INTERNAL AUDITS FOR LABORATORIES AND INSPECTION BODIES

PURPOSE

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

AUTHORSHIP

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FURTHER INFORMATION

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TABLE OF CONTENTS

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 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 a laboratory or inspection body periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the relevant Standard.

1.3 This publication has been prepared to give laboratories and inspection bodies guidance on how to establish a program for internal audits. It is assumed that the organisations have implemented a 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 an internal audit depends on the size, scope and organisational structure of the organisation, and many of the items described in this publication can be carried out in a simplified manner.

1.5 Further information on auditing is available in ISO 19011: 2002.

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 **Quality assurance** Part of quality management focused on providing confidence that quality requirements will be fulfilled. (ISO 9000)

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.

2.6 **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.

2.7 **Audit** Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. (ISO 9001)

Note: In this publication the term "internal audit" is used to emphasize that the audit is done by the organization itself.

2.8 **Auditor** Person with the competence to conduct an audit. (ISO 9000)

2.9 **Audit findings** Results of the evaluation of the collected audit evidence against audit criteria. (ISO 9000)

NOTE: Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

2.10 **Audit evidence** Records, statements of fact or other information which are relevant to the audit criteria and are verifiable (ISO 9000)

2.11 **Nonconformity** The non-fulfilment of a requirement. (ISO 9000).

3 OBJECTIVES OF INTERNAL AUDITS

3.1 The laboratory or inspection body should conduct internal audits of its activities to verify that its operations continue to comply with the requirements of its management system.

3.2 These audits should check that the management system fulfils the requirements of ISO/IEC 17025 or ISO/IEC 17020, whichever is applicable, or other relevant criteria documents, i.e. that there is conformity.

3.3 These audits should also check whether or not the requirements stated in the organisation's quality manual and related documents are applied at all levels of work.

3.4 The non-conformities found in internal audits give valuable information for the improvement of the organisation's management system and should thus be used as input to management reviews.

4 ORGANISATION OF INTERNAL AUDITS

4.1 The internal audits should be conducted on an annual basis according to a documented procedure.

4.2 Internal audits should be programmed such that each element of the quality management system is checked at least once a year. In large laboratories or inspection bodies it may be advantageous to establish a plan whereby the different elements of the management system or different sections of the organisation are audited throughout the year.

4.3 The quality manager is normally the audit program manager and may be the lead auditor.

4.4 The quality manager should be responsible for ensuring that the audits are carried out in accordance with the established plan.

4.5 Such audits should be carried out by qualified personnel who have sufficient technical knowledge of the operations they are auditing, and who are trained specifically in auditing techniques and processes. This should be documented in records.

4.6 The quality manager may delegate the task of performing audits provided that the person used is familiar with the organisation's management system and accreditation requirements and meets the requirements set out in 4.5.

4.7 In large organisations carrying out calibration and/or testing and/or inspection over a wide range of technical disciplines, it may be necessary for audits to be carried out by a team of individuals under the control of the quality manager.

4.8 In small organisations audits may be carried out by the quality manager alone. The management should, however, ensure that another person is given the task of auditing the quality manager's activities to ensure that the quality function is carried out satisfactorily.

4.9 Wherever resources permit, the auditor should be independent of the activity to be audited. Personnel should not audit their own activities or activities under their own direct responsibility except where there is no alternative and it can be demonstrated that an effective audit can be carried out. Laboratories and inspection bodies should pay particular attention to checking the effectiveness of an internal audit where it has been carried out by staff members who are not independent of the audited activities.

4.10 Where an organisation is accredited for calibration and/or testing and/or inspection at a client's site, or for sampling in the field, these activities should be included in the audit program.

4.11 Audits carried out by other parties, such as customers or an accreditation body, should not be considered as a substitute for internal audits.

5 PLANNING OF INTERNAL AUDITS

5.1 An audit plan including the audit scope, the audit criteria, the audit schedule, reference documents (such as the organisation's quality manual and audit procedure) and the names of audit team members, should be established by the quality manager.

5.2 Each auditor should be assigned specific management system elements or functional departments to audit. These assignments should be made by the lead auditor in consultation with the auditors concerned. Assigned auditors should have some technical knowledge of the departments they are to audit.

5.3 Working documents required to facilitate the auditor's investigations and to document and report results may include:

- criteria documents such as ISO/IEC 17025 or ISO/IEC 17020 and any supplementary documents
- laboratory or inspection body manuals and documents

- checklists used for evaluating quality management system elements (normally prepared by the auditor assigned to audit that specific element)

- forms for reporting audit observations, such as a “non-conformity” form or “correction action request” form. These permit the recording of the nature of the ”nonconformity”, the agreed corrective action, and the eventual confirmation that the action has been taken effectively.

5.4 An audit timetable should be developed by each auditor in conjunction with the auditee to ensure the smooth and systematic progress of the audit.

5.5 Prior to the actual audit, a review of documents, manuals, previous audit reports and records should be carried out to check for conformity with the management system requirements and to develop a checklist of key issues to be audited.

6 IMPLEMENTATION OF INTERNAL AUDITS

6.1 The key steps of an audit are planning, investigation, analysis, reporting, follow-up corrective action and close-out.

6.2 The opening meeting should introduce the audit team, confirm the audit criteria, review the audit scope, explain the audit procedure, clarify any relevant details, and confirm the timetable, including the time or date, and attendees for the closing meeting.

6.3 The investigation process for gathering objective evidence involves asking questions, observing activities, examining facilities, and examining records. The auditor examines the conformity of the activities with the management system.

6.4 The auditor uses the quality management system documents (quality manual, system procedures, test methods, work instructions, etc.) as references, and compares what is actually happening with what these quality management system documents state should happen.

6.5 At all times during the audit the auditor seeks objective audit evidence that the management system requirements are being fulfilled. Evidence should be collected as efficiently and effectively as possible, without prejudice, and without upsetting the auditees.

6.6 Nonconformities should be noted and should be investigated further by the auditor to identify underlying problems.

6.7 All audit findings should be recorded.

6.8 After all activities have been audited, the audit team should carefully review and analyse all of their findings to determine which are to be reported as nonconformities and which can be included as recommendations for improvement.

6.9 The audit team should prepare a clear, concise report, supported by objective audit evidence, of nonconformities and recommendations for improvement.

6.10 Nonconformities should be identified in terms of the specific requirements of the organisation's quality manual and related documents against which the audit has been conducted.

6.11 The audit team should hold a closing meeting with the senior management of the organisation and those responsible for the functions audited. The main purpose of this meeting is to present audit findings and to report to senior management in such a manner as to ensure that they clearly understand the results of the audit.

6.12 The lead auditor should present observations, taking into account their perceived significance. Both positive and negative aspects of the operations should be presented.

6.13 The lead auditor should present the audit team's conclusions regarding the quality management system's conformity with audit criteria, and the conformity of the operations to the management system.

6.14 Nonconformities identified during an audit should be noted, and the appropriate corrective action and the time frame for correction agreed with the auditee and recorded.

6.15 Records of the closing meeting should be kept.

7 FOLLOW-UP CORRECTIVE ACTION AND CLOSE-OUT

7.1 The implementation of the agreed corrective action is the responsibility of the auditee.

7.2 Whenever a non-conformity that may jeopardise the result of a calibration, test or inspection is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and has been shown to lead to satisfactory results. In addition, results that may have been affected by the non-conformity should be investigated and customers informed if the validity of corresponding calibration, test or inspection certificates/reports is in doubt.

7.3 The formal corrective action procedure may need to be followed to reveal the root causes of some problems and to implement effective corrective and preventive actions.

7.4 The auditor should check the effectiveness of corrective actions as soon as possible after the agreed time frame has elapsed. The quality manager should have the ultimate responsibility for confirming the clearance of nonconformities by the auditee and then closing them out.

8 RECORDS AND REPORTS OF INTERNAL AUDITS

8.1 A complete record of the audit should be maintained even where no nonconformities have been found.

8.2 Each of the nonconformities that have been identified should be recorded, detailing their nature, their possible cause(s), corrective action(s) required and appropriate time frames for their clearance.

8.3 Following the audit close-out, a final report should be prepared which should summarise the outcome of the audit and include the following information:

(a) the name(s) of the auditor(s);
(b) the date of the audit;
(c) the areas audited;
(d) the details of all areas examined;
(e) the positive or good aspects of the operations;
(f) any nonconformity identified, linked to references to relevant documents;
(g) any recommendations for improvement;
(h) corrective action agreed, the time frame agreed for completion, and the person responsible for carrying out the action;
(i) corrective actions taken;
(j) the date of confirmation of completion of corrective action;
(k) the signature of the quality manager confirming close-out of corrective actions.

8.4 All records of audits should be stored for an agreed period of time.

8.5 The quality manager should ensure that the audit report and, where appropriate, individual nonconformities, are brought to the attention of the organisation's senior management.

8.6 The trends in results of internal audits and corrective actions should be analysed by the quality manager and a report prepared for review by senior management at the next management review meeting.

8.7 The purpose of such reviews is to ensure that the audits and the corrective actions are contributing to the continuing effectiveness of the quality management system as a whole.

9 REFERENCES

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

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 19011: 2002, Guidelines for quality and/or environmental management systems auditing

ISO 9000, 2000 Quality management system – Fundamentals and vocabulary