HKCAS Supplementary Criteria No. 11

HKAS Policy on Product and Management System Certification Schemes

1. INTRODUCTION

1.1 This document details HKAS policy on product and management system certification schemes that HKAS Executive grants accreditation under HKCAS. HKAS Executive accepts application and grants accreditation to certification bodies only for those certification schemes that satisfy the criteria set out in this document.

1.2 When submitting an application for accreditation, a certification body shall provide details of the certification scheme and all relevant supporting documents to HKAS Executive. HKAS Executive will accept an accreditation application only if the certification scheme satisfies the criteria set out in this document.

1.3 An accredited certification body shall ensure that a certification scheme it is accredited for providing certification continues to satisfy the criteria set out in this document. The accredited certification body shall inform HKAS Executive in writing immediately of any changes or proposed changes of the certification scheme that may affect its continuing conformity with the criteria set out in this document. The accredited certification body shall discuss with the parties concerned and come up with an action plan proposing measures to resolve any nonconformity or anticipated nonconformity. Accreditation of the certification body may be suspended or terminated when the certification scheme no longer satisfies the criteria set out in this document.

1.4 This document does not apply to certification schemes that are included or invoked by legislation/regulation, and/or developed by national, regional or international standardisation bodies.

2. GENERAL CRITERIA[1]

2.1 A certification scheme should cover the following elements**:**

2.1.1 **Selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;

2.1.2 **Determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample;

2.1.3 **Review, decision and attestation**, including the review of evidence from the determination stage. Conclusion based on the results of the review as to whether fulfilment of specified requirements has been demonstrated and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls, where applicable; and

2.1.4 **Surveillance and recertification, as applicable**, systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

2.2 A certification scheme shall include the following:

2.2.1 the objectives of the scheme for the specific industry or user group;

2.2.2 identification of the type (product or management system) and the object of certification;

2.2.3 the requirements, including any interpretations thereof, against which conformity is to be assessed (such as the certification standards, product specifications, legal

[1] The term ‘should’ is used in this section to indicate recognised means of meeting the requirements. A certification body can meet these in an equivalent way. The term ’shall’ is used in this section to indicate requirements which are mandatory.

standards)[2];

2.2.4 the way in which the certification body establishes the conformity (such as audit method, inspection protocol, inspection instruction, test method, procedure description, etc.) and the process required. The process shall fall under the scope of one of the IAF MLA Level 3 standards without any contradictions or exclusions;

2.2.5 any specific applications or explanations of ISO/IEC 17011, if applicable;

2.2.6 any specific applications or explanations of accreditation standard at Level 3, e.g. ISO/IEC 17021-1, ISO/IEC 17065, if applicable;

2.2.7 the method used to monitor that the certificate holder continues to conform to the requirements (such as re-certification period, surveillance frequencies, contents, activities, scopes, procedure), if applicable;

2.2.8 the statement of conformity which appears on the certification documents;

2.2.9 the requirements, including any interpretations thereof, that apply to the certification body with regard to its organisation, mode of operation, personnel, equipment, reporting, certificates, etc.

2.3 A certification scheme shall meet the following criteria:

2.3.1 the scheme has been developed with the participation of technically competent representatives of interested parties, or has been subject to formal review by such parties;

2.3.2 the scheme is such that it is possible to assess whether a subject product or management system is in conformity;

2.3.3 the scheme has credibility with industry, appropriate regulatory authorities or relevant professional groups;

2.3.4 the scheme is periodically reviewed with the involvement of representatives of interested parties as far as practicable and updated where necessary;

2.3.5 is publicly available for application without restriction by number of membership or other limitations;

[2] Where applicable, the requirements in the scheme should be written in terms of results or outcomes, together with limiting values and tolerances. The requirements in the scheme should be stated unambiguously using wording that is objective, logical, valid and specific and enable consistent application by organisation as well as evaluation across certification bodies.

2.3.6 where the scheme includes legal requirements, these shall be formulated in such a way that compliance is a condition for outcome of certification;

2.3.7 where scheme owner authorisation is given before accreditation, which implies that the certification body can perform certification activities covered by the scheme and may have the right to use the certification mark, the scheme shall require the certification body to be accredited in a defined period of time;

2.3.8 where the scheme provides for the use of certificates, marks or other statements of conformity, there should be a licence and/or rules or another form of enforceable agreement to control such use. Licences can include provisions relating to the ownership and use of the certificate, mark or the use of other statement of conformity in communications about the object of certification, and requirements to be fulfilled when the certification is no longer valid;

2.3.9 if any scheme specific requirements are placed on accreditation bodies, they shall not contradict or exclude any of the requirements of ISO/IEC 17011, relevant IAF guidelines, policies and other requirements[3].

2.3.10 certification schemes which imply or claim that products for certification have functions or properties that may be misleading will not be accepted. Claims or implications of functions or properties of products for certification shall have scientific proof which is accepted by relevant and widely recognised scientific or technological institutions.

2.4 An applicant / accredited certification body shall ensure the following requirements for the Scheme Owner (SO) are fulfilled:

2.4.1 The SO shall have a legally enforceable agreement with the certification bodies it authorises which, as a minimum, shall ensure that the certification bodies use the scheme as published by the SO, without any additions or reductions, and comply with SO rules for applying symbol/statement/mark, as appropriate.

2.4.2 The SO shall make a general description of the scheme publicly available without request. The scheme documents, including the criteria and process to be used in assessing conformity, shall be publicly available.

[3] The operation of HKAS is in conformity with ISO/IEC 17011 and relevant IAF and APAC requirements. HKAS reserves the right not to accept any additional requirements introduced by the scheme.

2.4.3 The SO should demonstrate that the scheme has been validated[4]. The validation should be documented and include the following aspects:

2.4.3.1 A description of the purpose of the scheme;

2.4.3.2 A description of the requirements of the scheme;

2.4.3.3 An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the scheme;

2.4.3.4 A description of the methods to be used for determining fulfilment of the requirements;

2.4.3.5 An analysis showing that the described methods to be used for determining fulfilment of the requirements are appropriate;

2.4.3.6 The decision on the conformity assessment activities to be used (including identification of the applicable conformity assessment standards); and

2.4.3.7 An analysis showing that the selected conformity assessment activities are appropriate.

2.4.4 In case the SO provides any clarification on the scheme to any interested party, this information shall also be available to the certification bodies and accreditation bodies.

2.4.5 The SO shall have a procedure for dealing with complaints relating to the scheme, ensuring that complaints processes of the certification bodies' clients, the certification bodies and accreditation bodies are not affected. Investigation and decision on complaints shall not result in any discriminatory actions[5].

2.4.6 An arrangement describing the relationship and the terms of cooperation between the SO and the certification bodies should be established. Any requirements for certification bodies or accreditation bodies shall be part of the scheme and not individual arrangements.

2.4.7 If the SO monitors the certification bodies, it should consider cooperation with the accreditation bodies and have a feedback mechanism to provide information on the performance of the certification bodies to the accreditation bodies concerned.

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[4] The validation can be in terms of pilot audits or by demonstrating that the scheme is based on available international or national standards.

[5] A description of the complaints handling process can be publicly available with or without request. Guidance on the complaints handling process is available in ISO 10002.

2.4.8 The SO should have a process for a periodic review of the scheme taking into account the experience gained and the feedback received from parties interested in the scheme.

2.4.9 The SO should monitor the development and review of the standards and other normative documents, whether its own or external, which define the specified requirements used in the scheme. Where changes in the normative documents of the scheme occur the SO should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the certification bodies' clients and, where necessary, other parties interested in the scheme[6].

2.4.10 Changes to the scheme that affect the output of the scheme, should be validated (see 2.4.3).

3. PRODUCT CERTIFICATION

3.1 In accordance with ISO/IEC 17065:2012 'Conformity assessment – Requirements for bodies certifying products, processes and services', a certification scheme is defined as a certification system related to specified products, to which the same specified requirements, specific rules and procedures apply. Based on this definition, the guidance standard ISO/IEC 17067:2013 and the accreditation standard ISO/IEC 17065:2012, the criteria set out in Clauses 3.2 to 3.9 are applicable to a product certification scheme. A scheme owner may refer to ISO/IEC TR 17026:2015, which provides an example of a certification scheme for tangible products, when developing a product certification scheme.

3.2 The certificate issued shall unambiguously identify the product, process or service for certification. The certificate issued based on the evaluation of the product, process or service shall be in line with the evaluation conducted.

[6] It is expected that the SO notifies the accreditation bodies before implementing the changes.

3.3 The requirements against which the products, services or processes are evaluated, are unambiguously specified. This is possible by referring to other documents, such as regulations, standards or technical specifications. The manner in which the requirements are described aims to enable objective determination of conformity. The limits and tolerances shall also be indicated. When defining the requirements that the object is evaluated against, Clauses 7.1.2 and 7.1.3 of ISO/IEC 17065:2012 shall be taken into consideration.

3.4 If requirements are also set to the management system within the scheme, these shall be considered as supporting. The fact that such requirements are included in the scheme shall not lead to a certificate regarding this management system.

3.5 The activities of the certification body apply in order to determine conformity may consist of design appraisal, testing, inspection and auditing or a combination of any of these. The methods used shall be demonstrably suitable for the relevant objective. The methods shall also describe if and how random spot-checks (and taking samples) are carried out. The scheme shall ensure that these activities are conducted in a harmonised manner.

3.6 A scheme shall describe in which manner the evaluation results are to be interpreted and the consequences associated with the results. This also means that any nonconformities that would preclude certification, or would be a cause of suspending or revoking the certificate, shall be described.

3.7 An applicant or accredited certification body shall conform to all requirements of ISO/IEC 17065:2012. A certification scheme may contain additional requirements to a certification body provided that these requirements do not deviate from the requirements of ISO/IEC 17065:2012.

4. MANAGEMENT SYSTEM CERTIFICATION

4.1 A certification scheme for certification of management system consists of the rules and procedures for certification of a specific management system based on specific requirements. A certification scheme for which an applicant or accredited certification body used for accreditation shall satisfy the criteria set out in Clauses 4.2 to 4.6.

4.2 The requirements against which the management system are assessed, are unambiguously specified. These requirements may be defined in an international or national standard or another document. In the latter case, the applicant or accredited certification body shall assess if the elements as described below are present:

- Policy
- Planning
- Implementation and Execution
- Assessment of Performance
- Improvement
- Management Review

4.3 An applicant or accredited certification body shall conform to all the requirements of ISO/IEC 17021-1:2015. A certification scheme may contain additional requirements to a certification body provided that these requirements do not deviate from the requirements of ISO/IEC 17021-1:2015. With respect to the certification audit magnitude, HKAS uses the principles as set out in relevant IAF Guidance or Mandatory documents. Certification schemes where the auditing effort is less extensive than indicated in these IAF documents will normally not be accepted for accreditation.

4.4 A certification scheme shall describe the system of monitoring on certificates issued. Monitoring shall consist of surveillance and recertification audits as stipulated in Clauses 9.6.2 and 9.6.3 of ISO/IEC 17021-1:2015.

4.5 A certification scheme shall describe in which manner the audit results are to be interpreted and the consequences associated with the results. This also means which nonconformities would preclude certification, or would be a cause for suspending or withdrawing the certificate, shall be described.

4.6 The certificate issued based on the certification audit shall be in line with the audit conducted. The certificate shall unambiguously describe the type of management system that was certified.

ANNEX

NORMATIVE DOCUMENTS

Unless otherwise specified, the latest editions of the following documents apply:

1. IAF Mandatory Document IAF MD 25:2022, Criteria for Evaluation of Conformity Assessment Schemes
2. ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services
3. ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

INFORMATIVE DOCUMENTS

Unless otherwise specified, the latest editions of the following documents apply:

1. ISO/IEC 17000, Conformity assessment – Vocabulary and general principles
2. ISO/IEC 17007, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment.
3. ISO/IEC 17011, Conformity Assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
4. ISO/IEC 17030, Conformity assessment – General requirements for third-party marks of conformity
5. ISO/IEC 17067:2013, Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes
6. ISO 10002, Quality Management – Customer Satisfaction – Guidelines for Complaints Handling in Organizations
7. ISO 19011, Guidelines for auditing management systems
8. ISO/IEC TR 17026:2015, Conformity assessment – Example of a certification scheme for tangible products
9. ISO/IEC Guide 23, Methods of indicating conformity with standards for third-party certification systems
10. ISO Guide 27, Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
11. ISO Guide 60, Conformity assessment – Code of good practice