



APLAC

Asia Pacific Laboratory Accreditation Cooperation

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Internal Audits for Laboratories

PURPOSE

To provide guidance for laboratories on how to establish a programme for internal audits

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1 Introduction

- 1.1 It is stated in ISO/IEC 17025 (1999) General Requirements for the Competence of Testing and Calibration Laboratories that a laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities including the type, range and volume of testing and/or calibration activities it undertakes.
- 1.2 ISO/IEC 17025 requires that a laboratory shall 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 quality system and this Standard.
- 1.3 This publication has been prepared to give laboratories guidance on how to establish a programme for internal audits. It is assumed that the laboratories have implemented a quality system that meets the requirements of ISO/IEC 17025.
- 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 laboratory and many of the items described in this publication can be carried out in a simplified manner.

2 Terminology

2.1 **Quality system** ° Organizational structure, procedures, processes and resources needed to implement quality management (ISO 8402)

2.2 **Quality management** ° That aspect of the overall management function that determines and implements the quality policy (ISO 8402)

2.3 **Quality assurance** ° All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. (ISO 8402)

2.4 **Audit** ° Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (ISO 8402)

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

2.5 **Management review** ° A formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives (ISO 8402)

2.6 **Quality manager** ° The staff member who has responsibility for the laboratory's quality system and its implementation and who, in this capacity, reports directly to top management

2.7 **Quality auditor**°@ Person qualified to perform quality audits (ISO 8402)

2.8 **Observation**°@ statement of fact made during an audit and substantiated by objective evidence.

2.9 **Objective evidence**°@ qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.

2.10 **Nonconformity**°@ The non-fulfilment of specified requirements. (ISO 8402)

3 Objectives of internal audits

- 3.1 The laboratory should conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system.
- 3.2 These audits should check that the quality system fulfils the requirements of ISO/IEC 17025 or other relevant criteria document (conformity).
- 3.3 These audits should also check whether or not the requirements stated in the laboratory'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 laboratory's quality system and should thus be used as input to the management reviews.

4 Organisation of internal audits

- 4.1 The internal audits should be carried out according to a documented procedure.
- 4.2 Internal audits should be programmed such that each element of the quality system is checked at least once a year. In large laboratories it may be advantageous to establish a plan whereby the different elements of the quality system or different sections of the laboratory are audited throughout the year.
- 4.3 The quality manager is normally the audit programme manager and may be lead the 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 shall 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.
- 4.6 The quality manager may delegate the task of performing audits provided that the person used is familiar with the laboratory's quality system and accreditation requirements and meets the requirements given in 4.5.

- 4.7 In large laboratories carrying out calibration and/or testing in 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 laboratories audits may be carried out by the quality manager alone. However, the management should 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 shall be independent of the activity to be audited. Personnel shall 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 has been carried out. Laboratories should pay particular attention to checking the effectiveness of an internal audit where it has been carried out by staff who are not independent of the audited activities.
- 4.10 Where a laboratory has accreditation for calibration and/or testing at a client's site, or for sampling in the field, these activities shall be included in the audit programme.
- 4.11 Audits carried out by other parties, such as customers or the accreditation body, shall 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 lab's quality manual and audit procedure) and audit team members, shall be established by the quality manager.

5.2 Each auditor shall be assigned specific quality system elements or functional departments to audit. These assignments should be made by the lead auditor in consultation with the auditors concerned. Assigned auditors shall 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 document such as ISO/IEC 17025 and any supplementary criteria.
- Laboratory manuals and documents.
- Checklists used for evaluating quality system elements (normally prepared by the auditor assigned to audit that specific element).
- Forms for reporting audit observations, such as 'non-conformance' 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 effectively taken.

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 system criteria 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°G
- 6.2 The opening meeting would 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 will involve asking questions, observing activities, examining facilities, and examining records. The auditor will be examining the conformity of the activities with the quality system.
- 6.4 The auditor will use the quality system documents as reference (quality manual, system procedures, test methods, work instructions, and so on), and compare what is actually happening with what these quality system documents state should happen.
- 6.5 At all times during the audit, the auditor will be seeking objective evidence that the quality system requirements are being fulfilled. Evidence should be collected as efficiently and effectively as possible and 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 observations should be recorded.
- 6.8 After all activities have been audited, the audit team should carefully review and analyse all of their observations 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 evidence of nonconformities and recommendations for improvement.
- 6.10 Nonconformities should be identified in terms of the specific requirements of the lab'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 laboratory and those responsible for the functions concerned. The main purpose of this meeting is to present audit findings and report to senior management in such a manner so 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 system's conformity with audit criteria and the conformance of the operations to the quality system.

6.14 Nonconformities identified during an audit should be noted and the appropriate corrective action and the time limit 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 or test is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and 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 and test 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 effectiveness of corrective actions should be checked by the auditor as soon as possible after the agreed time limit has elapsed. The quality manager should have the ultimate responsibility for confirming the clearance of nonconformity 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 limits for their clearance.

8.3 Following the audit closeout, 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) date of 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 along with their document references.

(g) any recommendations for improvement.

(h) corrective action agreed, the time period allowed for completion, and the person responsible for carrying out the action;

(i) Corrective actions taken.

(j) date of confirmation of completion of corrective action;

(k) signature of the quality manager confirming closeout 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 report of the audit and, where appropriate, individual nonconformity, are seen by the laboratory's senior management.

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

9 References

EA-4/04: 1996, Internal quality audits and management review for laboratories

ISO/IEC 17025: 1999, General requirements for the competence of testing and calibration laboratories

ISO 8402: 1994, Quality Management and Quality Assurance - Vocabulary

ISO 10011-1: 1990, Guidelines for auditing quality systems - Part1: Auditing

ISO 10011-2: 1990, Guidelines for auditing quality systems - Part2: Qualification criteria for quality system auditors

ISO 10011-3: 1990, Guidelines for auditing quality systems - Part3: Management of audit programmes.

ISO 9004-1: 1994, Quality management and quality system elements - Guidelines.