

HOKLAS 017:2016

Abridged Version

(Requirements and notes of ISO/IEC 17043 are not included in this document. This document should be read in conjunction with ISO/IEC 17043:2010)

Technical Criteria for Accrediting Proficiency Testing Providers

(ISO/IEC 17043:2010, Conformity Assessment –
General requirements for proficiency testing, MOD)

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1 Introduction

Hong Kong Accreditation Service (HKAS) offers accreditation service for proficiency testing providers under the test category of ‘Proficiency Testing Providers’ of the Hong Kong Laboratory Accreditation Scheme (HOKLAS). Participation in this accreditation programme is voluntary. This programme is designed for proficiency testing scheme providers wishing to demonstrate their competence and compliance with relevant internationally acceptable requirements for the development and operation of proficiency testing schemes through obtaining accreditation.

1.1 Basis of HOKLAS 017 Technical Criteria for Accrediting Proficiency Testing Providers

This booklet is a modified adoption of the International Standard, ISO/IEC 17043:2010 – ‘Conformity assessment – General requirements for proficiency testing’. ISO/IEC 17043:2010 was jointly published by International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

The title of this booklet varies from the ISO/IEC 17043:2010 and is entitled as ‘Technical Criteria for Accrediting Proficiency Testing Providers’.

1.2 Scope of Accreditation

This document specifies general requirements for the competence of providers of proficiency testing schemes. They are generic requirements for all types of proficiency testing schemes, and can be used as a basis for specific technical requirements for particular fields of application.

An accredited proficiency testing provider is accredited only for the specific proficiency testing schemes listed in its scope of accreditation. Schemes may be designed for any field of testing for any purpose, including for participants to satisfy the HKAS proficiency testing requirements.

The application procedure for proficiency testing provider is similar to the application procedure for laboratories under HOKLAS and is detailed in Annex AA of this document.

Accredited and applicant proficiency testing providers shall ensure that all tasks involved in the provision of a proficiency testing scheme included in its scope of accreditation are performed competently, whether they are carried out directly by itself or indirectly through collaboration with other parties.

1.3 Accreditation criteria

Accredited and applicant proficiency testing providers shall comply with the Regulations for HKAS Accreditation as documented in HKAS 002 and HOKLAS Supplementary Criteria No. 34. These regulations and criteria are applicable to all accredited and applicant proficiency testing providers.

Accredited and applicant proficiency testing providers shall also meet the technical and management requirements stated in this booklet. They are based on the requirements in the international standard ISO/IEC 17043:2010 'Conformity assessment – General requirements for proficiency testing'. ISO/IEC 17043:2010 provides a consistent basis for all interested parties to determine the competence of organisations that provide proficiency testing. In Sections 2 to 5 of this booklet, the normative references, terms and definitions, requirements and notes of ISO/IEC 17043:2010 are reproduced verbatim as the main text and relevant HOKLAS policies are given in shaded boxes following the main text. The notes provide clarification of the requirements, examples and guidance. A proficiency testing provider is considered to have met the requirements if it follows the guidance. Annexes A to C and bibliography at the end of this booklet are also reproduced from ISO/IEC 17043:2010. The annexes contained information on typical types of proficiency testing schemes, guidance on appropriate statistical methods, selection and use of proficiency testing schemes by laboratories, accreditation bodies, regulatory bodies, and other interested parties. Annexes AA and AB are also added following the original text of the ISO/IEC 17043:2010.

For the accreditation of proficiency testing providers, if there is any discrepancy in requirements described in ISO/IEC 17043:2010 and the other related documents including ISO/IEC 17025 and ISO 15189 (and other updated versions of relevant standards after their adoption by HKAS as accreditation criteria), the ISO/IEC 17043:2010 shall take precedence.

2 Normative references

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

3 Terms and definitions

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4 Technical requirements

4.1 General

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.1.H HOKLAS Policy on General

Testing and measurement activities carried out by a proficiency testing provider shall meet the requirements of ISO/IEC 17025 or ISO 15189 (for medical tests). As such, a proficiency testing provider shall, where relevant, comply with the requirements given in HOKLAS 003 or HOKLAS 015 with respect to its testing and calibration activities. The requirements given in other relevant HKAS and HOKLAS Supplementary Criteria documents relevant to the testing and calibration activities also apply.

If testing and measurement work is subcontracted, the requirements for subcontracting are given in Section 5.5 and the corresponding HOKLAS Policy 5.5.H of this document applies.

It should be noted that a proficiency testing provider is accredited for provision of proficiency testing schemes stated in its scope of accreditation. Any assessment on the testing or calibration activities it carries out is solely on their suitability in supporting the proficiency testing schemes. Therefore, the scope of accreditation of a proficiency testing provider does not cover the provision of the tests and calibrations for purposes other than those related to the provision of the proficiency testing schemes. Hence it shall not claim to be accredited for such tests or calibrations.

If the proficiency testing provider wishes to be accredited as a laboratory for the tests and calibrations it is carrying out, it may apply separately for accreditation as a laboratory under HOKLAS. In such cases, all relevant accreditation criteria and regulations of HOKLAS apply.

When reference materials are used by a proficiency testing provider, they shall be produced by competent reference material producers. Competent reference material producers are National Metrology Institutes or Designated Institutes that participate regularly and successfully in relevant key comparisons carried out by the Consultative Committees of the CIPM, the BIPM and the regional metrology organisations. A reference material producer accredited to ISO 17034 is also considered as a competent supplier.

4.2 Personnel

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.2.H HOKLAS Policy on Personnel

Coordinator

An applicant or accredited proficiency testing provider shall nominate an individual as the coordinator for each proficiency testing scheme included in its scope of accreditation. Among other duties, the coordinator shall participate in the preparation and endorsement of the report(s) for the relevant scheme(s).

The responsibility of the coordinator shall be clearly documented. In cases where external coordinator is used, there shall be written agreement between the coordinator and the proficiency testing provider defining the tasks for which the coordinator shall be responsible. In such a case, the coordinator shall report directly to the proficiency testing provider and is not considered a subcontractor.

The nominated coordinator shall have appropriate training, qualifications and experience in the field of the specific scheme. Before appointing a potential coordinator, the applicant or accredited proficiency testing provider shall assess and confirm the competence of the candidate. Such assessments and their results shall be recorded. During HOKLAS assessment, the coordinator shall be available for assessment. HKAS Executive shall be informed immediately when there is a change of coordinator for a particular scheme.

External advisory groups

When external advisory groups (or however named) are used, written arrangements shall be made. Such arrangements shall include, amongst others, the roles, functions, responsibilities and authorities of the groups, their establishment and operation procedures as well as the arrangements on how the advice is to be acted upon by the proficiency testing provider. There shall be effective communication between the proficiency testing provider and its advisory groups. The relationship between these groups and the proficiency testing provider shall be clearly defined and shown in the organisation and management structure.

Personnel for authorising reports

The person authorised to issue interim and final proficiency testing reports shall be either employed by, or under contract to, the provider. Before authorising the issue of the report(s), the person shall ensure that the content of the report is endorsed by the coordinator, and there is adequate access to advice and assistance from experts or its advisory groups, where necessary.

4.3 Equipment, accommodation and environment

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.3.H HOKLAS Policy on Equipment, accommodation and environment

A proficiency testing provider shall have documented procedures for handling and storage of proficiency test items. It shall be equipped with facilities that are suitable for processing the proficiency test items. All units of proficiency test items shall remain uniquely identifiable at all times.

An accredited or applicant proficiency testing provider may use its own testing and measurement facility(ies) or those provided by its subcontractors (See 5.5.H for policy on selection of subcontractors).

Accommodation and environmental condition requirements vary greatly depending on the nature of the proficiency test items and the examination or test to be conducted. Suitability of the accommodation and environmental conditions will be assessed against how they affect:

- (a) the integrity of the proficiency test items tested or examined;
- (b) the performance of laboratory equipment;
- (c) the competent performance of laboratory staff;
- (d) compliance with the conditions set in test or examination methods; and
- (e) safety of laboratory staff.

Consideration of environmental effects on proficiency test items to be tested or examined includes precautions necessary to prevent contamination and degradation. The areas for the proficiency test item preparation, preconditioning, testing or examination and storage shall be of adequate size, free from dust and fumes and protected from other environmental factors such as excessive temperature, high humidity and direct sunlight, which may affect the integrity of the samples. If proficiency test items require refrigeration before and after examinations, and for storage before and after distribution to participants, refrigerators or freezers of adequate capacity shall be provided. Temperature of the storage facilities shall also be monitored.

Sufficient storage space shall be available to store proficiency test items for the required periods in conditions designed to maintain their integrity.

Factors of the environment that may affect the performance of equipment include corrosion, temperature, humidity, vibration, electrical power stability, dust and electromagnetic influences. The location of all items of equipment likely to be affected by these factors shall be chosen to eliminate or minimise any adverse effects.

Accommodation and environmental conditions may also be judged on how it affects staff competence in performing specific activities. There shall be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimise noise.

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Adequate space shall also be provided for the proficiency testing provider's clerical and other functions (packaging, labelling, reporting, data processing and analysis activities) and for separate amenity facilities. All necessary services for gas, water, power (suitably stabilised if necessary), waste disposal and for extraction of fumes shall be available and be conveniently located.

Some examination methods also specify features of the environment in which sample preparation, and examination should take place. Where environmental features such as temperature and humidity ranges, airflow rates, illumination levels, etc., are specified, these conditions must be met in the relevant testing, examination and sample preparation sections of the proficiency testing provider. Monitoring equipment such as thermometers, hygrometers, psychrometers, thermohygrographs and anemometers, shall be available and be operated over the relevant testing, examination and sample preparation period specified by the methods. The monitoring equipment itself shall be calibrated in accordance with the equipment calibration schedules recommended by HKAS Executive.

When microbiological tests are being undertaken for the proficiency test items, the layout of the testing facility should generally provide for sample receipt, washing-up and sterilisation, media preparation and general testing areas, and should be designed to minimise potential contamination of samples and to ensure protection of testing staff. Proficiency testing providers involved in handling pathogenic organisms need to take special environmental precautions.

For certain testing activities under different HOKLAS test categories, there are other specific requirements on accommodation and environmental conditions. Those requirements are stated in the relevant HOKLAS supplementary criteria and where they are given, the proficiency testing provider shall comply with them. It should be emphasised that assessment of the proficiency testing provider's compliance with the relevant regulatory requirements is outside the scope of HKAS accreditation scheme.

The proficiency testing provider and its personnel shall follow local and international safety requirements. When the examination involves radionuclides, considerations should be given to bench space, shielded working space, storage, transportation and disposal of radioactive materials, safety of staff performing the examination and others working around. Handling of these radioactive materials shall comply with the local regulations, and staff involved shall be adequately trained and their health situation be closely monitored and documented.

The proficiency testing provider shall implement a system to ensure that the equipment used for manufacturing, handling, calibration and testing of proficiency test items are all properly calibrated, verified and maintained.

For chemical tests, regarding the use of reference material for calibration of equipment, the requirements given in HOKLAS Supplementary Criteria No. 1 apply.

4.4 Design of proficiency testing schemes

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.4.H HOKLAS Policy on Design of proficiency testing schemes

Although the design of proficiency testing schemes shall not be subcontracted, input and advice from experts or advisory groups on certain aspects of the schemes are allowed provided that the proficiency testing provider shall itself be competent to make the necessary judgement and decisions on the proper design of the proficiency testing schemes.

Where necessary, members of the advisory group can be experts with appropriate expertise from the provider's own organisation or from external source.

4.5 Choice of method or procedure

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.6 Operation of proficiency testing schemes

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.6.H HOKLAS Policy on Operation of proficiency testing schemes

The proficiency testing provider is usually responsible for the distribution and delivery of the proficiency test items, and sometimes the return of the test items. In such cases, it shall protect the integrity of the proficiency test items at all times before distribution and during transportation. There shall be documented instructions to personnel responsible for distribution and delivery regarding proper labelling, packaging and environmental condition during transportation.

Where the conditions of storage and transport of proficiency test items could affect the proficiency testing results, they shall be monitored and recorded. Where the test items require special precautions in handling, it is desirable to mark these precautions conspicuously on the packaging. It is also desirable to install a checking device to check whether the package has been mishandled, for instance, a minimum/maximum thermometer or a vibration detector could be considered.

Instructions for proper handling of proficiency test items shall be provided to any subcontractor responsible for delivery. When the proficiency test items are to be delivered by mail, requirements for packaging to meet relevant regulatory safety requirements shall be observed. There shall also be documented procedures to check the integrity of proficiency test items. Participants should be requested to record the conditions of the proficiency test items on receipt and provide feedback to the provider if discrepancy is detected. For test items circulated to participants, there may be a need to return the items to the proficiency testing provider for periodic checking or calibration.

Subcontractor to be responsible for the transport and distribution of the proficiency test items shall be selected according to the established criteria of the proficiency testing provider and its performance shall be evaluated. Training shall be provided to the responsible person(s) regarding the appropriate conditions of transport, handling precautions, biosafety requirement when relevant, and importance of maintaining confidentiality of participants.

4.7 Data analysis and evaluation of proficiency testing scheme results

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.7.H HOKLAS Policy on Data analysis and evaluation of proficiency testing scheme results

The evaluation of participants' performance shall be conducted by the proficiency testing provider itself. If data analysis is subcontracted, confidentiality of participants' identities shall be maintained and shall not be disclosed to the subcontractors. All original results provided by participants, processed data and analysed results shall be returned by the subcontractors to the proficiency testing provider for further evaluation of participants' performance.

4.8 Reports

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.8.H HOKLAS Policy on Reports

The preparation, approval and issue of interim report for each round and the annual summary report of a continuous proficiency testing scheme or the final report of a one-off scheme included in the scope of accreditation shall be carried out by the accredited proficiency testing provider and shall not be subcontracted.

HKAS endorsed proficiency testing reports shall be signed by a signatory nominated by the proficiency testing provider and approved by HKAS Executive in writing for signing such reports for specific proficiency testing schemes. Such a signatory is called an approved proficiency testing signatory. The person shall have in-depth understanding of the operation of the proficiency testing schemes and the relevant HKAS accreditation criteria. As approval is granted in the context of the proficiency testing schemes operated by the proficiency testing provider, it shall not be considered as a personal qualification.

A nominee for signatory approval for a scheme may not necessarily be the same person as the coordinator described in HOKLAS Policy 4.2.H. The coordinator, if different from the approved proficiency testing signatory, shall participate in the preparation and drafting of the report and shall communicate closely with the approved proficiency testing signatory for the final authorisation of the report.

When technical comments other than on the performance of participants are made in proficiency testing reports, they are not covered under the scope of accreditation of the proficiency testing provider. Where such comments are included in endorsed proficiency testing report, a clear and explicit disclaimer shall be given in the report that they are not covered under the scope of accreditation.

4.9 Communication with participants

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.9.H HOKLAS Policy on Communication with Participants

It is acceptable for a proficiency testing provider to issue statements of participation or performance to individual participants, but the full participant list shall not be published or made known to other participants to protect confidentiality and to avoid potential collusion.

Feedback and enquiries from participants shall be recorded. Technical feedback shall be reviewed, and, if necessary, suitable follow-up actions shall be taken.

4.10 Confidentiality

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

4.10.H HOKLAS Policy on Confidentiality

In general, all information on participants' performance and identity shall not be disclosed to any third party unless prior agreement with the concerned participants has been obtained or applicable laws or regulations stipulate such disclosure. Proficiency testing providers shall also take into consideration local regulatory requirements for the disclosure of confidential information. Where participants' identity and corresponding assigned codes have been disclosed, the proficiency testing provider shall record the identity of the person(s) and/or parties to whom such disclosure has been made. The proficiency testing provider shall also stipulate that the information shall not be disclosed to other parties or where appropriate, the condition under which the information may be disclosed.

5 Management requirements

5.1 Organisation

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.1.H HOKLAS Policy on Organisation

It is the responsibility of a proficiency testing provider to carry out its work in accordance with the relevant laws and regulations of Hong Kong or of the country where the proficiency testing provider is located. Assessment of the proficiency testing provider's compliance with the relevant regulatory requirements is however outside the scope of HKAS accreditation schemes.

An applicant or accredited proficiency testing provider shall be a legal entity and take responsibility for all activities involved in the operation of the proficiency testing scheme included in its scope of accreditation.

A proficiency testing provider's scheme could be designed for any field of testing for any purpose including for participants to satisfy the HKAS proficiency testing requirements. Each scheme shall be listed separately under its scope of accreditation, for instance, a scheme for chemical testing of construction materials, and another scheme for steel testing, etc.

Where a proficiency testing provider is part of a larger organisation, the organisational arrangements should be such that departments having conflicting interests, such as operation, commercial marketing or finance should not adversely influence the provider's compliance with the requirements of this document. In this regard, the proficiency testing provider should particularly take note of clause 5.1.4 if it also provides testing or calibration services to external customers. Suitable firewall shall be established to ensure that all information on the performance of participants is not disclosed to anyone including staff members who may have a conflict of interest. Furthermore, the proficiency testing provider shall provide evidence that its proficiency testing schemes are conducted with impartiality.

Where the proficiency testing provider's laboratory is also a participant of the concerned proficiency testing scheme, there shall be documented procedures and mechanisms established to prevent collusion and falsification of results; and the personnel involved in the operation of the proficiency testing scheme shall be different from the personnel participating in the scheme.

HKAS Executive considers individual proficiency testing provider (including all its subcontractors) on its merits and relates staff and management requirements to the range, complexity and frequency of schemes for which accreditation is sought. In some circumstances, adequate technical control may be achieved with a combination of staff. For example, a staff member exercising technical control may be relatively inexperienced with respect to one facet of the work, but another staff member working in close collaboration with him/her may complement him/her in that aspect. The accreditation in such a case will be reviewed if there is a major change in either person's duties.

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HOKLAS assessments will pay particular attention to the mode of supervision of staff. The management shall decide who can work under direction and who requires supervision. Each staff member of the proficiency testing provider, members of its advisory groups and its subcontractors shall be fully briefed or instructed on their respective roles and duties in the scheme. Adequate supervision shall be provided at each level of the staff structure to ensure close adherence to documented procedures at all times.

There shall be clearly defined and recognisable lines of authority and responsibility within the organisation. All staff members shall be aware of both the extent and limitations of their own responsibilities. A concise organisation chart shall be documented (preferably in the quality manual) showing the provider's overall organisation, its relationship with the parent organisation (if applicable), lines of responsibilities and relationships with subcontractors.

The technical management may be a designated technical manager or may comprise a number of designated technical managerial staff members, each of them responsible for a specified discipline or technical area. The responsibility of technical issues for all accredited activities shall be fully covered by the technical management.

The scope of responsibilities and authority of the quality manager shall be clearly defined and documented. The responsibilities of the quality manager or his/her designees shall include the following functions:

- (a) maintenance of the quality manual and associated operation documentation;
- (b) monitoring of the operation of the proficiency testing provider to verify continuing compliance with documented policies and procedures of the management system;
- (c) ensuring instruments used for preparation and testing of the proficiency test items are calibrated and maintained by the concerned laboratory;
- (d) selection, training and evaluation of internal auditors; and
- (e) scheduling and coordination of internal audits and management reviews.

5.2 Management system

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.2.H HOKLAS Policy on Management system

The management system of a proficiency testing provider need not be complex and its format will depend on a number of factors including the size of the organisation, number of staff members and the range, volume and complexity of the proficiency testing that it provides.

The quality manual describing the proficiency testing provider's management system shall be developed as a working document for use by the provider's staff members, and should not be developed as a checklist for presentation to the assessors. It shall be available for examination as a part of the accreditation process.

In cases where a proficiency testing provider is part of a larger organisation, part of the activities may already be incorporated in a quality manual covering an organisation's total range of operations. If so, it may be necessary to extract that information and expand on it to establish a manual specifically relating to the proficiency testing provider's functions.

The proficiency testing provider shall have a management system that clearly details the roles of, and relationship with, other relevant parties, including its subcontractors if they are used on an on-going basis (see also 5.1.H).

5.3 Document control

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.3.H HOKLAS Policy on Document control

All controlled documents shall be reviewed, and revised if necessary, at a suitable defined interval. Posted information and instructions, or any abridged version of controlled documents, related to testing or other activities that may affect the quality of the proficiency testing schemes shall be considered as controlled documents.

A proficiency testing provider shall note that all worksheets and record forms shall also be controlled under its document control system to maintain uniformity in the types of information to be recorded.

5.4 Review of requests, tenders and contracts

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.4.H HOKLAS Policy on Review of contracts

Detailed description of the proficiency testing scheme(s) in a catalogue or other notices, are regarded as conditions of the contract laid out to participants. When participants enrol in a scheme based on the information available in such catalogue or other notices, they are entering into a contract with the proficiency testing provider. Participants shall be informed in case of any changes to the conditions set out in the catalogue or relevant notices.

If the proficiency testing provider is prepared to enter into contracts to provide new proficiency testing schemes on request by other parties e.g. government departments or practitioners of the field, the provider shall have documented procedures to assess the request for the provision of new schemes and procedures to determine the commercial or technical viability or otherwise of the request.

When reviewing contracts, a proficiency testing provider shall ensure that any new scheme created is suitable for its intended purposes. The items for review shall include, in addition to those given in clause 5.4.1, where relevant, the measurand required, metrological traceability of the assigned values and the associated measurement uncertainty, and method for assessment of participants' performance.

For existing programmes, feedback from customers shall be taken into consideration when reviewing contracts.

5.5 Subcontracting services

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.5.H HOKLAS Policy on Subcontracting services

If a proficiency testing provider subcontracts any of its activities for the production, testing, measurement, packaging, storage, and distribution of the proficiency test items (i.e. PT materials/samples or measurement artefacts), or for data processing and distribution of the proficiency testing reports, the work and responsibilities of each subcontractor shall be clearly defined and documented.

The subcontractors

An applicant or accredited proficiency testing provider shall ensure that the subcontractor responsible for the testing/measurement activities, or other activities which have an impact on the quality of its proficiency testing schemes, operates under a suitable quality system, carries out the subcontracted activities according to well-defined documented procedures and meets the accreditation requirements in this booklet.

If the work to be subcontracted is a test or measurement, a subcontractor holding current accreditation by HKAS or a mutual recognition arrangement partner of HKAS for the relevant test or measurement is accepted as having adequately demonstrated its competence. Where the subcontractor is not accredited for such activities, HKAS may assess, reassess and monitor the competence of the subcontractor through on-site visits as part of the assessment or surveillance activity for the proficiency testing provider. Relevant requirements are documented in HOKLAS Supplementary Criteria No. 34.

When a proficiency testing provider assesses its subcontractors' competence, any document issued to subcontractors as a result of a successful assessment should state that it is only for the purpose of the contract and is not certification or accreditation.

When evaluating competence of a proficiency testing provider in testing or measurement activities, HKAS will take into consideration all relevant factors, including its performance in relevant external proficiency testing schemes. Where an accredited proficiency testing scheme is not available for such activities, the proficiency testing provider shall be required to demonstrate its competence through other forms of interlaboratory comparison.

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On-site assessment

HKAS will appoint an assessment team to conduct on-site assessments at the proficiency testing provider's own facility and where appropriate and necessary, also at its subcontractors' facilities.

Before seeking accreditation from HKAS, an applicant proficiency testing provider shall ensure that prior written consent has been obtained from all its subcontractors regarding on-site visits by the HKAS assessment team for the relevant activity. For the assessment of the relevant activities, the proficiency testing provider shall through agreement with the subcontractor, ensure that the obligations of an accredited or applicant organisation stated in Chapter 5 of HKAS 002 are fulfilled. In particular, the proficiency testing provider shall ensure that its subcontractors will provide necessary cooperation and support to the assessment team, including but not limited to demonstration of the performance of the activities, provision of any documents and data related to the subcontracted activities and access to files and records during the on-site visits and other assessment activities. Assessment of its subcontractors is an integral part of the assessments of the proficiency testing providers. Hence, all relevant accreditation criteria and regulations also apply to the assessments of the subcontractors of a proficiency testing provider. However, any nonconformity identified in the work of the subcontractor will be considered as nonconformity of the applicant or accredited proficiency testing provider. The proficiency testing provider is required to resolve to the satisfaction of HKAS Executive any nonconformity related to its subcontractors. In case the proficiency testing provider replaces its subcontractor, the new subcontractor will be assessed anew.

Moreover, it should be emphasised that accreditation is granted to the proficiency testing provider, not to its subcontractors. In this regard, the proficiency testing provider shall have a written agreement with its subcontractors which requires its subcontractors not to represent themselves to anybody that they are accredited with respect to the subcontracted activities. It is an obligation of an accredited proficiency testing provider to ensure that its subcontractors follow the relevant accreditation requirements and regulations. HKAS Executive may impose suspension of the accreditation when the proficiency testing provider fails to ensure that its subcontractors follow any of the HKAS accreditation regulation or requirement relevant to the situation concerned.

On-site visits, whether as part of the reassessments or surveillance activities, will be conducted at a frequency as documented in HOKLAS Supplementary Criteria No. 34. An accredited proficiency testing provider may apply for monitoring plan B or C when it meets the pre-requisites of the respective monitoring plans.

5.6 Purchasing services and supplies

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.6.H HOKLAS Policy on External services and supplies

There are two commonly encountered situations where a proficiency testing provider needs to seek external services and supplies :

- (a) Acquisition/Purchase of consumables or perishable items relating to the production of proficiency test items, e.g. culture media, chemical reagents, blood products, biological samples, reference materials:

There shall be documented criteria on the selection of supplies and records of evaluation of the selected supplies. Records shall be kept of the different brands of those items which bear a critical influence on the test or examination results. The records should, where appropriate, include results of the acceptance tests on each new batch prior to use. When a particular brand shows an undesirably high rejection rate, consideration should be given to exclude it from the list of acceptable source of supplies.

- (b) Purchase of equipment :

Separate records shall be kept for each manufacturer supplying major items of equipment. The records should include results of the acceptance tests and the subsequent maintenance history of their products. Manufacturers whose products consistently do not meet their stated performance specifications and/or show undesirably high proportion of instrument down time and/or are not supported by good after-sales service should be noted and their names removed from the list of acceptable suppliers.

It is further recommended that when choosing a supplier of service or products, priority should be given to those certified to ISO 9001 by an accredited certification body.

Applicant and accredited proficiency testing providers shall take note that the requirements given in Section 5.6 are, where relevant, also applicable to the purchasing of external services.

5.7 Service to the customer

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.8 Complaints and appeals

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.8.H HOKLAS Policy on Resolution of complaints

Proficiency testing providers shall note that when a complaint involving a HOKLAS accredited proficiency testing scheme is not satisfactorily resolved within 60 days from the date of its receipt, they are required to notify HKAS Executive the nature of the complaint immediately. HKAS undertakes to keep information provided confidential as per Section 2.3 of HKAS 002. Details of the regulations on complaints are given in Chapter 5 of HKAS 002.

5.9 Control of nonconforming work

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.9.H HOKLAS Policy on Identification and control of nonconformities

A proficiency testing provider shall address identified nonconformities properly. In addition to correcting them immediately, it shall initiate actions according to the requirements given in clause 5.9.1, which include a determination of whether the nonconforming work is an isolated incident or is due to some underlying causes with a possibility of recurrence. In the latter case, the requirement given in clause 5.9.2 shall be conformed to. It should be emphasised that all personnel need to be familiar with the procedures for handling nonconforming work. Providing training to relevant staff on the procedures is essential. Internal audit should cover the effectiveness of implementation in this aspect.

Any nonconformity identified in the work of the subcontractor will be considered as nonconformity of the applicant or accredited proficiency testing provider.

5.10 Improvement

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.10.H HOKLAS Policy on Improvement

The top management shall have the commitment and provide adequate resources to continually improve the effectiveness of the management system (see Section 5.2.3). All staff members shall be aware of the organisation's policy and objective on improvement. The idea of continual improvement should be ingrained in all aspects of operation of the organisation.

5.11 Corrective actions

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.11.H HOKLAS Policy on Corrective actions

Corrective actions may be initiated through findings in internal audits, external assessments by accreditation bodies, customer and staff feedback and complaints, analysis of quality control data, performance in proficiency testing schemes, incidence of nonconforming work, etc. Corrective actions shall be evaluated, prioritised and implemented according to an agreed timescale. Their effectiveness shall be monitored. Some corrective actions may involve a number of staff members as well as more than one facet of the operation. Hence, it is important that the Quality Manager or other designated staff member coordinates the work arising from such corrective actions.

It must be emphasised that corrections and corrective actions are different. ISO 9000:2015 defines correction as 'action to eliminate a detected nonconformity' whereas corrective action is defined as 'action to eliminate the cause of a detected nonconformity and to prevent recurrence'. Carrying out correction without taking proper corrective action is ineffective as the cause of the nonconformity still exists and hence the nonconformity will recur. Making correction only without taking corrective action is rarely acceptable unless extensive investigation has demonstrated convincingly that there is no underlying cause and the nonconformity will not recur.

To ensure that maximum benefit can be derived from handling nonconformities, management should insist that the real root cause of the problem be identified and addressed. In many cases, what is said to be the root cause is only a consequence of the root cause. For example, the ostensible root cause for an incompetent operator might be identified as inadequate training while the real root cause was that the training had been provided by an incompetent trainer.

Therefore, when a nonconformity is detected, the provider shall make the necessary correction, analyse the situation to find the real root cause and take action for its elimination. The nonconformity should only be considered adequately addressed if the actions taken have been proven effective in preventing recurrence of the nonconformity. Recurrence of nonconformity is an indication of ineffective corrective actions, which is a nonconformity against the requirements of this clause.

5.12 Preventive actions

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.12.H HOKLAS Policy on Preventive actions

Preventive actions shall be taken against needed improvements and potential nonconformities. This highlights the need for identifying potential problems and opportunities for improvement. In other words, the proficiency testing provider shall take a proactive approach rather than a passive and reactive approach. For example, instead of merely checking for conformities, internal audits should be more forward looking and oriented towards identifying areas of risks. Whenever an observation is identified in an audit, its level of risk should be assessed and suitable preventive actions recommended for preventing the occurrence of the nonconformities. In most cases, preventive actions should be commensurate with the probability of occurrence as well as the consequence of the potential problem.

In addition, preventive actions may also be taken in response to staff or customer feedback and complaints.

5.13 Control of records

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.13.H HOKLAS Policy on Control of records

In applying the criteria for this section, the following HOKLAS policies shall be noted :

- (a) Each proficiency testing provider shall maintain a record system designed to suit its particular requirements. The system shall be in compliance with this document but need not be an elaborate one.
- (b) Records to be kept by the proficiency testing provider shall include both technical and quality records.
- (c) Quality records to be kept include, but not limited to, the following:
 - (i) development history, design and validation of the PT scheme;
 - (ii) assessment of subcontractors;
 - (iii) authorisation of personnel involved;
 - (iv) the dates of each round of a scheme, the list of participants and their identification codes;
 - (v) the planned and actual dates of critical activities for each round.
- (d) Technical records relating to testing and calibration shall include all original observations and raw data and provide an unequivocal and direct link with the examined item. This applies equally to computer and manual record systems. If a provider uses an Information Management System, the system shall meet all the relevant requirements, including audit trail, data security, safety, integrity, etc. It shall be fully validated and records of validation shall be maintained. Proficiency testing providers shall keep back-up copies of electronic records within their retention period. They shall also have a system to ensure that electronic records remain accessible within that period even though the hardware and software of their computer system are being updated from time to time. In case if the testing activities are subcontracted, these requirements equally apply.
- (e) The provider's record system shall allow for ready retrieval of original observations and data pertinent to the testing results of any proficiency test item; and to the original results returned from each participant.
- (f) The record system shall include ready access to the following detailed information:
 - (i) full description of each proficiency test item, including its source;
 - (ii) identification of the proficiency test item;

continued.....

- (iii) identification of examination or testing method used;
 - (iv) identification of equipment and reference materials used;
 - (v) original observations and calculations for homogeneity and stability studies, and, if applicable, assigning value;
 - (vi) identification of persons performing the work;
 - (vii) original results returned from each participant;
 - (viii) results of data analysis, including details of statistical methods used.
- (g) Original observations shall be recorded immediately into bound notebooks, or onto properly designed proforma worksheets. Where data processing systems are used, records of raw data shall be retained unless data are (electronically) fed directly into the processing system. Evidence of counterchecking data transcribed from recorded raw data shall be available.
- (h) Sheets of plain paper shall not be used, not only because they are easily lost or discarded, but also because they engender a less disciplined approach to the recording of information.
- (i) Errors in calculations and incorrect transfers of data are major causes of incorrect reports. Calculations and data transfers shall be checked and signed or initialled, preferably by a second person. It is desirable to design workbooks and worksheets so that there is a dedicated place for the signature of the checking person.
- (j) The minimum period for retention of original test data, laboratory records, participants' returned results, corresponding data analysis, interim and final HKAS endorsed proficiency testing reports has been set by HKAS Executive to be three years unless a longer period is specified by the regulatory authorities, or in the relevant HKAS or HOKLAS Supplementary Criteria documents, or other requirements such as the customer's instructions. The retention period of at least three years for equipment records and the proficiency testing scheme operation procedures shall be counted from the date on which the use of the equipment or the operation procedures have been discontinued. Similarly, the retention period of at least three years for personnel records (including records of subcontractors) shall be counted from the date of departure of the personnel concerned.
- (k) Records relating to advisory groups shall be maintained and shall be subject to all the above requirements, where relevant. The records shall at least include the terms of reference, attendance records for meetings as well as notes of meetings.

5.14 Internal audits

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.14.H HOKLAS Policy on Internal audits

HOKLAS policy on internal audits is detailed in HKAS Supplementary Criteria No. 5.

Internal auditors shall be familiar with the accreditation criteria and the management system of proficiency testing providers.

5.15 Management reviews

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

5.15.H HOKLAS Policy on Management review

HOKLAS policy on management review is detailed in HKAS Supplementary Criteria No. 5.

The top management of a proficiency testing provider, including its quality manager and coordinators, shall participate in management review.

Annex A
(informative)

Types of proficiency testing schemes

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

Annex B
(informative)

Statistical methods for proficiency testing

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

Annex C
(informative)

Selection and use of proficiency testing

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

Bibliography

(The main text of this clause is the text of the same clause of ISO/IEC 17043:2010)

Annex AA

(Informative)

Procedures for HOKLAS Accreditation of Proficiency Testing Providers

Full details of the processes involved in achieving HOKLAS accreditation are given in Chapter 4 of HKAS 002 - Regulations for HKAS Accreditation. A brief summary of the main features is given below:

Step 1 – Initial Contact

- A. An organisation interested in seeking accreditation contacts HKAS Executive in writing.
- B. Documents relevant to application for accreditation of proficiency testing providers are available on the HKAS website at <http://www.hkas.gov.hk>. These include:

HKAS 002	Regulations for HKAS Accreditation
HOKLAS 005	Application for Laboratory Accreditation (including Proficiency Testing Providers and Reference Material Producers) / Extension of Scope of Accreditation
HOKLAS 006	Schedule of Accreditation Fees for Organisations within the Hong Kong Special Administrative Region
HOKLAS 017	Technical Criteria for Accrediting Proficiency Testing Providers (only the abridged version is available at HKAS website)
HOKLAS 018	Assessment/Reassessment Questionnaire for Proficiency Testing Provider
Relevant HKAS	and HOKLAS Supplementary Criteria and Information Notes

- C. The organisation lodges the application by providing the following to HKAS Executive
- (a) A completed Application Form (HOKLAS 005)
 - (b) A completed Application Questionnaire (HOKLAS 018)
 - (c) The documents specified in the Application Questionnaire
 - (d) Appropriate application fees as stated in HOKLAS 006

Step 2 – Preliminary Visit to Organisation

- A. Following examination of the documentation submitted by the organisation, HKAS Executive arranges a preliminary visit to :
- (a) answer any questions relating to HKAS regulations and technical criteria.
 - (b) identify any obvious and necessary improvements to existing practices.
 - (c) evaluate the readiness of the organisation for an accreditation, particularly whether the organisation's management system meets HKAS criteria.
 - (d) address any issues on the compilation of the organisation's quality manual.

Step 3 – Preparation for Assessment

- A. The organisation submits the final copies of its quality manual and operation procedures.
- B. HKAS Executive seeks any further information required from the organisation.
- C. HKAS Executive selects suitable technical assessors to undertake the on-site assessment of the organisation.
- D. Arrangements are made with the organisation for a mutually convenient date or dates for an on-site assessment of the organisation and its subcontractors.

NOTE : Applicant organisations may object on reasonable grounds to the assessors nominated for the assessment of their organisations.

Step 4 – Assessment of Organisation

- A. An on-site assessment is undertaken at the organisation and where necessary, also at its subcontractors.

NOTES : All key organisation personnel shall be available for interview during the on-site assessment.

The organisation may be asked to undertake typical procedures as part of the assessment process.

The provider shall be able also to demonstrate the competence of its testing facility(ies).

- B. On completion of the on-site assessment, the organisation's management is provided with an assessment report by the assessment team which includes:
- (a) the assessment team's recommendation regarding granting of accreditation for all or part of the areas sought by the applicant organisation;
 - (b) lists of any action which may be necessary before accreditation for all or part of the areas can be further considered;
 - (c) details of follow-up action.

Step 5 – Assessment Outcome

Generally, for reassessments and assessments for extension of accreditation within a specific category of proficiency testing for which the organisation is already accredited, the assessment report will be reviewed by HKAS Executive. Any amendment to the assessment report will be issued to the organisation within 10 working days of the assessment.

For initial assessment of a proficiency testing provider, the assessment report will be reviewed by HKAS Executive as well as the Accreditation Advisory Board (AAB). The reviewed assessment results will be issued to the organisation in the form of an outcome letter.

In most cases, there are specific matters requiring attention by the organisation before accreditation can be further considered, and these are listed in the assessment report or in the outcome letter.

Step 6 – Remedial Actions (if required)

- A. On receipt of formal reply from an applicant organisation that all required actions have been taken, HKAS Executive will take the necessary follow-up action. If the matters are of a minor nature, remedial actions may be confirmed through submission of supporting documents or through a brief visit by a member of HKAS Executive and where necessary with an assessor, but in some cases, a further on-site assessment may be needed.
- B. Assuming the remedial actions are found acceptable, a recommendation for accreditation will normally follow. A formal notification letter and a Certification of Accreditation will be issued.
- C. If an organisation does not agree with the decision made by HKAS Executive or AAB, it has the right to appeal (See Chapter 7 of HKAS 002 - Complaints and Appeals).

Step 7 – After Accreditation

- A. After accreditation has been granted, organisations are reassessed the following year and thereafter at intervals not exceeding two years. Surveillance visits will also be conducted. The purpose is to ensure that the standards required for continued accreditation are being maintained.

For the purpose of on-going surveillance, accredited organisations are required to provide the following information to HKAS Executive on an annual basis for review:

- (a) details of the planned proficiency testing programmes for the next twelve months;
- (b) details of any subcontractors used in the past twelve months and any forward plans for the use of subcontractors;
- (c) an example of at least one report for a proficiency testing programme recently conducted;
- (d) results in any proficiency testing/external quality assurance programme relevant to the scope of accreditation that the organisation's laboratory (or subcontractors') has participated, together with the results of investigations into outliers;
- (e) details of customer complaints received and the resolution of these complaints.

The organisation will be informed about the outcome of the review. There may require on-site assessment, depending on the outcome of the review.

- B. Organisations may seek to have their scope of accreditation extended or reduced or they may seek changes to their subcontracting laboratories. Such changes may require on-site assessment.

- C. Organisations are required under HOKLAS regulations to notify HKAS Executive immediately in writing of any changes in the organisation's circumstances which may affect their continued conformity with HKAS regulations or HOKLAS requirements. In addition to those specified in Chapter 5 of HKAS 002, the accredited proficiency testing provider shall also notify HKAS Executive if there is any change of its subcontractors or the contractual agreement with its subcontractors.

Annex AB
(Informative)

Variations to ISO/IEC 17043:2010 for HOKLAS 017:2010

This Annex lists out all variations of this booklet to ISO/IEC 17043:2010 as follows:

Clause	Modification
Forward, Introduction, 1 Scope	Replaced by '1. Introduction' and '1.1. Scope of accreditation' and '1.2 Accreditation criteria' under '1. Introduction'
4 Technical requirements	Add 4.1.H 'HOKLAS Policy on General'
	Add 4.2.H 'HOKLAS Policy on Personnel'
	Add 4.3.H 'HOKLAS Policy on Equipment, accommodation and environment'
	Add 4.4.H 'HOKLAS Policy on Design of proficiency testing schemes'
	Add 4.6.H 'HOKLAS Policy on Operation of proficiency testing schemes'
	Add 4.7.H 'HOKLAS Policy on Data analysis and evaluation of proficiency testing scheme results'
	Add 4.8.H 'HOKLAS Policy on Reports'
	Add 4.9.H 'HOKLAS Policy on Communication with Participants'
	Add 4.10.H 'HOKLAS Policy on Confidentiality'
5 Management requirements	Add 5.1.H 'HOKLAS Policy on Organisation'
	Add 5.2.H 'HOKLAS Policy on Management system'
	Add 5.3.H 'HOKLAS Policy on Document control'
	Add 5.4.H 'HOKLAS Policy on Review of contracts'
	Add 5.5.H 'HOKLAS Policy on Subcontracting services'
	Add 5.6.H 'HOKLAS Policy on External services and supplies'
	Add 5.8.H 'HOKLAS Policy on Resolution of complaints'

Clause	Modification
	Add 5.9.H 'HOKLAS Policy on Identification and control of nonconformities'
	Add 5.10.H 'HOKLAS Policy on Improvement'
	Add 5.11.H 'HOKLAS Policy on Corrective actions'
	Add 5.12.H 'HOKLAS Policy on Preventive actions'
	Add 5.13.H 'HOKLAS Policy on Control of records'
	Add 5.14.H 'HOKLAS Policy on Internal audits'
	Add 5.15.H 'HOKLAS Policy on Management review'
--	Add Annex AA 'Procedures for HOKLAS Accreditation of Proficiency Testing Providers'
--	Add Annex AB 'Variations to ISO/IEC 17043:2010 for HOKLAS 017:2010'

Explanation:

HOKLAS policies added serve as additional explanation of the requirements of ISO/IEC 17043:2010 and shall be regarded as mandatory under Hong Kong Laboratory Accreditation Scheme (HOKLAS).

Annex AB is an information annex listing out all variations of this booklet to ISO/IEC 17043:2010.