HOKLAS Supplementary Criteria No. 7

Internal Audits and Management Reviews

1 INTRODUCTION

1.1 It is a requirement of HOKLAS 003 that a laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration and testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned.

1.2 To gauge whether laboratory operation is actually meeting the requirements stated in quality documentation, HOKLAS requires laboratories to audit their testing and management activities at appropriate intervals such that each aspect of the quality system will be audited at least once a year. Where discrepancies are found, corrective actions shall be taken.

1.3 As laboratory operation is affected by factors both internal and external to the laboratory, a quality system which used to be suitable and adequate may need to be amended if there are changes to these factors. Therefore, HOKLAS also requires laboratories to review the suitability and adequacy of their quality system at least once a year. Necessary changes and improvements should also be introduced through this review.

1.4 This document explains the meaning of internal audit and management review and provides guidance to assist laboratories in establishing internal audit and management review procedures.

1.5 Internal audits and management reviews should be distinguished from each other as follows:

Internal audit	The term internal audit is used to describe the periodic check that a laboratory must perform to ensure that all aspects of its quality system (as laid down in its quality manual and supporting documentation) are fully implemented.

Management review	The term quality system review is used to describe the periodic and formal examination of the quality system that executive management shall make to ensure that the quality arrangements as documented in the quality manual continue to be adequate and effective in meeting both HOKLAS requirements and the laboratory's quality policies and objectives.

As an example, in auditing a certain operation, auditors should establish whether there is any non-compliance with the relevant procedure. Where discrepancies are found, the auditor should stipulate that the procedures shall be rigorously followed. On the other hand, if the procedure itself is found to be ineffective in meeting the stated objective, the person responsible for quality should bring this to the attention of the laboratory executive management who should review the adequacy of the procedure and implement any necessary changes. It is not the responsibility of the auditor to stipulate what amendments to the procedure are to be made. Nevertheless, the person responsible for quality may forward recommendations for consideration to the laboratory executive management.

In practice, recommendations of the auditors for less significant changes to quality system requirements may be accepted by the audited department and the quality manager and implemented without going through the laboratory executive management. However, making such changes shall be within the authority of the quality manager and the audited department. In this situation, certain review functions are performed during audits.

1.6 HOKLAS expects laboratories to distinguish clearly between internal audits and management reviews of the quality system in their quality manuals, and to have documented procedures for implementing them.

2 OBJECTIVES OF INTERNAL AUDITS

2.1 Internal audits shall be planned to establish whether :

(a) laboratory operation is in compliance with the documented procedures;

(b) all personnel, at all levels, are satisfactorily carrying out their assigned duties and responsibilities;

2.2 Internal audits should be designed to reveal the extent of compliance with requirements in all of the elements examined and should serve to check on the abilities and integrity of laboratory management and personnel at all levels.

2.3 Internal audit should serve to identify areas of risks where preventive actions may be required to avoid any potential nonconformances.

3 ESSENTIAL REQUIREMENTS FOR INTERNAL AUDITS

3.1 It is essential that :

(a) the laboratory has planned for internal audits in its quality system;

(b) the laboratory has nominated an adequately trained person, or persons, to be responsible for conducting internal audits, who wherever resources permit, be independent of the activity to be audited;

(c) all audit findings and any corrective actions that arise from them shall be recorded;

(d) all accredited tests shall be subject to internal audit at least once per year.

4 ROLE OF QUALITY MANAGER IN AUDITING

4.1 The Quality Manager is responsible for ensuring that the laboratory quality system is implemented on a day-to-day basis.

4.2 The Quality Manager is responsible for planning, recording and organising internal audits and ensuring that timely and effective corrective actions are being taken against deficiencies found. He or she should have sufficient standing and authority in the organisation to command respect and secure any changes or actions that are necessary to maintain a satisfactory quality system.

4.3 In a small laboratory, internal audits are usually carried out by the Quality Manager. In larger laboratories with a very wide range of calibration or testing activities, involving perhaps several technical disciplines, the Quality Manager may need to appoint several audit officers or deputies to cover specific areas or activities. Since staff should be, wherever possible, independent of the specific activities being audited, they are able to bring fresh views to bear. Staff required to carry out auditing shall be trained in the techniques of auditing and for these activities shall report to the Quality Manager who shall monitor and control their activities.

4.4 Where the laboratory appoints an external audit officer, the Quality Manager is responsible for ensuring that the person selected is trained in the techniques of auditing and is fully familiar with HOKLAS requirements, the laboratory's quality manual, and all relevant procedures.

4.5 Where a laboratory has accreditation for calibration and/or testing at a client's site, or for sampling in the field, these activities should be included in the audit programme.

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

5 PLANNING AND IMPLEMENTATION OF AUDITS

5.1 Internal audits shall be carried out to a pre-determined programme such that each aspect of the quality system is examined at least once per year. Typical aspects or areas being audited are shown in Annex I.

5.2 The audit programme shall include both horizontal and vertical audits. Horizontal audits involve checking, in detail, one of the aspects shown in Annex I. Vertical audits involve checking through the sequence of a test operation from receipt of sample to issue of report (or in the reverse direction).

5.3 Laboratories should carry out horizontal audits of each of the aspects shown in Annex I, across the whole laboratory. If horizontal audit is only carried out over selected departments, sections or part of the laboratory, it can only reveal some of the weaknesses that may exist in the quality system. This is particularly true when equipment, staff, etc, may be used by more than one department.

5.4 In a vertical audit, a number of calibration or test items, or samples, are selected at random from work that has passed through the laboratory. Each operation associated with these items or samples including registration, calibration or testing staff involved, equipment used, calibration or test methods and procedures used, quality control requirements, environmental conditions during calibration or testing, recording of results, reporting, storage and disposal, should be checked. If vertical audits are conducted more frequently than horizontal audits, it is important to vary the point of entry into the system, e.g., by selecting items on different occasions via reports or certificates, item numbers, operator records or retained calibration or test items. Since vertical audits do not check that calibrations or tests were being performed correctly they should be viewed as a complementary activity to horizontal auditing and should not replace the full audit plans shown in Annex I.

5.5 To ensure that horizontal and vertical audits are carried out at the appropriate frequency a forward plan shall be prepared which may take the form of a chart, such as that shown in Annex I, which covers one or two aspects each month with complete coverage being achieved over a period of 12 months. Where it is not practicable to carry out a complete audit programme covering all aspects of the quality system in one session, laboratories shall make sure that all aspects or areas are monitored over a 12 month period.

5.6 A "checklist" is frequently found useful by auditing personnel. This can take the form of a list of detailed areas for each of the aspects to be audited, to prevent the omission of specific areas. However checklists with Yes/No tick boxes should be avoided.

5.7 Laboratories should carry out additional unscheduled audits whenever there is reason to doubt the effectiveness of the quality system. For example, when a laboratory has received a complaint about its calibration or testing activities which cast doubt on the laboratory's compliance with its policies, procedures or standards, these activities shall be audited promptly.

5.8 When laboratories seek extension of accreditation, the management should ensure audits are carried out and corrective actions are taken before the HOKLAS assessment.

5.9 The management should ensure that someone is given the task of auditing the Quality Manager's activities to ensure that the quality function is carried out satisfactorily.

6 RECORDS OF AUDITS

6.1 Laboratories are required to maintain detailed documentary records of all audits. These records provide management with a continuous history of performance, and a means of identifying particular areas of weakness. All records shall be clearly documented and readily accessible.

6.2 Each non-compliance with the requirements of the quality system shall be fully recorded, with details of the underlying cause(s), corrective actions required, how and by whom they are to be implemented, and an agreed timescale for their achievement. The timescale shall be decided in consultation with the Quality Manager, who shall assess the seriousness of the non-compliances. In certain situations the laboratory may have to stop calibration or testing in a specific area until satisfactory remedial action has been implemented. It may also be necessary to take action with regard to work already completed which may now be considered dubious.

6.3 It is important that the Quality Manager and any audit officers monitor the implementation of the corrective actions to ensure that they are discharged within the agreed timescales.

6.4 Most laboratories find that the use of pro-formas is helpful in maintaining a record of the audit findings and subsequent actions. Such a form is illustrated in Annex II. The layout shown and the headings provided are not mandatory, but all the elements shown should be included in the laboratory's form of records.

6.5 Each audit report shall include the following :

(a) name of audit officer;

(b) date of audit;

(c) areas audited;

(d) details of aspects examined including sample numbers, equipment identification etc, where appropriate (even where no non-compliances were observed);

(e) any non-compliances observed or recommendation for improvement;

(f) underlying cause(s) of the non-compliances;

(g) corrective action agreed, responsibility for and time period for completion of corrective action;

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

(i) signature of Quality Manager confirming that the corrective action process has been completed and recommending whether or not discussion for preventive action is necessary.

6.6 It is recommended that audit findings are summarised. An example of a suitable form for this purpose is illustrated in Annex III. The summary will help to highlight areas of weakness and enable any deterioration of the quality system to be rapidly detected. The summary should include positive statements about satisfactory performance. The summary should be signed by both the Quality Manager and Chief Executive of the laboratory.

6.7 Where the audit summary reveals serious non-compliances, consideration should be given to auditing the relevant areas again in the near future to check that the actions taken are still effective.

6.8 In addition to the audit reports and audit summaries laboratories need to maintain a record of progress made with the audit programme.

6.9 Audit records shall be retained for a minimum of three years.

7 OBJECTIVE OF REVIEWS

7.1 Management reviews shall be planned to establish what changes, if any, are necessary to ensure that the quality arrangements for the laboratory continue to be effective in meeting both the laboratory's objectives and the HOKLAS requirements. The quality system may need modification because of changes that have taken place (or are expected to take place) in the organisation, facilities, staffing, equipment, procedures, activities or work-load of the laboratory. The need for changes in the quality system may also be indicated when the findings from all internal and external audits, feedback, complaints, internal verification practices, external proficiency testing and HOKLAS visits etc. are considered.

8 ESSENTIAL REQUIREMENTS FOR REVIEWS

8.1 It is essential that :

(a) management reviews are conducted by laboratory executive management;

(b) every aspect of laboratory operation shall be covered at least once a year;

(c) all factors which affects laboratory operations, both external and internal, shall be examined;

(d) management reviews take place at a pre-planned date;

(e) the laboratory ensures that the outcome of reviews is recorded and acted upon.

9 PLANNING AND IMPLEMENTATION OF REVIEWS

9.1 A management review may take many different forms and need not be a single activity carried out once a year. However, it shall be planned, and every aspect of the quality system shall be covered at least once a year and the laboratory's executive management shall be involved. In practice, the executive management should include at least the chief executive officer, members of the technical management team, the quality manager and the person under whose authority the quality manual has been issued.

9.2 A laboratory may hold one review meeting which covers all aspects, or several review meetings spread out throughout the year, each of which covers selected aspects. In order to make the review more fruitful, the person responsible for quality should collate all relevant information and present it to laboratory executive management before the meeting.

9.3 The suitability and effectiveness of every aspect of the quality system shall be evaluated against all factors which affect laboratory operation, both internal and external, and shall include at least the following items which will provide a measure of the laboratory's performance in achieving its quality objectives on a continuous basis:

(a) feedback on the implementation of the quality system and any previous review actions;

(b) results of internal audits and actions taken against discrepancies;

(c) results of HOKLAS assessment, reassessment and surveillance visits;

(d) results of proficiency tests and in-house quality control and verification practices;

(e) complaints and other forms of feedback from customers and staff, and results of any investigations;

(f) preventive actions taken and effectiveness of the introduced measures

(g) staff turn-over rate;

(h) adequacy of staff training;

(i) availability of new technology and equipment;

(j) adequacy of existing staff, equipment and other resources;

(k) the existing workload and customer demand for new services.

(l) reports from individual sectional managers/supervisors

Note: A typical agenda is suggested in Annex IV.

9.4 Of course, changes to the quality system will have been made throughout the year as a result of internal and external audit findings, etc. The review should evaluate the non-compliances revealed in audits and analyse the trend of test performance achieved to see if there are any recurring faults which may indicate an underlying failing of some aspect of the quality system.

9.5 It is likely that as a result of the review, action will need to be taken. An action plan should be drawn up. The plan would commonly include the implementation of changes to the quality procedures and updating of quality documents, request for additional staff and new equipment, training to be provided to new and existing staff, participation in proficiency test programmes, etc.

10 RECORDS OF MANAGEMENT REVIEWS

10.1 Laboratories are required to maintain detailed documentary records of all reviews. These may be in the form of minutes of the review meetings together with clear indications of the actions to be taken, by whom and by what date.

10.2 It is the Quality Manger's responsibility to ensure that all actions arising from reviews are recorded and discharged as required.

10.3 All records shall be clearly documented and readily accessible.

10.4 Records of reviews shall be retained for a minimum of three years.

HKAS Executive
May 2004

ANNEX I

AUDIT SCHEDULE FOR 2002

Aspect to be audited	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
Quality system and Organisation												
Document control and Control of records												
Review of request, tenders or contracts												
Subcontracting of tests and calibrations												
Purchasing services and supplies												
Service to the client and Complaints												
Control of non-conforming work, Corrective action and Preventive action												
Internal audits and Management reviews												
Personnel												
Accommodation and environmental conditions												
Test and calibration methods and method validation												
Equipment and Measurement traceability												
Sampling and Handling of test and calibration items												
Assuring the quality of test and calibration results												
Reporting the results												

ANNEX II

AUDIT REPORT No.: _____

PART A :
Aspects subject to Audit :

Details of activities, documents, methods, procedures, records, results and reports examined during audit (may refer to checklist) :

Audit Officer _____ Date _____

Audit Officer's Report
*Non-Compliances / Observations :-
*NONE / As below / See attached pages numbered _____ to _____
Recommendations :-

Signed _____ Date _____

Cause analysis
The cause(s) of the problem are:

Signed _____ Date _____

PART B : (Prepared by Quality Manager)
Agreed Corrective Action, timescale & Responsibility

Signed _____ Date _____

Audit Officer's follow up :-
Corrective Action taken : *Yes/No/In part only
Corrective Action has been : *Effective/Ineffective/Too soon to tell#

Signed _____ Date _____

PART C : (Verified by Quality Manager)
Audit report seen and closed out
Discussion for preventive action : *Yes/No

Signed _____ Date _____

*Delete as appropriate # Set a date for re-auditing if this is the case

ANNEX III

AUDIT SUMMARY

Aspect subject to Audit _____

Date of Audit _____

Audit Report Nos.	Satisfactory/Non-Compliance	Remarks

Signed _____ Date _____
Quality Manager

Signed _____ Date _____
Chief Executive

ANNEX IV

MANAGEMENT REVIEWS

Monday 3 June 2002
in Conference Room

A G E N D A

1. Chief Executive's introduction
2. Matters arising from previous review
3. HOKLAS assessment findings
4. Internal audit and client audit findings
5. Reports from supervisory and managerial staff
6. Quality Manual
7. Review of verification checks and proficiency tests
8. Customer feedback and complaints
9. Training for Junior Technicians
10. Policy on in-house calibrations
11. Forward plan and costings
12. Any other business

ATTENDEES :
(as appropriate to size of laboratory)

Chief Executive
Financial Executive
Technical Director
Head of Laboratory
Technical Managers
Quality Manager
Section Heads
Meeting Secretary