



# Standards for EQA Schemes in Laboratory Medicine

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## **0 Introduction**

### **0.1 General**

Since the implementation in January 1996 of its accreditation of providers of External Quality Assessment (EQA) CPA (UK) Ltd has, with some modifications, used standards based on the then current ISO 9001 Standard for quality management and the draft (at the time) of ISO 43 (Proficiency testing by Interlaboratory Comparisons). In the light of changes taking place in relevant International Standards, including the availability of the ILAC Guidelines (G-13) for the Requirements for the Competence of Providers of Proficiency Testing Schemes, these new standards (see section 4.0) have been drawn up and approved at a meeting of the CPA Board on 4 June 2003.

### **0.2 Approach**

The revision of the standards involved a number of principles.

- that a number of significant documents either published or in the process of being revised and published be adopted as source material (see section 2.0).
- that some conventions used in writing international standards<sup>1</sup> be adopted, namely that each clause (or standard in the case of CPA(UK)Ltd) shall have a title, that the use of the auxiliary verb ‘shall’ denotes a requirement and that the use of the auxiliary verb ‘should’ a recommendation
- that terms requiring definition would be defined in the terms and definitions clause (see section 3.0)

In drafting these new standards the extensive experiences gained in the practical implementation of the original CPA standards by both the EQA Scheme providers and their participant laboratories were used. These new standards are written in such a way that compliance with each standard should be unequivocally verifiable at an assessment visit.

### **0.3 Structure of the new standards**

Each individual standard (see section 4.0) has a defined structure, namely:

- a unique alphanumeric followed by a title
- a short explanatory passage (in italics) which, although not part of the standard, is intended to provide a context for the standard
- the clauses of the standard, each with a unique alphanumeric, that give the requirements of the standard
- where appropriate, explanatory notes which may contain recommendations

Where possible references are made to titled clauses of the source material (see section 2). For more detailed cross references, see ISO 9001:2000, ISO/IEC 17025:1999, ISO Guide 43-1 and 2:1997 and ILAC G13 ‘Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes.

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<sup>1</sup> Internationally the word “standard” is used to denote a normative document. Such documents are subdivided into clauses which are equivalent to standards in CPA (UK)Ltd usage

## **1 Scope and purpose**

This document specifies the requirements for the management of an EQA Scheme in Laboratory Medicine. It covers the organisation and quality management, the resources, and the evaluation and quality assurance activities required to ensure that EQA activities are conducted in such a manner that they meet the needs of the participants. It is intended that compliance with these new CPA standards would signify an ability of an EQA Provider, by appropriate accreditation procedures, to be found compliant with the International Standards and Guidelines referenced in the next section. It is recognised that in some areas of laboratory medicine, notably those involving tissue- and cell-based assessments, the EQA Scheme may be relatively small and due regard should be paid to this when the standards are applied.

## **2 References**

The following references are the source material used in the writing of these standards.

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

ISO 9000:2000 Quality management systems-Fundamentals and vocabulary

ISO 9001:2000 Quality management systems-Requirements

ISO Guide 43-1: 1997(E) Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing Schemes.

ISO Guide 43-2: 1997(E) Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing Schemes by laboratory accreditation bodies.

ILAC-G13-2000: Guidelines for the requirements for the competence of providers of proficiency testing Schemes.

PrEN14136 Use of external quality assessment Schemes in the assessment of the performance of in vitro diagnostic examination procedures.

## **3 Terms and definitions**

For purposes of this document the following terms and definitions apply. If a term and its definition is given in a source material reference (see 2), this is acknowledged in square brackets following the definition.

### **3.1 accreditation**

procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

### **3.2 annual joint review**

annual review of employee/employer requirements, undertaken to establish mutually acceptable objectives for a defined period of time

### **3.3 audit**

systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled [ISO 9000:2000]

**3.4 corrective action**

action taken to eliminate the cause of a detected nonconformity or other undesirable situation

**NOTE**

Corrective action is taken to prevent reoccurrence whereas preventive action is taken to prevent occurrence  
[ISO 9000:2000]

**3.5 effectiveness**

measure of the extent to which planned activities are realised and planned results achieved

[ISO 9000:2000]

**3.6 efficiency**

relationship between the result achieved and the resources used [ISO 9000:2000]

**3.7 external quality assessment (EQA) (in laboratory medicine)**

assessment by an external agency of the quality of performance (of a medical laboratory)

**NOTES**

1. This term is equivalent to and cannot be distinguished from 'Proficiency Testing' used by other organisations.

2. This assessment is not limited to analytical performance in individual laboratories: it may also include interpretation of test results, quality of advice given to clinicians, diagnosis and the evaluation of methods.

**3.8 EQA Scheme**

the design, operation and management of an EQA activity in laboratory medicine

**3.9 EQA Scheme management**

those persons, headed by the EQA Scheme organiser, who manage EQA Scheme(s)

**3.10 EQA Scheme organiser**

an individual responsible for the direction of EQA Scheme(s)

**3.11 EQA Scheme provider**

an organisation that provides EQA Scheme(s)

**3.12 EQA Scheme Steering Committee**

a group of appropriate experts and clinical advisers that guides and steers the overall operation of EQA Scheme(s)

**3.13 materials**

consumables, calibrators, reagents, calibration material used in the operation of EQA Scheme(s)

**3.14 nonconformity**

nonfulfilment of a requirement [ISO 9000:2000]

**3.15 organisation**

group of people and facilities with an orderly arrangement of responsibilities, authorities and relationships [ISO 9000:2000]

**3.16 organisational structure**

orderly arrangement of responsibilities, authorities and relationships between people [ISO 9000:2000]

### **3.17 participant**

a laboratory or individual pathologist or scientist providing a clinical service participating in EQA Scheme(s)

**NOTE**

Participant in EQA has the same meaning as ‘user’ in laboratory accreditation

### **3.18 premises**

physical environment in which an organisation carries out particular functions

### **3.19 preventive action**

action taken to eliminate cause of a potential nonconformity or other potentially undesirable situation

**NOTE**

Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent reoccurrence  
[ISO 9000:2000]

### **3.20 procedure**

specified way to carry out an activity or process [ISO 9000:2000]

**NOTE**

When the term ‘procedure’ is used in this document a written procedure is required which is subject to document control, regular review and revision.

### **3.21 proficiency testing**

*see* External Quality Assessment (3.8)

### **3.22 quality improvement**

part of a quality management system focused on continually increasing effectiveness and efficiency

**NOTE**

the term ‘continual quality improvement’ is used when quality improvement is progressive and the organisation actively seeks and pursues improvement opportunities [ISO 9000:2000]

### **3.23 quality management system**

system to establish a quality policy and quality objectives and to achieve those objectives  
[ISO 9000:2000]

### **3.24 quality manual**

document describing the quality management system of an organisation [ISO 9000:2000]

**NOTE**

quality manuals may vary in detail and format to suit the size and complexity of an individual organisation

### **3.25 quality objective**

something sought, or aimed for, related to quality

**NOTE**

Quality objectives should be based on the organisation’s quality policy [ISO 9000:2000]

### **3.26 quality policy**

overall intentions and direction of an organisation related to the fulfilment of quality requirements

**NOTE**

the quality policy should be consistent with the overall policy of the organisation and should provide a framework for the setting of quality objectives [ISO 9000:2000]

**3.27 record**

document stating results achieved or providing evidence of activities performed [ISO 9000:2000]

**3.28 requirement**

need or expectation that is stated, customarily implied or obligatory [ISO 9000:2000]

**3.29 review**

activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives [ISO 9000:2000]

**3.30 revision**

introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness and efficiency to achieve established objectives

**3.31 validation**

confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000:2000]

**3.32 work environment**

set of conditions under which a person operates [ISO 9000:2000]

## 4 The standards

The standards are presented in eight sections:

- A Organisation and quality management system
- B Personnel
- C Premises and environment
- D Equipment, information systems and materials
- E Organisation and design of the EQA Scheme
- F Operation of the EQA Scheme
- G Communication with participants
- H Evaluation and improvement

There is a distinct relationship between these sections. Section A describes the organisation of an EQA Scheme and its quality management system which uses resources (Sections B, C and D) to undertake the organisation, design and operation of the EQA Scheme and communication with the participants (Sections E, F and G). The quality management system and the organisation, design and operation of the EQA Scheme including communication with the participants are continually evaluated and improved (Section H). The results from the continual evaluation activities feed back to maintain and, where required, improve the quality management process to ensure that the needs of participants are met.

## A ORGANISATION AND QUALITY MANAGEMENT SYSTEM

### A1 Organisation and management

*EQA Scheme management demonstrates its commitment to fulfilling the needs of its participants by clearly defining the way in which the Scheme is organised and managed*

- A1.1** The EQA Scheme, or the parent or host organisation of which it is a part, shall be an entity that is legally identifiable.
- A1.2** There shall be evidence of a contractual relation with any parent or host organisation. [NOTE 1]
- A1.3** The EQA Scheme shall be organised and operate in conformity with CPA's "Standards for EQA Schemes in Laboratory Medicine".
- A1.4** The EQA Scheme shall have:
- personnel with the authority, training and resources to carry out their duties
  - arrangements that ensure the protection of its participants' confidential information
  - arrangements to ensure that management and personnel are free from any commercial, financial and other internal and external pressures that may adversely affect the quality of their work
  - policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity.
- A1.5** EQA Scheme management shall, with the aid of organisational charts:
- define the organisation and management of the EQA Scheme and its place in a parent organisation
  - specify the responsibility, authority and interrelationships of all personnel.
- A1.6** EQA Scheme management shall have regular meetings at which records shall be kept and agreed action points noted with an appropriate and agreed timescale.

#### NOTES

- 1 In the UK there shall be a contract between an NHS host organisation and an EQA Scheme housed within it.

#### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.1 Organisation
- **ISO 9001:2000** 5.1 Management commitment
- **ILAC-G13:2000** 2.2.1 / 2.2.2

## **A2 Needs of participants**

*It is an essential prerequisite of an EQA Scheme that the organisation and management relates to the attainable needs of its participants.*

- A2.1** The EQA Scheme shall determine the needs with participants (E1) and specify them as objectives. [NOTE 1]
- A2.2** The needs of participants shall be regularly reviewed (see H1). [NOTE 1]
- A2.3** The EQA Scheme shall demonstrate its commitment to participants by:
- a) establishing a quality policy (A3)
  - b) establishing a quality management system (A4)
  - c) performing management reviews (A11)
  - d) ensuring the availability of necessary resources (Standards in B, C and D).

### NOTES

- 1 These needs should be determined and reviewed with the help and support of the EQA Scheme Steering Committee.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.7 Service to the client
- **ISO 9001:2000** 5.2 Customer focus
- **ILAC-G13:2000** 3.7.4

### A3 Quality policy

*A quality policy provides the basis for running an EQA Scheme in a manner that will fulfil the needs of its participants.*

**A3.1** EQA Scheme management shall establish a quality policy [NOTE 1] that includes the following:

- a) a statement of the intention with respect to the standard of services, including a commitment to meet the needs of participants
- b) a statement of the purpose of the quality management system (A4) including quality objectives (A4.3) and procedures to achieve continual quality improvement (H5)
- c) a requirement that personnel are familiar with the contents of the quality manual and all procedures relevant to their work
- d) a commitment to good professional practice
- e) a commitment to the health, safety and welfare of all staff and visitors
- f) a commitment to comply with relevant environmental legislation
- g) a commitment to continuing compliance with CPA (EQA) standards.

**A3.2** EQA Scheme management shall ensure that the quality policy is:

- a) signed and issued by a person with appropriate authority
- b) communicated, understood, available and implemented
- c) reviewed for suitability and effectiveness at the annual management review (A11).

#### NOTES

- 1 Where the EQA Scheme is part of a larger organisation its quality policy should be consistent with other policies in the organisation.

#### CROSS REFERENCES

- |                             |       |                |
|-----------------------------|-------|----------------|
| • <b>ISO/IEC 17025:1999</b> | 4.2   | Quality system |
| • <b>ISO 9001:2000</b>      | 5.3   | Quality policy |
| • <b>ILAC-G13:2000</b>      | 2.1.2 |                |

## A4 Quality management system

*A quality management system provides the integration of organisational structure, procedures, processes and resources needed to fulfil a quality policy and thus meet the needs of participants*

- A4.1** EQA Scheme management shall establish a quality management system.
- A4.2** Roles, responsibilities and authority of all personnel shall be defined to ensure the establishment, implementation and maintenance of the quality management system.
- A4.3** EQA Scheme management shall be responsible for:
- a) preparing a quality manual (A6)
  - b) appointing a quality manager (however named) (A7)
  - c) establishing a procedure for document control (A8)
  - d) establishing a procedure for control of technical and quality records (A9)
  - e) conducting a management review (A11)
  - f) control of clinical and other test material (F1).

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.2 Quality system
- **ISO 9001:2000** 5.5 Administration (of a quality system)
- **ILAC-G13:2000** 2.1.1 / 2.1.2

## A5 Quality objectives and plans

*Implementation of a quality policy requires the establishment of quality objectives and plans.*

**A5.1** EQA Scheme management shall establish written quality objectives which shall be consistent with the quality policy and regularly reviewed (A3).

**A5.2** EQA Scheme management shall have plans to achieve and maintain its quality objectives.

### CROSS REFERENCES

- **ISO/IEC 17025:1999**            4.2        Quality system
- **ISO 9001:2000**             5.4.1      Quality objectives
- 5.4.2      Quality planning

## **A6 Quality manual**

*A quality manual describes the quality management system and includes the quality policy and arrangements for its implementation.*

**A6.1** EQA Scheme management shall be responsible for the preparation of a quality manual.

**A6.2** The quality manual shall include:

- a) the quality policy
- b) a description of the quality management system
- c) a presentation of the organisational structure
- d) an outline of the structure of the documentation used in the quality management system [NOTE 1].

**A6.3** Personnel shall be familiar with and work to current versions of the quality manual and all referenced documentation.

**A6.4** The quality manual shall be reviewed regularly, updated as required and any changes communicated to all personnel concerned.

### NOTES

- 1 The outline should refer to procedures for the management of resources (sections B, C and D), EQA Scheme design, organisation and operation (sections E, F and G) and the evaluation and improvement processes (H).

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.2 Quality system
- **ISO 9001:2000** 5.5.5 Quality manual
- **ILAC-G13:2000** 2.1.3 / 2.1.4

## A7 Quality manager

*The quality manager is the individual who ensures that the quality management system functions correctly.*

- A7.1** EQA Scheme management, or management of the parent organisation, shall appoint a quality manager [NOTE 1].
- A7.2** The quality manager's reporting arrangements to the EQA Scheme organiser shall be agreed.
- A 7.3** The quality manager, irrespective of other responsibilities [NOTE 2], shall have defined authority for:
- ensuring the quality management system is implemented and maintained
  - reporting on the functioning and effectiveness of the quality management system
  - coordinating awareness of the needs of participants.

### NOTES

- The quality manager should have responsibility for the implementation and maintenance of the quality management system but not for undertaking all the tasks involved. The term quality manager is equivalent to 'management representative' as used by ISO.
- The quality manager may be engaged full time or part time on quality management. They may or may not have other responsibilities in the parent organisation or the EQA Scheme itself but should not be the EQA Scheme organiser.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.1 Organisation and management
- **ISO 9001:2000** 5.5.3 Management representative
- **ILAC-G13:2000** 2.1.5

## A8 Document control

*Document control is an essential part of a quality management system.*

- A8.1** EQA Scheme management shall establish a procedure to control all documents (internally generated and from external sources) [NOTE 1] required for the quality management system. This procedure shall ensure that:
- a) documents are approved for use by authorised personnel prior to issue
  - b) documents contain a unique identifier; a review date or date of issue, revision version, the total number of pages and the name of the authoriser
  - c) there is a readily accessible master list or equivalent document control procedure. This identifies the current revision status and distribution of documents in order to prevent the use of invalid and/or obsolete documents
  - d) documents shall be legible, readily identifiable and retrievable
  - e) documents shall be regularly reviewed and updated as required.
- A8.2** Only current versions of documents shall be available at the appropriate locations.
- A8.3** EQA Scheme management shall determine, with regard to current legislation, regulations and guidelines, the appropriate retention times for documents removed from current use.

### NOTES

- 1 Documents may be on various media, whether hard copy or electronic and may be digital, analog, photographic or written.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.3 Document control
- **ISO 9001:2000** 5.5.6 Control of documents
- **ILAC-G13:2000** 2.3.1 / 2.3.2

## A9 Control of technical and quality records

*The control of technical and quality records is an essential part of a quality management system.*

- A9.1** EQA Scheme management shall establish a procedure(s) for controlling technical records [NOTE 1] and quality records [NOTE 2] that includes:
- identification and indexing
  - security
  - retention
  - storage and retrieval
  - disposal.
- A9.2** EQA Scheme management shall determine which technical and quality records (including those of external origin) [NOTE 3] are to be retained and for how long. Notice shall be taken of relevant current legislation, regulations and guidelines.
- A9.3** Quality records shall be readily available to demonstrate compliance with the requirements and operation of the quality management system (section H).
- A9.4** Technical records shall be readily available in order to reconstruct an audit trail in response to problems and the need for corrective action.

### NOTES

- 1 Technical records should include records made during the overall operation of the EQA Scheme (sections E, F, and G) and include internal quality control records.
- 2 Quality records should include records made during quality evaluation procedures (section H)
- 3 Records of external origin should include accreditation visit reports, health and safety reports.

### CROSS REFERENCES

- |                             |                 |                            |
|-----------------------------|-----------------|----------------------------|
| • <b>ISO/IEC 17025:1999</b> | 4.12            | Control of records         |
| • <b>ISO 9001:2000</b>      | 5.5.7           | Control of quality records |
| • <b>ILAC-G13:2000</b>      | 2.11.1 / 2.11.2 |                            |

## A10 Control of clinical material

*The control of clinical material is an essential part of a quality management system.*

**A10.1** EQA Scheme management shall establish a procedure(s) for controlling clinical material that includes:

- a) identification and indexing
- b) security
- c) retention
- d) storage and retrieval
- e) disposal.

**A10.2** EQA Scheme management shall determine the clinical material to be retained and for how long. Notice shall be taken of current legislation, regulations and guidelines.

**A10.3** Retained clinical material shall be stored in a way that ensures the validity of a repeat examination.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** -
- **ISO 9001:2000** -

## **A11 Management review**

*A review of the quality management system serves to identify any changes required, to meet the needs of participants, and any action needed to ensure the continuation of the service*

**A11.1** EQA Scheme management shall conduct an annual review of the quality management system and all its services [NOTE 1]. The review shall include:

- a) reports from managerial and supervisory personnel
- b) assessment of participant satisfaction and complaints (H2)
- c) internal audit of quality management system (H3)
- d) internal audit of EQA Scheme operation (H4)
- e) reports of assessments by outside bodies
- f) status of preventive, corrective and improvement actions (H5)
- g) major changes in organisation and management, resource (including staffing) or process
- h) follow up of previous management reviews.

**A11.2** Findings of the management review and the actions to be taken shall be recorded. EQA Scheme management shall ensure that actions are discharged within an appropriate and agreed timescale.

**A11.3** The management review shall contain an executive summary, a copy of which shall be sent annually to CPA(UK) Ltd.

### NOTES

- 1 Elements of the review could be undertaken at different times in the year to lessen the impact on the service and allow more detailed audit.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.14 Management reviews
- **ISO 9001:2000** 5.6 Management review
- **ILAC-G13:2000** 2..1.3

## B PERSONNEL

### B1 Professional direction

*Professional direction is essential for the proper performance of an EQA Scheme in laboratory medicine .*

**B1.1** The EQA Scheme shall be directed by an organiser with appropriate scientific training and experience in the field of operation. [NOTE 1]

#### NOTES

1 In some circumstances there may be joint organisers or an organiser working closely with an external adviser.

#### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.2 Personnel
- **ISO 9001:2000** 6.2 Human resources
- **ISO 43:1** 5.1.1 / 5.1.2
- **ILAC-G13:2000** 3.1.1 / 3.1.2

## B2 Staffing

*The staff are the single most important asset*

- B2.1** EQA Scheme management shall ensure that there are appropriate numbers of staff, with the required education and training, to meet the demands of the service and appropriate legislation and regulations.
- B2.2** Registration of staff shall be in accordance with national legislation and regulations.
- B2.3** EQA Scheme management staffing shall have access to individual(s) [NOTE 1] with the following roles:
- a) quality manager (A6)
  - b) health and safety officer (C4)
  - c) training officer.

### NOTES

- 1 These individuals may be engaged full time or part time with regard to these specific responsibilities and may or may not have other responsibilities in the parent organisation or the EQA Scheme itself

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.1 Organisation and management  
5.2 Personnel
- **ISO 9001:2000** 5.5.3 Management representative  
6.2 Human resources
- **ISO 43:1** 5.2.1
- **ILAC-G13:2000** 3.1.2 - 3.1.5

### B3 Personnel management

*Personnel management ensures that staff contribute fully and effectively to the service, while receiving fair and consistent treatment*

**B3.1** EQA Scheme management shall ensure that the procedure(s) [NOTE 1] for personnel management include:

- a) staff recruitment and selection
- b) staff orientation and induction (B4)
- c) job descriptions and contracts (B5)
- d) staff records (B6)
- e) staff annual joint review (B7)
- f) staff meetings and communication (B8)
- g) staff training and education (B9)
- h) grievance procedures and staff disciplinary action.

#### NOTES

- 1 If the EQA Scheme is part of a parent organisation, reference shall be made in the procedure for personnel management to those procedures undertaken by management in the parent organisation (in some instances these may be outside the control of EQA Scheme management).

#### CROSS REFERENCES

- **ISO/IEC 17025:1999**            5.2    Personnel
- **ISO 9001(2000)**            6.2    Human resources

## B4 Staff orientation and induction

*A comprehensive orientation and induction programme is an important element in the introduction of new members of staff*

**B4.1** EQA Scheme management shall ensure that all staff participate in a staff induction programme [NOTE 1] that includes information on:

- a) the EQA Scheme and, if applicable, its parent organisation
- b) terms and conditions of employment
- c) confidentiality and data protection
- d) health and safety
- e) occupational health services
- f) job description including an organisational chart
- g) staff facilities.

**B4.2** A record shall be kept of participation in the induction programme.

### NOTES

- 1 This standard should also apply to temporary and agency staff .

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.2 Personnel
- **ISO 9001:2000** 6.2.2 Training, awareness and competency

## B5 Job descriptions and contracts

*Written job descriptions and contracts enable staff to know their duties, responsibilities and rights*

**B5.1** All staff shall have contracts of employment which are in compliance with national legislation and provide clear terms and conditions of service [NOTE 1].

**B5.2** All staff shall have job descriptions that include:

- a) a job title
- b) the location within the organisation
- c) accountability
- d) the main purpose of the job
- e) the main duties and responsibilities
- f) a reference to the staff annual joint review (see B7).

### NOTES

- 1 This should specify employment on EQA Scheme activities even when this is only a small portion of the contract within the parent organisation.

### CROSS REFERENCES

- ISO 9001:2000                      5.2      Personnel

## B6 Staff records

*Maintenance of accurate staff records is an essential part of personnel management.*

**B6.1** EQA Scheme management shall ensure confidentiality of staff records in accordance with local guidelines and national legislation.

**B6.2** Staff records [NOTES 1 and 2] shall include:

- a) personal details
- b) employment details
- c) job description
- d) terms and conditions of employment
- e) a record of staff induction and orientation
- f) a record of attendance at fire lectures
- g) evidence of training including continuing professional development
- h) relevant educational and professional qualifications
- i) certificate of registration, if relevant
- j) absence record
- k) accident record
- l) a record of staff annual joint reviews
- m) occupational health record
- n) record of disciplinary action.

### NOTES

- 1 If the EQA Scheme is part of a larger organisation staff records may be held by the parent organisation but should be available for inspection on an accreditation visit if requested.
- 2 With respect to most of the items in B6.2 (especially j, k, l, m, n) the inspectors should only seek assurance that they exist as they are either the individual's property or are confidential.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.2 Personnel
- **ILAC-G13:2000** 3.1.7

## B7 Staff annual joint review

*Achievement of EQA Scheme and personal objectives is facilitated by regular staff appraisal.*

**B7.1** EQA Scheme management shall ensure that all staff shall participate in an annual joint review [NOTE 1] that includes consideration of:

- a) stated quality objectives and plans of the EQA Scheme (A5)
- b) job description of the staff member
- c) personal objectives of the staff member
- d) training and development of the staff member.

**B7.2** All staff performing annual joint reviews shall have received training and those staff participating shall have had a full explanation of the process. [NOTE 2]

**B7.3** Records shall be kept of all staff reviews (B6).

### NOTES

- 1 The terms 'annual joint review' and 'annual appraisal' are both used in laboratory medicine and considered to be equivalent.
- 2 Attendance at both training and annual joint review itself should be documented.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.2 Personnel
- **ISO 9001:2000** 6.2.2 Training, awareness and competency

## B8 Staff meetings

*Regular staff meetings are a mechanism for maintaining good communications and disseminating information on all aspects of the service*

**B8.1** There shall be regular meetings open to all staff in order to provide the opportunity for exchange of information.

**B8.2** Records shall be kept and made available to staff and actions audited.

### CROSS REFERENCES

- **ISO 9001:2000** 5.5.4 Internal communication

## B9 Staff training and education

*Access to continuing education and training is important for all grades of staff and participation in Continuing Professional Development Schemes is a method of achieving this.*

- B9.1** There shall be a training and education programme for all members of staff governed by the following criteria:
- a) all staff shall be given the opportunity for further education and training in relation to the needs of the service and their professional development.
  - b) training and education shall be in accordance with any relevant guidelines from the relevant professional and registration bodies
- B9.2** All trainee staff shall have a designated supervisor.
- B9.3** There shall be access to the resources for training and education, that includes:
- a) access to reference material and information services
  - b) access to a conveniently situated quiet room for private study
  - c) staff attendance at meetings and conferences
  - d) financial support.
- B9.4** Records shall be kept of all training and education (B6).

### CROSS REFERENCES

- **ISO/IEC 17025:1999**            5.2      Personnel
- **ISO 9001:2000**                6.2.2    Training, awareness and competency
- **ILAC-G13:2000**               3.1.6 / 3.1.7

## C PREMISES AND ENVIRONMENT

### C1 Premises and environment

*There must be sufficient space to ensure that work is performed safely and efficiently.*

- C1.1** The premises shall provide a working environment in which staff can perform required functions in accordance with relevant legislation and guidelines.
- C1.2** The premises shall have space for the following:
- the functioning and use of all equipment
  - separation of incompatible activities [NOTE 1] (see F standards)
  - facilities for staff (C2)
  - facilities for storage (C3).
  - facilities for sample packaging and distribution (E4 and F2).
- C1.3** Access to the premises shall be restricted to authorised personnel. [NOTE 2]
- C1.4** Communication systems shall meet the needs and requirements of participants.

#### NOTES

- This includes separation of office from laboratory space
- Safety and confidentiality are the issues here.

#### CROSS REFERENCES

- |                             |     |  |
|-----------------------------|-----|--|
| • <b>ISO/IEC 17025:1999</b> | 5.3 | Accommodation and environmental conditions |
| • <b>ISO 9001:2000</b>      | 6.3 | Facilities                                 |
|                             | 6.4 | Work environment                           |

## C2 Facilities for staff

*All staff need facilities to ensure personal safety, comfort and hygiene.*

**C2.1** The premises shall have staff facilities that are readily accessible and include:

- a) safe and secure working arrangements
- b) sufficient toilet accommodation
- c) shower facilities where required
- d) a rest area
- e) access to a supply of drinking water
- f) secure storage for personal effects
- g) storage for protective clothing.

### CROSS REFERENCES

- **ISO/IEC 17025:1999**            5.3      Accommodation and environmental conditions
- **ISO 9001:2000**                6.3      Facilities

### C3 Facilities for storage

*The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples, reagents and records.*

**C3.1** There shall be separate storage facilities, as required, for:

- a) technical and quality records (A8)
- b) raw materials, materials in process and finished materials for distribution
- c) hazardous substances (C4)
- d) reagents (D3).
- e) Waste material for disposal

**C3.2** The storage facilities shall be in accordance with all relevant legislation, regulations and guidelines.

#### CROSS REFERENCES

- **ISO/IEC 17025:1999**            5.3      Accommodation and environmental conditions
- **ISO 9001:2000**                6.3      Facilities

## **C4 Health and safety**

*A health and safety statement and procedures to implement it are required to ensure a safe environment*

- C4.1** EQA Scheme management shall be responsible for:
- defining and implementing health and safety procedures
  - ensuring that there is a safe working environment in accordance with current safety guidelines and legislation
  - providing personal protective equipment
  - delegating day to day management of health and safety to the appointed health and safety officer (B2)
  - providing model rules for staff and visitors to the EQA Scheme facilities
  - where applicable, nominating a consultant microbiologist responsible for infection control.
- C4.2** All staff shall be aware of their responsibilities relating to health and safety.
- C4.3** EQA Scheme management shall establish a health and safety procedure(s) [NOTE 1] that includes:
- action in the event of fire
  - action in the event of a major spillage of dangerous chemicals or clinical material
  - action in the event of inoculation accident
  - reporting and monitoring of accidents and incidents
  - risk assessments including COSHH or equivalent
  - disinfection processes
  - decontamination of equipment (D1)
  - chemical handling (D3)
  - storage and disposal of waste
  - procedures for handling, transportation and referral of materials to participants.
- C4.4** Containment facilities shall conform to the requirements of the guidelines as appropriate to the materials being handled and the manipulations being performed.
- C4.5** There shall be sufficient safety notices that staff are aware of the risks and safe practice required.
- C4.6** Work areas shall be clean, uncluttered and well maintained and there shall be evidence of good housekeeping procedures.

### NOTES

- This procedure(s) may be in the form of a Health and Safety Handbook readily available to staff.
- The health and safety officer (B2.3) may be engaged full time or part time on health and safety and may or may not have other responsibilities in the parent organisation or the EQA Scheme itself .

### CROSS REFERENCES

- |                             |     |  |
|-----------------------------|-----|--|
| • <b>ISO/IEC 17025:1999</b> | 5.3 | Accommodation and environmental conditions |
| • <b>ISO 9001:2000</b>      | 6.3 | Facilities                                 |
|                             | 6.4 | Work environment                           |

## D EQUIPMENT, INFORMATION SYSTEMS AND MATERIALS

### D1 Procurement and management of equipment

*The proper procurement and management of equipment ensures that the needs of participants can be met.*

- D1.1** EQA Scheme management shall ensure that the equipment is [are] sufficient and appropriate to provide the service.
- D1.2** EQA Scheme management shall establish and document a procedure for the procurement and management of equipment that includes:
- assessment and justification of need
  - selection
  - acceptance
  - training
  - maintenance, service and repair
  - decontamination
  - record of instrument failure and subsequent corrective action
  - planned replacement and disposal
  - adverse incident and vigilance reporting.
- D1.3** There shall be an inventory of equipment that includes:
- name of manufacturer
  - serial number
  - date of purchase or acquisition
  - record of contracted maintenance
  - record of equipment breakdowns.

#### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.5 Equipment
- **ISO 9001:2000** 6.3 Facilities
- **ILAC-G13:2000** 3.3.2.1 (e)

## D2 Management of data and information

*The proper management of data and information is essential.*

- D2.1** EQA Scheme management shall ensure the availability of data and information required to provide a service that meets the needs of participants.
- D2.2** EQA Scheme management shall establish a procedure(s) for the management of data and information, that includes:
- a) security
  - b) access
  - c) confidentiality and data protection
  - d) backup systems
  - e) storage, archive and retrieval
  - f) secure disposal.
- D2.3** EQA Scheme management shall ensure compliance with relevant legislation and regulations in relation to data protection.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 5.5 Equipment
- **ISO 9001:2000** 6.2 Facilities
- **ISO 43:1** 5.3
- **ILAC-G13:2000** 2.11.1.4

### D3 Management of materials

*It is essential to have proper management of all materials.*

- D3.1** EQA Scheme management shall ensure the availability of all materials (including calibration material) required to provide a service [NOTE 1].
- D3.2** EQA Scheme management shall establish a procedure(s) for the management of materials [NOTE 1] that includes:
- a) selection, purchasing and ordering
  - b) assessment of suppliers
  - c) receipt and verification of identity and condition
  - d) issue and inventory management
  - e) risk assessment through classification of hazard and exposure potential and assignment of handling precautions when appropriate
  - f) safe disposal.
- D3.3** Materials [NOTE 1] shall be correctly identified with the date of receipt, lot numbers, first use and expiry.

#### NOTES

- 1 This standard should cover any material, whether in use or not, within the EQA Scheme responsibility; this standard may have little or no relevance for some EQA Schemes

#### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.6 Purchasing supplies and services
- **ISO 9001:2000** 7.4 Purchasing

## **E ORGANISATION AND DESIGN OF EQA SCHEME**

### **E1 Organisation, scope and strategy**

*The EQA Scheme is planned, designed and run to meet clear objectives to assess and maintain an acceptable level of service in medical laboratories*

**E1.1** There shall be a document describing the EQA Scheme.

**E1.2** This document shall include:

- a) aims and objectives of the EQA Scheme(s)
- b) details of EQA Scheme and senior staff (A1.4)
- c) the repertoire of EQA services provided
- d) performance criteria (E5)
- e) complaints procedure (G2)
- f) procedures for appraisal and improvement of the service. (H standards)

#### CROSS REFERENCES

- **ISO 43:1** 5 Organisation and design  
5.1.2 abc
- **ILAC-G13:2000** 3.3.1.1

## **E2 External professional advice**

*It is essential that the EQA Scheme has procedures for regular external review of the service provided and its objectives.*

- E2.1** There shall be a formally constituted EQA Scheme Steering Committee to advise the EQA Scheme Organiser [NOTES 1 and 2].
- E2.2** The EQA Scheme Steering Committee shall include relevant experts and members representing participants' interests.
- E2.3** There shall be formal arrangements for communication with the appropriate National Quality Assurance Advisory Panel [NOTE 3] for Schemes providing a service to UK participants [NOTE 4].
- E2.4** The EQA Scheme Steering Committee shall approve changes in EQA scheme design, including the introduction of new services and cessation of existing services.

### NOTES

- 1 In most areas of EQA provision, external advice is provided by a group called a 'Steering Committee'. Alternative names are acceptable provided the function is fulfilled. This may be supplemented by, or undertaken by, participant meetings provided these are representative (G1).
- 2 The Royal College of Pathologists (UK) has established a national steering committee for histopathology which serves different functions. This does not replace the need for a Steering Committee for each EQA Scheme.
- 3 Where possible this should include a NQAA Panel representative having observer status at meetings.
- 4 For EQA Schemes operating outside the UK, without UK participants, performance oversight arrangements similar to those provided by the UK Panels would be expected to operate.

### CROSS REFERENCES

- **ISO 43:1** 5.1.1 / 5.1.20 / 5.2.2 / 5.2.3
- **ILAC-G13:2000** 3.3.1.2 / 3.3.1.3

### **E3 Extent of participation**

*The geographical distribution and numbers of participants should be such as to maximise the effectiveness of the EQA Scheme.*

- E3.1** Participation in an EQA Scheme shall be available to all medical laboratories in the relevant geographical area [NOTE 1].
- E3.2** Participation shall also be open to other laboratories including research, veterinary and non-UK laboratories if the nature of the EQA Scheme so permits.
- E3.3** There shall be sufficient numbers of participants to ensure meaningful evaluations of performance (E4).
- E3.4** Arrangements for participation, including confidentiality, shall be described in a participants manual (G1).

#### NOTES

- 1 This may be UK-wide or restricted to specific parts of the UK depending on the basis of the Scheme organisation, strategy and/or funding and the nature of the EQA material. Analogous considerations apply to non-UK Schemes.

#### CROSS REFERENCES

- **ISO 43:1** 5.1.2 (d,e) / 5.4.2 (c) / 5.7.3 / 7.1
- **ILAC-G13:2000** 3.8.1 / 3.8.2

## **E4 EQA Scheme design: sample distribution and analysis of results**

*The nature and numbers of samples distributed and a valid design and analysis of the results are key features of an effective EQA Scheme.*

- E4.1** The nature of samples distributed shall reflect the clinical service delivered by the participants [NOTE 1].
- E4.2** The numbers and frequency of samples distributed shall be sufficient to contribute to an effective assessment of the service provided by the participant .
- E4.3** There shall be evidence for the validity [NOTE 2] of the EQA Scheme design and evaluation of performance including:
- a) a clear description of methods for assigning values to EQA materials
  - b) procedures used for calculating the dispersal of results among participants and for identifying outliers
  - c) evidence for differences in performance between groups of participants
  - d) evidence of NQAA Panel approval (E2, E5).

### NOTES

- 1 The EQA samples may consist of clinical specimens, electronic digitised images, reports for interpretation or other relevant items.
- 2 It is recognised that in some EQA schemes in laboratory medicine a numerical analysis and statistical validity are not possible.

### CROSS REFERENCES

- **ISO 43:1** 5.1.2 (f, g, j) / 5.4
- **ILAC-G13:2000** 3.3.4.2

## E5 Assessment and evaluation of performance

*An assessment and evaluation of performance is a key educational function of EQA Schemes.*

- E5.1** There shall be documented defined participation criteria and performance criteria, qualitative and/or quantitative, for each examination included in the Scheme.
- E5.2** These performance criteria shall be approved by the relevant National Quality Assurance Advisory Panel or equivalent body based on advice from the appropriate EQA Scheme Steering Committee (see E2).
- E5.3** There shall be written definitions of acceptable performance and the procedures to be followed when this is not met:
- a) with respect to an individual participant
  - b) in informing the relevant NQAA Panel or equivalent body
  - c) in consultation with manufacturers of relevant diagnostic materials.
- E5.4** All actions taken in relation to performance shall be recorded.

### CROSS REFERENCES

- **ISO 43:1** 5.1.2 (n), 6.5, 2, 6.6
- **ISO 43:2**
- **ILAC-G13:2000** 3.6.2

## E6 Sub-contractors and collaborators

*If any element of the EQA Scheme (for example, manufacture of samples, packaging and distribution, statistical analysis of results) is contracted out, it is important to ensure that it is controlled so as not to compromise the effectiveness of the service.*

**E6.1** There shall be written procedures for the initiation and review of sub-contracted elements in an EQA Scheme including:

- a) evidence of a contractual arrangement
- b) specification for EQA materials, samples or services
- c) documented procedures for testing sub-contracted products and storage of batch data
- d) procedures for regular review of the performance of the sub-contractor or collaborator [NOTE 1].

### NOTES

- 1 Where material(s) is provided by a participant, the provider should where possible be from an accredited source.

### CROSS REFERENCES

- **ISO 43:1** 5.5.1
- **ILAC-G13:2000** 2.4 / 2.5 / 2.6

## F OPERATION OF THE EQA SCHEME

### F1 Preparation of test items

*It is essential that the quality of the test items used in EQA Schemes in laboratory medicine is sufficient to meet the demands of the service.*

- F1.1** The EQA material shall resemble as closely as possible the relevant clinical material [NOTE 1].
- F1.2** Where the material used in EQA samples is of human (or non-human animal) origin due regard shall be paid to ethical considerations [NOTE 2].
- F1.3** The preparation and use of EQA materials shall conform to all relevant safety standards, provisions and legislation.
- F1.4** Materials at different stages of manufacture shall be kept separate.
- F1.5** There shall be written standard operating procedures for all stages of manufacture, including in- process controls and documentation of batch manufacture.
- F1.6** There shall be specifications for the uniformity, stability and shelf-life of EQA materials .

#### NOTES

- 1 Where it is not possible to use human materials the reasons for this should be explained.
- 2 Ethical considerations include anonymity of EQA material.

#### CROSS REFERENCES

- **ISO 43:1** 5.1.2 (f,g) / 5.5 / 5.6
- **ILAC-G13:2000** 3.3.2.1 – 3.3.2.3

## F2 Packaging and accompanying documentation

*The participant must receive EQA samples that are correctly and safely packaged and with clear instructions for their use and the return of results.*

**F2.1** There shall be documented procedures to ensure the integrity of batches of EQA materials including:

- a) the distribution of the correct samples
- b) sufficient material to allow the examination(s) to be undertaken
- c) unique identifier for all containers of the same sample.

**F2.2** Packaging and distribution of EQA materials shall conform to all relevant legislation and codes of practice (e.g. of the postal, air freight services).

**F2.3** There shall be a information insert to include:

- a) unique identifier(s) for the EQA sample(s)
- b) procedures for handling samples
- c) procedures for return of results
- d) where relevant, sufficient clinical information to allow an analysis of the EQA sample
- e) where relevant, procedures for onward transmission of materials [NOTE 1].

### NOTES

- 1 In some EQA Schemes, there is a slide-circulation procedure whereby samples are sent after examination from one participant to another .

### CROSS REFERENCES

- **ISO 43:1** 5.1.2 (h,i,j,k) / 6.2 / 6.3
- **ILAC-G13:2000** 3.3.3, 3.5.1

### F3 Receipt of results

*The quality and effectiveness of the service can be impaired by inadequate procedures for reception of participants' results.*

- F3.1** There shall be a documented procedure for reception of results [NOTE 1] from participants including:
- a) records of date of receipt of results
  - b) validation and checking
  - c) communications with participants prior to data analysis [NOTE 2].

- F3.2** There shall be procedures for storage and retrieval of participants' results.

#### NOTES

- 1 This includes procedures covering the receipt of results by electronic transmission.
- 2 It may be necessary to check unclear results (e.g on a faxed return) with participants though this should be an infrequent occurrence.

#### CROSS REFERENCES

- **ISO 43:1** 6.4.1
- **ILAC-G13:2000** 3.6.1.5

## F4 Data entry and statistical analysis

*The success of an EQA Scheme depends critically on a timely and accurate entry and analysis of participants' results.*

- F4.1** There shall be a documented procedure for validation of data entry prior to statistical analysis [NOTE 1].
- F4.2** There shall be a defined and documented procedure for identifying outliers, blunders (non-analytical errors) and handling of results expressed in non-standard or inconsistent units.
- F4.3** Procedures for statistical analysis shall be defined and documented.
- F4.4** Procedures for handling of results received after the “closing date” or for amended results submitted by the participant shall be defined and documented.

### NOTES

- 1 This includes procedures covering the receipt of results by electronic transmission.

### CROSS REFERENCES

- **ISO 43:1** 6.4.1 / 6.4.3 / 5.1.2 (l)
- **ILAC-G13:2000** 3.6.1 / 3.3.4

## F5 Reports to participants

*Reports to participants have a strong educational impact and should be clearly presented.*

- F5.1** Following each distribution a report shall be completed and sent to the participants. It shall include:
- a clear identification of the Scheme, distribution date and report number
  - statistical data and summaries of results of both individual participants and appropriate groupings
  - analyses of performance over time.
- F5.2** Any interpretative comments shall be clearly presented and explained.
- F5.3** Reports to participants shall be validated prior to dispatch.
- F5.4** Reports shall be sent to participants in a timely manner and the date when the report was sent shall be recorded for audit purposes.

### CROSS REFERENCES

- **ISO 43:1** 6.5.1 / 6.5.2 / 5.7.3 / 5.1.2 (m)
- **ILAC-G13:2000** 3.6 / 3.2

## G COMMUNICATION WITH PARTICIPANTS

### G1 Arrangements for participation

*It is important that participants are informed about the details of the EQA Scheme and their rights and responsibilities.*

**G1.1** There shall be a participants' manual which shall include:

- a) the terms and conditions of participation
- b) the practical details of Scheme design and procedures
- c) the mechanism for communication between EQA Scheme staff and participants [NOTES 1 and 2]
- d) the criteria for acceptable participation and performance (E5)
- e) the complaints procedure (G2)
- f) the responsibilities of the participants.

#### NOTES

- 1 Meetings with participants form a useful channel of communication.
- 2 In some EQA Schemes there is a 'distributor' between the EQA Organiser and the participants; inter-communications should be clearly defined.

#### CROSS REFERENCES

- **ISO 43:1** 6.7 / 5.7.1 / 5.7.3 / 5.2.1 (h,k)
- **ILAC-G13:2000** 3.7.1 / 3.4.1 / 3.4.2

## G2 Communication procedures and participant feedback

*Two-way communication between the EQA Scheme organisers and the participants is an essential component of efficient and effective Schemes in laboratory medicine.*

- G2.1** There shall be procedures [NOTE 1] for providing technical advice to participants [NOTE 2].
- G2.2** Communications to and from participants shall be recorded, logged and action taken documented.
- G2.3** There shall be a defined complaints procedure which is documented in the participants' manual.
- G2.4** Reports to participants shall form a regular part of the communication process (F5) [NOTE 2].

### NOTES

- 1 This could include specification of which staff are competent and eligible to provide this advice.
- 2 Meetings with participants form a useful channel of communication.

### CROSS REFERENCES

- **ISO 43:1** 6.5.2 / 6.5.3 / 5.1.2 (m)
- **ILAC-G13:2000** 3.6.3.1 – 3.6.3.3

## H EVALUATION AND IMPROVEMENT

### H1 Evaluation and improvement processes

*Ongoing evaluation and improvement processes are essential to ensure that the service provided by the EQA Scheme meets the needs of participants.*

**H1.1** EQA Scheme management shall establish a procedure(s) that includes:

- a) assessment of participant satisfaction and complaints (H2) [NOTE 1]
- b) internal audit of quality management system (H3)
- c) internal audit of the EQA Scheme operation (H4)
- d) quality improvement (H5).

**H1.2** The results of these evaluation and improvement processes shall be made available to staff, the EQA Scheme Steering Committee, and to others as required.

**H1.3** Analysis, recording and interpretation of the evaluation data shall form part of the management review (A9).

#### NOTES

- 1 A participants' meeting is a valuable forum for this.

#### CROSS REFERENCES

- |                      |            |                                       |
|----------------------|------------|---------------------------------------|
| • ISO/IEC 17025:1999 | 4          | Management requirements               |
| • ISO 9001:2000      | 8          | Measurement, analysis and improvement |
| • ISO 43:1           | 5.8        |                                       |
| • ILAC-G13:2000      | 2.7 – 2.13 |                                       |

## H2 Assessment of participant satisfaction and complaints

*The purpose of assessing participant satisfaction and monitoring complaints is to establish that the service provided meets the needs of participants.*

**H2.1** EQA Scheme management shall:

- a) establish processes for obtaining and monitoring data on participant satisfaction and complaints [NOTE 1] which shall be recorded, reviewed and acted upon
- b) ensure that performance targets are met
- c) assess the clinical relevance of the EQA Scheme design (E4) and the reliability of interpretative reports in conjunction with the advisory group and participants (F5).

### NOTES

- 1 A 'complaint' indicates that a potential deficiency in the service has been identified and requires a response. Some complaints are minor and readily addressed; others may involve significant technical and/or clinical issues.

### CROSS REFERENCES

- **ISO/IEC 17025:1999** 4.8 Complaints
- **ISO 9001:2000** 8.2.1 Customer satisfaction
- **ISO 43:1**
- **ILAC-G13:2000** 2.7 / 2.12

### H3 Internal audit of quality management system

*Internal audit provides evidence to demonstrate that the quality management system has been effectively established, implemented and maintained.*

**H3.1** EQA Scheme management shall establish an internal audit of the quality management system.

**H3.2** The internal audit process shall be:

- a) planned and scheduled
- b) conducted against agreed criteria
- c) carried out by personnel trained in internal audit [NOTE 1].

**H3.3** The record of internal audit shall include:

- a) the activities, areas or items audited
- b) any nonconformities or deficiencies found
- c) the recommendations and time scale for corrective and preventive actions.

**H3.4** The results of internal audit shall be regularly evaluated and the decisions taken documented, monitored, reviewed and acted upon.

#### NOTES

- 1 Where practicable internal audit should be conducted by personnel who are independent of the work being audited, e.g. personnel from one section auditing another section.

#### CROSS REFERENCES

- |                      |               |                 |
|----------------------|---------------|-----------------|
| • ISO/IEC 17025:1999 | 4.13          | Internal audits |
| • ISO 9001:2000      | 8.2.2         | Internal audit  |
| • ISO 43:1           |               |                 |
| • ILAC-G13:2000      | 2.12 / 2.13.1 |                 |

## H4 Internal audit of EQA Scheme operation

*Internal audit of the operation of the EQA Scheme is required to ensure that it is being conducted according to agreed procedures.*

**H4.1** There shall be internal audit of the operation of the EQA Scheme.

**H4.2** The internal audit process shall be:

- a) planned and scheduled
- b) conducted against agreed criteria
- c) carried out by personnel trained in internal audit [NOTE 1].

**H4.3** The record of internal audit shall include:

- a) the activities, areas or items audited
- b) any nonconformities or deficiencies found
- c) the recommendations and time scale for corrective actions.

**H4.4** The results of internal audit shall be regularly evaluated and the decisions taken documented, monitored and communicated.

### NOTES

- 1 Where practicable internal audit should be conducted by personnel who have experience of EQA and are independent of the work being audited, i.e. personnel from one section auditing another section.

### CROSS REFERENCES

- |                             |       |  |
|-----------------------------|-------|--|
| • <b>ISO/IEC 17025:1999</b> | 4.9   | Control of nonconforming testing and/or calibration work |
| • <b>ISO 9001:2000</b>      | 8.2.3 | Measuring and monitoring of processes                    |
| • <b>ILAC-G13:2000</b>      | 2.8   |  |

## **H5 Quality improvement**

*Continual quality improvement is an essential part of maintaining and improving EQA Schemes in laboratory medicine.*

**H5.1** There shall be a process for continual quality improvement. This shall include corrective action, preventive action and improvement processes.

**H5.2** Corrective action shall be established for identification and elimination of the causes of nonconformities. The process shall include:

- a) investigation of nonconformities and recording of results
- b) determination of and responsibility for corrective action
- c) implementation of corrective action within an agreed time scale
- d) monitoring of corrective action taken.

**H5.3** Preventive action shall be taken to reduce nonconformities. The procedures shall include:

- a) investigation of the causes of potential nonconformities and recording of results
- b) determination of and responsibility for preventive action
- c) implementation of preventive action required and an agreed timescale
- d) ensuring that the preventive action taken is effective, recorded and submitted for management review.

**H5.4** The results of the quality improvement programme shall form a part of the development, training and education of all staff.

### **CROSS REFERENCES**

- **ISO/IEC 17025:1999**      4.10    Corrective action  
   4.11    Preventive action
- **ISO 9001:2000**        8.5     Improvement
- **ILAC-G13:2000**       2.9 / 2.10