

**C302 – GENERAL CHECKLIST: ILAC G-13:2007 PROFICIENCY TESTING PROVIDER
ACCREDITATION PROGRAM**

This checklist is intended for use in association with A2LA assessments, and is not to be publicly distributed. Use of this document is restricted to A2LA employees, contractors, and applicant and accredited proficiency testing providers. Any other use of this document is prohibited.

The following pages present the requirements for the A2LA Accreditation Program for Providers of Proficiency Testing Programs. These requirements are based on those contained in the ILAC-G13:2007 “ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes”. This document is based on ISO Guide 43-1 (1997) and on the relevant elements of ISO/IEC 17025:2005 applicable to characterization, homogeneity and stability testing of proficiency testing materials. 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 9000:2000 are included to eliminate the need for separate recognition of a provider’s management system. The PT Provider’s policies and procedures must meet these requirements. Requirements that include the need for a **written** policy, procedure or arrangement are **shaded**. Revisions resulting from the ILAC-G13:2007 version of the standard are in **bold italics**. **Proficiency Testing Providers applying and maintaining accreditation under this program shall also meet the requirements established in the A2LA Advertising Policy and the A2LA Traceability Policy.**

PT Provider Instructions: This checklist must be completed and submitted as part of the application for accreditation in order to help both the PT Provider and assessor(s) prepare for the assessment. **Correct completion of this checklist may save a significant amount of assessment time and cost.** Complete the document reference identifiers in the checklist's second column (labeled "Reference") for all **shaded** requirements. The appropriate “reference” must identify the document (quality manual, SOPs, etc) and include a “locator” to facilitate identification of the appropriate portion(s) of the relevant document (page number, section number, etc.).

The management system documentation and supporting records must be available for the assessor’s review.

Assessor Instructions: Review the PT Provider’s documented management system to verify compliance with the applicable requirements. Assess to verify that the documented management system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item (please note that gray shading in the N/A section indicates the clause is always applicable for all types of laboratories, both commercial and captive). Record comments related to any requirement on the space provided. All deficiencies must be identified and explained in the assessor deficiency report. Assess the PT Provider’s technical competence to provider specific PT schemes. Please also complete the separate C104 – General Checklist: Reference to A2LA Accredited Status-A2LA Advertising Policy. The proficiency testing providers themselves are not required to complete C104 prior to the assessment. IMPORTANT NOTE: An asterisk (*) in the comments section indicates that the assessor must document the specific traceable objective evidence reviewed in association with that requirement. Objective evidence information is mandatory for those clauses.

PT Provider NAME _____ City: _____ State: _____

Technical Manager: _____

Quality Manager: _____

Essential Personnel and Their Unique Capability¹ _____

¹ An Essential Personnel is anyone whose absence or departure would reduce the PT Program’s competence to operate one or more PT programs, and would necessitate removal from the PT Provider’s Scope of Accreditation, any PT program for which that person is contributing unique capabilities.

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Type of Assessment (please indicate):

Full Assessment

Surveillance Assessment

To the best of my knowledge, all proficiency testing provider document references below as well as actual practices have been assessed for compliance with the relevant clauses of ILAC-G13:2007 and the A2LA General Requirements for Accreditation of Proficiency Testing Providers. I hereby attest that all ‘Yes’ marked compliance clauses, whether initialed or not, meet the aforementioned requirements. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

Assessor Signature: _____ Date: _____

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
SECTION 2 MANAGEMENT REQUIREMENTS					
2.1 Organization					
2.1.1 The provider, or the organization of which it is part, shall be an entity that can be legally identifiable <i>and accountable</i> .					
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 <i>Guidelines</i> and to satisfy the needs of the participants, regulatory authorities, and accrediting bodies.					

Requirement	Reference	[RESERVED FOR ASSESSORS ONLY]			
		Compliance			Comments
		Y	N	NA	
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 organization performing testing, calibration, or accreditation activities, then the provider shall identify the responsibilities of key personnel in the organization 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 minimize 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, <i>including procedures for protecting the electronic storage and transmission of results</i> ;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 organization and management structure of the provider, its place in any parent organization, 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;					
<i>g) provide adequate supervision of technical staff, including trainees, by persons familiar with procedures for each activity;</i>					
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) <i>shall</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;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
j) appoint deputies for key managerial personnel;					
<i>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;</i>					
<i>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.</i>					
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, <i>programs, procedures and instructions to the extent necessary</i> to assure the quality of all aspects of proficiency testing. <i>The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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). <i>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:</i>					
<i>a) the provider management's commitment to good professional practice and to the quality of its proficiency testing services to its customers;</i>					
<i>b) the management's statement of the provider's standard of service;</i>					
<i>c) the purpose of the management system related to quality;</i>					
<i>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</i>					
<i>e) management's commitment to comply with these Guidelines and to continually improve the effectiveness of the management system.</i>					
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.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.2.5 <i>Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.</i>					
2.2.6 <i>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.</i>					
2.2.7 The roles and responsibilities of technical management and the quality manager, including their responsibility <i>for ensuring compliance with this International Standard</i> , shall be defined in the quality manual.					
2.2.8 <i>Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.</i>					
2.3 Document control					
2.3.1 General					
The provider shall establish and maintain procedures to control all documents <i>that form part of its management system</i> (internally generated, or from external sources), <i>such as regulations, standards, other normative documents, scheme protocols, test and/or calibration methods, as well as drawings, software specifications, instructions and manuals.</i>					
2.3.2 Document approval and issue					

Requirement	Reference	[RESERVED FOR ASSESSORS ONLY]			
		Compliance			Comments
		Y	N	NA	
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 <i>document control procedure</i> identifying the current revision status and <i>distribution of documents</i> 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.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 <i>function</i> 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.					
<i>2.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.</i>					
<i>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, initialed and dated. A revised document shall be issued as soon as practicable.</i>					
<i>2.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerised systems are made and controlled.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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;					
<i>c) the proficiency testing scheme is technically appropriate for participants.</i>					
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.				*	
<i>2.4.3 The review shall also cover any work that is subcontracted by the provider.</i>					
<i>2.4.4 The customers shall be informed of any deviation in the contract or agreed scheme design.</i>					
<i>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.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.5 Subcontracting services					
2.5.1 <i>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.</i>					
2.5.2 <i>The provider shall inform participants, in writing, of services that are, or may be, subcontracted.</i>					
2.5.3 <i>The provider shall be responsible for the subcontractor's work.</i>					
2.5.4 The provider shall maintain a register of all <i>subcontractors</i> used in the provision of proficiency testing schemes and <i>a record of the competence assessment against relevant parts of these Guidelines and other appropriate standards for the work in question.</i>				*	
2.6 Purchasing services and supplies					
2.6.1 The provider shall have a policy and procedures for the selection of services and supplies <i>that it uses</i> that affect the quality of its proficiency testing schemes. <i>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.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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.					*
<i>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.</i>					*
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.					*
2.7 Service to the customer					
<i>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.</i>					
<i>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.</i>					*

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.8. Complaints					
The provider shall have a <i>policy</i> and procedure for the <i>resolution</i> 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, <i>together with any decision about the acceptability of the nonconforming work</i> ;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
d) where necessary, customers are notified and the results of nonconforming proficiency test items or statistical evaluations already issued to participants are recalled, <i>destroyed or ignored;</i>					
e) the responsibility for authorisation of the resumption of work is defined.					
2.9.2 Where the evaluation indicates that nonconforming work could recur or that there is doubt about the provider's or <i>subcontractor's</i> compliance with their own policies and procedures, the corrective action procedure in 2.11 shall be promptly followed.					
2.10 Improvements					
<i>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.</i>					
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 <i>work</i> or departures from the policies and procedures in the management system or with <i>technical operations</i> have been identified.					

Requirement	Reference	[RESERVED FOR ASSESSORS ONLY]			
		Compliance			Comments
		Y	N	NA	
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 <i>Where corrective action is needed</i> , 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. <i>Corrective actions shall be appropriate to the magnitude and risk of the problem.</i> <i>The provider shall document and implement any required changes resulting from corrective action investigations.</i>					
2.11.4 Monitoring of corrective actions The provider shall monitor the results to ensure that the corrective actions taken have been effective.					

Requirement	Reference	[RESERVED FOR ASSESSORS ONLY]			
		Compliance			Comments
		Y	N	NA	
<p>2.11.5 Additional audits</p> <p><i>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.</i></p>					
2.12 Preventive action					
<p>2.12.1 <i>Required improvements and potential sources of nonconforming work, either technical or concerning the management system, shall be identified.</i> 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.</p>					
<p>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.</p>					
2.13 Control of records					
2.13.1 General					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.13.1.1 The provider shall establish and maintain procedures for identification, collection, indexing, access, <i>filing</i> , storage, maintenance and disposal of quality and technical records. <i>Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.</i>					
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.					
2.13.1.3 All records shall be held secure <i>and in confidence, and in accordance with relevant legislation.</i>					
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					
<i>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:</i>					
<i>a) Instructions to participants</i>					
<i>b) Participants original responses</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) <i>Collated data for statistical analysis</i>					
d) <i>Final reports (generic and individual)</i>					
<i>Sufficient information shall be retained to establish an audit trail for the processing of results from proficiency testing rounds.</i>					
<i>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.</i>					
<i>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 initialed 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.</i>					
2.14 Internal audits					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 <i>Guidelines</i> . The internal audit program shall address all elements of the management system, including the <i>technical procedures and proficiency test item preparation, storage, distribution and reporting activities</i> 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.					
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 <i>The area of audited activity</i> , the audit findings and corrective actions that arise from them shall be recorded.					*
<i>2.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.</i>					*

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
2.15 Management reviews					
2.15.1 <i>In accordance with a pre-determined schedule</i> and procedure, the provider's <i>top management</i> 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:					*
- <i>the suitability of policies and procedures;</i>					
- reports from management and supervisory personnel;					
- the outcome of recent internal audits;					
- corrective and preventive actions;					
- assessments by external bodies;					
- <i>changes in the volume and type of work;</i>					
- customer feedback;					
- <i>complaints;</i>					
- <i>recommendations for improvement;</i>					
- <i>other relevant factors, such as resources and staff training.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 timescales.					*
SECTION 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 Personnel					
3.1.1 The coordination and conduct of proficiency testing schemes shall only be undertaken by providers having <i>competence</i> with interlaboratory comparisons and with the particular type of proficiency test items. Providers or associated <i>subcontractors</i> shall also have competence in the measurement of the properties being determined, e.g. for assignment of values, and homogeneity and stability testing.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
3.1.2 The provider and associated <i>subcontractors</i> 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.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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					
<i>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.</i>					
<i>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.</i>					
<i>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.</i>					
<i>3.2.4 Facilities shall be available to ensure the safe decontamination and disposal of all materials that are potentially toxic or hazardous.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 and address <i>and affiliation</i> of the coordinator and other personnel involved in the design and operation of the scheme;					
c) the <i>objectives</i> , 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 <i>subcontractors</i> involved in the provision of the scheme (e.g. sampling, test item processing, homogeneity testing and assigning property values);					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
f) the number and <i>type</i> 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;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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;					
<i>p) the origin and traceability of any reference values.</i>					
3.3.1.3 The provider shall ensure access to technical expertise and detailed experience in the relevant field of testing, <i>calibration or inspection, as well as statistics</i> . 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 (<i>e.g. objectives, number of proficiency test items, frequency of distribution, reporting procedures, evaluation of results, type of scheme</i>);					
c) the nature of the proficiency test item(s) and test(s) <i>or calibration(s) or inspection(s)</i> selected, as well as a short description of the considerations underlying these choices, where appropriate;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
d) range of values to be expected for the <i>proficiency</i> test items;					
e) the test or calibration methods to be used;					
<i>f) sourcing appropriate proficiency test items;</i>					
g) <i>resolution of</i> 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, <i>including reporting units</i> and the number of significant figures <i>or decimal places to which results are to be reported;</i>					
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;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 <i>proficiency</i> 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.					
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.					
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.					
3.3.2.5 Materials used to manufacture proficiency test items should be obtained in accordance with relevant legal and ethical requirements.					
3.3.3 Homogeneity and stability testing					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
3.3.3.1 Where appropriate, the provider or its <i>subcontractors</i> 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 <i>proficiency test items</i> 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.					
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 <i>proficiency test item</i> is to be stored prior to distribution.					
3.3.3.4 <i>Proficiency test items</i> shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency test, <i>including storage and transport conditions</i> .					
3.3.4 Statistical design					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 <i>accuracy or uncertainty</i> (trueness and precision) required or expected for each <i>measurand in the proficiency test</i> ;					
b) the minimum number of participants in the scheme in order that meaningful evaluations may be made;					
c) the number of <i>proficiency test items</i> to be tested <i>or measured</i> and the number of repeat tests, <i>calibrations or measurements</i> to be conducted on each <i>proficiency test item</i> or for each determination;					
d) the procedures to be used to estimate the assigned value and, <i>where appropriate the uncertainty for each measurand</i> ;					
e) procedures to be used to identify <i>and/or handle</i> statistical outliers;					
<i>f) where appropriate, the statistical procedure for the evaluation of censored (removed) values;</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
g) where appropriate, the homogeneity and stability of proficiency test items.					
3.4 Choice of method or procedure					
3.4.1 Scheme participants shall normally be expected to use the test method, <i>calibration or measurement procedure</i> 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 <i>shall have a written policy relating to a procedure used</i> to permit comparison and comment on the results obtained by different test methods. <i>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.</i>					
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 <i>before sending samples, artefacts or other proficiency test items, providing the date upon which samples are likely to arrive or to be despatched.</i>					

Requirement	Reference	[RESERVED FOR ASSESSORS ONLY]			
		Compliance			Comments
		Y	N	NA	
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 <i>or calibration of the proficiency test items</i> , 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 <i>or measurement</i> .					
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.					
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 <i>received</i> . <i>Instructions may include an approximate range to facilitate the analytical process.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<i>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.</i>					
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 <i>subcontractors</i> shall identify, preserve and segregate all test materials and <i>proficiency test items</i> from all chemicals and other materials <i>that cause contamination or degradation</i> , from the time of preparation through to their distribution to scheme participants.					
3.5.2.2 The provider and any associated <i>subcontractors</i> 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 <i>proficiency test item</i> between preparation and distribution. Appropriate methods for authorising despatch to, and receipt from, such areas shall be defined.					
3.5.2.3 When appropriate, the condition of all stored or stocked <i>proficiency test items</i> and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.					
3.5.3 Packaging, labeling and distribution					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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.					
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 (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.					
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.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
3.6.1.8 The provider shall have documented criteria for determining whether <i>proficiency test items that have been distributed</i> and are subsequently determined to be unsuitable for evaluation, for example because of undetected 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, <i>applicable to all participants or its limitations known</i> , 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, <i>where appropriate</i> , taking measurement uncertainties into account;					
b) <i>time schedule for sample distribution and measurement carried out by participating laboratories;</i>					
c) variation within and between laboratories, and comparisons with any similar previous schemes or published precision data;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
d) variation between methods or procedures, if applicable;					
e) possible sources of error (with reference to extreme results) and suggestions for improving performance;					
<i>f) advice and educational feedback to participants as part of the continual improvement procedures of participating laboratories, where appropriate;</i>					
<i>g) situations where unusual factors make evaluation of results and commentary on performance impossible;</i>					
h) any other suggestions, recommendations or general comments;					
i) conclusions.					
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 <i>contact details</i> for the provider;					*

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
b) name and <i>contact details for the scheme coordinator</i> ;					
c) date of issue of the report;					
<i>d) page numbers and a clear indication of the end of the report</i> ;					
<i>e) confidentiality statement</i> ;					
f) report number and clear identification of the scheme;					
g) clear description of the <i>proficiency test items</i> used, including, where appropriate, details of the <i>proficiency test item's</i> preparation, homogeneity testing and <i>stability testing</i> ;					
h) laboratory participation codes and test results;					
i) statistical data and summaries, include assigned values and range of acceptable results and graphical displays;					
j) procedures used to establish any assigned value <i>or reference values, where applicable</i> ;					
k) details of the traceability and uncertainty of any assigned <i>or reference values</i> , where applicable;					
l) assigned values and summary statistics for test methods/procedures used by other participants (if different methods are used by different participants);					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
m) comments on participants' performance by the provider and technical advisers;					
n) procedures used to design and implement the scheme (which may include reference to <i>the current version</i> of a scheme protocol);					
o) procedures used to statistically analyze the data, where applicable (see Annex A for guidance);					
p) advice, where appropriate, on the interpretation of the statistical analysis;					
<i>q) any comments or recommendations, based upon the outcomes of the round.</i>					
3.6.3.3 Reports shall be made available to participants within specified timetables. In schemes such as long term measurement comparison schemes, <i>and if technically possible</i> , interim reports shall be issued to individual participants.					*
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. This should include details of the scope of the scheme, any fees for participation, and policies about which laboratories may participate.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
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 <i>appeal against the assessment of their performance in a proficiency testing scheme. The availability of this process shall be communicated to scheme participants.</i>					
3.7.4 <i>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.</i>				*	
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.					
3.8.3 <i>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.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<i>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.</i>					
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.					