## Version No.: 1.3 Document No.: ORA LABORATORY PROCEDURE ORA-LAB.4.9 Food and Drug Administration Page 1 of 3 Title: Effective Date: CONTROL OF NON-CONFORMING WORK 10-01-03 Revised: 01-20-12 **Sections Included in this Document/(Change History)** 1. Purpose 2. Scope 3. Responsibilities 4. Background 5. References 6. Procedure 7. Definitions 8. Records 9. Supporting Documents/(added ORA-QMS.005) 10. Attachments **Document History** 1. To establish a procedure and to assign responsibilities for identification, documentation and disposition of non-conforming work products. **Purpose** This procedure applies to the Office of Regulatory Affairs (ORA) laboratories 2. Scope and laboratory work products. This procedure directly concerns the laboratory's quality control program. **3.** ORA laboratories ensure that the authority and the responsibility for Responsibilities 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. None **Background** 5. None References

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.

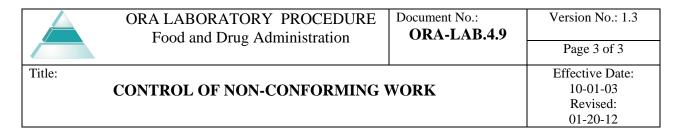
6.

**Procedure** 

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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	Local corrective action procedure	
<b>Documents</b>	ORA-QMS.005, Control of Non-conforming Processes, Services or Product	
10. Attachments	None	

Document History						
Version	Status	Date	Location of	Name & Title		
No.	(I, R, C)	Approved	Change History	Author	Approving Official	
1.3	R	02/06/12	In Document	LMEB	LMEB	

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