HKIAS 003:2017

Abridged Version

(Requirements and notes of ISO/IEC 17020 are not included in this document. This document should be read in conjunction with ISO/IEC 17020:2012)

Technical Criteria for Accreditation of Inspection Bodies

(ISO/IEC 17020:2012, Conformity assessment – Requirements for the operation of various types of bodies performing inspection, MOD)

Hong Kong Accreditation Service
February 2017

Published by Innovation and Technology Commission
The Government of
the Hong Kong Special Administrative Region

36/F., Immigration Tower,
7 Gloucester Road,
Wan Chai, Hong Kong

ISBN 978-988-14500-5-0

TABLE OF CONTENTS

Page

Contents

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, certification bodies, inspection bodies, proficiency testing providers, reference material producers and greenhouse gas (GHG) validation or verification 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.

* *Endorsed report or certificate means a report or certificate that 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 a report or certificate)*

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 and GHG validation or 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 the international standard ISO/IEC 17011 and the criteria established by relevant international and regional cooperations of accreditation bodies. Participation in the three schemes is voluntary. HKAS may provide accreditation programmes for specific activities under each of these schemes.

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.

CONFIDENTIALITY

HKAS Executive will keep confidential all information provided by an organisation in relation to preliminary enquiries or to an application for accreditation and all information obtained in connection with an assessment of an organisation, such that only personnel who require the information for the assessment will have access to such information. Such personnel will include HKAS Executive and staff, assessors involved in the assessment and members of AAB (except where a conflict of interest arises). Without written consent of the organisation, HKAS Executive will not disclose confidential information of an applicant or accredited organisation outside HKAS Executive except as allowed in HKAS 002. However, an organisation shall note that it may be necessary to pass the HKAS' files, including any information in relation to it to persons responsible for evaluating the performance of HKAS under a mutual recognition arrangement which HKAS has concluded or intended to conclude with other accreditation bodies. HKAS will notify those persons the confidential nature of the information. Where the law requires any information to be disclosed to a third party, HKAS will, where possible and permitted by the law, inform the organisation concerned. Furthermore, HKAS will comply with the provisions under the Personal Data (Privacy) Ordinance (Cap. 486) and the rules under the Code on Access to Information of the Government.

i Basis of HKIAS 003 'Technical Criteria for Accreditation of Inspection Bodies' – ISO/IEC 17020:2012

This technical criteria booklet is applicable to inspection bodies of type A, B and C as defined in ISO/IEC 17020:2012.

This booklet is a modified adoption of the International Standard, ISO/IEC 17020:2012 – 'Conformity assessment – Requirements for the operation of various types of bodies performing inspection'. ISO/IEC 17020:2012 was jointly published by International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

The title of this booklet varies from the ISO/IEC 17020:2012 and is entitled as 'Technical Criteria for Inspection Bodies'. In Section 1 to 8, Annex A and B of this booklet, the requirements and notes of ISO/IEC 17020:2012 are reproduced verbatim as the main text and relevant HKIAS policies are given in shaded boxes following the main text. Annex AA to AB are also added following the original text of the ISO/IEC 17020:2012. HKIAS policies serve as additional explanation of the requirements of ISO/IEC 17020:2012 and are mandatory. The reference documents referred to in the HKIAS policy are given for information only. They are not part of the requirements unless explicitly stated as such.

The use of an international standard for recognising competence has led to increased confidence in inspection bodies and facilitated the acceptance of inspection results by authorities around the world. In this respect, HKAS has established a number of mutual recognition arrangements (MRAs) with other accreditation bodies. Signatories to the MRA recognise the equivalence of one another's accreditation and accept endorsed inspection reports issued by such inspection bodies. A list of HKAS MRA partners and their contact information is available from the HKAS website at www.hkas.gov.hk.

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 sets out the general, structural, resource, process and management system requirements which all HKIAS accredited inspection bodies shall meet. In addition, more detailed requirements specific to certain aspects are issued as individual HKAS and HKIAS Supplementary Criteria.

This and other criteria documents set out the requirements to be met by an inspection body but do not dictate how such requirements should be met. It is the responsibility of the inspection body's management to determine the best method to meet such requirements, the relative significance of individual activities to the overall quality of the inspection body and the emphasis and resource that should be allocated to each of them. The inspection body's management may be required to demonstrate to the assessment team that the method it has selected is adequate in meeting the requirements stated in criteria documents.

A list of HKAS and HKIAS Supplementary Criteria is available from HKAS Executive and the HKAS website. The HKAS website also provides links to other websites which provide useful information on accreditation and inspection body operation.

ii Scope of accreditation – What activities may be accredited under HKIAS

Each inspection body accredited under HKIAS will have the specific inspection activities for which it is accredited clearly given in its 'scope of accreditation'.

HKAS Executive will define from time to time the specific areas which are available for accreditation under HKIAS. These areas are called 'inspection fields' and the fields currently available for accreditation include:

- Construction products
- Consumer products
- Indoor air quality inspection

Other inspection fields may be added when significant needs are identified.

An inspection body may apply to be accredited for one or more inspection activities in a specific inspection field and may seek to have its scope of accreditation expanded or reduced as its needs change. Any expansion of an accreditation will normally require a full assessment of the inspection body's competence to perform the additional inspection activities.

All accredited inspection bodies are reassessed at regular intervals to ensure continuing conformity with HKIAS requirements at all times for all accredited activities. In addition, their performance is monitored closely through surveillance visits and other appropriate means.

iii Accreditation criteria

Applicant inspection bodies have to demonstrate conformity with the accreditation criteria in this booklet and relevant HKAS/HKIAS supplementary criteria as well as the regulations listed in HKAS 002 before accreditation can be granted. Accredited inspection bodies shall comply with the same criteria at all times for maintaining accreditation. Accredited and applicant inspection bodies may also be required to demonstrate to HKAS Executive that they can perform competently all the activities proposed for accreditation. Additionally, they shall maintain complete integrity and impartiality in all circumstances. In addition, inspection bodies should operate, when relevant, in accordance with ISO/IEC 17025 when performing laboratory tests in support of inspection.

Annex AA is a list of selected documents published by ISO and international and regional accreditation cooperations. Unless otherwise stated in other parts of this booklet, they are provided for information only and are not part of the accreditation criteria.

Inspection (ISO/IEC 17020) and product certification (ISO/IEC 17065) can be similar. It must be appreciated that one body may carry out and seek accreditation for more than one function of conformity assessment. This booklet is laying down requirements for inspection only. It should be quite evident that a body carrying out product certification in accordance with ISO/IEC 17065 should be assessed against that standard. It is for the applicant body itself to request accreditation to a specific standard.

Introduction

This International Standard has been drawn up with the objective of promoting confidence in bodies performing inspections.

Inspection bodies carry out assessments on behalf of private clients, their parent organizations, or authorities, with the objective of providing information about the conformity of inspected items with regulations, standards, specifications, inspection schemes or contracts. Inspection parameters include matters of quantity, quality, safety, fitness for purpose, and continued safety compliance of installations or systems in operation. The general requirements with which these bodies are required to comply in order that their services are accepted by clients and by supervisory authorities are harmonized in this International Standard.

This International Standard covers the activities of inspection bodies whose work can include the examination of materials, products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements and the subsequent reporting of results of these activities to clients and, when required, to authorities. Inspection can concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements.

This International Standard can be used as a requirements document for accreditation or peer assessment or other assessments.

This set of requirements can be interpreted when applied to particular sectors.

Inspection activities can overlap with testing and certification activities where these activities have common characteristics. However, an important difference is that many types of inspection involve professional judgement to determine acceptability against general requirements, for which reason the inspection body needs the necessary competence to perform the task.

Inspection can be an activity embedded in a larger process. For example, inspection can be used as a surveillance activity in a product certification scheme. Inspection can be an activity that precedes maintenance or simply provides information about the inspection item with no determination of conformity with requirements. In such cases, further interpretation might be needed.

The categorization of inspection bodies as type A, B or C is essentially a measure of their independence. Demonstrable independence of an inspection body can strengthen the confidence of the inspection body's clients with respect to the body's ability to carry out inspection work with impartiality.

In this International Standard, the following verbal forms are used:

- 'shall' indicates a requirement;
- 'should' indicates a recommendation;
- 'may' indicates a permission;
- 'can' indicates a possibility or a capability.

1 Scope

This International Standard contains requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.

It applies to inspection bodies of type A, B or C, as defined in this International Standard, and it applies to any stage of inspection.

NOTE The stages of inspection include design stage, type examination, initial inspection, in-service inspection or surveillance.

2 Normative references

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3 Terms and definitions

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.1 Inspection

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.2 Product

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.3 Process

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.4 Service

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.5 Inspection body

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.6 Inspection system

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.7 Inspection scheme

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.8 Impartiality

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.9 Appeal

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

3.10 Complaint

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

4 General requirements

4.1 Impartiality and independence

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

4.2 Confidentiality

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

5 Structural requirements

5.1 Administrative requirements

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

5.2 Organization and management

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

5.2.I HKIAS Policy on Organization and Management

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

6 Resource requirements

6.1 Personnel

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

6.1.I HKIAS Policy on Personnel

HKIAS Policy on Competence Requirements for Personnel

The appraisal of personnel is a major part of each inspection body assessment as the performance of an inspection body depends largely on the skills of its personnel. The following categories of personnel will be assessed:

(a) inspectors,
(b) supervisory personnel, and
(c) management personnel.

The requirements for inspectors are covered in subclause 6.1.2 and 6.1.3. The requirements for supervisory personnel and management personnel are given below.

The need for supervisory and management personnel and requirements for their qualifications and experience will be carefully examined during the assessment of an inspection body. Factors which will be considered include:

(a) the size of the inspection body, the volume of the inspection work to be carried out, and the range of inspection activities included in the proposed scope of accreditation;

(b) the technical complexity of the inspection and the professional judgement involved;

(c) the frequency at which specific inspections are conducted by the inspection body, particularly those inspections that are judged to be highly experience dependent;

(d) the contact that the management personnel maintain with the development of methodology and adoption of new methodology within the inspection body. The more remote the management personnel are from the technical inspection operation, the more important would be the supervisory personnel in providing the necessary technical supervision.

Supervisory personnel shall have suitable qualifications or training and have sufficient authority, skills and experience to train and supervise their subordinates properly. They shall demonstrate appropriate understanding of the field of inspection in which they exercise supervision. They should also have the necessary knowledge and experience to evaluate the professional judgement made by their subordinates. In assessing qualifications, the balance between relevant academic qualifications and practical inspection experience will be examined in the light of the range of inspections performed by the inspection body, its complexity and the precision required.

Management personnel need not fully understand every field of inspection they manage but shall have adequate inspection experience. They shall have suitable qualifications or training, and have sufficient experience and ability to direct the operations of the inspection body, and to accept responsibility for the implementation of the quality system. For an inspection body seeking accreditation for a wide range of complex inspections, management personnel would be expected to hold professional qualifications such as membership of an appropriate professional body. For an inspection body engaged in a limited range of relatively simple inspections, management personnel who do not have any professional qualifications shall be able to demonstrate their competence by having relevant experience.

Continued…

HKIAS endorsed inspection reports and certificates shall be signed by HKIAS approved signatories and the requirements for these signatories are detailed in 7.4.l.

HKIAS Policy on Approved Inspectors

HKIAS may implement a system of approved inspectors for certain Inspection Fields. Approved inspectors are appraised to be competent by HKAS for carrying out specific inspections or specific types of inspections and the inspection results obtained by them may be reported in HKIAS endorsed inspection reports and certificates. Inspectors to be approved shall satisfy the requirements of subclause 6.1.2 and 6.1.3 and be nominated by the applicant or accredited inspection body. In particular, approved inspectors shall be proficient in performing the inspection and using the corresponding inspection equipment, understand the factors affecting the inspection results and possess the required knowledge to make professional judgements based on the examination results. They shall also be familiar with the Code of Conduct of the inspection body and maintain a high level of integrity and professionalism when performing inspections. The approval will be forthwith withdrawn upon any confirmed impropriety, unlawful act or corrupt practice of an approved inspector.

As approval is granted tor an inspector in the context that he/she is working for the inspection body under its management system, ‘approved inspector’ is not a personal qualification.

Details of the approved inspector system and specific requirements applicable to each type of inspection, including the qualification and experience requirements for approved inspectors and the approval procedures, are specified in a HKIAS Supplementary Criteria for a specific inspection field.

Colour vision defects and other sensory defects may prevent some people from performing some inspections satisfactorily (such as inspections involving colours). It is the responsibility of the inspection body’s management to ensure in such cases that colour vision problems or other sensory defects will not affect validity of inspection results.

6.2 Facilities and equipment

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

6.2.I HKIAS Policy on Facilities and Equipment

HKIAS Policy on Use and Maintenance of Equipment

(a) There should be documented instructions to control the use and operation of equipment to ensure that they are used by authorised operators only.

(b) A staff member of the inspection bodies shall be assigned the responsibility to ensure that the maintenance and necessary calibrations are conducted according to schedule.

(c) Inspection equipment should be maintained according to an established programme. Maintenance requirements depend on the type, material, construction and frequency of use. Items of equipment consisting of moving parts may require more frequent maintenance.

HKIAS Policy on Measurement Traceability

(a) HKAS Executive accepts calibration performed by one of the options specified in clause 2.1 of HOKLAS Supplementary Criteria No. 2 as evidence of traceability to SI units. Specific recommendations for calibration and recalibration of selected items of equipment required by inspection bodies operating in specific technical discipline are also given in HOKLAS Supplementary Criteria No. 2 or a HKIAS Supplementary Criteria for a specific inspection field. Such recommendations will be reviewed regularly. Inspection bodies should note that any recommendations on calibration, including recalibration intervals, are given for reference only. For any individual instrument, it is the responsibility of the inspection body to determine the appropriate calibration regime based on its application, construction and drift history. Inspection bodies should not adopt the recommendations indiscriminately in lieu of detailed investigation. More detailed guidance on determining calibration requirements is given in the same supplementary criteria.

(b) Calibration of some items of equipment may be performed by accredited inspection bodies themselves, provided that the inspection bodies have the necessary reference standards and materials and technical personnel having the competence to perform the calibration. In addition, the uncertainly of calibration achieved shall meet the requirements of the applications.

(c) Where the inspection bodies conduct in-house calibrations, the competence of the calibration staff, reference standards, calibration procedures including uncertainty estimation and adequacy of calibration records will be assessed during HKIAS assessments.

(d) Many items of equipment, and particularly for chemical analyses, are calibrated by comparative techniques using reference materials. The employment of reference materials to ensure demonstrated traceability to the SI units or the appropriate measurement standards is essential to the accuracy of results.

The metrological quality of such calibrations depends on:
- the uncertainty of the reference materials used;
- the appropriateness of the reference materials with respect to the practical conditions of use, taking into account the analytical method to be employed and the characteristics of the test samples.

Continued ….

(e) Inspection bodies should follow the guidelines specified in ISO Guide 33 on the use of reference materials for equipment calibration and assessment of a measurement process.

(f) Inspection bodies should note the following definitions:

Reference material (RM): Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a **measurement** or in examination of **nominal properties**.

NOTE 1 Examination of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a **measurement uncertainty**.

NOTE 2 Reference materials with or without assigned quantity values can be used for measurement precision control whereas only reference materials with assigned quantity values can be used for calibration or measurement trueness control.

NOTE 3 'Reference materials' comprise materials embodying quantities as well as nominal properties.

NOTE 4 A reference material is sometimes incorporated into a specially fabricated device.

NOTE 5 Some reference materials have assigned quantity values that are metrologically traceable to a measurement unit outside a system of units. Such materials include vaccines to which International Units (IU) have been assigned by the World Health Organisation.

NOTE 6 In a given measurement, a given reference material can only be used for either calibration or quality assurance.

NOTE 7 The specifications of a reference material should include its material traceability, indicating its origin and processing.

Certified reference material (CRM): Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

NOTE 1 'Documentation' is given in the form of a certificate.

NOTE 2 Procedures for the production and certification of reference materials are given, e.g. in ISO Guide 34 and ISO Guide 35.

NOTE 3 In this definition, 'uncertainty' covers both 'measurement uncertainty' and 'uncertainty associated with the value of a nominal property', such as for identity and sequence. 'Traceability' covers both 'metrological traceability' of a quantity value and 'traceability of a nominal property value'.

NOTE 4 Specified quantity values of certified reference materials require metrological traceability with associated measurement uncertainty.

(g) HOKLAS policy on the use and acceptability of CRMs and RMs for the calibration of equipment is detailed in HOKLAS Supplementary Criteria No. 1. An inspection body undertaking calibrations of equipment using CRMs or RMs shall demonstrate conformity with such policy to HKAS Executive.

6.3 Subcontracting

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

6.3.I HKIAS Policy on Subcontracting

(a) Assigning inspection work to operation offices within the organisation structure of the main office and operating under the same management system is not considered as subcontracting. However, operation of these operation offices may be assessed if they are to be included in the scope of accreditation. The inspection body will also be required to demonstrate that it can exercise effective supervision over the inspections performed by these operation offices.

(b) When an inspection body subcontracts inspection activities, it shall select a subcontractor inspection body which meets the same independence criteria as itself. (see subclause 4.1.6)

(c) One example of competence needed for the demonstration of the capability of a subcontractor is the technical competence needed to assess whether a particular testing facility of the subcontractor fulfils the requirements of ISO/IEC 17025.

(d) The HKAS regulations governing the reporting of results obtained by subcontractors are stipulated in clause 5.9 of HKIAS Supplementary Criteria No. 5.

7 Process requirements

7.1 Inspection methods and procedures

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

7.1.I HKIAS Policy on Inspection Methods and Procedures

HKIAS Policy on Non-standard Inspection Method or Procedure

(a) A non-standard method or procedure will be considered appropriate only if it has been shown to be effective and that its validation procedure is fully documented.

(b) An accredited inspection body may update and modify generic methods and procedures included in its scope of accreditation or implement new ones, to allow for technological progress or to satisfy the changing needs of customers. The amended methods will be considered as within the scope of accreditation provided that the process for making such changes are in accordance with documented procedures and the changes do not involve new inspection technology outside the scope of accreditation of the inspection body and are made after proper notification has been given to HKAS Executive.

HKIAS Policy on Contract and Work Order

In many inspection areas (e.g. in-service inspection based on national regulations) individual contracts are not signed with the clients. In these cases the work order is contained in some underlying documentation, e.g. regulations issued by regulatory authorities.

HKIAS Policy on Safety

'Safe manners' refers to the safety of personnel and the protection of surrounding environment.

7.2 Handling inspection items and samples

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

7.2.I HKIAS Policy on Handling Inspection Items and Samples

The system employed for storage and disposal of inspection items and information obtained during the inspection process shall comply with the confidentiality requirements stated in clause 4.2. The inspection body shall ensure that the same requirements are observed by its subcontractors and other individuals and organisations working for it.

7.3 Inspection records

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

7.3.I HKIAS Policy on Inspection Records

The specific features of inspection records and their verification which are required of accredited inspection bodies are:

(a) Each inspection body shall maintain a record system designed to suit its particular requirements. It needs not be an elaborate system but it shall include all raw inspection data and provide a traceable link between the item inspected and the report which is eventually issued based on the inspection result obtain from that item. This applies equally to computer and manual record systems.

(b) The system shall allow for ready retrieval of original inspection data pertinent to any issued inspection report or certificate, particularly:

- (i) details of the clients and the work order, including records of contract negotiation and telephone conversation;
- (ii) full description of each product design, product, service, process or plant inspected;
- (iii) the unique identifications of the inspected items;
- (iv) identification of inspection method and the sampling method;
- (v) identification of inspection equipment and where relevant, the specification of the equipment;
- (vi) original inspection and/or test observations, checklists and calculations;
- (vii) identification of the person performing the inspection and sampling;
- (viii) identification of where and when the inspection and sampling was performed;
- (ix) environmental conditions during the inspection and sampling, where relevant;
- (x) the results of any laboratory tests on the samples;
- (xi) the supporting rationale for any professional judgement;
- (xii) identification of the person checking the calculations and data transfer;
- (xiii) a copy of the issued inspection report or certificate. (This copy shall be a complete and exact copy of the report issued by the inspection body.)

(c) Errors in calculations and incorrect transfer of data from workbooks to inspection reports are major causes of incorrect inspection 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 place for the signature of the checking officer.

(d) Where inspection results are derived by electronic data processing techniques, the requirements stated in subclause 6.2.13 shall be complied with.

(e) Original inspection observations should be entered at the time of inspection or sampling into bound notebooks, or onto properly designed proforma worksheets. Where a data processing system is used, records of raw inspection data shall be retained unless such data are directly fed into the data processing system by electronic means.

Continued…

(f) Sheets of plain paper should 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 required by an inspection.

(g) Mistakes in recorded data should never be erased or deleted; they should be altered by crossing out the error and entering the correct information alongside. Any alterations to the inspection records should be clearly initialled or signed by the person making the correction.

For inspections which are impracticable to repeat for evaluating the correctness of inspection results, it is particularly important that the record system is capable of retaining sufficient objective evidence on how the inspection was performed. Photographs or video clips may be necessary to record how the inspection was performed and how the samples were obtained.

7.4 Inspection reports and inspection certificates

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

7.4.I HKIAS Policy on Inspection Reports and Inspection Certificates

HKIAS Policy on HKIAS Endorsed Inspection Reports and Certificates

(a) An inspection body may issue inspection reports and certificates in an electronic format in accordance with the requirements of this document, including those relating to the quality of reported results and protection of the confidentiality of the client information.

(b) Any amendment to reports or certificates shall be issued in the form of a document bearing an unique identification and include a statement having the meaning of 'This report/certificate supersedes report/certificate number xxx issued on date yy' or 'This document supplements report number xxx issued on date yy.'

(c) An inspection body shall conform with the following requirements when preparing HKIAS endorsed inspection reports and certificates:

(i) HKIAS endorsed inspection reports and certificates are governed by the regulations specified in HKIAS Supplementary Criteria No. 5.

(ii) It is the responsibility of a HKIAS approved signatory to ensure that all relevant information, including calculations and data relevant to an inspection report or certificate have been checked to be accurate before he/she signs that report or certificate.

HKIAS Policy on Approved Signatories for HKIAS Endorsed Inspection Reports and Certificates

(a) HKIAS endorsed inspection reports and certificates shall be signed by an approved signatory. An approved signatory is a supervisory or management officer nominated by the inspection body and subsequently assessed and approved by HKAS Executive to sign such reports or certificates.

(b) A person nominated for approved signatory status shall be competent to make critical evaluation of the inspection results and professional judgements. He/she shall spend sufficient time in the inspection body to enable him/her making this evaluation and shall occupy a position in the organisation's staff structure which makes him/her responsible for the adequacy of the inspection results. In addition, he/she shall be fully aware of the requirements detailed in this document, in HKAS 002 and HKIAS Supplementary Criteria No. 5. Approval may be granted for specific inspections or all inspections for which the inspection body is accredited.

(c) As approval is granted to a signatory in the context that he/she is working for the inspection body under its management system, 'approved signatory' is not a personal qualification.

(d) Signatory approval may be granted to management personnel, provided that they have maintained sufficient contact with inspection techniques to retain a faculty for critical evaluation of the inspection results and professional judgements.

Continued…

(e) The following attributes will be taken into account when the suitability of a staff member nominated for approval as a signatory is assessed:

(i) qualifications and experience;

(ii) position in the staff structure;

(iii) knowledge required of an inspector as detailed in subclause 6.1.2 and 6.1.3;

(iv) knowledge of the inspection procedures and the equipment used;

(v) knowledge of the procedure for recording, reporting and checking inspection results;

(vi) familiarity with the quality system of the inspection body;

(vii) awareness of the regulations and criteria of HKIAS, and particularly those referring to inspection reports and certificates;

(viii) awareness of the need to maintain complete integrity and impartiality in all operations and the Code of Conduct of the inspection body.

7.5 Complaints and appeals

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

7.5.I HKIAS Policy on Complaints and Appeals

When a complaint or an appeal involving HKIAS accredited inspection is not satisfactorily resolved within 60 days from the date of receipt, inspection bodies shall notify HKAS Executive in writing of the complaint or appeal.

7.6 Complaints and appeals process

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8 Management system requirements

8.1 Options

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.1.I HKIAS Policy on Management System

The management system of an inspection body needs not be complex but shall be suitable for the operation of the inspection body, taking into consideration all relevant factors, such as its size, number of staff members, its organisation structure, the range, volume and complexity of the inspections it performs, and whether it has any operation offices.

All documents of the inspection body's management system should be developed as working documents for use by managers and staff – not as checklists for presentation to inspection body assessors. It should be written in a language and a form which is readily understandable by its target users. For large and complex inspection bodies, the documentation system may be arranged in a hierarchical format. The top-level document states the objectives and policies and the lower level documents provide details of implementing those objectives and policies in specific areas. All documents shall be available for examination as a part of the accreditation process.

If the inspection activity is already addressed in a quality manual covering an organisation's total range of operations, it may be necessary to extract the relevant information and expand on it to establish a set of separate documents specifically relating to the inspection functions.

8.2 Management system documentation (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.3 Control of documents (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.4 Control of records (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.4.I HKIAS Policy on Control of Records

(a) All records and inspection reports shall be protected from loss, damage or misuse and retained in confidence to the client for an appropriate period.

(b) The period for retention of original inspection data, other inspection body records and test reports and documents has been set by HKAS Executive to be a minimum of three years unless otherwise required by law.

(c) Where an inspection body has operation offices at different locations, the inspection records should be retrievable from both the operation office responsible for the inspections and at the main office. The inspection records may be kept at the main office, the operation office or any suitable location.

8.5 Management review (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.6 Internal audits (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.7 Corrective actions (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

8.8 Preventive actions (Option A)

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

Annex A
(normative)

Independence requirements for inspection bodies

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

Annex B
(informative)

Optional elements of inspection reports and certificates

(The main text of this clause is the text of the same clause of ISO/IEC 17020:2012)

Annex AA
(informative)

Bibliography

Given below is a list of selected documents published by ISO, and international and regional laboratory accreditation cooperations, which are useful for inspection body operation. Some of the documents are available from their websites. Unless otherwise stated in other parts of this document, the documents are provided for information only and are not part of the accreditation criteria.

A. ISO
(www.iso.org)

ISO 9000	Quality Management Systems – Fundamentals and Vocabulary
ISO 9001	Quality Management Systems – Requirements
ISO/IEC 17025	General Requirements for the Competence of Testing and Calibration Laboratories
ISO 19011	Guidelines for Auditing Management Systems
ISO/IEC Guide 99	International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)

B. International Laboratory Accreditation Cooperation (ILAC)
(www.ilac.org)

ILAC Guidance (G-series)

ILAC G21:09/2012	Cross Frontier Accreditation – Principles for Cooperation

ILAC Policy (P-series)

ILAC P5:02/2016	ILAC Mutual Recognition Arrangement: Scope and Obligations
ILAC P8:12/2012	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
ILAC P9:06/2014	ILAC Policy for Participation in Proficiency Testing Activities
ILAC P10:01/2013	ILAC Policy on Traceability of Measurement Results
ILAC P15:07/2016	Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

C. Asia-Pacific Laboratory Accreditation Cooperation (APLAC)
(www.aplac.org)

APLAC TC002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC003	Management Review for Laboratories and Inspection Bodies

Annex AB
(informative)

Variations to ISO/IEC 17020:2012 for HKIAS 003:2017

This Annex lists out all variations of this booklet to ISO/IEC 17020:2012 as follows:

Section	Modification
Forward	Delete 'Forward' of ISO/IEC 17020:2012
–	Add 'HKAS Introduction'
5 Structural requirements	Add 5.2.I 'HKIAS Policy on Organization and Management'
6 Resource requirements	Add 6.1.I 'HKIAS Policy on Personnel'
	Add 6.2.I 'HKIAS Policy on Facilities and Equipment'
	Add 6.3.I 'HKIAS Policy on Subcontracting'
7 Process requirements	Add 7.1.I 'HKIAS Policy on Inspection Methods and Procedures'
	Add 7.2.I 'HKIAS Policy on Handling Inspection Items and Samples'
	Add 7.3.I 'HKIAS Policy on Inspection Records'
	Add 7.4.I 'HKIAS Policy on Inspection Reports and Inspection Certificates'
	Add 7.5.I 'HKIAS Policy on Complaints and Appeals'
8 Management system requirements	Add 8.1.I 'HKIAS Policy on Management System'
	Add 8.4.I 'HKIAS Policy on Control of Records'
Bibliography	Delete 'Bibliography' of ISO/IEC 17020:2012
–	Add Annex AA 'Bibliography'
–	Add Annex AB 'Variations to ISO/IEC 17020:2012 for HKIAS 003:2017'

Explanation:

HKIAS policies added serve as additional explanation of the requirements of ISO/IEC 17020:2012 and shall be regarded as mandatory under Hong Kong Inspection Body Accreditation Scheme (HKIAS).

Bibliography of this booklet (Annex AA) not only covers the bibliography of ISO/IEC 17020:2012, but also contains documents published international and regional laboratory accreditation cooperations, which are useful for inspection body operation.

Annex AB is an informative annex listing out all variations of this booklet to ISO/IEC 17020:2012.