EAL European cooperation for Accreditation of Laboratories

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Internal Audits and Management Review for Laboratories

PURPOSE

To provide guidance for laboratories on how to establish a programme for internal audits and management reviews.

Authorship

This publication is a revision of the earlier guidance Publication ELA-G3, to cover the needs of both testing and calibration laboratories. It will henceforth be a responsibility of EAL Committee 4.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Guidance Publications

This document represents a consensus of EAL member opinion and preferred practice on how the relevant clauses of the accreditation standards might be applied in the context of the subject matter of this document. The approaches taken are not mandatory and are for the guidance of accreditation bodies and their client laboratories. Nevertheless, the document has been produced as a means of promoting a consistent approach to laboratory accreditation amongst EAL member bodies, particularly those participating in the EAL Multilateral Agreement.

Further information

For further information about this publication, contact your National member of EAL, whose telephone and facsimile numbers are given below:

member	Calib National member	Testing National
Austria	BMwA Tel: +431 711 02 233 Fax: +431 714 35 82	BMwA Tel: +431 711 02 248 Fax: +431 714 35 82
Belgium	BKO/OBE Tel: +32 2 206 47 35 Fax: +32 2 206 57 45	BELTEST Tel: +32 2 206 46 80 Fax: +32 2 206 57 42
Denmark	DANAK Tel: +45 35 86 86 86 Fax: +45 35 86 86 87	DANAK Tel: +45 35 86 82 80 Fax: +45 35 86 86 87
Finland	FINAS Tel: +358 0 616 71 Fax: +358 0 616 7341	FINAS Tel: +358 0 616 71 Fax: +358 0 616 7467
France	COFRAC Tel: +33 1 44 68 82 33 Fax: +33 1 44 68 82 22	COFRAC Tel: +33 1 44 68 82 40 Fax: +33 1 44 68 82 23
Germany	DKD Tel: +49 531 592 8320 Fax: +49 531 592 9292	DAR Tel: +49 30 8104 1710 Fax: +49 30 8104 1717
Greece	Ministry of Commerce Tel: +30 1 38 14 168 Fax: +30 1 38 42 642	ELOT Tel: +30 1 201 5025 Fax: +30 1 202 0776
Iceland	ISAC Tel: +354 1 681 122 Fax: +354 1 685 998	ISAC Tel: +354 1 681 122 Fax: +354 1 685 998
Ireland	NAB Tel: +353 1 607 3003 Fax: +353 1 607 3109	NAB Tel: +353 1 607 3003 Fax: +353 1 607 3109
Italy	SIT Tel: +39 11 348 8933 Fax: +39 11 348 6384	SINAL Tel: +39 6 487 1176 Fax: +39 6 481 4563
Netherlands	RvA Tel: +3130 239 4500 Fax: +3130 239 4539	RvA Tel: +3130 239 4500 Fax: +3130 239 4539
Norway	NA Tel: +47 22 20 0226 Fax: +47 22 20 7772	NA Tel: +47 22 20 0226 Fax: +47 22 20 7772
Portugal	IPQ Tel: +351 1 294 8201 Fax: +351 1 294 8202	IPQ Tel: +351 1 294 8201 Fax: +351 1 294 8202
Spain	ENAC Tel: +34 1 457 32 89 Fax: +34 1 458 62 80	ENAC Tel: +34 1 457 32 89 Fax: +34 1 458 62 80
Sweden	SWEDAC Tel: +46 33 17 77 30 Fax: +46 33 10 13 92	SWEDAC Tel: +46 84 02 00 71 Fax: +46 87 91 89 29
Switzerland	SAS Tel: +41 31 963 3381 Fax: +41 31 963 3210	SAS Tel: +41 31 963 3412 Fax: +41 31 963 3210
United Kingdom	UKAS Tel: +44 181 943 7068 Fax: +44 181 943 7134	UKAS Tel: +44 181 943 6266 Fax: +44 181 943 7134

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1 Introduction

1.1 It is stated in the European standard EN 45001 *General Criteria for the Operation of Testing Laboratories* that a laboratory shall operate a quality system appropriate to the type, range and volume of work performed. A similar requirement is contained in ISO/IEC Guide 25(1990) *General Requirements for the Competence of Calibration and Testing Laboratories*.

1.2 EN 45001 requires that 'the quality system shall be systematically and periodically reviewed by or on behalf of management to ensure the continued effectiveness of the arrangements, and any corrective action taken.' A similar requirement for review is contained in ISO/IEC Guide 25.

1.3 In addition, ISO/IEC Guide 25 requires that a laboratory 'shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system.'

1.4 This publication has been prepared to give laboratories guidance on how to establish a programme for internal audits and quality system reviews. It is assumed that the laboratories have implemented a quality system that meets the requirements of EN 45001.

1.5 The guidelines given in this publication are of a general nature. The actual accomplishment of a internal audit or a quality system review 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. In some cases specific guidance pertaining to small laboratories are given in the publication.

2 Terminology

2.1	**Quality system**	organizational structure, procedures, processes and resources needed to implement quality management (ISO 8402)
2.2	**Quality 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.
2.3	**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)
2.4	**Quality manager**	staff member who has responsibility for the laboratory's quality system and its implementation and who, in this capacity, reports directly to top management
2.5	**Quality auditor**	person qualified to perform quality audits (ISO 8402)

3 Objectives of internal audits

3.1 An accredited laboratory should carry out internal audits at regular intervals to ensure that its quality system is fully implemented in practice. In these audits it should be checked whether or not the requirements stated in the laboratory's quality manual and related documents are applied at all levels of work. The non-compliances found at 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 discussed in Sections 8 to 11.

4 Organisation of internal audits

4.1 The internal audits should be carried out according to a written procedure that is described in the quality manual.

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 are audited throughout the year (Appendix A).

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

4.4 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.

4.5 In one-person laboratories, internal audits should be performed by an external body.

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. All auditors should be properly trained.

4.7 In large laboratories carrying out calibration 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. Auditors should not audit areas for which they have responsibility.

4.8 Where a laboratory has accreditation for calibration or testing on site, or for sampling, these activities must be included in the audit programme.

4.9 Audits carried out by other parties, such as customers or the accreditation body, cannot be considered to substitute or override the laboratory's own internal audit.

5 Planning of internal audits

5.1 The audit programme should provide for both **horizontal** and **vertical** audits.

5.2 A **horizontal audit** is a detailed check of a quality system element throughout the total range of calibration or testing activities covered by the accreditation. Examples of such elements are staff training, reference standards, calibration and maintenance of equipment, calibration and test methods.

5.3 A **vertical audit** is a detailed check that all quality system elements associated with a calibration or test are implemented in a specific assignment. In a vertical audit, a representative number of performed tests/ calibrations are selected at random from work that has recently passed through the laboratory. The vertical audit should include, where possible, the repetition of the calibration or test involved. Each aspect of the laboratory's activities associated with the selected calibrations or tests should be checked including:

(a) sample handling;

(b) staff involved;

(c) calibration and maintenance of equipment;

(d) calibration and test methods and procedures used;

(e) quality control requirements;

(f) environmental conditions during calibration and/or testing;

(g) calibration and test records and the reporting of results;

(h) storage of data.

5.4 In addition to regular internal audits, it may be necessary to perform special, unscheduled audits. Such audits may be initiated:

(a) as a result of a customer's complaint which raises doubts about the laboratory's compliance with its own policies and procedures;

(b) through the detection of an anomalous result (eg unacceptable results in an interlaboratory comparison);

(c) to confirm that corrective actions and other changes of the quality system have been carried out and are effective.

6 Implementation of internal audits

6.1 It should be the responsibility of the quality manager to make final decisions concerning the scope, extent and type of internal audit to be carried out.

6.2 In order to make the audit easier to carry out, the report formats should be formalised to the extent found necessary. For example, it may be practicable to use standardised forms for:

(a) listing the elements of the quality system to be audited;

(b) noting non-compliances and agreed corrective actions including follow-up activities;

(c) summarising the outcome of the audit.

6.3 The results of an internal audit must be based on objective facts.

6.4 In an internal audit, the whole quality system should be audited. Assuming that the system fulfils the requirements of EN 45001, special attention should thus be paid to ensure that:

6.4.1 Organisation and management

(EN 45001, sub-clauses 5.1 and 5.4.2; ISO/IEC Guide 25, clause 4)

(a) the quality policy has been implemented in such a way that it is followed and understood in the laboratory;

(b) management and staff responsibilities and job descriptions are documented;

(c) the quality manual is maintained up-to-date.

6.4.2 Staff

(EN 45001 sub-clause 5.2; ISO/IEC Guide 25, clause 6)

(a) all staff are properly trained;

(b) calibrations and tests are carried out only by authorised staff;

(c) the performance of staff carrying out calibrations and/or tests is observed;

(d) information on relevant qualifications, training and experience of staff is recorded and kept up-to-date.

6.4.3 Testing and measuring equipment

(EN 45001, sub-clause 5.3.3; ISO/IEC Guide 25, clauses 8 and 9)

(a) where the concept of traceability is applicable, the reference standards, including any reference materials, are traceable to national or international standards as evidenced by valid calibration certificates or other documents showing the calibration status of the standards;

(b) reproducibility of results affected by reference standards for which the concept of traceability is not applicable is demonstrated through participation in interlaboratory comparisons;

(c) the laboratory's results in proficiency testing and interlaboratory comparisons are evaluated and the necessary corrective actions, if any, taken;

(d) reference standards are used only for calibration;

(e) where relevant, the long-term behaviour of reference standards is evaluated;

(f) the internal calibration programme ensures that all measuring or test equipment having an effect on the validity of calibrations and tests is properly calibrated or verified, and that these operations are documented in sufficient detail;

(g) measuring or test equipment and working standards are, where relevant, subjected to in-service checks between regular calibrations;

(h) the proper functioning of measurement or test equipment and working standards that have been removed from their normal location is checked before they are used again for their intended purpose;

(i) the programme for the maintenance of measuring or test equipment and working standards is properly implemented so that any item subjected to overloading or mishandling, or giving suspect results or shown to be defective is taken out of service, repaired and after subsequent calibration or verification shown to perform satisfactorily before it is taken back to service;

(j) the maintenance of measuring or test equipment and working standards is documented in sufficient detail;

(k) each item of equipment, including equipment taken out of service, is labelled, marked or otherwise identified to indicate its calibration status;

(l) the written procedures for the use of measuring or test equipment are appropriate and are being used by the staff operating the equipment.

6.4.4 Calibration and test methods and procedures

(EN 45001, sub-clause 5.4.1; ISO/IEC Guide 25, clause 10)

(a) calibration and test methods and procedures are unambiguous and sufficiently detailed for their purpose;

(b) calibration and test methods and procedures in use are current, approved versions;

(c) calibration and test methods and procedures are available to staff and used by them;

(d) documented in-house methods have been properly approved;

(e) all calculations and data transfers are subject to appropriate checks;

(f) procedures exist for the estimation/calculation of uncertainty in measurement;

(g) procedures for any in-house preparation of reference materials are documented;

(h) reference materials and other measurement standards are properly stored and labelled;

(i) where appropriate, the laboratory takes part in relevant proficiency testing and interlaboratory comparison schemes;

(j) calibrations and tests are being carried out in accordance with the relevant method;

(k) if the laboratory is planning to extend the scope of its accreditation the internal audit should include checks of validation procedures, verifications etc.

6.4.5 Environment

(EN 45001, sub-clause 5.3.2; ISO/IEC Guide 25, clause 7)

(a) the environmental conditions in which calibrations and/or tests are being carried out are appropriate;

(b) where appropriate, records of environmental conditions are maintained; records of environmental conditions are examined to determine whether calibrations and/or tests have been performed in a period when the environment did not fulfil the requirements;

(c) the measuring equipment used to monitor environmental conditions is properly calibrated;

(d) access to and use of all areas is adequately controlled.

6.4.6 Handling of test samples or items

(EN 45001, sub-clause 5.4.5; ISO/IEC Guide 25, clause 11)

(a) the procedure for identifying calibration and test samples or items is being followed;

(b) the procedure for storage and preparation of calibration and test samples or items are available to the staff and are being followed;

(c) the procedures for the reception, retention and disposal of calibration and test samples or items are in use.

6.4.7 Calibration and test certificates/ reports

(EN 45001, sub-clause 5.4.3; ISO/IEC Guide 25, clause 13)

(a) calibration and test certificates/reports are signed by an authorised signatory;

(b) calibration and test certificates/reports contain all the required information;

(c) original data and copies of calibration and test certificates/reports are correctly stored for the designated period of time;

(d) corrections and additions to calibration and test certificates/reports are made on separate documents that are suitably marked and meet the relevant requirements for such documents;

(e) calibration certificates and test reports do not state opinions, judgements or recommendations not based on direct measurement results and specifications.

6.4.8 Complaints

(EN 45001, sub-clause 6.1; ISO/IEC Guide 25, clause 16)

(a) the actions taken by the laboratory following a formal complaint are in accordance with the defined complaints procedure;

(b) the complaint file is readily available and contains the necessary information and is kept up-to-date;

(c) complaints, together with other discrepancies, are fed into the management review.

6.4.9 Subcontracting

(EN 45001, sub-clause 5.4.7; ISO/IEC Guide 25, clause 14)

(a) where a laboratory subcontracts part of a calibration or test to another laboratory, evidence is at hand that the subcontractor is competent to perform the service in question and complies with the requirements of EN 45001;

(b) detailed records of parts of calibrations and tests that are subcontracted and of laboratories that are used as subcontractors are being maintained.

6.5 The audit should not be restricted to items listed in 6.4.1 to 6.4.9, but should include all elements of the laboratory's quality system, including any additional requirements specified by the accreditation body or other bodies with whom the accreditation body cooperates.

6.6 Non-compliances found as a result of an audit should be recorded and the appropriate corrective action and the time limit for correction agreed.

6.7 Whenever a non-compliance 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-compliance should be investigated and customers informed if the validity of corresponding calibration and test certificates/reports is in doubt.

6.8 The implementation of the agreed corrective action and its effectiveness should be checked as soon as possible after the agreed time limit has elapsed. The quality manager should have the ultimate responsibility for checking the clearance of non-compliances.

7 Documentation of internal audits

7.1 A complete record of the audit should be maintained even where no non-compliances have been found.

7.2 Each non-compliance identified should be recorded, detailing the nature of the non-compliance, its possible cause(s), corrective action required and an appropriate time limit for its clearance.

7.3 Following the audit a report should be prepared which should 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) any non-compliances identified;

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

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

(h) signature of the quality manager confirming corrective action.

7.4 The quality manager should ensure that the report of the audit and, where appropriate, individual non-compliances, are seen by the laboratory's senior management.

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

8 Organisation of management reviews

8.1 The senior management of the laboratory should be responsible for conducting reviews of the quality system.

8.2 Those members of senior management having overall responsibility for the design and implementation of the laboratory's quality system, and for taking any decisions resulting from the findings of internal audits, should be involved in management reviews.

8.3 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 review are recorded.

8.4 The quality manager should also be responsible for ensuring that any action identified during a review is implemented within the agreed time limit.

9 Objectives of management reviews

9.1 Management reviews should be planned to establish what changes, if any, are necessary to ensure that the quality arrangements for the laboratory continue to meet both the laboratory's needs and the requirements of EN 45001.

9.2 The quality system may need to be modified because of changes that have taken place (or are expected to take place) in the organisation, facilities, staffing, equipment, procedures, activities or workload of the laboratory.

9.3 The need for changes to the quality system may also arise as a result of findings from internal or external quality audits, surveillance or re-assessment visits by an accreditation body, or complaints from customers.

10 Planning and implementation of management reviews

10.1 Management reviews should be carried out at least once every twelve months. The review should be programmed and the meeting should be attended by the senior management, including the person under whose authority the quality manual has been issued. It is essential that the Head of the Laboratory, the Technical Manager, the Quality Manager and the section heads are present. It is recognised that in a small laboratory, one person may be fulfilling more than one of the above functions.

10.2 The review should be conducted in a systematic manner using a formal agenda. This should include at least the following items:

(a) matters arising from the previous review;

(b) reports on surveillance and re-assessment visits carried out by any accreditation body;

(c) reports on audits by customers or other approval bodies;

(d) results of internal audits carried out since the last review;

(e) results of the laboratory's participation in any proficiency testing or inter-laboratory comparison schemes and the need for such participation in other areas of calibration and/or testing;

(f) results of in-house quality control checks;

(g) details of any complaints received from customers;

(h) need for amendment of the quality system, including the quality manual;

(i) plan for the implementation of decided changes to the quality system, including a timetable;

(j) adequacy of current human and equipment resources;

(k) future plans and estimates for new work, additional staff, new equipment etc;

(l) training of new staff and updating of existing staff.

10.3 It should be the quality manager's responsibility to ensure that all actions arising from reviews are carried out as required.

11 Records of management reviews

11.1 All management reviews should be documented. The documentation 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 in what time limit.

11.2 It should be the quality manager's responsibility to ensure that all actions arising from reviews are recorded and discharged as required.

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

12 References

EN 45001:1989, *General criteria for the operation of testing laboratories.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

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

ISO 10011-1:1990, *Guidelines for auditing quality systems- Part 1:Auditing.*

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

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

NAMAS M51, *Quality audit and quality system review in Calibration and Testing laboratories* (March 1991).

NORDTEST NT TECHN REPORT 146, *About procedures for internal quality audits of testing laboratories* (January 1991).

Appendix A

Example of an audit programme

Caltest Laboratories Ltd - TESTING LABORATORY
AUDIT PROGRAMME FOR 199_

Aspect to be audited	EN 45001 Reference	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Organisation	3, 4, 5.1			~~14 / 3 J M B~~		CHECK				○			
Staff and training	5.2						○						
Testing & measuring equipment	5.3					○							
Calibration	5.3				10 / 4 J M B						○		
Test methods	5.4.1	15 / 1 J M B					○			○			
Test performance	5.2, 5.4.1	~~15 / 1 J M B~~			11 / 4 CHECK J M B								
Environment	5.3.2							○					
Sample handling	5.4.5		~~14 / 2 J M B~~		11 / 4 CHECK J M B								
Records	5.4.4	16 / 1 J M B									○		
Test reports	5.4.3						○						○
Complaints & anomalies	5.3.3 5.4.2 (g)(h)							○					
Sub-contracting	5.4.7				10 / 4 J M B							○	
Support services and supplies	Proc.No. 1												○
Site testing	Proc.No. 2			14 / 3 J M B									
Sampling	Proc.No. 3		14 / 2										

Notes:

A Programme shown is completed up to 30 April.

B This appendix is an example that must be studied and modified by the laboratory according to its own needs and organisation (see Section 4).

C One possible approach to maintain a record of progress made with the audit programme is to mark the boxes against each aspect listed in this appendix in the following manner:

○ indicates audit due in month shown in audit programme;

10 / 4 J M B indicates audit carried out by J M Brown and completed on 10 April with no non-compliances;

~~15 / 1 J M B~~ indicates audit carried out by J M Brown and completed on 15 January with some non-compliances recorded;

CHECK indicates additional check audit now required to ensure all non-compliances recorded during previous audit are corrected;

11 / 4 CHECK J M B check audit completed by J M Brown on 11 April with all actions corrected.