORA) laboratories and laboratory work products. This procedure directly concerns the laboratory's quality control program.

3. Responsibilities

ORA laboratories ensure that the authority and the responsibility for controlling non-conformances are delegated to the appropriate management authorities. These authorities are authorized to halt any analytical testing or procedures related to the nonconformance and to invalidate test results that are affected. The responsible personnel authorized to resume work after a nonconformance is identified in the laboratory's corrective action procedure.

4. Background

None

5. References

None

6. Procedure

A. Non-conformances can occur at various places within the quality system and technical operations, examples include customer complaints, unacceptable quality control samples, instrument problems, samples, environmental problems that affect results, purchased materials for laboratory use, staff observations, management reviews and audits.

B. Identified non-conformances with any procedure, quality control parameter or customer requirement are documented on the laboratory's corrective action form and initiate the laboratory's corrective action

process. This process involves the evaluation of the impact on quality and operations.

C. When a non-conformance is detected, laboratory data is held and not released until the problem is resolved and verified by laboratory management in accordance with the corrective action process. Resumption of work is performed after the corrective action has been taken and approved.

D. Non-releasable data is not approved by management until product disposition has been made and documented. Dispositions or actions taken on a non-conforming work product are:

- Rework – action taken on non-conforming product so that it will fulfill the specified requirements;
- Redone – action taken to re-collect sample or reanalyze (redo) sample to bring the product into conformance;
- Use as is – approving the use of non-conforming 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
- Unable to use – action taken if unable to resolve the problem. The receiver is notified that the data cannot be reported.

E. Reworked or redone products are reviewed to verify that they comply with specifications.

F. When necessary, the customer is notified of the non-conformance and specifications may be changed depending on the usage of the data, for example, informational purposes only.

G. A customer supplied product (sample) which is lost, damaged or otherwise unsuitable will be annotated in the Field Accomplishment and Compliance Tracking System (FACTS) and reported to the customer verbally or electronically.

H. 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 control 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 control program. These identified quality objectives are the critical elements that would cause a non-conforming product if not met.

7. Definitions

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

8. Records

Corrective Action form

9. Supporting Documents

Local corrective action procedure

10. Attachments

None

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
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