HKAS Policy Document No. 3

HKAS Policy for Accreditation of Proficiency Testing Providers according to ISO/IEC 17043:2023 under HOKLAS (ISO/IEC 17043:2023 HOKLAS Policy)

Introduction

This document provides HKAS policy for accreditation of proficiency testing (PT) providers according to ISO/IEC 17043:2023 under the Hong Kong Laboratory Accreditation Scheme (HOKLAS). This document contains policy that serves as additional explanation of the requirements of ISO/IEC 17043:2023 and is mandatory. This document shall therefore be read in conjunction with ISO/IEC 17043:2023. More detailed requirements specific to certain administrative aspects and technical disciplines are issued as individual HKAS and HOKLAS Supplementary Criteria.

1 Scope

(No additional explanation)

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

4.1 Impartiality

(a) Where a PT provider is part of a larger organisation, the organisation shall be arranged such that departments having conflicting interests, such as laboratory operation, commercial marketing or finance would not influence the PT provider’s conformity with the requirements of ISO/IEC 17043:2023. Furthermore, the PT provider shall provide evidence that its PT schemes are conducted with impartiality. (ISO/IEC 17043:2023 Cl 4.1.2)

4.2 Confidentiality

(a) If any PT activity is subcontracted, confidentiality of the participants' identities shall be maintained and shall not be disclosed to the subcontractors. (ISO/IEC 17043:2023 Cl 4.2.5)

(b) It is acceptable for a PT 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to issue statements of participation or performance to individual participants, but the full participant list shall not be published or made known to other participants to protect confidentiality and to avoid potential collusion. (ISO/IEC 17043:2023 Cl 4.2.5)

5 Structural requirements

(a) It is the responsibility of the PT provider to carry out its work in accordance with the applicable Laws and Regulations of Hong Kong. It should be emphasized that assessment of a PT provider's compliance with the relevant regulatory requirements is outside the scope of HKAS accreditation schemes. (ISO/IEC 17043:2023 Cl 5.4)

(b) There shall be clearly defined and recognisable lines of authority and responsibility within the organisation. All staff shall be aware of both the extent and limitations of their own responsibilities. A concise organisation chart shall be documented showing the PT provider's overall organisation and lines of responsibility. (ISO/IEC 17043:2023 Cl 5.5)

(c) 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 PT provider. There shall be effective communication between the PT provider and its advisory groups. The relationship between these groups and the PT provider shall be clearly defined and shown in the organisation and management structure. (ISO/IEC 17043:2023 Cl 5.5)

(d) An applicant or accredited PT provider shall nominate an individual as the coordinator for each PT 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 PT provider defining the tasks for which the coordinator shall be

responsible. In such a case, the coordinator shall report directly to the PT provider and is not considered a subcontractor. (ISO/IEC 17043:2023 Cl 5.5 b))

6 Resource requirements

6.1 General

(a) When PT providers conduct tests, measurements, calibrations or produce reference materials in support of the PT activities within their scope of accreditation, they shall fulfil the relevant requirements of ISO/IEC 17025:2017 (or ISO 15189:2022 for medical testing) and ISO 17034:2016, as well as the requirements given in the relevant HKAS Policy Documents and HOKLAS Supplementary Criteria documents. Besides, they shall be aware that they are not directly accredited for the testing, measurement, calibration or reference material production activities concerned and therefore shall not claim accreditation for such activities. (ISO/IEC 17043:2023 Cl 6.1.2 & 6.1.3)

6.2 Personnel

(a) HKAS Executive will pay particular attention to the mode of supervision of staff during assessments. The management shall decide who can work under direction and who requires supervision. Each staff member of the PT provider, members of its advisory groups and its subcontractors shall be fully briefed or instructed on their respective roles and duties in the schemes. Adequate supervision shall be provided at each level of the staff structure to ensure close adherence to documented procedures at all times. (ISO/IEC 17043:2023 Cl 6.2.2 a))

Note: HKAS Executive considers an individual PT 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.

(b) Training shall be provided to the personnel responsible for transport and distribution of the PT items, regarding the appropriate conditions of transport, handling precautions, biosafety requirement when relevant, and

importance of maintaining confidentiality of participants. (ISO/IEC 17043:2023 Cl 6.2.2 a))

(c) The nominated coordinator as mentioned in Cl 5(d) shall have appropriate training, qualifications and experience in the field of the specific scheme. Before appointing a potential coordinator, the applicant or accredited PT provider shall assess and confirm the competence of the candidate. Such assessments and their results shall be recorded. During on-site assessments, the coordinator shall be available for assessment. HKAS Executive shall be informed immediately when there is a change of coordinator for a particular PT scheme. (ISO/IEC 17043:2023 Cl 6.2.2 a), 6.2.3, 6.2.5)

(d) The person authorised to issue interim and final PT 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. (ISO/IEC 17043:2023 Cl 6.2.6 e))

6.3 Facilities and environmental conditions

(a) Sufficient storage space shall be available to store PT items for the required periods in conditions designed to maintain their integrity. If PT items require refrigeration, e.g. 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. (ISO/IEC 17043:2023 Cl 6.3.2)

6.4 Externally provided products and services

(a) If a PT provider subcontracts any testing, calibration, PT or reference material production activities in support of its PT activities to a subcontractor where the subcontractor is not accredited for such activities, HKAS Executive reserves the right to assess the PT provider's evaluation and monitoring of its subcontractor's performance through on-site visits. The PT provider shall have, where applicable, legally enforceable arrangements with the subcontractor that commit the subcontractor to provide, on request, access to HKAS assessment teams to conduct such visits at the subcontractor's site(s). The arrangements shall also include access to any system and technical records related to the subcontracted activities. (ISO/IEC 17043:2023 Cl 6.4.2)

(b) If a PT provider subcontracts any of its activities for the production, testing, measurement, packaging, storage, and distribution of the PT items (i.e. PT materials/samples or measurement artefacts), or for data processing and distribution of the PT reports, the work and responsibilities of each subcontractor shall be clearly defined and documented. (ISO/IEC 17043:2023 Cl 6.4.4 a))

(c) The PT provider shall ensure that its subcontractor responsible for the testing/measurement activities, or other activities which have an impact on the validity of its PT schemes, operates under a suitable management system, carries out the subcontracted activities according to well-defined documented procedures and meets the requirements of the relevant accreditation standards, e.g. ISO/IEC 17025:2017. (ISO/IEC 17043:2023 Cl 6.4.4 b))

(d) When a PT 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. (ISO/IEC 17043:2023 Cl 6.4.4 c))

(e) If a PT provider subcontracts the distribution and delivery of PT items, it shall ensure that the integrity of the PT items is protected at all times during the distribution and delivery. Instructions for proper handling of PT items shall be provided to the subcontractor. (ISO/IEC 17043:2023 Cl 6.4.5)

7 Process requirements

7.1 Establishing, contracting and communicating the PT scheme objectives

(a) When reviewing contracts, a PT provider shall ensure that any new scheme created is suitable for its intended purposes. The items for review shall include, where relevant, the measurand required, metrological traceability of the assigned values and the associated measurement uncertainty, and method for assessment of participants' performance. (ISO/IEC 17043:2023 Cl 7.1.1.2)

(b) For existing programmes, feedback from customers shall be taken into consideration when contracts are being reviewed. (ISO/IEC 17043:2023 Cl 7.1.1.2)

7.2 Design and planning of a PT scheme

(a) Where the PT provider's laboratory is also a participant of the concerned PT scheme, there shall be documented procedures and mechanisms established to prevent collusion and falsification of results. The personnel involved in the operation of the PT scheme shall be different from the personnel participating in the scheme. (ISO/IEC 17043:2023 Cl 7.2.1.3 i))

7.3 Production and distribution of PT items

(No additional explanation)

7.4 Evaluation and reporting of PT scheme results

(No additional explanation)

7.5 Control of PT scheme process

(No additional explanation)

7.6 Handling of complaints

(No additional explanation)

7.7 Handling of appeals

(No additional explanation)

8 Management system requirements

8.1 General requirements

(No additional explanation)

8.2 Management system documentation

(No additional explanation)

8.3 Control of management system documents

(a) Posted information and instructions, or any abridged version of controlled documents, related to testing or other activities that may affect the quality of the PT schemes shall be considered as controlled documents. (ISO/IEC 17043:2023 Cl 8.3.1)

8.4 Control of records (Option A)

(a) Records relating to advisory groups shall be maintained. The records shall at least include the terms of reference, attendance records for meetings as well as notes of meetings. (ISO/IEC 17043:2023 Cl 8.4.1)

(b) The minimum period for retention of records set by HKAS Executive is four years unless a longer period is specified by regulatory authorities, in relevant HKAS or HOKLAS Supplementary Criteria, or in other requirements such as the customer's instructions. For records generated in each PT round, the retention period of at least four years shall be counted from the date on which the PT round was completed. For equipment and operation records, the retention period of at least four years shall be counted from the date on which the use of the equipment or the operation stopped. For personnel records, the retention period of at least four years shall be counted from the date of departure of the staff member concerned. (ISO/IEC 17043:2023 Cl 8.4.3)

8.5 Actions to address risks and opportunities

(No additional explanation)

8.6 Improvement

(No additional explanation)

8.7 Corrective actions

(No additional explanation)

8.8 Internal audits

(No additional explanation)

8.9 Management reviews

(a) The top management of a PT provider, including its coordinators, shall participate in management review. (ISO/IEC 17043:2023 Cl 8.9.1)