**Sections Included in this Document and Change History**
(Document No. changed from 4.14 to 4.15)



## 1. Purpose

Management performs, as a minimum, annual reviews to determine the fitness and effectiveness of the quality system in achieving the stated quality objectives. This procedure establishes the method by which management reviews are performed within the [Name].

## 2. Scope

This procedure applies to [Name] quality system.

## 3. Responsibilities

A. [Third Level Manager]:

- provides information for review,
- assists in investigation of action items, and as directed
- ensures implementation of any system change identified in their respective area.

B. [Second Level Manager]:

- provides requested information as needed,
- may assist in the review activities, and
- ensures action items and plans issued are investigated and identified system change completed in their respective area.

C. [First Level Manager]:

- conducts management review, assigns action items and plans and approves system changes; and
- designates personnel to assist in the management review activities.

D. [Quality System Manager (QSM)]

- coordinates and collects the information for the management review,
- assembles summary report and documents action items and plans,
- monitors implementation of system changes approved as a result of action items and plans, and
- maintains management review reports.

**4. Background**

None(FDA)

**5. References**

EAL-G3, Internal Audits and Management Review for Laboratories.

**6. Procedure**

A. Management review

1. As a minimum, an annual review of the quality system is performed. The predetermined schedule covering the elements of the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025 is found in Section 10 of Attachment A. This review examines the quality system and determines if it meets the conditions set by the agency and the standards. The review will serve as a guide in making future determinations towards the effectiveness and direction of the quality system. The quality system may need to be modified due to changes that have or are expected to take place in the organization, facilities, staffing, equipment, activities or workload.

2. The Quality System Manager assimilates the needed information and records for the review and forwards them to the [First Level Supervisor], [Second Level Supervisor], [Third Level Supervisor].

3. The review consists, but is not limited to the following:

   - suitability of policies and procedures;
   - reports from managerial and supervisory personnel;
   - outcome of recent internal audits;
   - effectiveness of previous actions taken;
   - corrective and preventive actions;
   - assessments by external bodies;
   - results of interlaboratory comparisons or proficiency tests;
   - changes in the volume and type of the work;
   - client feedback;
   - complaints;
   - recommendations for improvement, and
   - other factors, such as quality control activities, resources and staff training.

4. The [First Level Supervisor, Second Line Supervisor] consolidates the findings and distributes the report to the [Second Line Supervisor, Third Line Supervisor] and [Quality System Manager]

5. If needed, a corrective action form is initiated for identified action items and plans by the QMS Manager for the assigned personnel to complete. Investigation is undertaken and findings submitted to the [First Level Manager, Second Level Manager] and [Quality System Manager].

6. Action items and plans are closed when the results of the investigation are implemented or are judged as having no added value to the quality

system.

**7. Definitions**

Effectiveness – Effectiveness results when system requirements are routinely met.

Management review – Management review is the evaluation of the quality system by management to determine its effectiveness, suitability and future direction.

Requirement – A requirement is a declared, implied or routine need or expectation.

Suitability – Suitability is the property of a system with attributes that address the requirements for quality outlined in ISO/IEC 17025.

**8. Records**

Management Review Report
Action items and plans

**9. Supporting Documents**

Volume II, Section 1, ORA-LAB.4.11 Corrective Action Procedure
Volume II, Section 1, ORA-LAB.4.12 Preventive Action Procedure

**10. Attachments**

Attachment A: Management Review Schedule
Attachment B: Management Review

**Document History**

| Version No. | Status (I, R, C) | Date Approved | Location of Change History | Name & Title | |
|---|---|---|---|---|---|
| | | | | Author | Approving Official |
| 1.2 | R | 12/31/07 | In Document | LMEB | LMEB |
| | | | | | |

Approving Official's signature: _____ Date: _____

Date of Management Review _____

Quarter Performed: First _____ Second _____ Third _____ Fourth _____

Elements listed below are included in each management review:

1. Quality System (4.2)

2. Contract Review (Workplan and Changes in Work Load) (4.4)

3. Complaints (4.8)

4. Corrective Actions (4.11)

5. Preventive Action (Action Items/Plans) (4.12)

6. Audit Results (4.14)

7. Effectiveness of Previous Action Items from Management Reviews (4.12, 4.15)

8. Training Program Summary (5.2)

9. Resources
   Personnel (5.2) ____ Facility (5.3) ____ Equipment (5.5)____ Material (5.6) ____

10. Proficiency Testing Results (5.9)

Elements listed below are included and are found in internal audits for the management review.

1st Quarter: 4.1, 4.3

2nd Quarter: 4.6

3rd Quarter: 4.9, 4.11

4th Quarter: 5.4, 5.8, 5.10

DATE:

FROM: [Name]

TO: [Name]

SUBJECT: [Year] Management Review of Quality Management System

The annual management review was performed on [Date]. The purpose of this review of the quality management system is to monitor and evaluate the quality and fitness for use of services to agency needs. The review ensures the fitness and effectiveness of the quality management system.

Synopsis of findings includes: (a) policies and procedures, (b) managerial reports, (c) previous audits, (d) effectiveness of previous actions, (e) corrective actions and preventive actions (action items and plans), (f) outside assessments, (g) proficiency results, (h) changes in workload, (i) complaints, (j) resources, (k) training, and (l) other.

Conclusion

Recommendations

Provide a statement on the overall effectiveness of the [Name] quality management system.