APLAC

Asia Pacific Laboratory Accreditation Cooperation

MANAGEMENT REVIEW FOR
LABORATORIES AND INSPECTION BODIES

PURPOSE

This document gives laboratories and inspection bodies guidance on how to establish and implement a program for management reviews.

AUTHORSHIP

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1.   INTRODUCTION

1.1   It is stated in ISO/IEC 17025 2005 General Requirements for the Competence of Testing and Calibration Laboratories that a laboratory shall establish, implement and maintain a quality management system appropriate to the scope of its activities including the type, range and volume of testing and/or calibration activities it undertakes. In ISO/IEC 17020 1998 there is a similar requirement placed on inspection bodies.

1.2   ISO/IEC 17025 and ISO/IEC 17020 respectively require that the executive management of the laboratory or inspection body periodically conduct a review of the organisation's management system and testing and/or calibration and/or inspection activities to ensure their continuing suitability and effectiveness, and to introduce any necessary changes or improvements.

1.3   This publication has been prepared to give organisations guidance on how to establish a program for management reviews. It is assumed that the organisations have implemented a quality management system that meets the requirements of ISO/IEC 17025 or ISO/IEC 17020, whichever is applicable.

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

2   TERMINOLOGY

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 organisation with regard to quality. (ISO 9000)

2.3   **Quality management** Coordinated activities to direct and control an organisation 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 laboratory or inspection bodies should periodically conduct a review of the organisation's quality management system and testing and/or calibration and/or inspection activities 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 organisation continue to meet the organisation's needs. The review should also ensure that the management system of the organisation continues to conform to the requirements of ISO/IEC 17025 or ISO/IEC 17020, whichever is applicable.

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

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.

4   **ORGANISATION OF MANAGEMENT REVIEWS**

4.1   The senior management of the organisation 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 organisation's management system, for the technical operations of the organisation 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 organisation, technical management, the quality manager and any section heads are present.

It is recognised that, in a small organisation, one person may be fulfilling more

than one of the above functions. Good management reviews can occur even in single person organisations.

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 organisation;

(h)   reports on audits by customers or other approvals bodies and follow-up actions;

(i)   trends analysis of results of the organisation'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.
(o)   Recommendations for improvement.

6.3   Results of the management review should feed into the organisation'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

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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 organisation'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.

8   REFERENCES

ISO/IEC 17020:1998, General criteria for the operation of various types of bodies performing inspection

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

ISO 9000: 2000, Quality management and quality assurance - Vocabulary