Sections Included in this Document and Change History
(Document No. changed from 4.10 to 4.11)

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3. Responsibilities/(3. D. Quality Management System Manager changed to Quality System Manager (QSM))
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Document History

1. Purpose

This procedure establishes the process to identify, track, complete the investigation of the problem and correct the causes of existing non-conformances including complaints in products, processes, the [Laboratory Name] Quality Management System, and services in the [Laboratory Name]. The cornerstone of corrective actions is written and retrievable documentation of actions taken and follow-up monitoring to determine that corrective actions have been performed and documented.

2. Scope

This procedure is applicable to all organizational units and personnel in the [Laboratory Name].

3. Responsibilities

A. [Third Level Manager]:

- initiates, performs and oversees corrective action;
- assigns corrective action to personnel; and
- reviews corrective action taken by personnel and approves or recommends further corrective action.

B. [Second Level Manager]:

- implements corrective action procedure in respective branch,
- assigns corrective action to identified [Third Lever Manager], and

- reviews and approves corrective action taken by [Third Level Manager].

C. [First Level Manager]:

- ensures corrective action procedure is implemented and monitored,
- assigns corrective action to responsible [Second Level Manager], and
- reviews and approve corrective action taken by [Second Level Manager].

D. Quality System Manager (QSM):

- establishes corrective action and problem report form and procedure;
- monitors the progress and status of corrective actions for timely completion,
- reviews completed forms for effectiveness and assigns follow-up actions and date due, if deemed necessary;
- maintains corrective action and problem report (CAPR) database; and
- maintains and files copies of objective evidence which support verification and validation of actions taken.

E. Staff:

- initiates and performs corrective action for non-conformances; and
- complete corrective action and problem report form to document problem, area or situation investigated, findings and action taken.

4. Background	None
5. References	None

6. Procedure

The corrective action process is illustrated in the flow chart. The seven steps illustrated are as follows:

1. When a non-conformity is detected suspend work and evaluate the situation. Take action to identify non-conformance. Obtain Corrective Action and Problem Report (CAPR) form.

2. Complete the first section on the CAPR form.

3. Begin investigation to resolve the problem by examining the extent of the problem. Note internal and external observations and area or situations looked at during the investigation. Complete the next section of the CAPR.

4. Note findings and causes with supporting evidence. Complete next section of CAPR form. Determine whether root cause analysis is required and assign a priority level.

5. Determine cause and perform root cause analysis, if possible. Decide action to be taken. Perform corrective action. Complete the next section of the CAPR form.

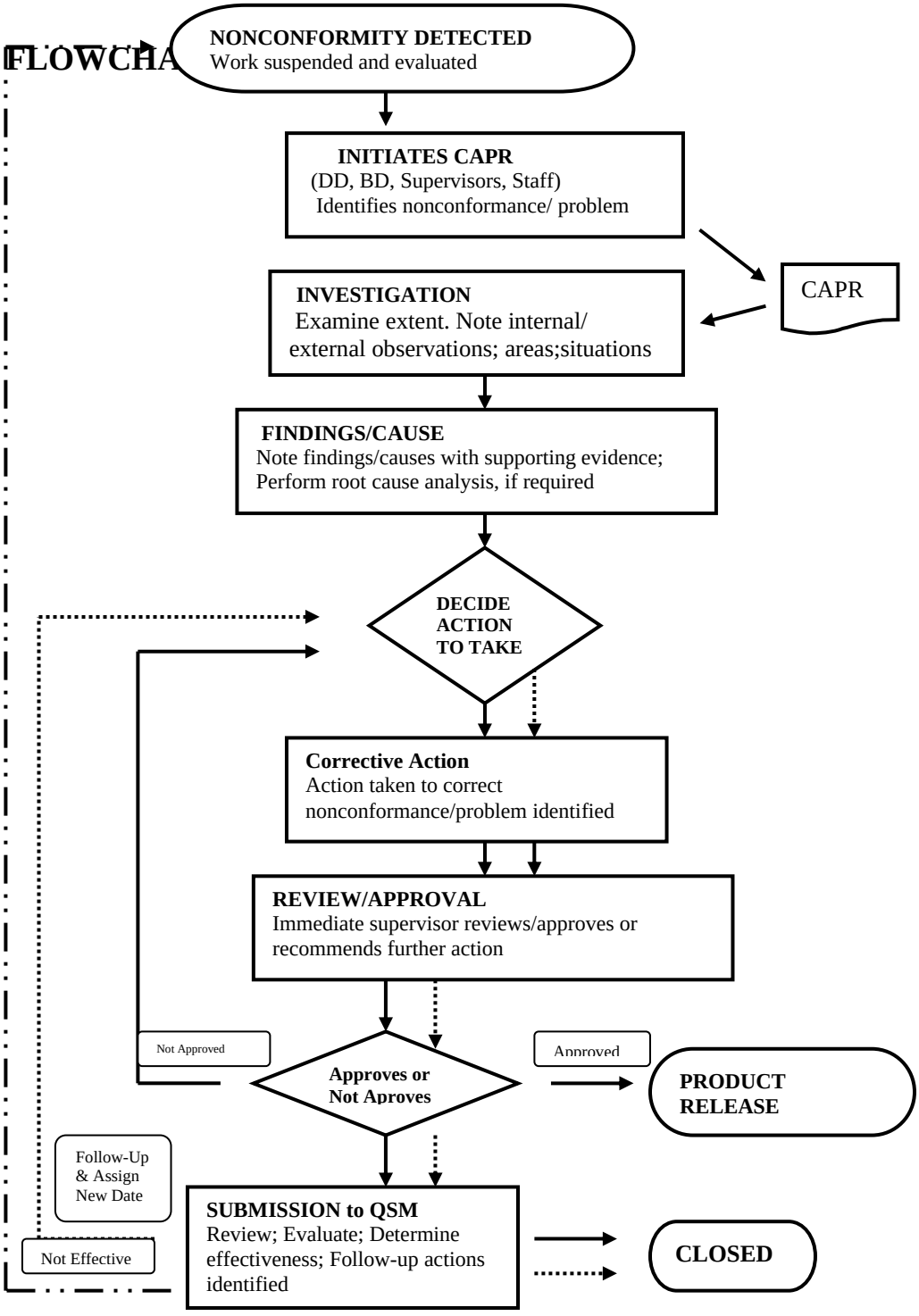
6. Submit CAPR form to immediate supervisor and QSM for review and approval. The supervisor will review and perform one of the following actions:

    - Not approve the actions taken and recommend further actions to be taken. Additional corrective action will be implemented, reviewed and approved.

    - Approve the corrective action and enter in name and date on form, release the product *and* submit the CAPR form and supporting documentation to the QSM within 30 days of date action initiated.

7. The QSM reviews, evaluates and determines effectiveness of actions taken. The process may be approved and closed or further follow up actions may be identified and returned, or determined to be ineffective, and a corrective action process initiated to correct non-conformity.

6.1 Flowchart



6.2 Corrective Action

A. Accountability for Corrective Actions

1. The QSM serves as the focal point for data quality, instrument problems, report and action quality and for feedback on district operations and corrective actions taken.

2. Corrective action at the technical level is initiated and corrected by the analyst, technician, officer or supervisor. The person whom created the problem, fixes it.

3. The QSM detects and corrects systematic problems which may occur in the course of daily work by maintaining surveillance over stated quality objectives and requirements, audits, and complaints.

4. The CAPR form is located on the [Location]. A sequential number will be assigned by the QSM and serves as the tracking mechanism.

B. Initiation and Completion of Corrective Action

1. The investigation of suspected quality problems is initiated as a result of quality control criteria being exceeded, specified requirements not being met, audit findings indicating systematic problems, or as a result of a complaint.

2. Corrective actions are of two kinds:

   - On-the-spot or immediate corrective action to correct or repair non-conforming data, reporting or equipment, that are actions routinely made by analysts, technicians and supervisors; and

   - Long-term corrective action to eliminate causes of non-conformance or a complex deficiency that are actions normally identified by audits.

3. A CAPR form is to report the non-conformity. This form provides the steps for a closed-loop process that includes:

   a. initiation and identification of nonconformity,

b. investigation (examine extent),

c. findings and conclusions,

d. determination of cause to prevent reoccurrence,

e. corrective action taken and implemented, and

f. follow-up by the QSM to ensure that the corrective action is a fix and succeeded in achieving the results desired and is effective.

4. Work is suspended and evaluated. Action is taken to identify the non-conformance. Begin investigation to resolve the problem.

5. The findings are recorded on the CAPR form. Examples of findings or causes include:

   - equipment failure;
   - incomplete or nonexistent procedures;
   - non-compliance with procedures and regulations;
   - improper collection, storage, handling, or preparation;
   - calculation errors or transcription errors; and
   - lack of training.

6. The cause and, if possible, the root cause is determined to prevent reoccurrence of the non-conformity and to provide a permanent solution.

7. The conclusions and actions taken are recorded on the CAPR form. Examples of conclusions and actions may include:

   - equipment repaired,
   - procedures revised or created,
   - product reworked to comply with procedures or regulations,
   - correct calculation employed or transcription error corrected, and
   - proper training given.

8. The initiator's immediate Supervisor approves the action or recommends further action.

C. Submission to QSM and Follow-up:

1. Completed CAPRs with supporting documentation are submitted to the

QSM for filing within 30 days of date action initiated.

2. The QSM reviews the form and evaluates the implementation and effectiveness of the corrective action (e.g. Are quality objectives met?).

3. If deemed necessary, follow-up actions will be identified and a new date for completion set and approved.

4. When there is objective evidence that the actions are completed and effective, the QSM approves and closes the CAPR.

5. If the CAPR was initiated due to a complaint, the CAPR is not closed until the customers has been contacted and confirmed that their concerns have been met. See Section 1, ORA-LAB.4.8 Complaints.

6. The nature of the non-conformity and status of this process is reported to the District Director or Laboratory Director and Branch Directors monthly by the QSM.

7. The effectiveness of corrective actions are monitored and verified during audits and management review.

D. Product Release

1. Data, reports, and actions are not released until the problem is resolved and verified by the Supervisor or Branch Director. 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.

2. In the event that a non-conformity has been identified and previous reported data is suspect, the customer is notified and if possible the product brought into limits by rework or reanalysis to confirm the validity of what was reported. If in error, a corrected report will then be sent.

7. Definitions

Corrective action - This is an endeavor taken to eliminate the causes of a detected non-conformance, defect or other undesirable situation in order to prevent reoccurrence.

Corrective action and problem report form - Form is used to initiate corrective action.

Non-conformance - This is 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.

Cause - A cause is a fundamental deficiency that results in a non-conformance and is to be corrected to prevent reoccurrence of the same, or similar, non-conformance.

Signature – A signature is a handwritten, electronically written, or electronically typed name of an individual or entity that indicates an act of approval, disapproval, review, or recommendation.

8. Records

Corrective Action and Problem Report (CAPR) form
CAPR database

9. Supporting documents

[Name] - Audits
[Name] – Complaints

10. Attachments

Attachment A: Corrective Action and Problem Report Form

Document History

Version No.	Status (I, R, C)	Date Approved	Location of Change History	Name & Title	
				Author	Approving Official
1.4	R	12/31/07	In Document	LMEB	LMEB

Approving Official's signature: _____ Date: _____

ID#_____

FDA/ORA [NAME]
CORRECTIVE ACTION AND PROBLEM REPORT

Initiated by:_____Supervisor_____Date:_____

Affected Project(s) and/or Analysis:_____

Problem(s):

_____

_____

_____

_____

Priority: Low __ Med __ High __ Root Cause Required: Yes __

Major Area/Situations Investigated:

_____

_____

_____

_____

Findings:

_____

_____

_____

_____

Conclusion/Corrective Action:

_____

_____

_____

_____

Initiator:_____Date:_____Supervisor_____Date:_____

Submitted to QSM:_____ Date:_____

FOLLOW UP:_____ Due Date:_____Date Closed: _____

Approved: ☐ Approved: ☐

Findings:

_____

_____

_____

Quality System Manager _____