

Standards for the Medical Laboratory

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0 Introduction

0.1 General

Since its incorporation on the 6th January 1992, CPA (UK) Ltd has, with some modifications, used standards based on the laboratory sections of the Canadian, Australian and UK standards for healthcare. In 1996 the first drafts of a new international standard, ISO 15189 Quality management in the medical laboratory, were circulated for discussion. In the light of changes taking place in relevant International Standards, the Board of CPA (UK) Ltd established a Standards Revision Group (SRG) to review existing standards. The new standards (see section 4.0) were approved at a meeting of the CPA Board on 8 December 2000 and are reviewed annually.

0.2 Approach

At the outset the SRG established a number of principles for its work.

- 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 standards¹ 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 SRG also drew upon the extensive experience gained in the practical implementation of the original CPA standards by both the user laboratories and by CPA in conducting assessment visits. The SRG sought to write these new standards in such a way that compliance with each standard would be unequivocally verifiable at an assessment visit.

0.3 Structure of the 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, give the requirements of the standard
- where appropriate, explanatory notes which may contain recommendations
- cross references to clauses of the source material

Where possible references are made to titled clauses of the source material (see section 2).

For more detailed cross references, see ISO 15189:2007 Annex A that has tables between ISO 15189 and ISO 9001:2000 and ISO 15189 and ISO/IEC 17025:2005.

¹ 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 a medical laboratory. It covers the organisation and quality management, the resources, and the evaluation and quality assurance activities required to ensure that pre examination, examination and post examination activities of the laboratory are conducted in such a manner that they meet the needs and requirement of the users. It is intended that compliance with these new CPA standards would signify an ability of a laboratory, by appropriate certification or accreditation procedures to be found compliant with the Essential Criteria and International Standards referenced in the next section (2 References).

2 References

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

ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence
(ISO 15189:2007)

ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories

ISO 9001:2000 Quality management systems-Requirements

ISO 9000:2005 Quality management systems-Fundamentals and vocabulary

ISO 22870:2006 Point-of-care testing (POCT) – Requirements for Quality and competence

European Communities Confederation of Clinical Chemistry: Essential Criteria for Quality Systems of Medical Laboratories Eur J Clin Chem Clin Bioch 1997;35:121-132

European Communities Confederation of Clinical Chemistry: Additional Essential Criteria for Quality Systems of Medical Laboratories Eur J Clin Chem Clin Bioch 1998;36:249-252

Material that is useful for supporting and interpreting these standards can be found in a separate document included on the CPA support website.

3 Terms and definitions

For purposes of this document the following terms and definitions apply. If a term and its definition is based on 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 audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled [ISO 9000:2000]

NOTE

Clinical audit is audit applied to clinical activities

3.4 corrective action

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

NOTE

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

3.5 department

section of a laboratory in which a single pathology discipline pursues its activities

3.6 effectiveness

extent to which planned activities are realised and planned results achieved [ISO 9000:2000]

NOTE

Clinical effectiveness is effectiveness applied to clinical activities

3.7 efficiency

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

3.8 examination

set of operations having the object of determining the value or characteristics of a property

NOTE

In some countries and disciplines (e.g. microbiology) examination is the total activity of a number of tests, observations or measurements [ISO 15189:2007]

3.9 laboratory

grouping of departments

3.10 laboratory director

competent person(s) with responsibility for, and authority over, a laboratory [ISO 15189:2007]

3.11 laboratory management

person(s) who manage the activities of the laboratory headed by the laboratory director [ISO 15189:2007]

3.12 materials

consumables, calibrators, reagents, calibration material used in the performance of an examination

3.13 multidisciplinary laboratory

laboratory in which two or more pathology disciplines work in an integrated manner

3.14 nonconformity

nonfulfilment of a requirement [ISO 9000:2000]

3.15 organisation

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

3.16 organisational structure

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

3.17 post examination process

post analytical phase

processes following the examination including systematic review, formatting and interpretation, authorisation for release, reporting and transmission of results and storage of samples of the examinations [based on ISO 15189:2007]

3.18 pre examination process

pre analytical phase

steps starting in chronological order from the clinician's request, including examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the examination procedure starts

[based on ISO 15189:2007]

3.19 premises

physical environment in which an organisation carries out particular functions

3.20 preventive action

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

NOTE

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

3.21 procedure

specified way to carry 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.

3.22 quality improvement

part of a quality management 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 [based on ISO 9000:2000]

3.23 quality management system

management system to direct and control an organisation with regard to quality

[ISO 9000:2000]

3.24 quality manual

document specifying the quality management system of an organisation

NOTE

quality manuals may vary in detail and format to suit the size and complexity of an individual organisation [ISO 9000:2000]

3.25 quality objective

something sought, or aimed for, related to quality

NOTE

Quality objectives are generally based on the organisation's quality policy [ISO 9000:2000]

3.26 quality planning

part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil quality objectives [ISO 9000:2000]

3.27 quality policy

overall intentions and direction of an organisation related to the fulfilment of quality requirements as specified by laboratory management

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 [based on ISO 9000:2000]

3.28 record

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

3.29 referral laboratory

external laboratory to which a sample is submitted for supplementary or confirmatory examination procedure and report [ISO 15189:2007]

3.30 remedial action

action taken to mitigate the immediate effects of a nonconformity.

3.31 requirement

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

3.32 review

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

3.33 revision

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

3.34 user

person or organisation using the services of the laboratory e.g. users may include clinicians, health care bodies, health insurance companies, and pharmaceutical companies

3.35 user dissatisfaction (complaint)

user opinion of the degree to which the service provided has failed to meet their requirements

3.36 user satisfaction

user opinion of the degree to which the service provided has met their requirements

3.37 validation

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

3.38 work environment

set of conditions under which work is performed [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 Pre examination process
- F Examination process
- G The post examination phase
- H Evaluation and quality assurance

There is distinct relationship between these sections. Section A describes the organisation of a laboratory and its quality management system which uses resources (Sections B, C and D) to undertake pre examination, examination and post examination processes (Sections E,F and G). The quality management system and the pre examination, examination and post examination processes are continually evaluated and quality assured (Section H). The results from the continual evaluation and quality assurance activities feed back to maintain and where required improve the quality management process and to ensure that the needs and requirements of users are met.

A ORGANISATION AND QUALITY MANAGEMENT SYSTEM

A1 Organisation and management

Laboratory management demonstrates its commitment to fulfilling the needs and requirements of its users by clearly defining the way in which the laboratory is organised and managed.

A 1.1 The laboratory, or the parent organisation of which it is a part, shall be an entity that can be held legally responsible.

A 1.2 The laboratory shall be organised and operate in conformity with CPA's "Standards for the Medical Laboratory".

A 1.3 The laboratory shall have:

- a) personnel with the authority, training and resources to carry out their duties [NOTE 1]
- b) arrangements to ensure that the quality of work is not adversely affected by any improper internal or external commercial, financial or other pressures
- c) arrangements that ensure the protection of its users' confidential information and proprietary rights
- d) arrangements that address any activities that would diminish confidence in its impartiality or integrity.

A 1.4 Laboratory management shall, with the aid of organisational charts:

- a) define the organisation and management of the laboratory, its place in a parent organisation and its relationship to any other organisation with which it may be associated
- b) specify the responsibility, authority and interrelationships of all personnel.

A 1.5 Laboratory management shall have regular meetings. Records shall be kept and agreed action points noted. Laboratory management shall ensure that actions are discharged within an appropriate and agreed timescale.

NOTES

1 Deputies should be appointed for all key functions. Individuals may have more than one function.

CROSS REFERENCES

- **ISO 15189:2007** 4.1 Organisation and management

A2 Needs and requirements of users

It is an essential prerequisite of a quality service that the organisation and management of the laboratory relates to the needs and requirements of its users and that any formal agreements are documented.

A 2.1 Laboratory management shall determine the needs and requirements with users (E1) and specify them as objectives for the organisation and management of the laboratory.

A 2.2 Needs and requirements of users shall be regularly reviewed (H2).

A 2.3 Laboratory management shall demonstrate its commitment to users by:

- a) establishing a quality policy (A3)
- b) establishing a quality management system (A4)
- c) establishing quality objectives and plans (A5)
- d) performing management reviews (A11)
- e) ensuring the availability of necessary resources (Standards in B,C and D).

A 2.4 Where laboratory management enters into a formal agreement to provide medical laboratory services, it shall establish a documented procedure for the establishment and review of such agreements to ensure that:

- a) the users' requirements, including the examination procedures to be used, are adequately defined, documented and understood (F 2)
- b) the laboratory has the capability and resources to meet the requirements
- c) procedures selected are appropriate and able to meet the agreement requirements and clinical needs (F1)
- d) customers / users are informed of any deviation from the agreement
- e) agreements make reference to any work referred by the laboratory to a third party
- f) reviews include all aspects of the agreement
- g) review records include any significant changes to the agreement and pertinent discussions and
- h) when an agreement needs to be amended after work has commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties.

CROSS REFERENCES

- **ISO 15189:2007**
 - 4.4 Review of contracts
 - 5.4 Pre-examination procedures
 - 5.8 Reporting of results

A3 Quality policy

A quality policy provides the basis for running a laboratory in a manner that will fulfil the needs and requirements of its users.

A 3.1 Laboratory management shall establish a quality policy [NOTE 1] that includes the following:

- a) the scope of the service the laboratory intends to provide
- b) a statement of the laboratory's intention with respect to the standard of services, including a commitment to meet the needs and requirements of users
- c) a statement of the purpose of the quality management system (A4) including a commitment to set quality objectives (A5) and to achieve continual quality improvement (H6)
- d) a requirement that personnel are familiar with the contents of the quality manual and all procedures relevant to their work
- e) a commitment to good professional practice
- f) a commitment to the health, safety and welfare of all staff and visitors to the laboratory
- g) a commitment to comply with relevant environmental legislation
- h) a commitment to continuing compliance with CPA(UK)Ltd accreditation standards.

A 3.2 Laboratory management shall ensure that the quality policy is:

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

NOTES

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

CROSS REFERENCES

- **ISO 15189:2007** 4.2 Quality management system

A4 Quality management system

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

A 4.1 Laboratory management shall establish a quality management system.

A 4.2 Roles, responsibilities and authority of all personnel shall be defined to ensure the establishment, implementation and maintenance of the quality management system.

A 4.3 Laboratory management shall be responsible for:

- a) setting quality objectives and undertaking quality planning (A5)
- b) preparing a quality manual (A6)
- c) appointing a quality manager (however named) (A7)
- d) establishing a procedure for document control (A8)
- e) establishing a procedure for control of process and quality records (A9)
- f) establishing a procedure for control of clinical material (A10)
- g) conducting a management review (A11).

CROSS REFERENCES

- **ISO 15189:2007** 4.2 Quality management system

A5 Quality objectives and plans

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

A 5.1 Laboratory management shall establish written quality objectives that shall be consistent with the quality policy and regularly reviewed (A3).

A 5.2 Laboratory management shall have plans to achieve and maintain its quality objectives.

CROSS REFERENCES

- **ISO 15189:2007** 4.2 Quality management system

A6 Quality manual

A quality manual describes the quality management system of a laboratory and includes the quality policy and arrangements for its implementation.

A 6.1 Laboratory management shall be responsible for the preparation of a quality manual.

A 6.2 The quality manual shall include:

- a) a quality policy
- b) a description of the quality management system
- c) a presentation of the organisational structure
- d) description of the roles and responsibilities of laboratory management (including the quality manager), involved in ensuring compliance with these Standards
- e) an outline of the structure of the documentation used in the quality management system [NOTE 1].

A 6.3 Personnel shall be familiar with and work to current versions of the quality manual and all referenced documentation.

A 6.4 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), pre examination, examination and post examination processes (sections E, F and G) and the quality management system evaluation (H).

CROSS REFERENCES

- **ISO 15189:2007** 4.2 Quality management system

A7 Quality manager

The quality manager is the individual who ensures, on behalf of laboratory management, that the quality management system functions correctly.

- A 7.1** Laboratory management or management of the parent organisation shall appoint a quality manager [NOTE 1].
- A 7.2** The quality manager's reporting arrangements shall be agreed between laboratory management and management of the parent organisation.
- 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 to laboratory management on the functioning and effectiveness of the quality management system
 - coordinating awareness of the needs and requirements of users.

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 comparable with management representative (as described in ISO 9001:2000 para 5.5.2)
- 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 laboratory.

CROSS REFERENCES

- **ISO 15189:2007** 4.2 Quality management system

A8 Document control

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

A 8.1 Laboratory 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 title, unique identifier, a review date or date of issue or revision version, (or all of these) 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 [NOTE 2].

A 8.2 Only current versions of documents shall be available at the appropriate locations.

A 8.3 Laboratory 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.

2 If in exceptional circumstances the document control system allows for the amendment of documents by hand. The procedures and authorities for such amendments are defined and pending the re-issue of documents they are clearly marked, initialled and dated, and a revised document is re-issued as soon as practicable.

CROSS REFERENCES

- **ISO 15189:2007** 4.3 Document control

A9 Control of process and quality records

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

A 9.1 Laboratory management shall establish a procedure(s) for controlling process records [NOTE 1] and quality records [NOTE 2], that includes:

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

A 9.2 Laboratory management shall determine which process and quality records (including quality records of external origin) are to be retained and for how long. Notice shall be taken of current legislation, regulations and guidelines. [NOTE 3]

A 9.3 Quality records shall be readily available to demonstrate compliance with the requirements and operation of the quality management system (section H).

A 9.4 Process records shall be readily available in order to reconstruct the process of any examination.

NOTES

- 1 Process records should include records made during pre examination, examination and post examination processes (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, external quality assessment reports, health and safety reports.

CROSS REFERENCES

- **ISO 15189:2007** 4.13 Quality and technical records

A10 Control of clinical material

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

A 10.1 Laboratory management shall establish a procedure(s) for controlling clinical material that includes [NOTE 1] :

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

A 10.2 Laboratory management shall determine the clinical material to be retained and for how long. Notice shall be taken of current legislation, regulations and guidelines.

A 10.3 Retained clinical material shall be stored in a way that ensures the validity of a repeat examination.

NOTES

1 Clinical material includes any primary specimens/samples and relevant preparations made in the course of examination.

CROSS REFERENCES

- **ISO 15189:2007** 5.7 Post-examination procedures

A11 Management review

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

A 11.1 Laboratory management shall conduct an annual review of the laboratory's quality management system (including the quality policy and objectives) and all its services. The review shall include:

- a) reports from managerial and supervisory personnel
- b) assessment of user satisfaction and complaints (H2)
- c) internal audit of quality management system (H3)
- d) internal audit of examination processes (H4)
- e) external quality assessment reports (H5)
- f) reports of assessments by outside bodies
- g) status of preventive, corrective and improvement actions (H6)
- h) quality indicators that monitor the laboratory's contribution to patient care
- i) major changes in organisation and management, resource (including staffing) or process
- j) follow up of previous management reviews.

A 11.2 Findings of the management review and the actions to be taken shall be recorded. Laboratory management shall ensure that actions are discharged within an appropriate and agreed timescale.

A 11.3 The management review shall contain an executive summary, a copy of which shall be sent to CPA(UK) Ltd.

CROSS REFERENCES

- **ISO 15189:2007** 4.15 Management review

B PERSONNEL

B1 Laboratory director

Laboratory direction is essential for the proper performance of a laboratory.

- B 1.1** The laboratory shall be directed by a person or persons who have executive accountability and the competence to assume responsibility for the services provided.
- B 1.2** The responsibilities of the laboratory director or designee(s), shall include clinical, scientific, professional, consultative, advisory, organisational, administrative and educational activities relevant to the services provided.
- B 1.3** The laboratory director may delegate selected duties and/or responsibilities to persons with appropriate competence. The laboratory director shall have the ultimate accountability for the overall operation and direction of the service.
- B 1.4** The duties of the laboratory director or designee(s) shall be documented.
- B 1.5** The laboratory director or designee(s) shall have demonstrable competence to assume responsibility for the services provided in order to:
- ensure that the needs and requirements of service users are met (A2)
 - ensure that there are appropriate numbers of staff with the required education, training and competence to provide a service that meets the needs and requirements of the users (B2)
 - ensure that all staff participate in appropriate educational programmes (B9)
 - ensure the safety of all members of staff, visitors and patients (C5)
 - select and monitor referral laboratories for quality of service (E6)
 - provide advice to users regarding the choice, use and interpretation of the examinations provided (G5)
 - ensure the quality of the services provided (H1)
 - monitor all work performed in the laboratory to determine that reliable information is being generated (H1)
 - address complaints, requests or suggestions from staff and/or users of the service (H2)
 - provide effective and efficient administration including budget planning and financial management and relate to senior management within the parent organisation
 - plan and direct research and development
 - serve as an active member of the clinical team, if applicable and appropriate
 - design and implement contingency plans to ensure that essential services are available at all times
 - relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community and the patient population served.

NOTES

- Competence is demonstrated by academic; postgraduate and continuing education and by evidence of continuing practice and experience that may be demonstrated by successful annual joint review.
- The Laboratory Director would be expected to have Medical Consultant status or equivalent and have competence at the level of the Membership of the Royal College of Pathologists or equivalent. Exceptions to this may occur for highly specialised services, but the need for clinical as well as managerial competence must be met.

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B2 Staffing

The staff are the single most important asset in any laboratory.

B 2.1 Laboratory 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 national legislation and regulations. [NOTE 1]

B 2.2 Registration of staff shall be in accordance with current national legislation and regulations.

B 2.3 The staffing shall include an individual(s) [NOTE 2] with the following roles:

- a) quality management (A7)
- b) training and education (B9)
- c) health and safety (C5).

NOTES

1 In a laboratory without on site consultants, consultant cover shall satisfy the following criteria:

- a) provision of a written statement of the sessional input to meet the needs of the service
- b) regular on site laboratory attendance as needed to match the needs of the service; normally at least weekly

2 These individuals may be engaged full time or part time with regard to these specific roles and may or may not have other roles in the parent organisation or the laboratory.

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B3 Personnel management

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

B 3.1 Laboratory management shall ensure that procedure(s) for personnel management include [NOTE 1]:

- 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 laboratory 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.

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B4 Staff orientation and induction

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

B 4.1 Laboratory management shall ensure that all staff participate in a staff induction programme that includes information on:

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

B 4.2 A record shall be kept of participation in the induction programme (see NOTE 1 of B6).

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B5 Job descriptions and contracts

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

B 5.1 Laboratory management shall ensure that 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 requirement for participation in staff annual joint review.

B 5.2 All staff shall have contracts of employment which are in compliance with current legislation and provide clear terms and conditions of service.

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B6 Staff records

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

B 6.1 Laboratory management shall ensure confidentiality of staff records in accordance with local guidelines and national legislation.

B 6.2 Staff records shall include [NOTE 1]:

- 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) a record of education and training including continuing professional development
- h) a record of competency assessments
- i) relevant educational and professional qualifications
- j) certificate of registration, if relevant
- k) absence record
- l) accident record
- m) a record of staff annual joint reviews [NOTE 2]
- n) occupational health record
- o) record of disciplinary action.

NOTES

1 If the laboratory 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 items B6.2 (m,n,o) the inspectors should seek assurance that they exist.

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B7 Staff annual joint review

Achievement of laboratory and personal objectives is facilitated by regular staff appraisal.

B 7.1 Laboratory management shall ensure that all staff participate in an annual joint review that includes consideration of the:

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

B 7.2 All staff performing annual joint reviews shall have received training and those staff participating shall have had a full explanation of the process.

B 7.3 Records shall be kept of all staff joint reviews (B6).

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

B8 Staff meetings

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

B 8.1 There shall be regular meetings open to all staff in order to provide the opportunity for exchange of information [NOTE 1].

B 8.2 Records shall be kept and made available to staff.

NOTE

1 The information should cover all aspects of the laboratory service and in particular the effectiveness of the quality management system.

CROSS REFERENCES

- **ISO 15189:2007** -

B9 Staff training and education

Access to continuing education and training is important for all grades of laboratory staff and participation in Continuing Professional Development schemes is a method of achieving this for relevant staff groups.

B 9.1 There shall be a training and education programme for all members of staff governed by the following criteria:

- a) training and education shall be in accordance with the policies of the parent organisation and guidelines from the relevant professional and registration bodies
- b) all staff shall be given the opportunity for further education and training in relation to the needs of the service and their professional development.

B9.2 The training programme shall, as appropriate, include the following:

- a) assigned work processes and procedures
- b) the quality management system
- c) applicable computer system(s)
- d) health and safety, including the prevention or containment of the effects of adverse incidents; and
- e) the ethics and confidentiality of information.

B9.3 Competency to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary. Records of competency assessments shall be kept (B6).

B 9.4 There shall be 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.

B 9.5 Records shall be kept of all training and education (B6).

B 9.6 Laboratory management shall appoint a training officer (B2).

CROSS REFERENCES

- **ISO 15189:2007** 5.1 Personnel

C PREMISES AND ENVIRONMENT

C1 Premises and environment

A department requires sufficient space to ensure that work is performed safely and efficiently.

C 1.1 The premises shall provide a working environment in which staff can perform required functions [NOTE 1] in accordance with national legislation and guidelines.

C 1.2 The premises shall have space for the following:

- a) the functioning and use of all equipment
- b) specimen reception (E5)
- c) separation of incompatible activities
- d) facilities for staff (C2)
- e) facilities for patients (C3)
- f) facilities for storage (C4).

C 1.3 Access to the premises shall be restricted to authorised personnel.

C1.4 Communication systems shall meet the needs and requirements of users.

NOTE

- 1 Particular attention should be given to monitoring, controlling and recording environmental conditions as required by relevant specifications or where they may influence the quality of the results of examinations. Attention should be paid to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature and sound and vibration as appropriate to the technical activities concerned.

CROSS REFERENCES

- **ISO 15189:2007**
 - 5.2 Accommodation and environmental conditions
 - 5.3 Laboratory equipment

C2 Facilities for staff

All staff need facilities, within the department, to ensure personal safety, comfort and hygiene.

C 2.1 The premises shall have staff facilities that are readily accessible and include:

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

C 2.2 There shall be overnight accommodation, when necessary, that is conveniently sited and secure.

CROSS REFERENCES

- **ISO 15189:2007** 5.2 Accommodation and environmental conditions

C3 Facilities for patients

The facilities available for patients should provide for privacy during reception and sampling and be suitable for the examination being performed.

C 3.1 Facilities for specimen collection and examination of patients shall include:

- a) a waiting/reception area with suitable facilities and access for disabled persons
- b) a phlebotomy area which offers privacy and recovery facilities
- c) toilet facilities for patients separate from those provided for staff.

C 3.2 There shall be notices advising patients and visitors of health and safety precautions.

CROSS REFERENCES

- **ISO 15189:2007** 5.2 Accommodation and environmental conditions

C4 Facilities for storage

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

C 4.1 There shall be separate storage facilities, as required, for:

- a) process and quality records (A9)
- b) clinical material (A10)
- c) blood and blood products
- d) hazardous substances (C5)
- e) drugs, vaccines and other therapeutics
- f) reagents (D3)
- g) waste material for disposal.

C 4.2 The storage facilities shall be in accordance with national legislation, regulations and guidelines.

CROSS REFERENCES

- **ISO 15189:2007** 5.2 Accommodation and environmental conditions

C5 Health and safety

A health and safety statement, and procedures to implement it, are required to ensure a safe environment in the laboratory for staff, patients and visitors.

C 5.1 Laboratory management shall be responsible for:

- a) defining and implementing health and safety procedures
- b) ensuring that there is a safe working environment in accordance with current safety guidelines and legislation [NOTE 1]
- c) providing personal protective equipment
- d) delegating day to day management of health and safety to the appointed health and safety officer (B2)
- e) providing model rules for staff and visitors to the laboratory
- f) where applicable, nominating a consultant microbiologist responsible for infection control and regular reporting to the Communicable Disease Surveillance Centre.

C 5.2 All staff shall be aware of their responsibilities relating to health and safety.

C 5.3 Laboratory management shall establish a health and safety procedure(s) that includes: [NOTE 2]

- a) action in the event of fire
- b) action in the event of a major spillage of dangerous chemicals or clinical material
- c) action in the event of inoculation accident
- d) reporting and monitoring of accidents and incidents
- e) COSHH/risk assessments
- f) disinfection processes
- g) decontamination of equipment (D1)
- h) chemical handling (D3)
- i) storage and disposal of waste
- j) specimen collection and handling, transportation, reception and referral to other laboratories (E3-E6).

C 5.4 Laboratory containment facilities shall conform to the requirements of the Advisory Committee on Dangerous Pathogens (ACDP) guidelines as appropriate to the testing being performed.

C 5.5 There shall be sufficient safety notices and labelling of the laboratory environment such that staff are aware of the risks and safe practice required.

C 5.6 Work areas shall be clean, uncluttered and well maintained and there shall be evidence of good housekeeping procedures.

NOTES

- 1 A copy of the latest Health & Safety Executive inspector report shall be available to assessors.
- 2 This procedure(s) may be in the form of a Health and Safety Handbook readily available to staff.

CROSS REFERENCES

- **ISO 15189:2007**
 - 5.2 Accommodation and environmental conditions
 - 5.7 Post examination procedures

D EQUIPMENT, INFORMATION SYSTEMS AND MATERIALS

D1 Procurement and management of equipment

The proper procurement and management of equipment ensures that the laboratory can fulfil the needs and requirements of users.

D 1.1 Laboratory management shall ensure that the equipment is sufficient and appropriate to provide the service [NOTE 1].

D 1.2 Laboratory management shall establish a procedure(s) for the procurement and management of equipment, that includes:

- a) assessment and justification of need
- b) selection
- c) acceptance
- d) training
- e) preventive maintenance, service and repair
- f) calibration and monitoring of the instruments, reagents and analytical systems
- g) decontamination
- h) record of instrument failure and subsequent corrective action
- i) planned replacement and disposal [NOTE 2]
- j) adverse incident and vigilance reporting.

D 1.3 There shall be an inventory of equipment that includes:

- a) name of manufacturer
- b) serial number
- c) date of purchase or acquisition
- d) current location, where appropriate
- e) record of contracted maintenance
- f) record of equipment breakdowns.

D1.4 The programmes for preventive maintenance, calibration and monitoring of function shall be documented and at a minimum, follows manufacturer's recommendations.

NOTE

1 In those cases where the laboratory needs to use equipment outside its permanent control, e.g. Point-Of-Care Testing, laboratory management should ensure that the requirements of this Standard are met.

2 When selecting equipment, account should be taken of the use of energy and future disposal (care of the environment).

CROSS REFERENCES

- **ISO 15189:2007**
 - 4.6 External services and supplies
 - 5.3 Laboratory equipment

D2 Management of data and information

The proper management of data and information in the laboratory is essential for the provision of the service.

D 2.1 Laboratory management shall ensure the availability of data and information required to provide a service that meets the needs and requirements of users.

D 2.2 Laboratory 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.

D 2.3 Laboratory management shall ensure compliance with current national legislation and regulations in relation to data protection.

CROSS REFERENCES

- **ISO 15189:2007** 5.3 Laboratory equipment
Annex B (informative) Laboratory Information systems

D3 Management of materials

It is essential to have proper management of all the materials used in the provision of the service.

D 3.1 Laboratory management shall ensure the availability of reagents, calibration and quality control material required to provide a service which meets the needs and requirements of users.

D 3.2 Laboratory management shall establish a procedure(s) for the management of reagents, calibration and quality control material 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.

D 3.3 Materials in use shall be correctly identified with the date of receipt, lot numbers, first use and expiry.

CROSS REFERENCES

- **ISO 15189:2007** 4.6 External services and supplies

E. PRE EXAMINATION PROCESS

E1 Information for users and patients

To facilitate proper use of the services, departmental policies, procedures and repertoire should be provided in a readable and manageable form. Users particularly require information about the availability of clinical advice, as well as the scope and limitations of the service.

E 1.1 There shall be up to date information for users. This shall be prepared in consultation with the users. (A2 and H2).

E 1.2 The information for users shall include:

- a) contact details of key members of staff
- b) the location of the laboratory
- c) services offered by the laboratory
- d) times of opening of the laboratory
- e) details of any out of hours service or shift system
- f) instructions for completion of the request form
- g) instructions for transportation of samples, including any special handling needs
- h) availability of clinical advice and interpretation
- i) the names and addresses of laboratories to which work is routinely referred
- j) the laboratory's repertoire including specimens required, sample volumes, special precautions, turnaround time and reference ranges
- k) a list of those key factors which are known to affect the performance of the test or the interpretation of the results
- l) time limits for requesting additional examinations.

E 1.3 There shall be up to date information for patients. This shall be prepared in consultation with patients or representative groups.

E 1.4 The information for patients shall include:

- a) an explanation of any clinical procedure to be performed
- b) instructions regarding preparation for the procedure.

CROSS REFERENCES

- | | | |
|-------------------------|-----|--------------------------------------|
| • ISO 15189:2007 | 4.5 | Examination by referral laboratories |
| | 4.7 | Advisory services |
| | 5.4 | Pre-examination procedures |

E2 Request form

Correctly designed and properly completed request forms are essential for the performance of all laboratory tests to the benefit of the patient and the satisfaction of the requesting physician.

E 2.1 The design of the request form shall allow the inclusion of the following items [NOTE 1]:

- a) sufficient information to allow unequivocal identification of the patient
- b) identification(s) and the location of the requesting individual
- c) date and time of specimen collection
- d) type of specimen and, where appropriate, anatomical site of origin
- e) investigations requested
- f) date and time of receipt of samples by the laboratory
- g) relevant clinical information
- h) identification of priority status
- i) location(s) to which the results are to be sent
- j) laboratory accession number.

E 2.2 The laboratory shall encourage the proper completion of request forms.

E2.3 The laboratory shall determine in discussion with users the manner in which requests (including verbal requests) are to be communicated to the laboratory.

NOTES

1 The request form may be in paper or electronic format.

CROSS REFERENCES

- **ISO 15189:2007**
 - 5.4 Pre-examination procedures
 - 5.5 Examination procedures

E3 Specimen collection and handling

Proper preparation of the patient, specimen collection and handling are essential for the production of valid results by a laboratory.

E 3.1 Laboratory management shall establish a procedure(s) for the specimen collection and handling that includes:

- a) checking the completion of the request form and confirming the identity of the patient
- b) checking that the specimen container is labelled correctly
- c) checking that the patient is appropriately prepared
- d) ensuring that the specimen is collected correctly
- e) minimising the risk of interchange of samples and sub samples
- f) ensuring that environmental and storage conditions are fulfilled
- g) ensuring the safe disposal of all materials used in specimen collection
- h) ensuring that high risk specimens are identified and processed correctly
- i) ensuring that all spillages and breakages are dealt with correctly
- j) minimising the risk to ensure the safety of the specimen collector, carrier, the general public and the receiving laboratory.

E 3.2 These procedures shall be available to users of the service and those who are responsible for specimen collection and handling.

E 3.3 The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.

CROSS REFERENCES

- **ISO 15189:2007** 5.5 Examination procedures

E4 Specimen transportation

Specimen transportation systems need to ensure the timely arrival of specimens at the correct destination at minimum risk to both laboratory and non-laboratory personnel.

E 4.1 Laboratory management shall establish a procedure(s) for the transportation of specimens, that includes [NOTE 1]:

- a) ensuring the safety of the courier, the general public and receiving laboratory
- b) packaging, labelling and despatch
- c) ensuring that the specimens arrive within a time frame appropriate to the nature of the requested examinations and protects the specimens from deterioration
- d) reporting incidents during transportation that may affect the quality of the specimen or the safety of personnel.

E 4.2 The procedures for the transportation of specimens shall meet all regulatory requirements.

NOTES

- 1 Where laboratory management do not directly manage or control the transport of specimens, a system should be established with consultation between laboratory and hospital safety advisors and be subject to safety audit.

CROSS REFERENCES

- **ISO15189:2007**
 - 5.4 Pre-examination procedures
 - 5.5 Examination procedures

E5 Specimen reception

For examinations to be correctly performed, specimens have to be received into the laboratory efficiently and safely.

E 5.1 Laboratory management shall establish a procedure(s) for specimen reception that includes:

- a) linking of the request and specimen [NOTE 1]
- b) recording of request form and specimen information [NOTE 2]
- c) recording the date and time of receipt of specimens
- d) handling urgent specimens
- e) ensuring staff safety.

E 5.2 There shall be a procedure(s) for specimen rejection that includes:

- a) the criteria for rejection of specimens
- b) the recording of rejected specimens
- c) notification of the user concerning rejected specimens.

E 5.3 Authorised personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.

NOTES

- 1 This includes linking the primary specimen to any sample portions prepared in reception or subsequently
- 2 The data may be recorded in paper or electronic format.

CROSS REFERENCES

- **ISO 15189:2007** 5.5 Examination procedures

E6 Referral to other laboratories

Procedures are required to ensure that specimens/data sent to referral laboratories, and to consultants for second opinions in, are efficiently handled.

E 6.1 Laboratory management, with the advice of users where appropriate, shall establish a procedure(s) for referral of specimens to other laboratories and to consultants who are to provide second opinions that includes:

- a) evaluating and selecting referral laboratories and consultants in terms of competence to perform the requested examinations and ensuring that there are no conflicts of interest
- b) maintaining a record of all referral laboratories and the relevant repertoire [NOTE 1]
- c) maintaining a record of all specimens referred
- d) recording of dispatch dates
- e) monitoring the return of reports from the referral laboratory or referral consultant
- f) defining the respective responsibilities for the interpretation and reporting of referred examinations (see also G2.4)
- g) periodically reviewing the arrangements with referral laboratories to ensure that requirements including terms of EQA performance and turnaround times continue to be met.

NOTES

- 1 Referral laboratories should where possible, be accredited by CPA or equivalent accreditation body or meet the requirements of the sender's quality management system.

CROSS REFERENCES

- **ISO 15189:2007** 4.5 Examination by referral laboratories

F EXAMINATION PROCESS

F1 Selection and validation of examination procedures

The selection of examination procedures needs to be clear, appropriate and subject to regular evaluation with the users.

F 1.1 Examination procedures, including those for sampling, shall meet the needs and requirements of users.

F 1.2 Examination procedures shall be validated for their intended use prior to introduction, and the methods used and results obtained, recorded.

F 1.3 When examination procedures are changed so that results or their interpretation may be significantly different, the implications shall be explained to users, prior to the introduction of the change.

CROSS REFERENCES

- **ISO 15189:2007** 5.5 Examination procedures

F2 Examination procedures

Adherence to examination procedures is essential to ensure a quality diagnostic laboratory service.

F 2.1 There shall be procedures for the conduct of all examinations that include and/or refer to, as applicable, the following [NOTE 1]:

- a) clinical relevance / purpose of examination
- b) principle of examination
- c) specimen requirements and means of identification
- d) equipment and special supplies
- e) reagents, standard or calibrants and internal control materials
- f) calibration
- g) instructions for the performance of the examination
- h) limitations of the examination, including interferences, cross reactions and reportable intervals
- i) recording and calculation of results
- j) internal quality control procedures and criteria against which examination processes (measurement and observation) are judged
- k) reporting reference limits
- l) alert/critical values, where appropriate
- m) responsibilities of personnel in authorising, reporting, and monitoring reports
- n) hazards and safety precautions
- o) performance criteria.

F2.2 All examination procedures shall be readily available in relevant sections of the laboratory.

NOTES

- 1 If the laboratory utilises the instructions for use written by the manufacturer, they shall be in accordance with the criteria set out in F2.1. Any deviations shall be validated, reviewed and documented.

CROSS REFERENCES

- **ISO 15189:2007**
 - 5.5 Examination procedures
 - 5.7 Post examination procedure

F3 Assuring the quality of examinations

A comprehensive programme of internal quality control is essential to ensure the quality of all laboratory examinations.

F 3.1 The laboratory shall ensure the quality of examinations by performing them under controlled conditions that include as applicable:

- a) implementation of appropriate pre examination processes
- b) the provision of trained staff , appropriate premises and environmental conditions equipment and materials information systems, and the use of documented procedures
- c) the use of internal quality control (F3.2)
- d) the determination of uncertainty (F3.3)
- e) calibration of measuring systems (F3.4)
- f) verifying the comparability of results (F3.5)
- g) and participating in external quality assessment schemes (H5).

F 3.2 There shall be procedures for internal quality control (IQC) of all examinations which verify that the intended quality is achieved. These shall include:

- a) records of date, source and storage requirements of IQC material
- b) the process of validation of IQC material prior to routine use
- c) appropriate statistical procedures
- d) where applicable, acceptance criteria for results obtained on IQC material in use.
- e) ensuring that all IQC results are recorded, regularly evaluated and subsequent remedial and corrective actions taken recorded.

F3.3 The laboratory shall determine the uncertainty of results, where relevant and possible.

F3.4 The laboratory shall have a programme of calibration of measuring systems and verification of trueness designed to ensure that results are traceable, where possible, to SI units or to a stated reference material.

F3.5 The laboratory shall have a mechanism for ensuring that examinations performed using different procedures or equipment or at different sites give comparable results, in particular, throughout clinically appropriate intervals.

CROSS REFERENCES

- **ISO 15189:2007** 5.6 Assuring the quality of examination procedures

G THE POST EXAMINATION PHASE

G1 Reporting results

The purpose of the laboratory is to produce the results of examinations in reports that are correct, timely, unambiguous and clinically useful.

G 1.1 Laboratory management shall establish in consultation with users procedure(s) for reporting results which shall include:

- a) the report (G2)
- b) the telephoned report (G3)
- c) the amended report (G4)
- d) clinical advice and interpretation (G5)
- e) mechanisms for notifying the requester when an examination is delayed [NOTE 1].

G 1.2 The laboratory shall in consultation with users, establish turnaround times for each examination that reflect clinical needs and have a mechanism for monitoring nonconformities and recording remedial or corrective action.

NOTE

- 1 This does not mean that the clinical personnel are to be notified of all delays in examinations, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.

CROSS REFERENCES

- **ISO 15189:2007** 5.8 Reporting of results

G2 The report

The main method of communicating the results of examinations to the users of the laboratory is by the production of a report.

G 2.1 The report [NOTE 1] shall be clear, unambiguous, and contain sufficient information to enable the user to interpret the results.

G 2.2 The report shall be designed to comply with the needs of the users and with the requirements of the local medical records system.

G 2.3 The report shall allow the inclusion of the following items:

- a) the laboratory name
- b) the unequivocal identification of the patient
- c) requester and/or address for delivery
- d) type of specimen, date and time of collection
- e) time and date of report
- f) results, including reasons if no examination is performed (E5)
- g) reference intervals as appropriate
- h) interpretive comments as appropriate
- i) highlighting of abnormal results and/or inclusion of critical limits
- j) status of report as appropriate, eg. copy, interim or supplementary
- k) where possible, the identification of person(s) verifying results and authorising the release of the report.

G 2.4 Reports or letters issued following receipt of the results from referral laboratories shall additionally:

- a) include a means of identifying the referral laboratory [NOTE 2]
- b) include all the results
- c) incorporate appropriate interpretive comments of the referral laboratory
- d) When examination results from a referral laboratory need to be transcribed by the referring laboratory there are instructions for verifying the correctness of transcription

G 2.5 There shall be a mechanism for ensuring the reports are handled and transmitted confidentially.

NOTES

- 1 The report may be in written or electronic form.
- 2 Where the referral laboratory is identified by a code the name and address of the referral laboratory is available on request (E1).

CROSS REFERENCES

- **ISO 15189:2007** 5.8 Reporting of results

G3 The telephoned report

Laboratories are frequently required to telephone reports to users. The method by which this is done needs to be clearly defined to minimise the risk of error.

G 3.1 Laboratory management shall establish a procedure(s) for giving reports by telephone which includes:

- a) the circumstances in which reports may be given
- b) the nominated individuals who may give reports
- c) the individuals who may receive reports
- d) a method of mutual identification of the patient between reporter and receiver
- e) a confirmation of correct transmission
- f) the mechanism for recording the event
- g) the maintenance of confidentiality
- h) the process for sending a follow up report.

CROSS REFERENCES

- **ISO 15189:2007** 5.8 Reporting of results

G4 The amended report

A process is required in the laboratory to ensure that amended reports are issued when necessary.

G 4.1 Laboratory management shall establish a procedure(s) for issuing amended reports which shall include [NOTE 1]:

- a) the criteria for issuing amended reports
- b) the authorisation of staff able to amend reports
- c) the identification to the user of amended reports
- d) a process for recording the issue of amended reports
- e) the reason for issuing an amended report
- f) the instigation of remedial, corrective and/or preventive action, if required
- g) a process for archiving amended results.

NOTES

- 1 An amended report is a report that is changed in any way after the initial report has been sent out.

CROSS REFERENCES

- **ISO 15189:2007** 5.8 Reporting of results

G5 Clinical advice and interpretation

The provision of interpretive comments on reports is an essential role of the laboratory service. The frequency of such comments may vary between specialties.

G 5.1 Laboratory management shall ensure that advice on examinations and the interpretation of results is available to meet the needs and requirements of users.

G5.2 Interpretive comments on reports shall be clear, succinct and unambiguous.

G5.3 Clinical advice and interpretive comments shall only be provided by authorised personnel with appropriate training.

G5.4 There shall be systematic communication between laboratory staff and clinical staff to promote effective utilisation of laboratory services and to consult on scientific and logistic matters. Where appropriate a record of such meetings shall be kept.

CROSS REFERENCES

- **ISO 15189:2007** 4.8 Resolution of Complaints

H EVALUATION AND QUALITY ASSURANCE

H1 Evaluation and improvement processes

Ongoing evaluation and improvement processes are essential to ensure that the service provided by the laboratory meets the needs and requirements of users.

H 1.1 Laboratory management shall establish a procedure(s) that includes:

- a) Assessment of user satisfaction and complaints (H2)
- b) Internal audit of quality management system [NOTE 1] (H3)
- c) Internal audit of examination processes [NOTE 2] (H4)
- d) External quality assessment (H5)
- e) Reports from external assessment bodies
- f) Quality improvement, including corrective and preventive action and the monitoring of quality indicators (H6)
- g) Identification and control of nonconformities (H7).

H 1.2 The results of these evaluation and improvement processes shall be made available to staff, and to users as required.

H 1.3 Analysis, recording and interpretation of the evaluation data shall form part of the management review (A11).

NOTES

- 1 System performance relates to the organisation, quality management system (section A) and associated resources (sections B, C, D).
- 2 Process performance relates to pre examination, examination, and post examination processes (sections E, F, G).

CROSS REFERENCES

- **ISO 15189:2007** 4 Management requirements

H2 Assessment of user satisfaction and complaints

The purpose of assessing user satisfaction and monitoring complaints is to establish that the service provided by the laboratory meets the needs and requirements of users.

H 2.1 Laboratory management shall:

- a) establish processes for obtaining and monitoring data on user satisfaction and complaints. Users comments shall be recorded, reviewed and acted upon
- b) meet performance targets in all areas [NOTE 1]
- c) assess the clinical relevance of laboratory investigations performed and the reliability of interpretive reports in conjunction with the users
- d) participate in the evaluation of clinical effectiveness, audit and risk management activities of the parent organisation or external bodies.

NOTES

1 Performance targets may include turnaround times.

CROSS REFERENCES

- **ISO 15189:2007** 4.8 Resolution of complaints

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.

H 3.1 Laboratory management shall establish an internal audit of the quality management system.

H 3.2 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].

H 3.3 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.

H 3.4 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 of a laboratory/department auditing another section.

CROSS REFERENCES

- **ISO 15189:2007** 4.14 Internal audits

H4 Internal audit of examination processes

Internal audit of pre examination, examination and post examination processes is required to ensure that they are being conducted according to agreed procedures. Internal quality control helps to ensure that the examinations are being correctly performed.

H 4.1 There shall be internal audit of the pre examination, examination and post examination processes.

H 4.2 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].

H 4.3 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.

H 4.4 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 are independent of the work being audited, i.e. personnel from one section of a laboratory/department auditing another section.

CROSS REFERENCES

- **ISO 15189:2007**
 - 4.14 Internal audits
 - 5.6 Assuring the quality of examination processes

H5 External quality assessment

Participation in External Quality Assessment (sometimes known as Proficiency Testing) schemes is an essential element in informing both providers and users of the quality of the service provided. Such schemes have a major educational component and may include either the analytical service of a laboratory and/or the interpretations provided by individual members of staff.

H 5.1 There shall be participation in approved External Quality Assessment Scheme(s) appropriate to the examinations and interpretations provided [NOTES 1 and 2].

H 5.2 A record of results against the agreed performance criteria in approved EQA Schemes shall be maintained.

H 5.3 The record of the performance in EQA shall be reviewed and communicated to staff and the decisions taken recorded, monitored and acted upon [NOTE 3].

H 5.4 When a formal inter-laboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated [NOTE 4].

NOTES

1. Approved EQA Schemes are Schemes that are accredited by CPA (EQA) or by another organisation accrediting to standards based upon ILAC G13:2000. This should include an appropriate scientific Steering Committee and National Quality Assurance Advisory Panel reporting arrangements.
2. External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.
3. For certain EQA Schemes, the permission of the participant may be required before the records of performance are made available to users.
4. Mechanisms may include exchange of samples and preparations such as slides and digital images between laboratories.

CROSS REFERENCES

- **ISO 15189:2007** 5.6 Assuring the quality of examination processes

H6 Quality improvement

Continual quality improvement is an essential part of maintaining and improving laboratory services.

H 6.1 There shall be a process for continual quality improvement. This shall include, remedial action, corrective action, preventive action, monitoring of quality indicators and improvement processes.

H 6.2 Corrective action shall be taken to eliminate the root causes of nonconformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered [NOTE 1]. The process shall include:

- a) investigation of the root causes 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.

H 6.3 Preventive action shall be taken to eliminate the causes of potential nonconformities.[NOTE 2]
The procedures shall include:

- a) investigation of the root 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.

H 6.4 The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination, and post-examination processes and their relationship to effective patient care. The objectives of quality indicators, their methodology and duration of measurement shall be established prior to implementation [NOTE 3].

H 6.5 The results of the quality improvement programme shall form a part of the development, training and education of all staff.

NOTE

1 Action taken at the time of the nonconformity to mitigate its immediate effects is considered 'remedial' action, only action taken to remove the root cause of the problem that is causing the nonconformity is considered true 'corrective action'

2 Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e., nonconformities). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance and the monitoring of quality indicators

3 Quality indicators to monitor non-examination processes, such as customer, user and worker complaints and satisfaction, laboratory safety and environment, and continuing education may provide valuable management insights.

CROSS REFERENCES

- **ISO 15189:2007**
 - 4.10 Corrective action
 - 4.11 Preventative action
 - 4.12 Continual improvement

H7 Identification and control of nonconformities

Procedures are required that ensure that non conformities in pre examination, examination and post examination processes are effectively managed to minimise the risks to users

H 7.1 Laboratory management shall establish procedure(s) that are implemented when nonconformities are identified in any aspect of its pre examination, examination or post examination processes. These nonconformities may be procedural or a failure to meet the specified requirements of the quality management system, users or external organisations. The procedure shall ensure that [NOTE 1]:

- a) the responsibilities and authorities for the management of the nonconformities are designated
- b) the remedial actions to be taken are defined
- c) examinations are halted and reports withheld as necessary
- d) the medical significance of any nonconforming examinations is considered, and where appropriate, the user (requesting clinician) informed
- e) the results of any nonconforming examinations already released are recalled or appropriately identified, as necessary
- f) the responsibility for authorisation of the resumption of examinations is defined, and
- g) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate corrective action.

NOTES

- 1 Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, staff comments, reporting and certificate checking, laboratory management reviews, and internal and external audits.

CROSS REFERENCES

ISO 15189:2007	4.9	Identification and control of nonconformities
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