ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes

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PREAMBLE

Proficiency testing is a powerful quality assurance tool enabling laboratories to monitor their performance and compare their results with similar laboratories Proficiency testing schemes which are used by laboratory accreditation bodies as part of the process to assess the ability of laboratories to competently perform tests and measurements for which accreditation is held. Proficiency tests complement the on-site laboratory review by technical specialists.

Proficiency testing is one type of interlaboratory comparison study, and similar studies may be conducted for various different purposes. These could include education, establishing the effectiveness and accuracy of test methods, checking the performance of individual laboratory staff, or determining the characteristics of a material to a particular degree of accuracy (such as in preparation of reference materials).

Laboratories and accreditation bodies will be better placed to use the results of external proficiency testing schemes as an aid in the accreditation process if they are confident that such schemes are operated competently and in harmony with appropriate requirements. Other users of proficiency testing schemes may also have additional confidence if the schemes have been independently accredited.

For the selection of proficiency testing schemes by laboratories, and their acceptance during laboratory assessment, the technical specifications of ISO/IEC Guide 43 Parts 1 and 2 also form a sound basis.

The following sections of this document provide appropriate requirements for competence of providers of proficiency testing schemes.

These Requirements have been developed with the following major features:

They are a basis for recognising the competence of providers of proficiency testing schemes. The organisation which is responsible for coordinating and providing a proficiency testing scheme should ensure that all tasks involved in the provision of such a scheme have been performed competently, whether they are carried out by the coordinating organisation itself or in combination with subcontractors.

Accordingly, it is the provider (and any sub-contractual arrangements used by the provider) which should be evaluated for compliance with these Guidelines.

The *Guidelines* are based on the technical elements of ISO Guide 43-1:1997 and on the *relevant* elements of ISO/IEC 17025:2005, including the management system requirements and the technical requirements for the characterisation, homogeneity and stability testing of proficiency test items. Requirements from ISO 15189 regarding various uses of proficiency testing and the need for proficiency testing to cover other sources of error are accommodated in this revision. Additionally, relevant elements of ISO 9000:2005 are included to eliminate the need for separate recognition of a provider's quality management system.

In ISO Guide 43-1:1997, the Introduction on page (v) identifies various uses of interlaboratory comparisons. As with ISO Guide 43, these ILAC *Guidelines* apply only to the use of interlaboratory comparisons for the purpose of proficiency testing (i.e. to determine individual and collective laboratory performance for specific tests or measurements, and to monitor laboratories' continuing performance).

Note: Proficiency Testing schemes are sometimes known by different names (e.g. External Quality Assessment (EQA) schemes or laboratory performance studies).

PURPOSE

This document is directed to providers of proficiency testing schemes who wish to demonstrate their competence, for the purposes of accreditation or other recognition, by formal compliance with a set of internationally acceptable requirements for the planning and implementation of such schemes.

AUTHORSHIP

This publication was prepared by the ILAC Proficiency Testing Consultative Group.

SECTION 1 : GENERAL

1.1 Scope

These *Guidelines* set out the criteria which a provider of proficiency testing schemes (and associated subcontractors) shall meet in order to be recognised as competent to provide specific types of proficiency testing schemes.

These *Guidelines* also provide guidance for any organisation that is creating requirements for the competence of providers of proficiency testing schemes.

1.1.1 It is the responsibility of the provider to ensure that the requirements (i.e. both technical and management) are met by the provider and any associated subcontractors.

Note: To avoid confusion, only those statements which include the word "shall" are meant to be requirements.

1.1.2 It is recognised that there may be a number of alternative methods used by providers to comply with these *Guidelines* and throughout the document *Notes* provide information on possible sources of guidance. Such *Notes* do not form an integral part of the *Guidelines.*

1.1.3 Where clauses of these Guidelines *are considered to meet the existing requirements of ISO/IEC Guide 43-1:1997, ISO/IEC 17025:2005, ISO 15189:2003 or ISO 9001:2000, these are cross-referenced in Appendix B.*

1.1.4 Providers complying with these *Guidelines* are considered to operate in accordance with the principles of ISO 9001:2000 as applied to the design and provision of specific types of proficiency testing schemes.

1.2 References

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

ISO Guide 34:2000, *Reference materials – General requirements for the competence of reference material producers*.

ISO Guide 35:2006, *Reference materials - General and statistical principles for certification*.

ISO/IEC Guide 43-1 (1997), *Proficiency testing by interlaboratory comparisons - Part 1: Development and operation of proficiency testing schemes*.

ISO 15189 (2003), *Medical laboratories – Particular requirements for quality and competence*.

ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary*.

ISO 9001:2000, *Quality management systems - Requirements*.

The International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories. *Pure Appl. Chem*., 78 (1), 145-196 (2006).

Evaluation of Matrix Effects: Approved Guideline, CLSI/NCCLS Document EP14A2. Clinical and Laboratory Standards Institute, Wayne, PA, 2005.

ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*.

1.3 Definitions

For the purpose of these Guidelines, the following definitions apply in addition to those described in ISO/IEC Guide 43-1:1997 and in ISO/IEC 17025:2005.

1.3.1 Coordinator

The person with responsibility for coordinating all of the activities involved in the operation of a proficiency testing scheme.

1.3.2 External Quality Assessment (EQA)

Interlaboratory comparisons and other external performance evaluations that may extend throughout all phases of the testing cycle, including interpretation of results.

Note: The primary objectives of EQA are educational, and may be supported by additional elements.

1.3.3 Participant

A laboratory that receives proficiency test items and submits results for review by the proficiency test scheme provider.

1.3.4 Proficiency test item

A sample, product, artefact, piece of equipment or measurement standard sent to one or more participants in a proficiency testing scheme.

1.3.5 Proficiency testing round

A single complete sequence of circulation of proficiency test items to all participants in a proficiency test scheme.

1.3.6 Proficiency testing scheme

Interlaboratory comparisons designed and operated to assess laboratory performance in specified areas of testing, measurement, calibration or inspection.

Note: A scheme might cover a particular type of test, calibration, inspection or a number of tests, calibrations or inspections on particular products, items or materials.

1.3.7 Provider

A body (organisation or firm, public or private) that undertakes the design and conduct of a proficiency testing scheme.

1.3.8 Subcontractor (Collaborator)

A body, (organisation or firm, public or private) engaged to perform activities for a proficiency testing scheme provider, the correct performance of which is essential to the effective delivery of the proficiency testing scheme.

1.3.9 Supplier

Organisation or person that provides a product or service that is used for the production of proficiency test items or the operation of proficiency testing schemes.

SECTION 2 : MANAGEMENT REQUIREMENTS

2.1 Organisation

2.1.1 The provider, or the organisation of which it is part, shall be an entity that can be legally identifiable and accountable.

2.1.2 It is the responsibility of the provider to carry out its proficiency testing operations in such a way as to meet the requirements of these *Guidelines* and to satisfy the needs of the participants, regulatory authorities, and accrediting bodies.

2.1.3 The management system shall cover work carried out in the provider's permanent facilities, or in associated temporary facilities.

2.1.4 If the provider is part of an organisation performing testing, calibration, or accreditation activities, then the provider shall identify the responsibilities of key personnel in the organisation that have an involvement in or influence on the proficiency test evaluations, in order to identify potential conflicts of interest.

2.1.5 The provider shall:

a) have managerial and technical personnel with the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or the procedures for providing proficiency testing schemes and to initiate actions to prevent or minimise such departures;

b) have arrangements to ensure that its management and personnel are free from commercial, financial and other internal and external pressures that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgment or operational integrity;

e) define the organisation and management structure of the provider, its place in any parent organisation, and the relations between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the provision of proficiency testing schemes;

g) provide adequate supervision of technical staff, including trainees, by persons familiar with procedures for each activity;

h) have technical management, which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of proficiency testing procedures;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. The quality manager shall have direct access to the highest level of management at which decisions are taken on the provider's policies or resources;

j) appoint deputies for key managerial personnel;

Note: Where providers have a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for all major functions.

k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system;

2.1.6 Top management shall ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the management system.

2.2 Management system

2.2.1 The provider of a proficiency testing scheme shall establish, implement and maintain a management system appropriate to its scope of activities including the type, range and volume of proficiency testing that it provides.

2.2.2 The provider shall define and document its policies, programs, procedures and instructions to the extent necessary to assure the quality of all aspects of proficiency testing. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

Note: These include, but are not limited to, proficiency test item quality (e.g. homogeneity and stability), characterisation (e.g. equipment calibration and method validation), assignment of property values (e.g. use of appropriate statistical procedures), evaluation of participating laboratories' performance, distribution of proficiency test items, storage and transport procedures, statistical treatment of test results, and reporting.

2.2.3 The provider's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a) the provider management's commitment to good professional practice and to the quality of its proficiency testing services to its customers;

b) the management's statement of the provider's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with the proficiency testing activities familiarise themselves with the quality documentation and implement the policies and procedures in their work; and

e) management's commitment to comply with these Guidelines and to continually improve the effectiveness of the management system.

2.2.4 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

2.2.5 Top management shall communicate to the organisation the importance of meeting customer requirements as well as statutory and regulatory requirements.

2.2.6 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

2.2.7 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with these Guidelines, shall be defined in the quality manual.

2.2.8 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

2.3 Document control

2.3.1 General

The provider shall establish and maintain procedures to control all documents that form part of its management system (internally generated, or from external sources), such as regulations, standards, other normative documents, scheme protocols, test and/or calibration methods, as well as drawings, software specifications, instructions and manuals.

2.3.2 Document approval and issue

2.3.2.1 All documents issued to personnel as part of the management system shall be reviewed and approved for use by authorised personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

2.3.2.2 The procedures adopted shall also ensure that:

a) authorised editions of appropriate documents are available at all locations where operations essential to the effective provision of proficiency testing schemes are performed;

b) documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

2.3.2.3 Management system documents generated by the provider shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages, or a mark to signify the end of a document, and issuing authority.

2.3.3 Document changes

2.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review and approval, unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

2.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

2.3.3.3 If the provider's document control system allows for the amendment of documents by hand pending re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be issued as soon as practicable.

2.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerised systems are made and controlled.

2.4 Review of requests, tenders and contracts

2.4.1 The provider shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews shall ensure that:

a) the requirements, including those for methods, measuring equipment and proficiency test items to be used, are adequately defined, documented and understood;

b) the provider has the capability and resources to meet the requirements;

c) the proficiency testing scheme is technically appropriate for participants.

Note 1: This review is particularly important when a customer wishes to have a scheme created for a specific purpose or if a customer requires a different level or frequency of participation from that normally offered.

Note 2: The review can be simplified when the proficiency test scheme is fully described in a catalogue or other notice, and the participant is enrolling for a routine shipment.

2.4.2 Records of such reviews, including any changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements, and/or the results of the work during the period of execution of the contract.

2.4.3 The review shall also cover any work that is subcontracted by the provider.

2.4.4 The customers shall be informed of any deviation in the contract or agreed scheme design.

2.4.5 If a contract needs to be amended after the scheme is underway, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

2.5 Subcontracting services

2.5.1 When a provider subcontracts work, this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with relevant parts of these *Guidelines*, and other appropriate standards.

2.5.2 The provider shall inform participants, in writing, of services that are, or may be, subcontracted.

Note: This notification may, for example, take the form of a statement in the scheme protocol such as the following: "Various aspects of the proficiency test scheme may from time to time be subcontracted. When subcontracting occurs it is placed with a competent subcontractor and the provider is responsible to the scheme participants for the subcontractor's work."

2.5.3 The provider shall be responsible for the subcontractor's work.

2.5.4 The provider shall maintain a register of all subcontractors used in the provision of proficiency testing schemes and a record of the competence assessment against relevant parts of these *Guidelines* and other appropriate standards for the work in question.

2.6 Purchasing services and supplies

2.6.1 The provider shall have a policy and procedures for the selection of services and supplies that it uses that affect the quality of its proficiency testing schemes. Procedures shall exist for the purchase, reception, and storage of reagents, proficiency test items, reference materials, and other consumable materials relevant for the proficiency testing schemes.

2.6.2 The provider shall ensure that purchased supplies, equipment and consumable materials that affect the quality of schemes are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements. Records of actions taken to check compliance shall be maintained.

2.6.3 Purchasing documents for items affecting the quality of proficiency testing schemes shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

2.6.4 The provider shall evaluate suppliers of critical consumables, supplies and services which affect the quality of proficiency testing schemes, and shall maintain records of these evaluations, and list those approved.

Note to requirements in Clauses 2.6.1, 2.6.2, 2.6.3 and 2.6.4: It is understood that some providers may be required to implement their purchasing procedures according to policies defined by their parent or a host agency.

2.7 Service to the customer

2.7.1 The provider shall be willing to cooperate with customers, including participants and accreditation bodies, or their representatives, in clarifying customers' requests and in monitoring the provider's performance in relation to the work performed, provided that the provider assures confidentiality to other customers.

2.7.2 The provider shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, proficiency testing schemes, and customer service.

2.8 Complaints

The provider shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the provider.

2.9 Control of nonconforming activities

2.9.1 The provider shall have a policy and procedure that shall be implemented when any aspect of its proficiency testing activities does not conform to its own procedures or the agreed requirements of the customer.

The policy and procedure shall ensure that:

a) responsibilities and authorities for the management of nonconforming work are designated and actions (including halting work of ongoing programmes and

withholding reports, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) corrective action is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, customers are notified and the results of nonconforming proficiency test items or statistical evaluations already issued to participants are recalled, destroyed or ignored;

e) the responsibility for authorisation of the resumption of work is defined.

Note: Requirement (d) extends to notifying customers when it is discovered that a proficiency test item was deficient or that an error has occurred in the statistical report of the scheme.

2.9.2 Where the evaluation indicates that nonconforming work could recur or that there is doubt about the provider's or subcontractor's compliance with their own policies and procedures, the corrective action procedure in 2.11 shall be promptly followed.

2.10 Improvements

The provider shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

2.11 Corrective action

2.11.1 General

The provider shall establish a policy and procedures and shall designate appropriate personnel for implementing corrective actions when nonconforming work or departures from the policies and procedures in the management system or with technical operations have been identified.

Note: The identification of problems with the management system or with proficiency testing activities can occur at various places within the management system such as: customer complaints, quality control, checking of proficiency test items and statistical evaluations, staff observations or supervision, management reviews and internal or external audits.

2.11.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

2.11.3 Selection and implementation of corrective actions

Where corrective action is needed, the provider shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be appropriate to the magnitude and risk of the problem.

The provider shall document and implement any required changes resulting from corrective action investigations.

2.11.4 Monitoring of corrective actions

The provider shall monitor the results to ensure that the corrective actions taken have been effective.

2.11.5 Additional audits

Where the identification of nonconforming activities or departures from authorised procedures cast doubts on the provider's compliance with its own policies and procedures, or on its compliance with these *Guidelines*, the provider shall ensure that the appropriate areas of activity are audited in accordance with clause 2.14 as soon as possible.

2.12 Preventive action

2.12.1 Required improvements and potential sources of nonconforming work, either technical or concerning the management system, shall be identified. When improvement opportunities are identified, or if preventive action is required, action plans shall be developed, implemented and monitored, to reduce the likelihood of such nonconforming work and to take advantage of the opportunities for improvement.

2.12.2 The procedure for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective.

2.13 Control of records

2.13.1 General

2.13.1.1 The provider shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

2.13.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

Note: Records may be in the form of any type of media, such as hard copy or electronic storage media.

2.13.1.3 All records shall be held secure and in confidence, and in accordance with relevant legislation.

2.13.1.4 The provider shall have procedures to protect and back-up records stored electronically and to prevent unauthorised access or amendment of these records.

2.13.2 Technical records

2.13.2.1 The provider shall retain records of all technical data relating to each proficiency testing round for a defined period, these shall include, but may not be limited to:

a) Instructions to participants

b) Participants original responses

c) Collated data for statistical analysis

d) Final reports (generic and individual)

Sufficient information shall be retained to establish an audit trail for the processing of results from proficiency testing rounds.

2.13.2.2 Data entry, checking and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

2.13.2.3 When mistakes occur in records or reports, each mistake shall be crossed out, not erased, made illegible, or deleted, and the correct result entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

2.14 Internal audits

2.14.1 The provider shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and these *Guidelines*. The internal audit program shall address all elements of the management system, including the technical procedures and proficiency test item preparation, storage, distribution and reporting activities leading to the provision of a proficiency testing scheme. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Note: The cycle for internal auditing should normally be completed in one year.

2.14.2 When audit findings cast doubt upon the effectiveness of the operations including the suitability and correctness of proficiency test items, procedures, statistical evaluations and data presentation, the provider shall take timely corrective action and shall notify its customers and/or participants in proficiency testing schemes whose activities may have been affected.

2.14.3 The area of audited activity, the audit findings and corrective actions that arise from them shall be recorded.

2.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

2.15 Management reviews

2.15.1 In accordance with a pre-determined schedule and procedure, the provider's top management shall periodically conduct a review of the provider's management system and proficiency testing activities to ensure their continued suitability and effectiveness, and to introduce any necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures;
- reports from management and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- changes in the volume and type of work;
- customer feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as resources and staff training.

Note 1: A typical period for conducting a management review is once every 12 months.

Note 2: Results should feed into the provider's planning system and should include the goals, objectives and action plans.

Note 3: A management review includes consideration of related subjects at regular management meetings.

2.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed timescale.

Note: Where the provider is part of a larger organisation it may be appropriate to hold a separate review meeting to cover proficiency testing activities

SECTION 3: TECHNICAL REQUIREMENTS

3.0 General

This section specifies the requirements that a provider, and any of its associated subcontractors, must meet in order to demonstrate that they are technically competent to provide specific types of proficiency testing schemes.

3.1 Personnel

3.1.1 The coordination and conduct of proficiency testing schemes shall only be undertaken by providers having competence with interlaboratory comparisons and with the particular type of proficiency test items. Providers or associated subcontractors shall also have competence in the measurement of the properties being determined, e.g. for assignment of values, and homogeneity and stability testing.

Note 1: In new areas of proficiency testing, it is possible that no one would have direct experience with proficiency testing within that area.

Note 2: In evaluating the measurement competence of a provider's laboratory, or the laboratory contracted to perform tests, measurements, or calibrations related to these schemes, possession of laboratory accreditation to ISO/IEC 17025: 2005 or ISO 15189:2003 for appropriate tests, calibrations, and/or measurements will satisfy the requirement for demonstration of competence. In circumstances where the laboratory does not hold accreditation, it should demonstrate that the operations comply with the relevant requirements of ISO/IEC 17025 or ISO 15189.

3.1.2 The provider and associated subcontractors shall have managerial personnel with the necessary authority, resources and technical competence required to discharge their duties.

3.1.3 Measurement of the properties of interest (e.g. in determining the homogeneity and stability of proficiency test items) and statistical treatment of participants' results shall be completed by, or under the supervision of, a technically-competent manager qualified preferably both in terms of suitable academic qualifications and relevant work experience.

3.1.4 The provider's management shall define the minimum levels of qualification and experience necessary for the key positions within its organisation.

3.1.5 The provider shall have sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.

3.1.6 The provider shall ensure that staff receive additional training, when necessary, to ensure competent performance of measurements, operation of equipment and any other activities which affect quality. Where possible, objective measures should be used to assess the attainment of competence through training.

Note 1: This may include attendance at appropriate seminars, courses, meetings and conferences.

Note 2: The need to periodically retrain staff should be considered. Staff training and retraining policies should take account of technological change and aim at continual skills upgrading.

3.1.7 The provider shall maintain an up-to-date record of the education and training that each staff member has received. The effectiveness of training actions taken shall be evaluated. These records shall provide evidence that individual staff members have the

necessary theoretical and practical background, and that their competence to perform their assigned tasks has been assessed.

3.2 Accommodation and environment

3.2.1 The provider shall ensure that there is appropriate accommodation for the organisation of the proficiency test(s), including facilities for sample reception, handling, proficiency test item manufacturing, storage, despatch, and retrieval of materials, data, communications and records.

3.2.2 The provider shall ensure that all facilities provided are safe and , meet appropriate health and safety requirements. Where appropriate, written procedures for the decontamination of items of equipment and working space shall be available.

Note: Facilities should meet all safety (including biosafety) requirements relevant to personnel, the environment and the community, although it may be beyond the jurisdiction of the accreditation body to inspect for these requirements. National or international requirements shall apply as appropriate.

3.2.3 Where different activities are carried out in the same premises, consideration shall be given to the appropriate separation of these activities according to the potential for adverse effects on the proficiency test items e.g., contamination.

3.2.4 Facilities shall be available to ensure the safe decontamination and disposal of all materials that are potentially toxic or hazardous.

3.3 Organisation and design logistics

3.3.1 Planning

3.3.1.1 The provider shall identify and plan those processes which directly affect the quality of the scheme and shall ensure that they are carried out in accordance with prescribed procedures.

3.3.1.2 The provider shall document a plan before commencement of the scheme, that typically should include the following information:

a) the name and address of the provider of the proficiency testing scheme;

b) the name, address, and affiliation of the coordinator and other personnel involved in the design and operation of the scheme;

c) the objectives, nature and purpose of the scheme;

d) where appropriate, a procedure for selection of scheme participants, or criteria to be met before participation is allowed;

e) the names and addresses of subcontractors involved in the provision of the scheme (e.g. sampling, test item processing, homogeneity testing and assigning property values);

f) the number and type of expected participants in the scheme;

g) a description of the manner in which proficiency test items are to be obtained, processed, checked and distributed, which takes account, in its design, of the major sources of analytical errors involved in the area of proficiency testing offered;

h) a description of the information which is to be supplied to participants (pre-notification) and the time schedule for the various phases of the scheme;

i) the expected initial and target dates or deadlines of the scheme, including, where appropriate, the dates on which testing or calibration is to be carried out by participants;

j) for on-going schemes, the frequency or dates upon which proficiency test items are to be distributed to participants;

k) information on methods or procedures which participants may need to use to perform the tests or measurements (commonly their routine procedures);

l) an outline of the statistical analysis to be used, including the determination of assigned values and any outlier detection techniques;

m) a description of the data or information to be returned to participants;

n) the basis of performance evaluation techniques, where appropriate;

o) a description of the extent to which test results, and the conclusions that will be based on the outcome of the scheme, are to be made public;

p) the origin and traceability of any reference values.

3.3.1.3 The provider shall ensure access to technical expertise and detailed experience in the relevant field of testing, calibration or inspection, as well as statistics. This may be achieved, for example, by establishing an advisory, expert or steering group, however named.

3.3.1.4 Technical expertise shall be used, as appropriate, to determine matters such as the following:

a) nomination of the most significant tests or calibrations required to be undertaken on the proficiency test items;

b) design of the scheme (e.g. objectives, number of proficiency test items, frequency of distribution, reporting procedures, evaluation of results, type of scheme);

c) the nature of the proficiency test item(s) and test(s) or calibration(s) or inspection(s) selected, as well as a short description of the considerations underlying these choices, where appropriate;

d) range of values to be expected for the proficiency test items;

e) the test or calibration methods to be used;

f) sourcing appropriate proficiency test items;

g) resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items or in providing a stable reference value for a measurement artefact;

h) preparation of detailed instructions for participants;

i) preparation of any standardised reporting formats to be used by participants, including reporting units and the number of significant figures or decimal places to which results are to be reported;

j) comments on any technical difficulties or other remarks raised by participants;

k) provision of advice in assessing the technical competence of participating laboratories;

l) establishment of criteria for performance assessment;

m) comments on the performance of participants as a whole and, where appropriate, groups of participants or individual participants ;

n) technical commentary on the summary report;

o) provision of advice for participating laboratories (within limits of confidentiality), either individually or within the report;

p) responding to feedback from participating laboratories.

3.3.2 Preparation of proficiency test items

3.3.2.1 The provider shall have a procedure and provide resources to ensure that proficiency test items comply with the plan described in Section 3.3.1.

Note: The provider should give due consideration to the preparation of sufficient numbers of proficiency test items to allow for the need to replace any such items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses may include training aids for participants or use as a reference material. (The requirements for the competence of reference material producers are detailed in ISO Guide 34.)

3.3.2.2 The provider shall have a procedure to ensure appropriate acquisition, collection, handling, storage and where required, disposal of all proficiency test items.

3.3.2.3 The provider shall be able to demonstrate that the proficiency test items are sufficiently homogeneous for the particular proficiency testing scheme.

Note 1: A relatively inhomogeneous material may be the best available, and may therefore still be useful as a proficiency test material provided the uncertainties of the assigned property values take due account of this.

Note 2: In some cases it is not feasible for proficiency test items to be subjected to homogeneity and stability testing. Such cases would include, for example, where proficiency test items are taken from patients, with limited amounts of material available. In these circumstances the proficiency test provider should have evidence to demonstrate that the procedures used to collect, package and distribute the proficiency test items are capable of maintaining homogeneity and stability, or some other form of justification.

3.3.2.4 When producing matrix proficiency test items, these should, where practicable, have the same or nearly the same matrix as routine test material in order to simulate the measurement process as closely as possible.

Note: An example of a protocol for establishing such similarity is given in document CLSI/NCCLS EP14-A2.

3.3.2.5 Materials used to manufacture proficiency test items should be obtained in accordance with relevant legal and ethical requirements

Note: Where this applies, providers should comply with the general ethical requirements as stated in Annex C of ISO 15189:2003. For some applications it may be possible to use non-human material;. for example, recombinant material for spiking purposes.

3.3.3 Homogeneity and stability testing

3.3.3.1 Where appropriate, the provider or its subcontractors shall use a statistically random selection of a representative number of samples from a batch of test material to assess the homogeneity of the material.

This assessment procedure shall be documented and be conducted, where applicable, in accordance with acceptable statistical designs.

3.3.3.2 The assessment of homogeneity should be performed after the proficiency test items have been packaged in the final form and before distribution to participants unless, for example, stability studies indicate that it should be stored in bulk form. In some cases, an intermediate homogeneity check may be necessary, for example, before sealing into ampoules.

Note: Homogeneity testing may on some occasions not be done prior to distribution for practical, technical, or logistical reasons, but great caution must be exercised if it is not done or if it is done after test results have been received. In all cases, the provider is required to document the procedure by which it is ensured that homogeneity is adequate.

3.3.3.3 Where appropriate, the property values to be determined in the proficiency testing scheme shall be measured periodically, preferably over a range of conditions under which the proficiency test item is to be stored prior to distribution.

3.3.3.4 Proficiency test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency test, including storage and transport conditions.

Note 1: If the proficiency test item is used for schemes extending over a lengthy period of time, then, depending on the nature of the item, it may also be necessary to carry out stability checks during the period of use.

Note 2: Criteria for suitable homogeneity and stability should be based on the effect that heterogeneity and instability will have on the uncertainty of the participant's result, and thereby on the evaluation of the acceptability of a participant's result.

3.3.4 Statistical design

3.3.4.1 The provider shall document the statistical model and data analysis techniques to be used, together with a description of the reasons for their selection, and shall ensure that they are carried out in accordance with prescribed procedures.

3.3.4.2 Appropriate statistical design of a proficiency testing scheme is essential. In designing a scheme the provider shall give careful consideration to the following:

a) the accuracy or uncertainty (trueness and precision) required or expected for each measurand in the proficiency test;

b) the minimum number of participants in the scheme in order that meaningful evaluations may be made;

c) the number of proficiency test items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each proficiency test item or for each determination;

d) the procedures to be used to estimate the assigned value and, where appropriate the uncertainty for each measurand;

e) procedures to be used to identify and/or handle statistical outliers;

f) where appropriate, the statistical procedure for the evaluation of censored (removed) values;

g) where appropriate, the homogeneity and stability of proficiency test items.

Note 1: In the absence of reliable information concerning (a), it may be necessary to conduct a preliminary interlaboratory comparison to obtain it.

Note 2: In cases where a proficiency test scheme involve an insufficient number of participating laboratories to allow for a statistically meaningful analysis of results, the scheme provider must document, and provide to participants, details of the alternative approaches used to analyse the scheme data.

3.4 Choice of method or procedure

3.4.1 Scheme participants shall normally be expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with routine procedures used in their laboratories. In certain circumstances the scheme coordinator may instruct participants to use a specified method.

3.4.2 Where participants are permitted to use a method of their choice, the provider shall have a written policy relating to a procedure used to permit comparison and comment on the results obtained by different test methods. The coordinator shall be aware of which different test methods for any measurand are technically equivalent, and take steps to assess participants' result using these methods accordingly.

3.5 Conduct of proficiency testing schemes

3.5.1 Instructions to participants

3.5.1.1 The provider shall give participants early prior notice before sending samples, artefacts or other proficiency test items, providing the date upon which samples are likely to arrive or to be despatched.

3.5.1.2 The provider shall give detailed documented instructions to all participants. Such instructions may, for example, be included as an integral part of the scheme protocol.

3.5.1.3 Instructions to participants shall include details of factors which could influence the testing or calibration of the proficiency test items, for example, conditions of storage, the nature of the materials or test items, whether the scheme is limited to selected test methods, and the timing of the testing or measurement.

3.5.1.4 Specific instructions on the manner of recording and reporting test or calibration results shall include, but are not necessarily limited to, the units of measurement, the number of significant figures or decimal places, reporting basis (e.g. on dry weight, or “as received'), and the latest date for receipt of test results.

Note: For consistency in the presentation of test results, and for ease of statistical treatment, standardised report sheets are often prepared and distributed to participants. They are sometimes supplemented by asking participants to also submit a test report or calibration certificate in their usual format.

3.5.1.5 Scheme participants shall be instructed to treat proficiency test items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the proficiency testing scheme which require departure from this principle).

3.5.1.6 The assigned value(s) shall not be disclosed to participants until after the results have been received. Instructions may include an approximate range to facilitate the analytical process.

In some schemes such as those that involve perishable materials or where proficiency test items may circulate to several participants, preliminary or anticipated results may be provided before final results are disclosed.

Note: This allows for early investigation of possible error.

3.5.2 Materials handling and storage

3.5.2.1 In order to avoid contamination of the test material, the provider and any associated subcontractors shall identify, preserve and segregate all test materials and proficiency test items from all chemicals and other materials that cause contamination or degradation, from the time of preparation through to their distribution to scheme participants.

3.5.2.2 The provider and any associated subcontractors shall ensure adequate packaging of all proficiency test items and shall provide secure storage areas and/or stock rooms which prevent damage or deterioration of any proficiency

test item between preparation and distribution. Appropriate methods for authorising despatch to, and receipt from, such areas shall be defined.

Note: It is possible for a homogeneous sample to contain an unstable analyte (for example, vitamins in feed), or for a stable analyte (for example, dioxins or PCBs) to be present in a sample subject to decomposition during storage.

3.5.2.3 When appropriate, the condition of all stored or stocked proficiency test items and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.

3.5.3 Packaging, labelling and distribution

3.5.3.1 The provider shall control packaging and marking processes to the extent necessary to ensure conformity with relevant regional, national and/or international safety and transport requirements.

Note: The proper distribution of samples can present severe problems for some types of material; for example, those which require uninterrupted storage in cold conditions or which should not be exposed to X-rays, shock or vibration. Most types of chemical materials would benefit from air-tight packaging to avoid contamination by atmospheric contaminants, for example, fuel vapours or engine exhaust gases which may be encountered during transport.

3.5.3.2 In schemes where participating laboratories are required to transport the proficiency test items to other participants, laboratories shall be supplied with documented instructions for this transport.

3.5.3.3 The provider shall ensure that material labels are securely attached to the packaging of individual proficiency test items and are designed to remain legible and intact throughout the proficiency test round.

3.5.3.4 The provider shall have procedures to allow the confirmation of delivery of the proficiency test items

3.6 Data analysis and interpretation of scheme results

3.6.1 Data analysis and records

3.6.1.1 Data processing equipment shall be adequate for all data entry and statistical analysis requirements and shall be capable of providing timely and valid results.

3.6.1.2 The provider shall designate a person to be responsible for the effective operation of the data processing system and shall define the role and responsibility for this position in the operation of proficiency test schemes.

3.6.1.3 All data processing equipment and system software shall be properly maintained and validated in accordance with documented procedures before being brought into use. The results of such maintenance and operational checks shall be recorded. Software maintenance shall include a back-up regime and system recovery plan.

3.6.1.4 Results received from participants shall be promptly recorded and analysed by appropriate statistical procedures. Procedures shall be established and

implemented to check the validity of data entry, data transfer and statistical analysis. Data sheets, computer back-up files, printouts and graphs shall be retained for a specified period.

3.6.1.5 Data analysis shall generate summary measurement and performance statistics and associated information consistent with the proficiency testing scheme statistical model and objectives.

3.6.1.6 The influence of extreme results on summary statistics shall be minimised by the use of appropriate tests to detect statistical outliers, or by the use of robust statistics.

3.6.1.7 The provider shall have documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, for example, gross errors, miscalculations and transpositions.

3.6.1.8 The provider shall have documented criteria for determining whether proficiency test items that have been distributed are subsequently determined to be unsuitable for evaluation, for example because of unexpected inhomogeneity, instability or contamination. (Refer also to Section 3.3.2.3).

3.6.2 Evaluation of performance

3.6.2.1 The proficiency testing scheme provider shall be responsible for ensuring that the method of evaluation is appropriate for maintenance of the credibility of the scheme. Such a method shall be documented, applicable to all participants or its limitations known, and shall include a description of the basis upon which the evaluation is made.

3.6.2.2 The provider shall, where appropriate, enlist the assistance of technical advisers, which may include a specialist with appropriate knowledge of statistics, to provide expert commentary on the performance of participants with regard to the following:

a) overall performance against prior expectations, where appropriate, taking measurement uncertainties into account;

b) time schedule for sample distribution and measurement carried out by participating laboratories;

c) variation within and between laboratories, and comparisons with any similar previous schemes or published precision data;

d) variation between methods or procedures, if applicable;

e) possible sources of error (with reference to extreme results) and suggestions for improving performance;

f) advice and educational feedback to participants as part of the continual improvement procedures of participating laboratories, where appropriate;

g) situations where unusual factors make evaluation of results and commentary on performance impossible;

h) any other suggestions, recommendations or general comments;

i) conclusions.

Note 1: It may be useful to provide individual summary sheets for participants periodically during or after completion of a particular scheme. These may include updated summaries of performance for individual laboratories over successive rounds of an on-going scheme. Such summaries can be further analysed and trends highlighted if required.

Note 2: For schemes involving different manufacturers' instruments or in-vitro diagnostics the results should be evaluated according to the same protocol.

3.6.3 Reports

3.6.3.1 General

The content of proficiency testing scheme reports will vary depending on the purpose of a particular scheme, but each report shall be clear and comprehensive and include data on the distribution of results from all participants, together with an indication of the performance of individual participants.

3.6.3.2 The following information shall normally be included in reports of proficiency testing schemes:

a) name and contact details for the provider;

b) name and contact details for the scheme coordinator;

Note: Other names and contact details can be included, where appropriate, including details of subcontractors and steering committee members.

c) date of issue of the report;

d) page numbers and a clear indication of the end of the report;

e) confidentiality statement;

f) report number and clear identification of the scheme;

g) clear description of the proficiency test items used, including, where appropriate, details of the proficiency test item's preparation, homogeneity testing and stability testing;

h) laboratory participation codes and test results;

i) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;

j) procedures used to establish any assigned value or reference value;

k) details of the traceability and uncertainty of any assigned or reference values, where applicable;

l) assigned values and summary statistics for test methods/procedures used by other participants (if different methods are used by different participants);

m) comments on participants' performance by the provider and technical advisers (e.g. the scheme's advisory, steering or expert group);

n) procedures used to design and implement the scheme (which may include reference to the current version of a scheme protocol);

o) procedures used to statistically analyse the data, where applicable (see Appendix A for guidance);

p) advice, where appropriate, on the interpretation of the statistical analysis;

q) any comments or recommendations, based upon the outcomes of the round.

Note: For schemes operated on a regular basis, it may be sufficient to have simpler reports such that many of the recommended elements in this clause could be excluded from routine reports, but included in scheme protocols or in periodic summary reports and provided upon request to participants.

3.6.3.3 Reports shall be made available to participants within specified timetables. In schemes such as long term measurement comparison schemes, and if technically possible, interim reports shall be issued to individual participants.

Note 1: Although, ideally, all original data supplied should be reported to all participants, it may not be possible to achieve this in some very extensive schemes. Participants should receive at least the results from all participants in summary (e.g. tabulated or graphical) form.

Note 2: The provider should hold copyright of all reports issued in order that any data from scheme reports appearing in publications will be correctly used and referred.

3.7 Communication with participants

3.7.1 The provider shall make available to prospective participants detailed information, for example in the form of a scheme protocol, on how to apply to participate. This should include details of the scope of the scheme, any fees for participation, and policies about which laboratories may participate.

Note: Subsequent communication with participants may be by means of a letter, newsletter and/or reports, together with periodic open meetings.

3.7.2 Participants shall be advised promptly by the provider of any changes in scheme design or operation.

3.7.3 There shall be documented procedures for enabling participants to appeal against the assessment of their performance in a proficiency testing scheme. The availability of this process shall be communicated to scheme participants.

3.7.4 All communications between participants and the provider shall be recorded and filed so that they can be easily accessed, but also with due regard for confidentiality.

3.8 Confidentiality

3.8.1 The identity of participants in a proficiency testing scheme shall usually (see Note) be confidential and known only to the minimum number of persons involved in the provision and evaluation of the scheme.

3.8.2 All information supplied by a participant to the provider shall be treated as confidential.

Note: Participants may elect to waive confidentiality within the scheme for the purposes of discussion and mutual assistance, for example, to improve performance. Confidentiality may also be waivedby the participant for regulatory or accreditation purposes. In most instances, the proficiency results should be provided to the relevant authority by the participants themselves.

3.8.3 When an accrediting body requires the proficiency test results to be directly provided by the scheme coordinator, the participants shall be made aware of the arrangement in advance of participation.

3.8.4 In exceptional circumstances, when a regulatory authority requires the proficiency test results to be directly provided to the authority by the scheme coordinator, the participants shall be notified of this action in writing.

3.9 Collusion and falsification of results

Proficiency testing schemes shall, where practicable, be designed to ensure that there is as little opportunity as possible for collusion and falsification of results.

Note: Although all reasonable measures should be taken by the provider to prevent collusion, it should be appreciated that it is the responsibility of the participants to avoid it. Collusion and falsification are unethical and constitute scientific fraud.

APPENDIX A - Commonly-used Statistical Methods for Treatment of Proficiency Test Data

This appendix presents information for guidance only. It discusses basic international consensus guidance documents for selecting statistical methods, and reference to appropriate general consensus references.

To assist providers of proficiency testing schemes, information on the selection and use of statistical procedures for the treatment of proficiency test data is given ISO 13528:2005. Recommendations in ISO 13528 are reviewed and in some cases modified in the IUPAC Harmonized Protocol for proficiency testing of chemical analytical laboratories (2006). Guidance on homogeneity testing for reference materials is given in ISO/IEC Guide 35, while special considerations for acceptance for use in proficiency testing are given in the IUPAC and ISO 13528 documents..

The subjects covered in these documents include:

- *Demonstration of proficiency test item homogeneity and stability*

  The requirements call for a demonstration of "sufficient homogeneity" and standard statistical techniques, including a statistically random selection of a representative number of sample. Techniques for this are detailed in ISO 13528 and in the 2006 IUPAC Harmonized Protocol. These documents define "sufficient homogeneity" relative to the evaluation interval for the proficiency test.

  There are different requirements in Guide 35, which is for determining reference values and their uncertainty, and therefore uses analysis of variance techniques; and the procedure used in the ISO 13528 and IUPAC Harmonized Protocol recommendations, which are based on allowances for uncertainty due to inhomogeneity relative to the evaluation interval.

- *Determination of the assigned value and its uncertainty*

  Assigned values can be determined by formulation or reference values, or can be determined by consensus, either of experts within a scheme, or by consensus of participants. These methods of determining the assigned value all have different uncertainties, and they are presented in the documents in that preference order (lower uncertainty).

  There is little discussion of assigned values for non-quantitative measurands, since these are usually determined by manufacture or by expert review.

- *Robust statistical techniques and the treatment of extreme results(including outlier removal);*

  The ISO standard and IUPAC recommendations allow for the use of alternative statistical methods, so long as they are statistically valid for the application and are fully described to participants. This allows, for example other robust techniques or conventional statistics after outlier removal. One general technique is presented for robust means and standard deviations.

- *Calculation of performance statistics*

This includes consideration of performance on single proficiency test items as well as combined performance scores. There are examples of variability measures for calculation of performance statistics; and the accommodation of measurement uncertainty.

- *Evaluation of performance*

  This includes consideration of initial performance and monitoring of performance over time. Considerations for criteria, including fitness for purpose or consensus criteria, presentation of graphical techniques, including error bars, histograms, Shewhart charts, and Youden plots.

  Annex C of ISO/IEC Guide 43:1 (1997) contains an extensive bibliography of publications covering.

  - Terms and definitions
  - Criteria in proficiency testing for accreditation
  - Interlaboratory comparisons
  - Statistical techniques for collaborative tests
  - Robust statistics
  - Proficiency testing and pathology laboratories

APPENDIX B - (Informative) Cross-references between ILAC G13:2007, ISO 9001:2000, ISO/IEC Guide 43-1:1997, ISO/IEC 17025:2005 and ISO 15189:2003

Cross-references between elements of the *ILAC Requirements for the Competence of Providers of Proficiency Testing Schemes* and, where relevant, ISO 9001:2000, ISO/IEC Guide 43-1:1997, ISO/IEC 17025:2005 and ISO 15189:2003.

Requirements for Competence of Proficiency Testing Providers (ILAC G13)		ISO 9001:2000	ISO/IEC Guide 43-1:1997	ISO/IEC 17025:2005	ISO 15189:2003
2.1.1	Legal identity	-	-	4.1.1	4.1.1
2.1.2	Meeting guidelines	-	-	4.1.2	4.1.3
2.1.3	Coverage	-	-	4.1.3	4.1.3
2.1.4	Identifying conflicts of interest	-	-	4.1.4	4.1.4
2.1.5	Organisational management	-	-	4.1.5	4.1.5
2.1.6	Communication Process	-	-	4.1.6	-
2.2.1	Management system	4.1 & 4.2.2	-	4.2.1	4.2.1
2.2.2	Policy objectives	5.1, 5.3 & 5.4.1	-	4.2.2	4.2.3
2.2.3	Documented management system	4.2.1 & 4.2.2	-	4.2.1	4.2.4
2.2.4	Management commitment	5.1	-	4.2.3	4.2.3
2.2.5	Meeting requirements	5.1 & 5.2	-	4.2.4	4.1.2
2.2.6	Supporting procedures and structure	4.2.1 & 4.2.2	-	4.2.5	4.2.4
2.2.7	Roles/responsibility	5.5.1	-	4.1.5	4.1.5
2.2.8	Integrity of system	5.4.2	-	4.2.7	-
2.3.1	Document control procedures	4.2.3	-	4.3.2	4.3.1
2.3.2	Document approval and issue	4.2.3	-	4.3.2	4.3.2
2.3.3	Document changes	4.2.3	-	4.3.3	4.3.2
2.4.1	Contract review	7.2.1 & 7.2.2	-	4.4.1	4.4.1
2.4.2	Records of contract reviews	7.2.2	-	4.4.2	4.4.2
2.4.3	Review includes subcontractors	7.4.1	-	4.4.3	4.4.3
2.4.4	Customers informed of deviations in scheme	7.2.2 & 7.2.3	-	4.4.4	4.4.4
2.4.5	Amendment of contracts	7.2.2 & 7.2.3	-	4.4.5	4.4.5
2.5.1	Selection of subcontractors	7.4.1	-	4.5.1	4.5.1
2.5.2	Informing customers of subcontracted work	7.2.3	-	4.5.2	4.5.3
2.5.3	Providers responsibility for subcontracted work	7.4.1	-	4.5.3	-
2.5.4	Register of subcontractors	-	-	4.5.4	4.5.3
2.6.1	Supply selection policies	7.4.2	-	4.6.1	4.6.1
2.6.2	Use of adequate services/supplies	7.4.1 & 7.5.4	-	4.6.2	4.6.2
2.6.3	Compliance with requirements	7.4.3 & 7.5.4	-	4.6.3	4.6.1 & 4.6.2
2.6.4	Evaluation and approval	7.4.3 & 7.5.4	-	4.6.4	4.6.4
2.7.1	Cooperation with customers	7.2.1 & 7.2.3	6.7	4.7.1	4.7
2.7.2	Customer feedback	7.2.3	6.7.3	4.7.2	4.8
2.8	Complaints	8.3 & 8.5.2	-	4.8	4.8
2.9	Nonconforming activities	8.5.2 & 8.5.3	-	4.11.2	4.9.1
2.9.1	Control of non-conforming work	8.5.2	-	4.9.1	4.9.1
2.9.2	Correction of non-conforming work	8.5.2	-	4.9.2	4.9.2
2.10	Improvements	8.5	-	4.10	4.12
2.11.1	Corrective Actions	8.5.2	-	4.11.1	4.10
2.11.2	Cause analysis	8.5.2	-	4.11.2	4.10.1
2.11.3	Selection and implementation of CAs	8.5.2	-	4.11.3	4.10.1 & 4.10.2
2.11.4	Monitoring of CAs	8.5.2	-	4.11.4	4.10.3
2.11.5	Additional audits	-	-	4.11.5	-
2.12.1	Preventive Actions	8.5.3	-	4.12.1	4.11.1
2.12.2	Preventive action procedure	8.5.3	-	4.12.2	4.11.2
2.13.1.1	Identification etc of records	4.2.4	-	4.13.1.1	4.13.1
2.13.1.2	Storage of records	4.2.4	-	4.13.1.2	4.13.2
2.13.1.3	Security of records	4.2.4	-	4.13.1.3	4.13.2
2.13.1.4	Security of data	4.2.4	-	4.13.1.4	-
2.13.2	Technical records	4.2.4	-	4.13.2.1-3	4.13
2.14.1	Internal audits	8.2.2	-	4.14.1	4.14.1
2.14.2	Corrective action for NCRs	8.2.2 & 8.5.2	-	4.14.2	4.14.2
2.14.3	Audit records	8.2.2 & 4.2.4	-	4.14.3	4.13.3
2.14.4	Follow up activities	8.2.2	-	4.14.4	4.14.3
2.15.1	Periodic management reviews	5.6.1 & 8.5.1	-	4.15.1	4.15.1
2.15.2	Record of findings of mgt reviews	5.6.1	-	4.15.2	4.15.4
3.1.1	Staff experience, etc requirements	6.1, 6.2.1 & 6.2.2	-	5.2.1	5.1.2, 5.1.3 & 5.1.4

Requirements for Competence of Proficiency Testing Providers (ILAC G13)		ISO 9001:2000	ISO/IEC Guide 43-1:1997	ISO/IEC 17025:2005	ISO 15189:2003
3.1.2	Managerial staff and resources	6.1, 6.2.1 & 6.2.2	5.2.1	5.2.1	5.1.3 & 5.1.5
3.1.3	Measurement staff and resources	6.2.1 & 6.2.2	5.2.2	5.2.1 & 5.2.5	5.1.5
3.1.4	Minimum levels of qualifications & experience	6.2.1 & 6.2.2	-	5.2.2	5.1.6
3.1.5	Adequate personnel	6.1 & 6.2.1	-	5.2.1	5.1.5 & 5.1.6
3.1.6	Additional training needs	6.2.2	-	5.2.1 & 5.2.2	5.1.2 & 5.1.9
3.1.7	Records of training	6.2.2	-	5.2.5	5.1.2
3.2.1	Accommodation and environment	6.3 & 6.4	-	5.3.1, 5.3.2 & 5.3.3	5.2.1
3.2.2	Health and Safety requirements	-	-	-	5.2.1, 5.2.2, 5.2.6 & 5.2.10
3.2.3	Adverse effects	-	-	5.3.2 & 5.3.3	5.2.5 & 5.2.6
3.2.4	Decontamination and disposal	-	-	-	5.2.10
3.3.1.1	Program planning	-	5.1.2	4.4	4.4
3.3.1.2	Documented plan	7.5.1	5.1.2	-	-
3.3.1.3	Establishment of specialist working group	7.3.4	5.2.2	-	4.7
3.3.1.4	Responsibilities of working group	-	5.2.3	-	4.7
3.3.2.1	Preparation of proficiency test items	-	5.5.1	-	-
3.3.2.2	Sample handling procedures	-	5.5.2	5.8	5.4.2 & 5.4.3
3.3.2.3	Homogeneity testing	-	5.5.2 & 5.6.2	-	-
3.3.2.4	Matrix matching	-	5.5.3 & 5.6.2	-	-
3.3.2.5	Legal and ethical samples	-	-	-	Annex C
3.3.3.1	Selection of items for homogeneity testing	-	5.6.2	-	-
3.3.3.2	Testing after packaging	-	5.6.2	-	-
3.3.3.3	Periodic checking of properties	-	5.6.2	-	-
3.3.3.4	Stability checking of properties	-	5.6.3	-	-
3.3.4.1	Statistical model and data analysis	-	5.4.1 & 5.6.2	-	-
3.3.4.2	Appropriate statistical design of program	-	5.4.2	-	-
3.4.1	Participants' choice of method	-	5.4.2 & 5.7.1	-	-
3.4.2	Requested details of methods	-	5.7.3	-	-
3.5.1.1	Early advice to participants	-	-	-	-
3.5.1.2	Detailed instruction with samples	-	6.2.1 & 6.7.1	-	-
3.5.1.3	Details of factors affecting testing	-	6.2.2	-	-
3.5.1.4	Recording and reporting results	-	6.2.3	-	-
3.5.1.5	Treat samples as normal samples	-	6.2.4	-	-
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3.8.3	Information to accrediting body	-	-	-	-
3.8.4	Information to regulator	-	7.1	-	-
3.9	Falsification of data	-	7.2	-	-

APPENDIX C Bibliography

(Informative)

(1) ISO/IEC 17000:2004, Standardisation and related activities - General vocabulary.

(2) ISO/IEC Guide 43-2:1997, Proficiency testing by interlaboratory comparisons - Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies.

(3) ASTM E1301-95 Standard Guide for Proficiency Testing by Interlaboratory Comparisons.

(4) ISO 3534-1:1993, Statistics - Vocabulary and symbols - Part 1: Probability and general statistical terms.

(5) ISO 5725-1:1994, Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions.

(6) ISO 5725-2:1994, Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.

(7) ISO 5725-4:1994, Accuracy (trueness and precision) of measurement methods and results - Part 4: Basic methods for the determination of the trueness of a standard measurement method.

(8) ISO Guide to the expression of uncertainty of measurement (1995).

(9) VIM:1993, International vocabulary of basic and general terms in metrology (under revision).

(10) Standards for EQA schemes in laboratory medicine. Version 4.02, December 2004. Clinical Pathology Accreditation (UK) Ltd. Sheffield, UK, 2004.

(11) National Occupational Standards for External Quality Assessment, HCS-EQA1 toHCS-EQA12. Competence Framework for Healthcare Science. (www.skillsforhealth.org.uk/view_framework.php?id=73)

(12) European Commission G*uidelines for the Production and Certification of Reference Materials: 1997*, Document BCR/01/97 Part A.

(13) Eurachem document 2000 (Second edition): *Quantifying Uncertainty in Analytical Measurement*.

(14) ISO/TS 21748:2004 *Guide to the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*.

(15) EN14136:2004 *Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures.*

(16) ISO 13528:2005 *Statistical methods for use in proficiency testing by interlaboratory comparisons.*