

HKCAS 023:2017

**Abridged Version**

**(Requirements and notes of ISO/IEC 17065 are not included in this document. This document should be read in conjunction with ISO/IEC 17065:2012.)**

# Technical Criteria for Accreditation of Product Certification Bodies

(ISO/IEC 17065:2012, Conformity  
assessment – Requirements for bodies  
certifying products, processes and services,  
MOD)

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## HKAS Introduction

The Hong Kong Accreditation Service (HKAS) was set up in 1998 by the Government of the Hong Kong Special Administrative Region to provide accreditation service to the public. It was formed through the expansion of the Hong Kong Laboratory Accreditation Scheme (HOKLAS). HKAS now offers accreditation for laboratories, proficiency testing providers, reference material producers, certification bodies, validation or verification bodies and inspection bodies. It may offer other accreditation services in the future when the need arises.

The principal aims and objectives of HKAS are:

- to upgrade the standard of operation of conformity assessment bodies;
- to offer official recognition to competent conformity assessment bodies which meet international standards;
- to promote the acceptance of endorsed reports and certificates\* issued by accredited conformity assessment bodies;
- to conclude mutual recognition arrangements with other accreditation bodies; and
- to eliminate the need for repetition of conformity assessment in the importing economies and thereby reducing costs and facilitating free trade across borders.

\* *An endorsed report or certificate means a report or certificate on which the accreditation status of HKAS or its mutual recognition arrangement partners has been claimed (e.g. by bearing the accreditation symbol or a statement on the accreditation status of the accredited conformity assessment body)*

The operating cost of HKAS is funded by the Government and is partly recovered by charging fees for services provided by HKAS.

HKAS Executive is responsible for administering HKAS and its accreditation schemes. At present, there are three schemes: the Hong Kong Laboratory Accreditation Scheme (HOKLAS) for laboratories, proficiency testing providers and reference material producers, the Hong Kong Certification Body Accreditation Scheme (HKCAS) for certification bodies, validation and verification bodies, and the Hong Kong Inspection Body Accreditation Scheme (HKIAS) for inspection bodies. All accreditation schemes of HKAS are operated in accordance with the requirements of an international standard, i.e. ISO/IEC 17011, and the criteria established by relevant international and regional cooperations of accreditation bodies. Participation in the three schemes is voluntary.

Organisations applying for accreditation or those that have been accredited under any of the three schemes are required to demonstrate that:

- they are competent to perform the specific activities for which they are applying for accreditation or have been accredited;
- they have implemented an effective management system which complies with the accreditation criteria of the relevant scheme; and
- they comply with all the regulations in HKAS 002 'Regulations for HKAS Accreditation'. These regulations are the governing rules for the administration of the three schemes and contain the obligations of any organisation which has applied for HKAS accreditation or has been accredited by HKAS.

HKAS will grant accreditation for an activity to an organisation only when it meets the conditions given in clause 4.15 of HKAS 002.

## **i Basis of HKCAS 023 ‘Technical Criteria for Accreditation of Product Certification Bodies’ – ISO/IEC 17065:2012**

This booklet serves as a domestic publication which is applicable to all certification bodies accredited by HKAS or seeking HKAS accreditation for certifying products, processes or services.

This booklet is the modified adoption of International Standard ISO/IEC 17065:2012 ‘Conformity assessment – Requirements for bodies certifying products, processes and services’. The ISO/IEC 17065:2012 which was jointly published by International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) provides requirements for accreditation of certification bodies certifying products, processes or services.

The title of this booklet varies from the ISO/IEC 17065:2012 and is entitled as ‘Technical Criteria for Accreditation of Product Certification Bodies’. In Section 1 to 8 and Annex A to B of this booklet, the requirements and notes of ISO/IEC 17065:2012 are reproduced verbatim as the main text and relevant HKCAS policies are given in shaded boxes following the main text. Annexes AA and AB are also added following the original text of the ISO/IEC 17065:2012. The notes provide clarification of the requirements. HKAS will consider that a certification body has met the requirements if it follows the notes. The HKCAS policies serve as additional explanation of the requirements of ISO/IEC 17065:2012 and shall be regarded as mandatory. The reference documents, if any, referred to in the HKCAS policies are given for information only. They are not part of the requirements unless explicitly stated as such. A complete list of modifications, together with their explanations, is given in Annex AB.

The term “shall” is used throughout this booklet to indicate those provisions which are mandatory. The term “should” is used to indicate guidance which, although not mandatory, is provided by HKAS as a recognised means of meeting the requirements.

This booklet set out the accreditation requirements that an accredited certification body shall meet. It is the responsibility of the certification body to determine the best method to meet such requirements, the relative significance of individual activities to the overall quality of the certification body and the emphasis and resource that should be allocated to each of them. The certification body’s management may be required to demonstrate to the assessment team that the method it has selected is adequate in meeting the accreditation requirements.

A list of HKAS and HKCAS Supplementary Criteria is available from HKAS Executive and the HKAS website. Such website also provides links to other websites which contain useful information on accreditation and certification body operation.

## **ii Scope of accreditation**

HKAS Executive will define from time to time the specific areas which are available for accreditation under HKCAS. Currently, HKAS has accredited product certification bodies in the areas of Chinese medicine, composite wood panels and products, construction materials and products, consumer products and food. Details are available at the website of HKAS.

All accredited certification activities of an accredited product certification body will be clearly shown in a 'scope of accreditation', which may include an identification of the accredited certification scheme and applicable products, a brief description of the certification activities and, where applicable, type of the certification scheme in accordance with ISO/IEC 17067.

### **iii Accreditation Criteria**

An applicant certification body shall demonstrate its conformity with the accreditation criteria in sections 4 to 8 of this booklet and relevant HKAS/HKCAS supplementary criteria as well as the regulations listed in HKAS 002 before HKAS Executive grants accreditation to the certification body. An accredited certification body shall comply with the same criteria at all times for maintaining accreditation. An applicant or accredited certification body may also be required to demonstrate to HKAS Executive that it can competently perform all activities proposed for accreditation or accredited activities. In addition, the applicant or accredited certification body shall maintain its integrity and impartiality under all circumstances.



## **Introduction**

**(The main text of introduction is the text of the same introduction of ISO/IEC 17065:2012.)**

# 1 Scope

**(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)**

## **2 Normative references**

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

### **3 Terms and definitions**

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

## 4 General requirements

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

### 4.1.C HKCAS Policy on Legal and Contractual Matters

It is the responsibility of the certification body to carry out certification activities in accordance with the applicable Laws and Regulations of Hong Kong and the country/economy where its certification activities are performed. It should be emphasised that assessment of the certification body's compliance with the relevant regulatory requirements is outside the scope of HKAS accreditation.

## **5 Structural requirements**

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

## 6 Resource requirements

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

### 6.1.C HKCAS Policy on Certification Body Personnel

#### HKCAS Policy on Competence Requirements for Certification Body Personnel

- (a) Unless otherwise specified in the certification scheme, a person responsible for performing evaluation activities should have at least a higher diploma in an engineering, technology or science discipline issued by a recognised tertiary educational institution in Hong Kong, or equivalent academic qualification, and at least five years of post-qualification work experience in the relevant industry. HKAS Executive may accept alternative academic qualification and/or work experience provided that the certification body is able to demonstrate that the person has the required competence to perform the evaluation activities.
- (b) Audit of a client's management system and/or production processes should be performed by an audit team which consists of a lead auditor and where necessary, auditor(s) and technical expert(s). The certification body may develop a system to train and authorize lead auditors and auditors with reference to Section 7 of ISO 19011.
- (c) In general, a lead auditor or an auditor should have sufficient audit experience to develop the required knowledge and skills. The audit experience should be gained while assuming the role of a trainee lead auditor or a trainee auditor under the direction and guidance of a competent lead auditor.
- (d) The certification body shall implement a system to continually monitor the performance of its personnel. The on-site performance of each lead auditor or auditor shall be evaluated at least once every three years. The evaluation shall cover all aspects of the activities that the lead auditor or auditor have been authorized by the certification body to perform. Corrective actions shall be taken if there is any doubt on the competence of the certification body personnel.
- (e) A technical expert who provides technical support to an audit team should work under the direction and close supervision of a competent lead auditor or auditor. Although the technical expert does not need training on auditing techniques, he/she should have the required qualification, experience and technical knowledge for the evaluation activities to be carried out. For example, the technical expert should:
  - (i) have an appropriate knowledge and understanding of the relevant industry;
  - (ii) have adequate knowledge in the design and production of the product to be evaluated;
  - (iii) be familiar with the product standard(s) and applicable regulatory requirements;
  - (iv) have sufficient understanding of the technical aspect of the product certification scheme and be able to effectively evaluate the client's conformity with the product certification scheme.

Continued...

**6.1.C HKCAS Policy on  
Certification Body Personnel**

- (f) Certification decision should be made by a person or a group of persons such as a committee. In case the decision is made by a person, he/she should hold a degree or above academic qualification in a relevant engineering, technology or science discipline issued by a recognised tertiary educational institution in Hong Kong, or equivalent qualification. On top of the academic qualification, he/she should have at least five years of experience in the relevant industry. If the decision is made by a group of persons, the group should collectively possess the required qualification and work experience.
- (g) Training and authorization of a person for carrying out inspection activities supporting the certification process should cover the following aspects:
  - (i) requirements of ISO/IEC 17020 and relevant HKAS/HKIAS supplementary criteria; and
  - (ii) principle and practice of the production processes for the specified product(s).
- (h) Training and authorization of a person for carrying out or witnessing testing activities at a testing laboratory should cover the following aspects:
  - (i) requirements of ISO/IEC 17025 and relevant HKAS/HOKLAS supplementary criteria; and
  - (ii) requirements of the applicable product standard(s).



## 7 Process requirements

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

### 7.4.C HKCAS Policy on Evaluation

- (a) In case evaluation is performed through witnessing testing activities at a test laboratory (e.g. a third-party laboratory or a laboratory controlled by the client), the certification body shall have measures to ensure that the laboratory is competent to perform the test, such as a periodic on-site evaluation of the laboratory by the certification body's qualified personnel in accordance with ISO/IEC 17025 and appropriate test methods/standards. Before witnessing the test, the certification body's responsible person should check the technical aspect of the laboratory which may affect the validity of the test results as detailed in ISO/IEC 17025. Record of witnessing, which shall include sufficient evidence to assure that the test results are valid, shall be retained by the certification body. The competence of certification body personnel authorized for witnessing testing activities will be assessed by HKAS during an on-site assessment visit. Where necessary, the HKAS assessment team will witness the witnessing of tests carried out by the certification body as part of the HKCAS assessment.
- (b) For a test conducted by a laboratory accredited to ISO/IEC 17025 by HKAS or its MRA partner, the competence of the laboratory is considered demonstrated if the test results are presented in an endorsed test report which bears the accreditation symbol of the accredited laboratory.

**7.7.C HKCAS Policy on Certification Documentation**

- (a) In accordance with IAF Resolution 2018-13, an accredited certification body shall not issue non-accredited certificates for products certified under its accredited product certification scheme. In other words, the certification body shall only issue HKCAS accredited certificates which bear the HKCAS accreditation symbol to its client for products certified under its accredited product certification scheme and in accordance with the requirements specified in HKAS 002 and relevant HKAS/HKCAS supplementary criteria.
- (b) A HKCAS accredited certificate shall only contain the results of certification for which the certification body is holding valid accreditation.
- (c) If there is an exception to the above IAF policy, the certification body shall submit the exception to HKAS Executive for approval. Once the exception is accepted by HKAS Executive, the certification body is still considered accredited for the concerned product certification scheme even though non-accredited certificates are issued.
- (d) The results of other activities which have not been accredited can only be included in a HKCAS accredited certificate if HKAS Executive has explicitly approved such inclusion in writing. The HKCAS accredited certificate which contains the said results shall clearly state that the activities are not covered by the HKCAS scope of accreditation of the certification body.
- (e) An applicant or accredited certification body shall provide the format of its proposed HKCAS accredited certificate to HKAS Executive for approval before use.

**7.9.C HKCAS Policy on Surveillance**

The certification body should have adequate knowledge of the distribution channels for the product being evaluated to ensure that its findings of market surveillance are meaningful and representative.

**7.12.C HKCAS Policy on Records**

- (a) A certification body shall keep complete records of all certification processes, including application, application review, evaluation, review, certification decision and surveillance, for at least 10 years after the date of termination or withdrawal of the certification of a certified product.
- (b) Where records are stored, retrieved, transmitted or processed electronically, the certification body shall establish and implement procedures to ensure the integrity and confidentiality of the records.
- (c) When the certification body has branch office(s), certification records should be retrievable within a reasonable time from its head office and any branch office involved in relevant certification process.

## **8 MANAGEMENT SYSTEM REQUIREMENTS**

(The main text of this clause is the text of the same clause of ISO/IEC 17065:2012.)

**Annex A**  
(informative)

**Principles for product certification bodies and their certification activities**

(The main text of this clause is the text of the same clause of  
ISO/IEC 17065:2012.)

**Annex B**  
(informative)

**Application of this International Standard for processes and services**

(The main text of this clause is the text of the same clause of  
ISO/IEC 17065:2012.)

## ANNEX AA

(informative)

### Bibliography

Given below is a list of documents for information only. Unless otherwise stated in other parts of this document, the documents are not part of the accreditation criteria.

- [1] ISO 9000, *Quality management systems — Fundamentals and vocabulary*
- [2] ISO 9001, *Quality management systems — Requirements*
- [3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organisations*
- [4] ISO/PAS 17001, *Conformity assessment — Impartiality — Principles and requirements*
- [5] ISO/PAS 17002, *Conformity assessment — Confidentiality — Principles and requirements*
- [6] ISO/PAS 17003, *Conformity assessment — Complaints and appeals — Principles and requirements*
- [7] ISO/PAS 17004, *Conformity assessment — Disclosure of information — Principles and requirements*
- [8] ISO/PAS 17005, *Conformity assessment — Use of management systems — Principles and requirements*
- [9] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*
- [10] ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*
- [11] ISO/IEC 17067, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*
- [12] ISO 19011, *Guidelines for auditing management systems*
- [13] ISO 31000, *Risk management — Guidelines*
- [14] ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*
- [15] ISO Guide 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*
- [16] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*
- [17] ISO/IEC TR 17026, *Conformity assessment — Example of a certification scheme for tangible products*

## ANNEX AB

(informative)

### Variations to ISO/IEC 17065:2012 for HKCAS 023:2017

This Annex lists out all variations of this booklet to ISO/IEC 17065:2012 as follows:

Clause	Modifications
Forward	Delete 'Forward' of ISO/IEC 17065:2012
–	Add 'HKAS Introduction'
4 Legal and contractual matters	Add 4.1.C 'HKCAS Policy on Legal and Contractual Matters'
6 Resource requirements	Add 6.1.C 'HKCAS Policy on Certification Personnel'
7 Process requirements	Add 7.4.C 'HKCAS Policy on Evaluation'
	Add 7.7.C 'HKCAS Policy on Certification Documentation'
	Add 7.9.C 'HKCAS Policy on Market Surveillance'
	Add 7.12.C 'HKCAS Policy on Records'
Bibliography	Delete 'Bibliography' of ISO/IEC 17065:2012
–	Add Annex AA 'Bibliography'
–	Add Annex AB 'Variations to ISO/IEC 17065:2012 for HKCAS 023:2017'

#### **Explanation:**

HKCAS policies added serve as additional explanation of the requirements of ISO/IEC 17065:2012 and shall be regarded as mandatory under Hong Kong Certification Body Accreditation Scheme (HKCAS).

Annex AB is an informative annex listing out all variations of this booklet to ISO/IEC 17065:2012.