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

ILAC-G13:2000

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PREAMBLE

Proficiency testing schemes are used by laboratory accreditation bodies as part of the assessment process to assess the ability of laboratories to perform competently tests for which accreditation is held. Proficiency tests complement the traditional technique of on-site laboratory review by technical specialists.

Some laboratory accreditation bodies develop and operate their own proficiency testing schemes. Their assessors may also, where appropriate, utilise the data generated by other interlaboratory test comparisons in which accredited laboratories participate.

It is recognised that schemes conducted by other organisations may have other primary aims, such as establishing the effectiveness and precision of test methods, checking the individual testing performance of laboratory staff, or determining the characteristics of a material to a particular degree of accuracy (such as in preparation of reference materials).

Assessors and laboratory 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.

This document is directed to providers of proficiency testing schemes who wish, on a voluntary basis, 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 proficiency testing schemes.

For the selection of proficiency testing schemes by laboratories, and their acceptance during laboratory assessment, the requirements 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 *Guidelines* have been developed with the following major features:

a) 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 collaborators.
[Note: Definition 1.3.2 refers]
Accordingly, it is the provider (and any subcontractual arrangements used by the provider) which should be evaluated for compliance with these *Guidelines.*

b) The *Guidelines* are based on ISO Guide43-1:1997 and on the *relevant* elements of ISO/IEC 17025:2000 applicable to the characterisation, homogeneity and stability testing of proficiency testing test materials. Additionally, relevant elements of ISO 9000:1994 are included to eliminate the need for separate recognition of a provider of proficiency testing schemes for compliance with ISO 9000:1994. Accordingly, the *Guidelines* have been prepared in two sections covering, respectively:

   (i) Management System Requirements;

   (ii) Technical Requirements.

c) 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 the performance of individual laboratories 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, on a voluntary basis, 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 proficiency testing schemes.

Note: Fulfilment of these Guidelines is not the only tool for establishing confidence in proficiency testing schemes.

The criteria are not applicable to proficiency testing between only two laboratories.

AUTHORSHIP

This publication was prepared by the ILAC Technical Accreditation Issues Committee and endorsed for publication by a decision of the ILAC General Assembly in 1999.

1 : GENERAL

1.1 Scope

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

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 and ISO/IEC 17025:2000 or ISO 9000:1994, these are cross-referenced in Annex 2.

1.1.4 Providers complying with these *Guidelines* are considered to comply also with the relevant requirements of ISO 9000 Series:1994 as applied to the design and provision of specific types of proficiency testing schemes.

1.2 References

ISO/IEC 17025:2000 *General requirements for the competence of calibration and testing laboratories.*

ISO Guide 35:1989 (under revision), *Certification of reference materials - General and statistical principles.*

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

ISO 9000 Series:1994, (under revision) *Quality management and quality assurance standards.*

European Commission Guidelines for the Production and Certification of Reference Materials: 1997, Document BCR/01/97 Part A.

The International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories. *Journal of AOAC International*, 76, No. 4, 1993, pp. 926-940.

Evaluation of Matrix Effects: Proposed Guideline, NCCLS Document EP-14P. National Committee for Clinical Laboratory Standards, Villanova, PA, 1994.

Eurachem document 1995 (under revision by Eurachem and CITAC): *Quantifying Uncertainty in Analytical Measurement.*

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 ISO/IEC 17025:2000.

1.3.1 **Provider**

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

1.3.2 **Collaborator (Subcontractor)**

A body, (organisation or firm (public or private)) that undertakes subcontracted activities for a proficiency testing scheme provider.

1.3.3 **Coordinator**

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

1.3.4 **Proficiency testing scheme**

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

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

1.3.5 **Proficiency testing round**

A single operation of a proficiency testing scheme.

2 : MANAGEMENT SYSTEM REQUIREMENTS

2.1 Quality Management System

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

2.1.2 The provider shall define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of proficiency testing, including test material quality (e.g. homogeneity and stability), characterisation (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures), evaluation of participating laboratories' performance, distribution of artefacts and test material, storage and transport procedures, statistical treatment of test results, and reporting.

The quality policy shall include a commitment to conduct proficiency testing schemes which conform to the technical requirements contained in Section 3 of these *Guidelines.*

2.1.3 The provider shall establish and maintain a documented quality management system appropriate to the type, range and volume of proficiency testing that it provides to ensure that the schemes conform to specified requirements.

The provider shall have a quality system that, in particular, covers the following:

a) aims, scope, statistical design and format of proficiency testing schemes;

b) operational procedures;

c) preparation and issuing of reports;

d) policies on confidential and ethical procedures;

e) computing and information systems;

f) collaboration and sub-contracting, where relevant;

g) fees for participation;

h) scope of availability of proficiency testing schemes;

i) general policies on participation;

j) use of scheme results;

k) procedures for handling complaints.

2.1.4 The documented quality management system shall specify which activities are undertaken by the provider and, where relevant, which activities are undertaken by collaborators, and shall include policies and procedures used by the provider to ensure that all activities conducted by collaborators comply with the relevant clauses of these *Guidelines*.

2.1.5 The documented quality management system shall define the roles and responsibilities of the technical manager and the quality manager (however named) and the coordinator, including their responsibilities for ensuring compliance with these *Guidelines.*

2.2 Organisation and Management

2.2.1 The provider, or the organisation of which it is part, shall be legally identifiable.

2.2.2 The provider:

a) shall have managerial personnel supported by technical personnel with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the quality management system or the procedures for providing proficiency testing schemes and to initiate actions to prevent or minimise such departures;

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

c) shall have policies and procedures to ensure the protection of confidential information and proprietary rights of participants in proficiency testing schemes;

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

e) shall define, with the aid of organisational charts, the organisation and management structure of the provider, its place in any parent organisation, and the relations between management, technical operations, support services, collaborators and the quality management system;

f) shall 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) shall 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;

h) should 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 these *Guidelines* are 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 proficiency testing policy or resources;

i) should, where possible, appoint deputies for key managerial personnel such as the coordinator, technical manager and quality manager.

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.

2.3 Document Control

2.3.1 **General**

The provider shall establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that forms part of its quality documentation.

2.3.2 **Document approval and issue**

2.3.2.1 All documents (including documented procedures) issued to personnel as part of the quality management system shall be reviewed and approved for use by authorised personnel prior to issue. A master list or equivalent identifying the current revision status of documents in the quality 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) all documents are uniquely identified;

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

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

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

e) obsolete documents retained for either legal or information preservation purposes are suitably marked.

2.3.3 **Document changes**

2.3.3.1 Changes to documents (including documented procedures) shall be reviewed and approved by the same personnel who conducted 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.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

2.4 **Request, Tender or Contract Review**

2.4.1 Each request, tender or contract for provision of a proficiency testing scheme shall be reviewed by the provider to ensure that:

a) the requirements are adequately defined, documented and understood;

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

c) any differences between the contract or order requirements and those in a tender are resolved.

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

2.4.3 The review shall include any work that is carried out by collaborators.

2.5 Use of Collaborators (Subcontractors)

2.5.1 The provider shall have procedures for evaluating and selecting collaborators on the basis of their ability to meet subcontracted requirements in terms of both their technical competence and any specific quality assurance requirements relevant to their tasks. The technical requirements to be satisfied by collaborators shall be equivalent to the technical requirements defined in Section 3 of these *Guidelines.*

2.5.2 The provider shall maintain a register of all collaborators used in the provision of proficiency testing schemes and include a record of any assessments made of their abilities to conduct subcontracted tasks.

2.6 Procurement of Services and Supplies

2.6.1 The provider shall have procedures for the selection of services and supplies that affect the quality of its proficiency testing schemes.

2.6.2 The provider shall use only those services and supplies that are of adequate quality to sustain confidence in its proficiency testing schemes.

2.6.3 When no formal approval of the quality of services and supplies is available, the provider shall have procedures to ensure that purchased materials and services comply with specified requirements and records of actions taken shall be maintained.

2.6.4 The provider shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements.

2.6.5 The provider shall maintain records of approved suppliers of services and supplies.

2.7 Client Feedback

The provider shall have procedures for the effective handling of complaints or other feedback received from participants. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the provider.

2.8 Control of Non-conforming Activities

2.8.1 The provider shall have a procedure to be implemented when it establishes that any aspect of its proficiency testing activities does not conform with its own procedures or the agreed requirements of a client.

The procedure shall ensure that:

a) responsibilities and authorities for the management of nonconforming work are designated;

b) the actions to be taken when a nonconformance is identified are defined;

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

d) work is halted if necessary;

e) remedial actions are taken promptly;

f) where necessary, the results of nonconforming test materials or statistical evaluations already issued to participants are recalled;

g) the responsibility for authorisation of the resumption of work is defined;

h) complete records are maintained, where practicable, of all nonconforming activities.

Note: Requirement (f) extends to notifying clients when it is discovered that a proficiency testing sample was inhomogeneous, or that an error has occurred in the statistical report of the scheme.

2.8.2 Where the evaluation indicates that the supply of nonconforming test materials could recur or that there is doubt about the provider's or collaborator's compliance with their own policies and procedures, the corrective action procedures in 2.9 shall be promptly followed to identify root causes of the problem and to eliminate these causes.

2.9 Corrective Action

2.9.1 **General**

The provider shall establish a policy and procedures and shall designate appropriate personnel for implementing corrective actions when nonconforming test materials or departures from the policies and procedures in the quality management system or with proficiency testing activities have been identified.

Any corrective action taken to eliminate the causes of nonconformances or other departures shall be appropriate to the problems and commensurate with the risks encountered.

The provider shall document and implement any required changes to the operational procedures resulting from corrective action investigations.

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

2.9.2 **Cause analysis**

Corrective action procedures shall include an investigation process to determine the root causes of the problem.

2.9.3 **Corrective actions**

The provider shall identify possible causes and potential corrective actions. It shall select the actions most likely to eliminate the problem and to prevent it recurring.

2.9.4 **Monitoring of corrective actions**

After having implemented the corrective action, the provider shall monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

2.10 Preventive Action

2.10.1 All operational procedures shall be systematically reviewed at regular intervals to identify any potential sources of nonconformances and any opportunities for improvement, either technical or within the quality management system. Action plans shall be developed, implemented and monitored, to reduce the likelihood of such nonconformances and to take advantage of the improvement opportunities.

2.10.2 After the implementation of preventive actions, the provider shall monitor the results to establish any reduction in nonconformances in this operational area, thereby establishing the effectiveness of the preventive action.

2.11 Records [See also Clause 3.6.1]

2.11.1 **General**

2.11.1.1 The provider shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. [See also Clause 3.6.1]

2.11.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable, and in facilities that provide a suitable environment to prevent damage, deterioration or loss. Retention times of records shall be established and recorded. [See also Clause 3.6.1.4]

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

2.11.1.3 All records shall be held secure.

2.11.1.4 The provider shall have procedures to protect electronically-held data at all times and to prevent unauthorised access to, or amendment of, such data.

2.11.2 **Technical records**

The provider shall establish and maintain a records system to suit its particular circumstances and to comply with any applicable regulations. The provider shall arrange for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), results from participants and scheme reports to be retained

until it is no longer probable that they will need to be referred to.

The results of each calibration, measurement (or series of either), or homogeneity or stability tests carried out by the provider and its collaborators, where appropriate, shall be reported accurately, legibly, indelibly, unambiguously and objectively, in accordance with any instructions in calibration, measurement or test methods. The results shall normally be reported in a calibration or measurement report and shall include all information necessary for interpretation of the calibration or measurement results and a summary of the method employed.

2.12 Internal Audits

2.12.1 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 quality management system and these *Guidelines*. The internal audit program shall address all elements of the quality management system, including the technical and test item preparation 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, wherever resources permit, be carried out by trained and qualified personnel who are independent of the activity to be audited.

Note 1: Personnel should not normally audit their own activities except where it is necessary and it can be demonstrated that an effective audit has been carried out.

Note 2: Audit personnel should also be independent of any parent organisation when those being proficiency tested are commercial competitors of the parent organisation.

2.12.2 When audit findings cast doubt upon the effectiveness of the operations or on the correctness or validity of test materials, procedures, proficiency testing results, or a scheme's implementation, the provider shall take timely corrective action and shall notify, in writing, its clients and/or participants in proficiency testing schemes whose activities may have been affected.

2.12.3 All audit findings and corrective actions that arise from them shall be recorded. The management shall ensure that these actions are discharged within an appropriate and agreed timescale.

2.13 Management Reviews

2.13.1 Senior management, unless they are from a parent organisation which has commercial competitors being proficiency tested by the proficiency testing scheme, shall periodically conduct a review of the provider's quality management system and proficiency testing procedures to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review should take account of reports from management and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, feedback from clients or participants and other relevant factors.

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

3 : TECHNICAL REQUIREMENTS

3.0 General

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

3.1 Management, Staffing and Training

3.1.1 The coordination and conduct of proficiency testing schemes shall only be undertaken by providers and associated collaborators having experience with interlaboratory test comparisons and with the particular type of test items and/or materials. Providers or associated collaborators 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 competence of a provider's laboratory, prior possession of laboratory accreditation to ISO/IEC 17025:2000 for appropriate tests and/or measurements will satisfy the requirement for demonstration of competence. In circumstances where the provider's laboratory does not hold accreditation, other factors which should be considered when evaluating the provider's compliance with these Guidelines will include satisfactory performance in appropriate proficiency testing schemes.

[Refer also to Section 3.2 on Collaborators].

3.1.2 The provider and associated collaborators 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 test materials) 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 posts 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: The need to periodically retrain staff should be considered. Staff training and retraining policies should take account of technological change and aim at continuous skills upgrading.

3.1.7 The provider shall maintain an up-to-date record of the training that each staff member has received. These records shall provide evidence that individual staff members have been adequately trained and that their competence to perform their assigned tasks has been assessed.

3.2 Collaborators (Subcontractors)

3.2.1 The provider shall be required to demonstrate that the collaborators' experience and technical competence are sufficient for their assigned tasks and comply with the relevant clauses of these *Guidelines*. [See also Clause 2.5.1]

3.2.2 Where the provider subcontracts any part of testing of a test material or test item (e.g. for assessment of homogeneity or stability), this work shall be placed with a competent laboratory. [Refer to Note under 3.1.1.]

3.2.3 In assessing the competence of a collaborator, the provider shall require information on the collaborator's knowledge of the subject and details of past experience in the field, for example, by providing acceptable results for comparable measurements.

3.2.4 The provider shall ensure that all details of the methodology, results and all the outcomes of monitoring of any collaborators are available and that a register or database of all collaborators and their accreditation or other form of competence determination is maintained.

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.

A plan should be agreed upon and shall be documented before commencement of the scheme, and typically would include the following information:

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

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

c) the 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 collaborators involved in the provision of the scheme (e.g. sampling, sample processing, homogeneity testing and assigning values);

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

g) a description of the manner in which 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 is to be carried out by participants;

j) for on-going schemes, the frequency or dates upon which 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.

3.3.1.2 The organisational and technical input of the different collaborators involved shall be identified, documented and regularly reviewed. A mechanism (e.g. a management/technical advisory group) shall be established to make recommendations on how to plan the activities involved in the provision of each proficiency testing scheme.

Note: These could include recommendations for the objectives of the scheme, the production and testing of test materials or test items prior to their distribution to participants, the determinations to be carried out by participants, distribution of test items, and the statistical treatment of test results and expected outcomes and targets.

3.3.1.3 The provider should establish an advisory group which shall include technical specialists with detailed experience in the relevant field of testing and include, or have access to, a statistician to design and implement each proficiency testing scheme and analyse the test results submitted by participants.

3.3.1.4 The responsibilities of an advisory group under the direction of a coordinator should include, but are not necessarily be limited to, consideration of the following:

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

b) design of the scheme (e.g. number of samples, whether uniform or split level design);

c) the nature of the test item(s) and test(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 test items;

e) where appropriate, the test methods to be used;

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

g) preparation of detailed instructions for participants;

h) preparation of any standardised reporting formats to be used by participants;

i) number of significant figures to which results are to be reported;

j) comments on any technical difficulties raised by participants;

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

l) appropriate measures for judging the competence of participants;

m) comments on the performance both of individual participants and on participation as a whole;

n) technical commentary on the summary report;

o) evaluation of the responses of participants performing poorly (if feedback is required).

3.3.2 **Preparation of test items**

3.3.2.1 In planning the overall process for preparation, testing and distribution of test materials and test items, the provider shall provide for, where appropriate, procedures and resources for:

a) material selection;

b) maintaining suitable environments for preparation and testing of test material;

c) material preparation;

d) measuring and testing;

e) calibration/validation of equipment and measurement methods;

f) assessing test material homogeneity;

g) assessing test material stability;

h) organising interlaboratory test comparisons with collaborators, where necessary; (see Note 1 below)

i) ensuring adequate storage facilities and conditions;

j) ensuring adequate packaging and labelling;

k) ensuring appropriate transport and distribution arrangements;

l) statistical analysis of test results and assigning values of measurands and associated uncertainties;

m) ensuring adequate reporting service to participants.

Note 1: Item (h) may apply where the scheme provider seeks to establish the capability of a potential collaborator to comply with these Guidelines by requesting that it participate in related proficiency testing schemes before using its services as a collaborator.

Note 2: The provider will need to give due consideration to preparation of additional test items, for potential use as reference materials, training aids for participants after results have been evaluated and to replace any test items lost or damaged during distribution.

3.3.2.2 The provider shall be able to demonstrate that the test material is sufficiently homogeneous for the particular proficiency testing scheme.

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

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

Note: An example of a protocol for establishing such similarity is given in document NCCLS EP-14P, published by the National Committee for Clinical Laboratory Standards, Villanova, PA, 1994.

3.3.3 **Homogeneity and stability testing**

3.3.3.1 The provider or its collaborators, where appropriate, 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 in accordance with acceptable statistical designs, for example, analysis of variance on replicate results under repeatability conditions. In the case of measurement artefacts, preliminary stability checks shall be made and periodic checks of assigned property values should be carried out throughout the course of the scheme.

Note: It is recognised that different experimental designs may be used for evaluation of homogeneity. Some guidance on possible techniques is given in ISO Guide 35 (under revision) and in_BCR/01/97 and the International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories. (See Clause 1.2 References.)

3.3.3.2 The assessment of homogeneity should be performed after the test material has been packaged in its 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 collated. 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 material is to be stored prior to distribution.

3.3.3.4 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.

Note: If the material is to be used for proficiency testing schemes extending over a lengthy period of time, then, depending on the nature of the sample material, it may also be necessary to carry out homogeneity checks during the period of its use.

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.

Note: Details of commonly used statistical procedures for the treatment of proficiency testing data are given in Annex A of ISO/IEC Guide 43-1 (1997).

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 trueness or precision required or expected of the tests;

b) the smallest differences to be detected between participating laboratories at a desired confidence level;

c) the number of participants in the scheme;

d) the number of samples to be tested and the number of repeat tests or measurements to be conducted on each sample or for each determination;

e) the procedures to be used to estimate the assigned value of each measurand;

f) procedures to be used to identify statistical outliers;

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

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

3.4 Choice of Method or Procedure

3.4.1 **General**

Scheme participants shall normally be permitted to use the test method or measurement procedure of their choice, which is 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, where appropriate, request details of the method used to permit comparison and comment on the results obtained by different test methods.

3.5 Conduct of Proficiency Testing Schemes

3.5.1 **Instructions to participants**
[See also Clause 3.7.1]

3.5.1.1 The provider shall give participants early warning of the intention to conduct a scheme to ensure that they are aware of the aims of the scheme and that their staff are available at the required time.

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 of the test materials, for example, conditions of storage, the nature of the materials or test items, the test procedure employed, and the timing of the testing.

3.5.1.4 Specific instructions on the manner of recording and reporting test results shall include, but are not necessarily limited to, the units of measurement, the number of significant figures, 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 in their usual format .

3.5.1.5 Scheme participants shall be required to treat proficiency test samples in the same manner as routine 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 collated.

Note: In some cases it may be appropriate to advise target ranges prior to testing.

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 collaborators shall identify, preserve and segregate all test materials and test items, for example, from all chemicals and other materials from the time of preparation through to their distribution to scheme participants.

3.5.2.2 The provider and any associated collaborators shall ensure adequate packaging of all test materials and shall provide secure storage areas and/or stock rooms which prevent damage or deterioration of any item or material 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 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 1: Adequate steps should be taken to make sure that samples are presented in such a manner to ensure that the integrity of the samples is maintained; 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.

Note 2: In some schemes, such as measurement comparisons, participating laboratories are required to transport the test items to other participants. In such cases the laboratories should be supplied with documented instructions for transport of test items.

3.5.3.2 The provider shall ensure that material labels are securely attached to the product packaging of individual units and are designed to remain legible and intact within the period of use in a proficiency test.

3.6 Data Analysis and Interpretation of Scheme Results

3.6.1 **Data analysis and records**
(see also Clause 2.11)

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. The provider shall also establish and maintain a description of all data processing equipment.

3.6.1.2 The provider shall define the role and responsibility and designate a person to be responsible for the effective operation of the data processing system.

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 documented statistical procedures. Documented 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.

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

Note: Annex A of ISO/IEC Guide 43-1 (1997) contains examples of statistical methods for treatment. Extreme results can provide important information and should not be disregarded in treatment of results of proficiency tests without due consideration.

3.6.1.7 The provider shall have documented criteria for determining whether test items are not suitable for evaluation, for example, because of undetected inhomogeneity, instability or contamination. (Refer also to Section 3.3.2.2)

3.6.2 **Evaluation of performance**

3.6.2.1 Where an evaluation of performance is required, 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 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 statistician, to provide expert commentary on the performance of participants with regard to the following:

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

b) variation within (intra) and between (inter) laboratories, and comparisons with any similar previous schemes or published precision data;

c) variation between methods or procedures, if applicable;

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

e) any other suggestions, recommendations or general comments;

f) 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: There are a number of alternative procedures for assessing the performance of participants. (See Reference in Annex A of ISO/IEC Guide 43-1 (1997).

3.6.3 **Proficiency testing scheme 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 address of the provider;

b) names and affiliations of persons involved in the design and conduct of the scheme;

c) date of issue of the report;

d) report number and clear identification of the scheme;

e) clear description of the items or materials used, including, where appropriate, details of sample preparation and homogeneity testing;

f) laboratory participation codes and test results;

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

h) procedures used to establish any assigned value;

i) details of the traceability and uncertainty of any assigned values, where applicable;

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

k) comments on participants' performance by the provider and technical advisers;

l) procedures used to design and implement the scheme (which may include reference to a scheme protocol);

m) procedures used to statistically analyse the data, where applicable. (see Annex 1 for guidance);

n) advice, where appropriate, on the interpretation of the statistical analysis.

Note: For schemes operated on a regular basis, it may be sufficient to have simpler reports such that many of the recommended elements in 3.6.3.2 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, interim reports shall be issued to individual participants.

Note: 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. graphical) form.

3.7 Communication with Participants

3.7.1 The provider shall provide prospective participants with detailed information, for example, in the form of a scheme protocol, on how to apply to participate in the program. 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 in writing by the provider of any changes in scheme design or operation.

3.7.3 There shall be documented procedures for enabling participants to refer to the provider if they disagree with the assessment of their performance in a proficiency testing scheme.

3.7.4 Feedback from participants should be encouraged so they may actively contribute to the development of a scheme.

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 group for the purposes of discussion and mutual assistance, for example, to improve performance. Confidentiality may also be waived for regulatory or accreditation purposes. In most instances, the proficiency results should be provided to the relevant authority by the participants themselves. In some cases, following consultation with the authority, the authority may require the results to be directly provided to the authority by the scheme coordinator. In the latter case, the participants must be made aware of and agree to the arrangements.

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.

APPENDIX A: COMMONLY-USED STATISTICAL METHODS FOR TREATMENT OF PROFICIENCY TEST DATA
(Information for Guidance only)

To assist providers of proficiency testing schemes, guidance on the selection and use of statistical procedures for the treatment of proficiency test data is given in Annex A of ISO/IEC Guide 43:1.

The subjects covered in this Annex include:

- *Determination of the assigned value and its uncertainty.*

  A description of the various procedures which can be used to establish assigned values. The determination of uncertainty of assigned values. The use of a nominal or ordinal scale when dealing with qualitative values. The use of a mean, median, mode or other robust measure when dealing with quantitative values. Methods of treating extreme results.

- *Calculation of performance statistics*

  Including consideration of performance on single test items, and combined performance scores. Examples of variability measures for calculation of performance statistics. Use of z scores and E_n numbers.

- *Evaluation of performance*

  Including consideration of initial performance and monitoring of performance over time. Fitness for purpose. Graphical techniques (error bars, histograms, Shewhart charts, Youden plots).

- *Preliminary determination of test item homogeneity*

In addition, Annex C of ISO/IEC Guide 43:1 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: CROSS-REFERENCES TO ISO 9000, ISO GUIDE 43-1 AND ISO/IEC 17025

Cross-references between elements of the *ILAC Requirements for the Competence of Providers of Proficiency Testing Schemes* and, where relevant, ISO 9001:1994, ISO Guide 43-1:1997 and ISO/IEC 17025:2000

ILAC Requirements		ISO 9001:1994	ISO Guide 43-1:1997	ISO/IEC 17025: 2000
2.1.1	Quality management system	4.2.1	-	4.2.1
2.1.2	QM policy objectives	4.1.1	-	4.2.2
2.1.3	Documented quality system	4.2.1 & 4.2.2	-	4.2.1
2.1.4	Activities specified	4.1.2.1 & 4.6.2	-	
2.1.5	Roles/responsibility	4.1.2	-	4.1.4
2.2.1	Legal identity	-	-	4.1.1
2.2.2	Coordinator requirements	4.1.2	-	-
2.3.1	Document control procedures	4.5.1	-	4.3
2.3.2	Document approval and issue	4.5.2	-	4.3.2
2.3.3	Document changes	4.5.3	-	4.3.3
2.4.1	Contract review	4.3.2	-	4.4.1
2.4.2	Records of contract reviews	4.3.3	-	4.4.2
2.4.3	Record includes subcontractors	4.6.2	-	4.4.3
2.5.1	Selection of subcontractors	4.6.2	-	4.5.1
2.5.2	Register of collaborators	4.6.2	-	4.5.4
2.6.1	Supply selection policies	4.6.1 & 4.7	-	4.6.1
2.6.2	Use of adequate services/supplies	4.6.1, 4.6.2 & 4.7	-	4.6.2
2.6.3	Compliance with requirements	4.6.4 & 4.7	-	4.6.3
2.6.4	Inspection & approval	4.6.4 & 4.7	-	4.6.4
2.6.5	Records of approved suppliers	4.6.4 & 4.7	-	4.6.4
2.7	Client feedback	4.14.2	6.7	4.7 & 4.8
2.8.1	Nonconformance with procedures	4.13	-	4.9.1
2.8.2	Corrective actions	4.14.2 & 4.14.3	-	4.9.2
2.9.1	Policy for CAs	4.14.1	-	4.9.2 & 4.10
2.9.2	Cause analysis	4.14.2	-	4.10.2
2.9.3	Selection of CAs	4.14.2	-	4.10.3
2.9.4	Monitoring of CAs	4.14.2	-	4.10.4
2.10.1	Preventive action review	4.14.3	-	4.11.1
2.10.2	Monitoring results of PAs	4.14.3	-	4.11.2
2.11.1.1	Identification etc of records	4.16	-	4.12.1.1
2.11.1.2	Storage of records	4.16	-	4.12.1.2
2.11.1.3	Security of records	4.16	-	4.12.1.3
2.11.1.4	Security of data	4.16	-	4.12.1.3
2.11.2	Technical records	4.16	-	4.12.2.1-3
2.12.1	Internal audits	4.17	-	4.13.1
2.12.2	Corrective action for NCRs	4.17	-	4.13.2
2.12.3	Management review of audit records	4.17	-	4.14.1
2.13.1	Periodic management reviews	4.1.3	-	4.14.1
2.13.2	Record of findings of mgt reviews	4.4.3	-	4.14.2
3.1.1	Staff experience etc requirements	4.1.2.2 & 4.18	-	5.2.1
3.1.2	Managerial staff and resources	4.1.2.2	5.2.1	5.2.5
3.1.3	Measurement staff and resources	4.1.2.2 & 4.18	5.2.2	5.2.5
3.1.4	Min. levels of qualifications & experience	4.1.2.2 & 4.18	-	5.2.2 & 5.2.4
3.1.5	Adequate personnel	4.1.2.2	-	5.2.1
3.1.6	Additional training needs	4.18	-	5.2.1 & 5.2.2

	ILAC Requirements	ISO 9001:1994	ISO Guide 43-1:1997	ISO/IEC 17025: 2000
3.1.7	Records of training	4.18	-	5.2.1
3.2.1	Appropriate collab. experience	4.6.2	-	4.5 & 5.2
3.2.2	Compliance with ISO/IEC Guide 25	-	-	4.5.1 & 4.5.2
3.2.3	Technical competence	-	-	4.5.1 & 4.5.2
3.2.4	Details of collaborators' methodology	4.6.2	-	-
3.3.1.1	Program planning	4.4 & 4.9	5.1.2	4.4 & 4.5.3
3.3.1.2	Identificn/ review of collaborators' input	4.6.2 & 4.9	-	-
3.3.1.3	Establishment of specialist working grp	-	5.1.1	-
3.3.1.4	Responsibilities of working group	-	5.2.3	-
3.3.2.1	Preparation of test items	4.9 & 4.10	5.5.1 & 5.6.2	-
3.3.2.2	Homogeneity test	4.9,4.10,4.12 & 4.4	5.5.2 & 5.6.2	-
3.3.2.3	Matrix matching	4.9, 4.10 & 4.12	5.5.3	-
3.3.3.1	Selection of items for homogeneity test	4.9 & 4.10	5.6.2	-
3.3.3.2	Testing after packaging	4.9, 4.10 & 4.12	5.6.2	-
3.3.3.3	Periodic checking of properties	4.9 & 4.10	5.6.3	-
3.3.3.4	Stability checking of properties	4.9 & 4.10	5.6.3	-
3.3.4.1	Statistical model and data analysis	4.20.1	5.4.1	-
3.3.4.2	Appropriate stat design of program	4.20.2	5.4.2	-
3.4.1	Participants' choice of method	-	5.7.1, 5.7.2	-
3.4.2	Requested details of methods	-	5.7.3	-
3.5.1.1	Early advice to participants	-	6.2.1 & 6.7.1	-
3.5.1.2	Detailed instruction with samples	-	6.2.1	-
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	-
3.5.1.6	Disclosure of assigned values	-	5.5.5	-
3.5.2.1	Identification/preservation of test items	4.8 & 4.15	5.6.1	-
3.5.2.2	Adequate packaging and storing	4.15	-	5.8.2 & 5.8.3
3.5.2.3	Reassessment of sample condition	4.15	5.6.3 & 5.6.4	5.8.1
3.5.3	Packaging, labelling and distribution	4.8 & 4.15	6.3	-
3.6.1.1	Adequacy and documentation of data processing equipment	4.11.1	5.3, 6.4	5.5.11
3.6.1.2	Role/responsibility of data system mgr	4.1.2	-	-
3.6.1.3	Maint and validn of equipt and software	4.11.1	-	-
3.6.1.4	Recording & processing of data	4.1.6	6.4.1	4.12.2
3.6.1.5	Summary stats	4.20	6.4.2	5.10
3.6.1.6	Tests for outliers	4.20	6.4.2	-
3.6.1.7	Criteria for non-conforming data	4.20	6.4.3	-
3.6.2.1	Evaluation of lab performance	-	6.6.1&6.6.4	-
3.6.2.2	Tech comments on lab performance	-	6.6.2 & 6.6.5	5.10.5
3.6.3.1	Program reports	4.16	6.5.1 & 6.5.3	5.10
3.6.3.2	Information in program reports	-	6.5.2 & 6.6.3	5.10
3.6.3.3	Promptness of reporting	-	6.5.4	-
3.7.1	Information on participation	-	6.7.1	-
3.7.2	Changes in program design	4.4	6.7.1	-
3.7.3	Procedures for participant feedback	4.14.2	6.7.2	-
3.7.4	Encouragement of participant feedback	-	6.7.3	-
3.8.1	Confidentiality of participant identity	-	7.1	-
3.8.2	Confidentiality of test data, etc	-	7.1	-
3.9	Falsification of data	-	7.2	-

APPENDIX C: BIBLIOGRAPHY

(1) ISO/IEC Guide 2:1996, *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 8402:1994, *Quality management and quality assurance - Vocabulary.*

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

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

(11) ISO 13528 (Draft 1998) *Statistical methods for use in proficiency testing by interlaboratory comparison.*

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ILAC-G10:1996	Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
ILAC-G11:1998	Guidelines on Assessor Qualification and Competence
ILAC-G12:2000	Guidelines for the Requirements for the Competence of Reference Material Producers
ILAC-G13:2000	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
ILAC-G14:2000	Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status
ILAC-G15:2001	Guidance for Accreditation to ISO/IEC 17025

Secretariat Documents (S Series)

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ILAC-S2:1998	Rules

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ILAC-P2: 2000	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition