NATA

LABORATORY

ASSESSMENT

WORKSHEET

This assessment worksheet has been designed to assist both the facility's staff and the assessment team. Facility staff can use this checklist as part of their preparation for an assessment to ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing.

There is NO need to return the completed checklist to NATA. The assessment team, i.e. the NATA lead assessor and the technical assessor can use this worksheet to assist in the collection of all relevant information during the assessment process.

References to the relevant clauses of the NATA Accreditation Criteria (NAC) have been provided. The Standard, the standard application document, the application document for the relevant field or program and any relevant annexes should also be checked for further details, as this worksheet provides only a brief summary of the clauses of the Standard.

Facility Name:

Accreditation No:

Date reviewed:

Review conducted by:

Version of LQM reviewed:

Facility website address:

Date checked:

Reference to NATA accreditation appropriate:

Comments:

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
TECHNICAL REQUIREMENTS			
4.1 General			
The development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having competence to conduct interlaboratory comparisons and access to expertise with the particular type of proficiency test items. Proficiency testing providers or their subcontractors shall also have competence in the measurement of the properties being determined. *NOTE ISO/IEC 17025 or ISO 15189 can be used to demonstrate the competence of a proficiency testing provider's laboratory, or the laboratory subcontracted to perform tests or measurements related to the proficiency testing schemes.* *ISO Guide 34 can be used to demonstrate the competence of producers of reference materials that provide proficiency test items.*			
4.2 Personnel			
4.2.1 The proficiency testing provider shall have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties.			
4.2.2 The proficiency testing provider's management shall define the minimum levels of qualification and experience necessary for the key positions within its organisation and ensure those qualifications are met.			
4.2.3 The proficiency testing provider shall use personnel who are either employed by, or under contract to it. Where contracted and additional technical and key support personnel are used, the proficiency testing provider shall ensure that such personnel are supervised and competent and that they work in accordance with the management system. *NOTE Where technical experts are used on an ad-hoc basis or as part of an advisory or steering group (see 4.4.1.4), the existence of formal agreements through, for example, group terms of reference or other means, can be considered to satisfy this requirement.*			

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		Yes	No
4.2.4 The proficiency testing provider shall authorise specific personnel to: a) select appropriate proficiency test items; b) plan proficiency testing schemes; c) perform particular types of sampling; d) operate specific equipment; e) conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the proficiency test item; f) prepare, handle and distribute proficiency test items; g) operate the data processing system; h) conduct statistical analysis; i) evaluate the performance of proficiency testing participants; j) give opinions and interpretations; and k) authorise the issue of proficiency testing reports.			
4.2.5 The proficiency testing provider shall maintain up-to-date records of the relevant authorisation(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which competence to perform their assigned tasks was assessed and confirmed.			
4.2.6 The proficiency testing provider shall formulate the objectives with respect to the education, training, and skills for each staff member involved with the operation of the proficiency testing scheme. The proficiency testing provider shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated needs of the proficiency testing provider. *NOTE It is advisable to consider the need to retrain staff periodically. Staff training policies can take account of technological change, the need to demonstrate ongoing competence and aim at continual skills upgrading.*			
4.2.7 The proficiency testing provider shall ensure that staff receive the necessary training to ensure competent performance of measurements, operation of equipment and any other activities which affect the quality of the proficiency testing scheme. The effectiveness of training activities shall be			

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evaluated. *NOTE Objective measures can be used to assess the attainment of competence.*			
4.3 Equipment, accommodation and environment			
4.3.1 The proficiency testing provider shall ensure that there is appropriate accommodation for the operation of the proficiency testing scheme. This includes facilities and equipment for proficiency test item manufacturing, handling, calibration, testing, storage and despatch, for data processing, for communications, and for retrieval of materials and records.			
4.3.2 The proficiency testing provider shall ensure that the environmental conditions do not compromise the proficiency testing scheme or the required quality of operations. Particular care shall be taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by subcontractors. The technical requirements for accommodation and environmental conditions that can affect the proficiency testing shall be documented.			
4.3.3 Access to and use of areas affecting the quality of proficiency testing schemes shall be controlled. The proficiency testing provider shall determine the extent of control based on its particular circumstances.			
4.3.4 The proficiency testing provider shall identify environmental conditions that can significantly influence the quality of the proficiency test items and any testing and calibration carried out, including conditions that are required by relevant specifications and measurement procedures. The proficiency testing provider shall control and monitor these conditions, and shall record all relevant monitoring activities. Relevant proficiency testing activities shall be stopped when the environmental conditions jeopardize the quality or the operations of the proficiency testing scheme.			

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NOTE Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.			
4.3.5 There shall be effective separation between neighbouring areas in which there are incompatible activities. Action shall be taken to prevent cross-contamination.			
4.3.6 Proficiency testing providers shall ensure that performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of proficiency testing items are appropriately validated and maintained.			
4.4 Design of proficiency testing schemes			
4.4.1 Planning **4.4.1.1** The proficiency testing provider shall identify and plan those processes which directly affect the quality of the proficiency testing scheme and shall ensure that they are carried out in accordance with prescribed procedures. *NOTE Stakeholders' interests can be considered in developing a plan and relevant information* *.*			
4.4.1.2 The proficiency testing provider shall not subcontract the planning of the proficiency testing scheme (see 5.5.2). *NOTE The proficiency testing provider can utilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4).*			
4.4.1.3 The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion: a) the name and address of the proficiency testing provider; b) the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the			

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proficiency testing scheme;			
c) the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the proficiency testing scheme;			
d) criteria to be met for participation;			
e) the number and type of expected participants in the proficiency testing scheme;			
f) selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round;			
g) a description of the range of values or characteristics, or both, to be expected for the proficiency test items;			
h) the potential major sources of errors involved in the area of proficiency testing offered;			
i) requirements for the production, quality control, storage and distribution of proficiency test items;			
j) reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;			
k) a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme;			
l) for continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants;			
m) any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements;			
n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;			
o) preparation of any standardized reporting formats to be used by participants;			
p) a detailed description of the statistical analysis to be used;			
q) the origin, metrological traceability and measurement uncertainty of any assigned			

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values; r) criteria for the evaluation of performance of participants; s) a description of the data, interim reports or information to be returned to participants; t) a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public; and u) actions to be taken in the case of lost or damaged proficiency test items.			
4.4.1.4 The proficiency testing provider shall have access to the necessary technical expertise and experience in the relevant field of testing, calibration, sampling or inspection, as well as statistics. This may be achieved, if necessary, by establishing an advisory group (named as appropriate).			
4.4.1.5 Technical expertise shall be used, as appropriate, to determine matters such as the following: a) planning requirements as listed in 4.4.1.3; b) identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items, or in the provision of a stable assigned value for a proficiency test item; c) preparation of detailed instructions for participants; d) comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds; e) provision of advice in evaluating the performance of participants; f) comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants; g) provision of advice for participants (within limits of confidentiality), either individually or within the report; h) responding to feedback from participants; and i) planning or participating in technical meetings with participants.			
4.4.2 Preparation of proficiency test items **4.4.2.1** The proficiency testing provider shall establish and implement procedures to ensure			

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that proficiency test items are prepared in accordance with the plan described in 4.4.1. *NOTE It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.*			
4.4.2.2 The proficiency testing provider shall establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. The procedures shall ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements.			
4.4.2.3 Proficiency test items should match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration.			
4.4.2.4 In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.			

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4.4.3 Homogeneity and stability **4.4.3.1** Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance. *NOTE 1 The requirements in this subclause are intended to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. Careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.* *NOTE 2 In some cases, it is not feasible for proficiency test items to be subjected to homogeneity and stability testing. Such cases would include, for example, when limited material is available to prepare proficiency testing items.* *NOTE 3 In some cases, materials that are not sufficiently homogeneous or stable are the best available; in such cases, they can still be useful as proficiency test items, provided that the uncertainties of the assigned values or the evaluation of results take due account of this (see B.3.1.3 and ISO 13528:2005, Annex B of the standard).* *NOTE 4 Considerations for homogeneity and stability are further discussed in ISO Guide 34, ISO Guide 35 and ISO 13528.*			
4.4.3.2 The procedures for the assessment of homogeneity and stability shall be documented and conducted, where applicable, in accordance with appropriate statistical designs. Where possible, the proficiency testing provider shall use a statistically random selection of a representative number of proficiency test items from the whole batch of test material in order to assess the homogeneity of the material. *NOTE In some cases, the use of a random stratified or systematic selection of proficiency test items from the whole batch is more appropriate.*			

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4.4.3.3 The assessment of homogeneity shall normally be performed after the proficiency test items have been packaged in the final form and before distribution to participants unless, for example, stability studies indicate that they should be stored in bulk form. *NOTE 1 Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.* *NOTE 2 On some occasions, homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons.*			
4.4.3.4 Proficiency test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency testing, including storage and transport conditions. When this is not possible, the stability shall be quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the proficiency test item, and/or taken into account in the evaluation criteria.			
4.4.3.5 When proficiency test items from previous rounds are retained for future use, the property values to be determined in the proficiency testing scheme shall be confirmed by the proficiency testing provider prior to distribution.			
4.4.3.6 In circumstances where homogeneity and stability testing is not feasible, the proficiency testing provider shall demonstrate that the procedures used to collect, produce, package and distribute the proficiency test items are sufficient for the purpose of the proficiency testing.			

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4.4.4 Statistical design **4.4.4.1** Statistical designs shall be developed to meet the objectives of the scheme, based on the nature of the data (quantitative or qualitative, including ordinal and categorical), statistical assumptions, the nature of errors, and the expected number of results (see standard B.3.2.2). *NOTE 1 Statistical design covers the process of planning, collection, analysis and reporting of the proficiency testing scheme data. Statistical designs are often based on stated objectives for the proficiency testing scheme, such as detection of certain types of errors with specified power or determination of assigned values with specified measurement uncertainty.* *NOTE 2 Data analysis methods could vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different proficiency test items.* *NOTE 3 In cases where the proficiency testing scheme design is mandated by a specification given by, for example, a customer, regulatory authority or accreditation body, the statistical design and data analysis methods can be taken directly from the specification.* *NOTE 4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.*			
4.4.4.2 The proficiency testing provider shall document the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results, and shall provide a description of the reasons for their selection and assumptions upon which they are based. The proficiency testing provider shall be able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures.			

4.4.4.3 In designing a statistical analysis, the proficiency testing provider shall give careful consideration to the following:
    a) the accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measurand or characteristic in the proficiency testing;
    b) the minimum number of participants in the proficiency testing scheme needed to meet the objectives of the statistical			

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design; in cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of results, the proficiency testing provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance; c) the relevance of significant figures to the reported result, including the number of decimal places; d) the number of proficiency test items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each proficiency test item or for each determination; e) the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria; f) procedures to be used to identify or handle outliers, or both; g) where relevant, the procedures for the evaluation of values excluded from statistical analysis; and h) where appropriate, the objectives to be met for the design and the frequency of proficiency testing rounds.			
4.4.5 Assigned values **4.4.5.1** The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose. *NOTE Metrological traceability is not always possible or appropriate.*			
4.4.5.2 Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty.			

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4.4.5.3 For proficiency testing schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme. *NOTE The required metrological traceability chain can differ depending on the type of proficiency test item, the measurand or characteristic, and the availability of traceable calibrations and reference materials.*			
4.4.5.4 When a consensus value is used as the assigned value (see Annex B of standard), the proficiency testing provider shall document the reason for that selection and shall estimate the uncertainty of the assigned value as described in the plan for the proficiency testing scheme.			
4.4.5.5 The proficiency testing provider shall have a policy regarding the disclosure of assigned values. The policy shall ensure that participants cannot gain advantage from early disclosure.			
4.5 Choice of method or procedure			
4.5.1 Participants shall normally be expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with their routine procedures. The proficiency testing provider may instruct participants to use a specified method in accordance with the design of the proficiency testing scheme.			
4.5.2 Where participants are permitted to use a method of their choice, the proficiency testing provider shall: a) have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods; b) be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly.			

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		Yes	**No**
4.6 Operation of proficiency testing schemes			
4.6.1 Instructions for participants **4.6.1.1** The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing the date on which the proficiency test items are likely to arrive or to be despatched, unless the design of the proficiency testing scheme makes it inappropriate to do so.			

4.6.1.2 The proficiency testing provider shall give detailed documented instructions to all participants. Instructions to participants shall include:
  a) the necessity 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);
  b) details of factors which could influence the testing or calibration of the proficiency test items, e.g. the nature of the proficiency test items, conditions of storage, whether the proficiency testing scheme is limited to selected test methods, and the timing of the testing or measurement;
  c) detailed procedure for preparing or conditioning, or both preparing and conditioning, of the proficiency test items before conducting the tests or calibrations;
  d) any appropriate instructions on handling the proficiency test items, including any safety requirements;
  e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement;
  f) specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability;
 	
NOTE This instruction usually includes parameters such as the units of measurement, the number of			

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significant figures or decimal places and reporting basis (e.g. on dry weight, or "as received"). g) the latest date for the provider to receive the proficiency testing or measurement results for analysis; h) information on the contact details of the proficiency testing provider for enquiries; and i) instructions on return of the proficiency test items, when applicable.			
4.6.2 Proficiency test items handling and storage **4.6.2.1** The proficiency testing provider shall ensure that proficiency test items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants.			
4.6.2.2 The proficiency testing provider shall provide secure storage areas or stock rooms, or both, which prevent damage or deterioration of any proficiency test item between preparation and distribution. Appropriate procedures for authorizing despatch to, and receipt from, such areas shall be defined.			
4.6.2.3 When appropriate, the condition of stored or stocked proficiency test items, chemicals and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.			
4.6.2.4 Where potentially hazardous proficiency test items, chemicals and materials are used, facilities shall be available to ensure their safe handling, decontamination and disposal.			
4.6.3 Packaging, labelling and distribution of proficiency test items **4.6.3.1** The proficiency testing provider shall control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements. *NOTE The proper distribution of proficiency test items can present severe problems for some types of material, e.g. those which require uninterrupted storage in cold conditions or which should not be*			

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exposed to X-rays, shock or vibration. *Most types of chemical materials would benefit from air-tight packaging to avoid contamination by atmospheric contaminants, e.g. fuel vapours or engine exhaust gases which can be encountered during transport.*			
4.6.3.2 The proficiency testing provider shall specify relevant environmental conditions for the transport of proficiency test items. Where relevant, the proficiency testing provider shall monitor the pertinent environmental conditions of the proficiency test item during transport and assess the impact of environmental influences on the proficiency test item.			
4.6.3.3 In proficiency testing schemes where participants are required to transport the proficiency test items to other participants, documented instructions for this transport shall be supplied.			
4.6.3.4 The proficiency testing provider shall ensure that labels are securely attached to the packaging of individual proficiency test items and are designed to remain legible and intact throughout the proficiency testing round.			
4.6.3.5 The proficiency testing provider shall follow a procedure to enable the confirmation of delivery of the proficiency test items. *NOTE This could be achieved in accordance with 4.6.1.1 by asking participants to inform the proficiency testing provider if proficiency test items have not been received in line with the schedule of dates provided.*			
4.7 Data analysis and evaluation of proficiency testing scheme results			
4.7.1 Data analysis and records **4.7.1.1** All data processing equipment and software shall be validated in accordance with procedures before being brought into use. Computer system maintenance shall include a back-up process and system recovery plan. The results of such maintenance and operational checks shall be recorded.			

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4.7.1.2 Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.			
4.7.1.3 Data analysis shall generate summary statistics and performance statistics, and associated information consistent with the statistical design of the proficiency testing scheme.			
4.7.1.4 The influence of outliers on summary statistics shall be minimized by the use of robust statistical methods or appropriate tests to detect statistical outliers.			
4.7.1.5 The proficiency testing provider shall have documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors.			
4.7.1.6 The proficiency testing provider shall have documented criteria and procedures to identify and manage proficiency test items that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination.			
4.7.2 Evaluation of performance **4.7.2.1** The proficiency testing provider shall use valid methods of evaluation which meet the purpose of the proficiency testing scheme. The methods shall be documented and include a description of the basis for the evaluation. The evaluation of performance shall not be subcontracted (see 5.5.2).			
4.7.2.2 Where appropriate for the purpose of the proficiency testing scheme, the proficiency testing provider shall 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 and between participants, and comparisons with any previous proficiency testing rounds, similar proficiency testing schemes, or published			

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precision data; c) variation between methods or procedures; d) possible sources of error (with reference to outliers) and suggestions for improving performance; e) advice and educational feedback to participants as part of the continual improvement procedures of participants; f) situations where unusual factors make evaluation of results and commentary on performance impossible; g) any other suggestions, recommendations or general comments; and h) conclusions. *NOTE It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular proficiency testing scheme. These can include updated summaries of performance for individual participants over successive proficiency testing rounds of a continuous proficiency testing scheme. Such summaries can be further analysed and trends highlighted, if required.*			
4.8 Reports			
4.8.1 Proficiency test reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants. The authorisation of the final report shall not be subcontracted (see 5.5.2). *NOTE Where all original data cannot be reported to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied.*			
4.8.2 Reports shall include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so: a) the name and contact details for the proficiency testing provider; b) the name and contact details for the coordinator; c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorising the report; d) an indication of which activities are subcontracted by the proficiency testing provider; e) the date of issue and status (e.g. preliminary, interim, or final) of the report; f) page numbers and a clear indication of			

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the end of the report; g) a statement of the extent to which results are confidential; h) the report number and clear identification of the proficiency testing scheme; i) a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment; j) the participants' results; k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays; l) procedures used to establish any assigned value; m) details of the metrological traceability and measurement uncertainty of any assigned value; n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation; o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants); p) comments on participants' performance by the proficiency testing provider and technical advisers; q) information about the design and implementation of the proficiency testing scheme; r) procedures used to statistically analyse the data; s) advice on the interpretation of the statistical analysis; and t) comments or recommendations, based on the outcomes of the proficiency testing round. _NOTE For continuous proficiency testing schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause could be excluded from routine reports, but included in proficiency testing scheme protocols or in periodic summary reports that are available to participants._			
4.8.3 Reports shall be made available to participants within planned timescales. In sequential proficiency testing schemes, e.g. where the turn-around time may be very long, and in schemes involving perishable materials, preliminary or anticipated results may be provided before final results are disclosed.			

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NOTE This allows for early investigation of possible error. **4.8.4** The proficiency testing provider shall have a policy for the use of reports by individuals and organisations.			

4.8.5   When it is necessary to issue a new or amended report for a proficiency testing scheme, this shall include the following:
   a) a unique identification;
   b) a reference to the original report that it replaces or amends; and
   c) a statement concerning the reason for the amendment or re-issue.			

4.9 Communication with participants			

4.9.1   The proficiency testing provider shall make detailed information available about the proficiency testing scheme. This shall include:
   a) relevant details of the scope of the proficiency testing scheme;
   b) any fees for participation;
   c) documented eligibility criteria for participation;
   d) confidentiality arrangements; and
   e) details of how to apply.			

4.9.2 Participants shall be advised promptly by the proficiency testing provider of any changes in proficiency testing scheme design or operation.			
4.9.3 There shall be documented procedures for enabling participants to appeal against the evaluation of their performance in a proficiency testing scheme. The availability of this process shall be communicated to proficiency testing scheme participants.			
4.9.4 Relevant records of communications with participants shall be maintained and retained, as appropriate.			
4.9.5 If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading.			

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4.10 Confidentiality			
4.10.1 The identity of participants in a proficiency testing scheme shall be confidential and known only to persons involved in the operation of the proficiency testing scheme, unless the participant waives confidentiality.			
4.10.2 All information supplied by a participant to the proficiency testing provider shall be treated as confidential. *NOTE Participants can elect to waive confidentiality within the proficiency testing scheme for the purposes of discussion and mutual assistance, e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In most instances, the proficiency testing results can be provided to the relevant authority by the participants themselves.*			
4.10.3 When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, the participants shall be made aware of the arrangement in advance of participation.			
4.10.4 In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing.			
5 MANAGEMENT REQUIREMENTS			
5.1 Organisation			
5.1.1 Is the provider, or the organisation of which it is part, legally identifiable?			
5.1.2 5.1.4 It is the responsibility of the proficiency testing provider to carry out its proficiency testing operations in such a way as to meet the requirements of this International Standard and to satisfy the needs of the participants, regulatory authorities and organizations providing recognition. The management system shall cover work carried out in the proficiency testing provider's permanent facilities, at sites away from its			

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Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
permanent facilities, and in associated temporary facilities. If the proficiency testing provider is part of an organization performing other activities, then the proficiency testing provider shall identify the responsibilities of key personnel in the organization that have an involvement in or could have influence on the proficiency test activities, in order to identify potential conflicts of interest. Where potential conflicts of interest are identified, procedures shall be put in place to ensure that all activities of the proficiency testing provider are conducted with impartiality.			
5.1.5 Does the provider: a) 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) 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) have policies and procedures to ensure the protection of confidential information and proprietary rights of participants in proficiency testing schemes;			
d) have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;			
e) 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, subcontractors and the quality management system;			
f) specify the responsibility, authority and			

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Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
inter-relationships of all personnel who manage, perform or verify work affecting the quality of the provision of proficiency testing schemes;			
g) 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 programs;			
h) 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 *Requirements* are implemented and followed at all times, and does the quality manager have direct access to the highest level of management at which decisions are taken on the proficiency testing policy or resources;			
i) where possible, have appointed deputies for key managerial personnel such as the technical and quality managers?			
5.2　Management system			
5.2.1　Has the provider of a proficiency testing scheme established, and does it implement and maintain, a quality management system appropriate to the scope of its activities, including the type, range and volume of proficiency testing that it provides?			
5.2.2 Has the provider defined and documented 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? Does the quality policy also include a commitment to provide proficiency testing schemes which conform to the technical			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
requirements contained in Section 4 of these *Requirements*?			
5.2.3 The proficiency testing provider's Management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (named as appropriate). The overall objectives shall be established and reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following: a) the management's commitment to the quality of its proficiency testing services to participants and other customers; b) the management's statement of the standard of service; c) the purpose of the management system related to quality; d) a requirement that all personnel concerned with the proficiency testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work; and e) the management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.			
5.2.4 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.			
5.2.5 Top management shall communicate to the organisation the importance of meeting customer requirements, as well as statutory and regulatory requirements.			
5.2.6 The quality manual shall include or make reference to the supporting procedures, including technical procedures. It shall outline the structure of the documentation used in the management system.			
5.2.7 Does the documented quality system define the roles and responsibilities of the technical manager and quality manager (however named) and the coordinator,			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
including their responsibilities for ensuring compliance with these Requirements.			
5.2.8 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.			
5.3 Document control			
5.3.1 General Has the provider established, and does it maintain, procedures to control all documents (both internally generated and from external sources) and other information that forms part of its quality documentation?			
5.3.2 Document approval and use **5.3.2.1** Are all documents (including documented procedures) issued to personnel as part of the quality management system reviewed and approved for use by authorised personnel prior to issue? Has a master list or equivalent identifying the current revision status of documents in the quality management system been established, and is it readily available to preclude the use of invalid and/or obsolete documents?			
5.3.2.2 Do the procedures adopted also ensure that: a) all documents are uniquely identified and 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 their 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 information preservation purposes are suitably marked?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	No
5.3.3 Document changes **5.3.3.1** ensure changes to documents are reviewed and approved by the same function that performed the original review, or a designate			
5.3.3.2 ensure where practical, the altered or new text is identified in the document or the appropriate attachments.			
5.3.3.3 ensure if hand written amendments are allowed, defined procedures are available, which include authorities, clear marking, initialling, dating, and formal re-issue.			
5.3.3.4 establish procedures to describe how changes in documents maintained electronically are made and controlled.			
5.4 Review of requests, tenders and contracts			
5.4.1 Is each request, tender or contract for provision of a proficiency testing scheme 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) the proficiency testing scheme is technically appropriate;			
5.4.2 Are records maintained of such reviews including any changes? Are records also 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?			
5.4.3 Do such reviews include any work that is carried out by subcontractors?			
5.4.4 The participants and other customers, as appropriate, shall be informed of any deviation in the contract or agreed proficiency testing scheme design.			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
5.4.5 If a request or contract is amended after the proficiency testing scheme is underway, the same review process shall be repeated and any amendments shall be communicated to all affected personnel.			
5.5 Subcontracting services			
5.5.1 When a proficiency testing provider subcontracts work, the proficiency testing provider shall demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.			
5.5.2 The proficiency testing provider shall not subcontract the planning of the proficiency test scheme (see 4.4.1.2), the evaluation of performance (see 4.7.2.1) or the authorisation of the final report (see 4.8.1). *NOTE This does not preclude the proficiency testing provider utilising advice or assistance from any advisors, experts or steering group.*			
5.5.3 The provider shall inform participants, in advance, in writing, of services that are, or may be, subcontracted. *NOTE This notification can, for example, take the form of a statement in the proficiency testing scheme documentation, such as the following: "Various aspects of the proficiency testing scheme can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the proficiency testing provider is responsible for this work."*			
5.5.4 The proficiency testing provider shall be responsible to the participants and other customers for the subcontractor's work, except in the case where a regulatory authority specifies which subcontractor is to be used.			
5.5.5 Does the provider maintain a register of all subcontractors used in the provision of proficiency testing schemes, and does it include a record of any assessments made of their abilities to conduct subcontracted tasks?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
5.6 Purchasing services and supplies			
5.6.1 Does the provider have procedures for the selection of services and supplies that affect the quality of its proficiency testing schemes?			
5.6.2 Ensure all purchased supplies that affect the quality are not used until verified as complying with defined specifications, and records of the actions taken to demonstrate compliance are maintained.			
5.6.3 Does the provider have procedures to ensure that purchased materials and services comply with specified requirements when no formal approval of the quality of services and supplies is available, and are records maintained of actions taken?			
5.6.4 Does the provider 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 and does the provider maintain records of approved suppliers of services and supplies? *NOTE: It is understood that some proficiency testing providers can be required to implement their purchasing procedures in accordance with policies defined by their parent company or a host organization.*			
5.7 Service to the customer			
5.7.1 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.			
5.7.2 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.			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	No
5.8 Complaints and Appeals			
Does the provider have procedures for the effective handling of complaints or other feedback received from participants? Are records maintained of all complaints and of the investigations and corrective actions taken by the provider?			
5.9 Control on nonconforming work			
5.9.1 Does the provider have procedures that shall 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? Do the procedures ensure that: a) the 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 non-conforming work is identified; b) an evaluation of the significance of the nonconforming work is made; c) a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work; d) proficiency testing scheme participants and other customers, as appropriate, are informed and the non-conforming proficiency test items or reports already sent to participants are recalled or disregarded; and e) the responsibility for authorisation of the resumption of work is defined.			
5.9.2 Where the evaluation indicates that the supply of nonconforming test materials could recur or where there is doubt about the provider's or subcontractors compliance with their own policies and procedures, are the corrective action procedures in Clause 5.11 promptly followed to identify root causes of the problem and to eliminate these causes?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
5.10 Improvement			
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 preventative actions and management review.			
5.11 Corrective action			
5.11.1 General Has the provider established a policy and procedures, and has it designated appropriate personnel for implementing corrective action when nonconforming test materials or departures from the policies and procedures in the quality management system have been identified? Is any corrective action taken to eliminate the causes of non-conformances or other departures appropriate to the magnitude of the problems and commensurate with the risks encountered? Has the provider documented and implemented any required changes to the operational procedures resulting from corrective action investigations?			
5.11.2 Cause analysis Do corrective action procedures include an investigation process to determine the root causes of the problem?			
5.11.3 Selection and implementation of corrective actions Does the provider identify possible causes and potential corrective actions, and does it select the actions most likely to eliminate the problem and to prevent it recurring?			
5.11.4 Monitoring of corrective actions After having implemented the action plans, does the provider monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	No
5.11.5 Additional audits Where the identification of nonconforming activities or departures from authorised procedures cast doubts on the compliance of the proficiency testing provider with its own policies and procedures, or on its compliance with this International Standard, the proficiency testing provider shall ensure that the appropriate areas of activity are audited in accordance with 5.14 as soon as possible. *NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness.* *An additional audit can be necessary only when a serious issue or risk to the proficiency testing scheme is identified.*			
5.12 Preventive action			
5.12.1 Are all operational procedures systematically reviewed at regular intervals to identify any potential sources of non-conformances and any opportunities for improvement, either technical or within the quality management system? Have action plans been developed, and are they implemented and monitored, to reduce the likelihood of such non-conformances and to take advantage of the improvement opportunities?			
5.12.2 After the implementation of preventive actions, does the provider monitor the results to establish any reduction in non-conformances in this operational area, thereby establishing the effectiveness of the preventive action?			
5.13 Control of records			
5.13.1 General **5.13.1.1** Has the provider established, and does it maintain, procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
5.13.1.2 Are all records legible, and are they 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? Have retention times been established and are they recorded? *Note: Records may be in the form of any type of media, such as hard copy or electronic storage media.*			
5.13.1.3 Are all records held secure and in confidence?			
5.13.1.4 Does the provider have procedures to protect electronically-held data at all times and to prevent unauthorised access to, or amendment of, such data? Has the provider established, and does it maintain, a records system to suit its particular circumstances and to comply with any applicable regulations? Does the provider 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 for a defined period until it is no longer probable that they will be needed or be referred to?			

5.13.2.1 The proficiency testing provider shall retain records of all technical data relating to each proficiency testing round for a defined period, including, but not necessarily limited to:
  a) results of homogeneity and stability testing;
  b) instructions to participants;
  c) participants' original responses;
  d) collated data for statistical analysis;
  e) information required for reports (see 4.8); and
  f) final reports (summary or individual, or both).			

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

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**

5.13.2.3 When mistakes occur in records and alterations are made, actions shall be taken to:
   a) identify the change and date of alteration;
   b) avoid loss of original data; and
   c) identify the person making the alteration.			

5.14 Internal audits			
5.14.1 Does the provider 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 requirement of the quality management system and these *Requirements*? Does the internal audit program 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? Is it the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by management? Are such audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity being audited?			
5.14.2 Where 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, does the provider take timely corrective action and does it notify, in writing, its clients and/or participants in proficiency testing schemes whose activities may have been affected?			
5.14.3 Are all audit findings and corrective actions that arise from them recorded? Does the management ensure that these actions are discharged within an appropriate and agreed timescale?			

REVIEW OF TECHNICAL ACTIVITIES

Requirements for Accreditation	Evidence (outcome of discussions with staff; observations; procedures & documentation reviewed)	Complies	
		Yes	**No**
5.15 Management reviews			
5.15.1 Does the senior management, unless they are from a parent organisation which has commercial competitors being proficiency tested by the proficiency testing scheme, 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? Is the review discharged within an appropriate and agreed timescale? *NOTE It is advisable that the programme for internal auditing of the management system be completed every 12 months.*			
5.15.2 Are findings from management reviews and the actions that arise from them recorded? Does the management ensure that those actions are discharged within an appropriate and agreed timescale?			