Title: **PREVENTIVE ACTION PROCEDURE**	Effective Date: 10-01-03 Revised: 01-20-12

Sections Included in this Document and Change History

1. Purpose

The procedure establishes the process to track and investigate potential non-conformances in the [Laboratory Name] Quality Management System. The cornerstone of preventive action is written and retrievable documentation of actions taken and follow-up monitoring to determine that preventive actions have been implemented and documented.

2. Scope

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

3. Responsibilities

A. [Third Level Manager]:

- initiates, performs, and oversees preventative action.

B. [Second Level Manager]:

- implements and oversees preventative action.

C. [First Level Manager]:

- ensures preventive action procedure is implemented and monitored, and
- identifies preventive actions in management review.

D. [Quality System Manager (QSM)]:

- verifies implementation of management review action plans, and
- maintains preventive action plans and documentation.

E. [Staff]:

- initiates and performs identified preventive action.

4. Background

None

5. References

None

6. Procedure

A. Preventive Action

1. Preventive action plans are part of a proactive process for improvement rather that a reaction to problems or complaints. Preventive action includes the use of sources of information such as processes and work operations which affect quality, audit results, quality records and complaints to detect, analyze and eliminate potential causes of non-conformances.

2. Preventive action includes the use of measurable quality objectives and requirements, validation and review processes, audits and management review, feedback and complaints, and the quality system and the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) requirements.

3. Proficiency samples, internal quality control samples and quality control (QC) charts are monitored for trends or biases.

4. The laboratory performs function verification and preventive maintenance on instrumentation. Service contracts with periodic manufacturer maintenance may be in effect for identified instruments.

5. Documented investigation using the corrective action form is initiated if a potential nonconformity is identified from any of the above processes.

6. The preventive action process consists of:

- reviewing potential problems;
- deciding the potential cause of the problems;
- deciding the course of action to eliminate the problem from occurring;
- putting the plan into action; and
- then ensuring or verifying the action solved the problem or is effective over time.

8. Preventive action plans are initiated once identified by starting a preventive action form. The Quality System Manager is responsible for follow-up and ensuring the action plans are completed.
9. Monitoring the information and effectiveness of the preventive action is accomplished by any of the following:

- control and process charts;
- performance measurements and training;
- customer inputs;
- employee suggestions and inputs;
- audits and management reviews; and
- management meetings

7. Definitions

Non-conformance – This is a 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.

Preventive action – This is an endeavor taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation to prevent occurrence.

8. Records

Preventive Action form
Action plans

9. Supporting Documents

[Laboratory Name]-Management Review
ORA-QMS.008, Preventive Action Procedure

10. Attachments

None

Document History					
Version No.	**Status** (I, R, C)	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**
1.2	R	11/16/05	In Document	LMEB	LMEB
1.3	R	12/06/06	In Document	LMEB	LMEB
1.4	R	12/31/07	In Document	LMEB	LMEB
1.5	R	02/06/12	In Document	LMEB	LMEB

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