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MANAGEMENT REVIEW FOR CABS

(VERBATIM ADOPTION OF APLAC TC 003)

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MANAGEMENT REVIEW FOR LABORATORIES AND INSPECTION BODIES

1.0 NATIONAL FOREWARD

This Document has been adopted by the Bangladesh Accreditation Board after the recommendation by the TCTL and endorsed by BAB without alternation of APLAC TC 003

2.0 BAB APLAC TC 003

3.0 PURPOSE

This document gives guidance to laboratories and inspection bodies on how to establish implement and maintained a program of internal audits.

4.0 AUTHORSHIP

This document was produced by the APLAC Technical Committee.

5.0 COPYRIGHT

6.0 FURTHER INFORMATION

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1. INTRODUCTION

1.1 This publication has been prepared to give organizations guidance on how to establish a program for management reviews. It is assumed that the organizations have implemented a quality management system that meets the requirements of Conformity Assessment Bodies (CABs).

1.2 The guidelines given in this publication are of a general nature. The actual accomplishment of a management review depends on the size, scope and organizational structure of the organization and, for a smaller organization many of the items described in this publication can be carried out in a simplified manner.

2. TERMINOLOGIES

2.1 **Management system:** The quality, administrative and technical systems that govern the operations of a laboratory. (ISO/IEC 17025)

2.2 **Quality management system:** Management system to direct and control an organization with regard to quality. (ISO 9000)

2.3 **Quality management:** Coordinated activities to direct and control an organization with regard to quality. (ISO 9000)

2.4 **Management review:** A regular systematic evaluation by top management of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives.

2.5 **Quality manager:** The staff member (by whatever title) who has responsibility for the laboratory's quality management system and its implementation, and who, in this capacity, reports directly to top management.

3. OBJECTIVES OF MANAGEMENT REVIEWS

3.1 The senior management of the CABs should periodically conduct a review of the organization's quality management system to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

3.2 Management review should be planned to establish what changes, if any, are necessary to ensure that the quality arrangements for the organization continue to meet the organization's needs. The review should also ensure that the management system of the organization continues to conform to the requirements of applicable International and National Standards.

3.3 The management review should also take note of changes that have taken place or need to take place in the organization, facilities, equipment, procedures, and/or activities of the Organization.

3.4 The need for changes to the system may also arise as a result of findings from internal or external quality audits, inter-laboratory comparisons or proficiency tests, surveillance visits or assessments by an accreditation body or complaints from customers.

3.5 The quality policy and goals should be reviewed and revised if necessary. Quality objectives and action plans for the coming year should be set.

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4. ORGANISATIONS OF MANAGEMENT REVIEWS

4.1 The top management of the organization should be responsible for conducting reviews of the management system.

4.2 Those members of senior management having overall responsibility for the design and implementation of the organization's management system, for the technical operations of the organization and for taking decisions resulting from the findings of internal audits and external assessments, should be involved in management reviews.

4.3 The quality manager should be responsible for ensuring that all reviews are conducted in a systematic manner according to an established procedure, and that the results of the management review are recorded.

4.4 The quality manager and operational managers should be responsible for ensuring that actions identified during the management review are implemented within the agreed time.

5. PLANNING OF MANAGEMENT REVIEWS

5.1 Management reviews should be conducted on an annual basis. The review should be programmed and the executive manager, senior operational management, the quality manager and the person under whose authority the quality manual has been issued, should attend the meeting. It is essential that the head of the organization, technical management, the quality manager and any section heads are present.

It is recognized that, in a small organization, one person may be fulfilling more than one of the above functions. Good management reviews can occur even in single person organizations.

6. IMPLEMENTATION OF MANAGEMENT REVIEWS

6.1 The management review should be conducted in a systematic manner using a formal agenda.

6.2 The review should include at least the following items:

(a) Matters arising from the previous management review;
(b) Quality policy and medium and long term goals;
(c) Suitability of quality and operational procedures, including the need for amendment of the system (including the quality manual);
(d) Reports from managerial and supervisory personnel;
(e) Results of internal audits carried out since the last management review, and follow-up actions;
(f) Analysis of corrective actions and preventive actions;
(g) Reports on surveillance visits and assessments carried out by the accreditation body, and follow-up actions by the organization;
(h) Reports on audits by customers or other approvals bodies and follow-up actions;
(i) Trends analysis of results of the organization's participation in proficiency testing or inter-laboratory comparison schemes, and the need for such participation in other areas of calibration and/or testing;
(j) Trends analysis of results of in-house quality control checks;
(k) Adequacy of current human and equipment resources;
(l) Future plans and estimates for new work, additional staff, new equipment, changed methods etc;
(m) Training requirements for new staff and for updating of existing staff;
(n) Trends analysis of complaints and other feedback received from customers;

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(o) Recommendations for improvement.

6.3 Results of the management review should feed into the organization's planning system and should include:

(a) Revision of the quality policy and medium and long term goals;
(b) A planned program for preventive action, including the setting of objectives for the coming year;
(c) Formal action plans, including time lines for the implementation of agreed changes to the management system and/or to the operations of the organization's objectives.

6.4 It should be the responsibility of management to ensure that all actions arising from the review are carried out as required and within appropriate and agreed time frames. Actions and their effectiveness should be monitored at regular management meetings.

7 RECORDS OF MANAGEMENT REVIEWS

7.1. Records should be kept of all management reviews. The records may be in the form of minutes of the review meetings together with clear indications as to the actions to be taken, by whom and with what time limits.

7.2. It should be the quality manager's responsibility to ensure that all actions arising from reviews are recorded.

7.3 The records should be readily accessible and retained for an agreed period of time.

9. REFERENCES

IAF/ILAC A4:2004, Guidance on the Application of ISO/IEC 17020.

ISO/IEC 17025: 2005 - General requirements for the competence of Testing and Calibration Laboratories

ISO 15189:2007 – General Requirements for Medical laboratories

ISO/IEC 17021:2006 – Requirements for bodies providing audit and certification of Management system

ISO/IEC 17020:1998 - General criteria for the operation of various types of Bodies performing Inspection

ISO/IEC 17024:1998 - General criteria for the operation of various types of Bodies performing Inspection

ISO 19011:2002- Guidelines for quality management systems auditing.

ISO 9000, 2000 - Quality Management system – Fundamentals and vocabulary