HOKLAS 022:2017

Abridged Version

(Requirements and notes of ISO 17034:2016 are not included in this document. This document should be read in conjunction with ISO 17034:2016)

Technical Criteria for Accreditation of Reference Material Producers

(ISO 17034:2016, General requirements for the competence of reference material producers, MOD)

Hong Kong Accreditation Service
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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, certification bodies, inspection bodies, proficiency testing providers, reference material producers and greenhouse gas validation and 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 bearing the accreditation symbol of HKAS or its mutual recognition arrangement partners

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 greenhouse gas 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 the relevant international standard, i.e. ISO/IEC 17011 and other criteria set by relevant international and regional cooperations of accreditation bodies. Participation in the three schemes is voluntary.

Organisations applying for accreditation or those 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.

The procedures for seeking HOKLAS accreditation and for processing applications are detailed in Annex AA of this booklet. HKAS will grant accreditation for an activity to an organisation only when it meets the conditions given in clause 4.15 of HKAS 002 – Regulations for HKAS Accreditation.

i. Basis of HOKLAS 022 Technical Criteria for Accreditation of Reference Material Producers - ISO 17034:2016

This technical criteria booklet is applicable to reference material producers (RMPs) only. The technical criteria for laboratories other than medical testing laboratories are given in ISO/IEC 17025 whilst HOKLAS 015 and HOKLAS 017 are published separately for medical testing laboratories and proficiency testing providers (PTPs) respectively.

This booklet is a modified adoption of International Standard, ISO 17034:2016 – 'General requirements for the competence of reference material producers'. This standard was published by International Organisation for Standardisation (ISO).

The title of this booklet varies from the ISO 17034:2016 and is entitled as 'Technical Criteria for Accreditation of Reference Material Producers'.

This standard specifies the general requirements for the competence and consistent operation of RMPs. It sets out the requirements in accordance with which reference materials (RMs) are produced.

This standard is intended to be used as part of the general quality assurance procedures of the RMP. Accreditation bodies can also use it in confirming and recognising the competence of RMPs.

This standard covers the production of all RMs, including certified reference materials (CRMs).

ISO/IEC 17025 is a normative reference of ISO 17034:2016. ISO 17034:2016 also makes reference to the requirements of ISO/IEC 17025 in various places where testing and calibration in support of the production of RMs are mentioned. For tests performed in the medical field, ISO 15189 can be used as a reference instead of ISO/IEC 17025.

The use of an international standard for recognising competence has led to increased confidence in the quality of RMs produced by accredited producers and facilitates the acceptance of these RMs for the establishment of metrological traceability of measurement results and other purposes. Building on this, the Asia Pacific Accreditation Cooperation (APAC) has established a mutual recognition arrangement (MRA) for RMP accreditation. Signatories to the APAC MRA for RMP accreditation recognise the equivalence of one another's accreditation. A list of signatories to the APAC MRA for RMP accreditation is available from the APAC website.

The value of accreditation to ISO 17034 is to ensure that appropriate information is available in the certificates or documentation of RMs purchased for the purpose of conducting method validation, ensuring traceability of measurement results, and/or instrument calibration. Lack of this information will impact the accuracy and validity of test and calibration results. The APAC MRA for accreditation of RMPs should enable regulators and users to purchase RMs from competent and appropriate accredited RMPs.

This booklet sets out the basic requirements which all HOKLAS accredited RMPs shall meet. More detailed requirements specific to certain administrative aspects and

technical disciplines are issued as individual HKAS and HOKLAS Supplementary Criteria.

The term ‘shall’ is used throughout this booklet to indicate requirements that are mandatory. The term ‘should’ is used to indicate recommendation which, although not mandatory, is a recognised means of meeting the requirements. The term ‘may’ indicates permission, while ‘can’ indicates a possibility or a capability.

This and other criteria documents set out the requirements to be met by an RMP accredited under HOKLAS but do not dictate how such requirements should be met. It is the responsibility of the RMP’s management to determine the best method to meet such requirements, the relative significance of individual activities to the overall quality of the RMP and the emphasis and resource that should be allocated to each of them. The RMP’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 the criteria documents.

A list of HKAS and HOKLAS Supplementary Criteria is available from the HKAS Executive and the HKAS website (www.hkas.gov.hk). This website also provides links to other websites which provide useful information on accreditation.

ii. Scope of accreditation - What activities may be accredited under HOKLAS

Each organisation accredited under HOKLAS will have the specific activities for which it is accredited clearly given in its 'scope of accreditation'. In this regard, each RMP will have the specific RMs for which it is accredited to produce clearly given in its 'scope of accreditation'.

The HKAS Executive will define from time to time the specific areas which are available for accreditation under HOKLAS. These areas are called 'test categories' and the categories currently available for accreditation are:

- Calibration Services
- Chemical Testing
- Chinese Medicine
- Construction Materials
- Electrical and Electronic Products
- Environmental Testing
- Food
- Forensic Testing
- Medical Testing
- Miscellaneous
- Pharmaceutical Products
- Physical and Mechanical
- Proficiency Testing Providers
- Reference Material Producers
- Testing Required By The China Compulsory Certification System (CCC)
- Textiles and Garments
- Toys and Children's Products
- Veterinary Testing

Other test categories may be added when significant needs are identified.

An organisation may apply to be accredited for one or more activities in specific test categories 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 organisation's competence to perform the additional activities. All accredited organisations are reassessed at regular intervals to ensure continuing conformity with HOKLAS requirements at all times for all accredited activities. In addition, their performance is monitored closely through surveillance visits, participation in proficiency testing programmes and other appropriate means.

For RMPs, the accreditation is granted for the production of specified RMs by specified production process. An applicant or accredited RMP need not be competent to perform all the activities included in the production process. It may subcontract selected activities to competent organisations. However, certain activities as detailed in 6.2.3 of this document shall not be subcontracted. An applicant or accredited RMP shall inform HKAS Executive immediately of any change or intended changes which may affect its conformity with relevant accreditation criteria in accordance with 5.9 of HKAS 002. In addition to changes listed in that clause, HKAS Executive shall be notified of changes to the production process, such as changes in testing and calibration methods and changes of subcontractors.

iii. Accreditation criteria

Applicant organisations have to demonstrate conformity with the criteria listed in the following Sections of this document as well as the criteria in the relevant Supplementary Criteria and the regulations listed in HKAS 002 before accreditation can be granted, and accredited organisations shall comply with the same criteria at all times for maintaining accreditation. In particular, for RMPs, all activities related to testing and calibration in support of the production of RMs shall meet the relevant HOKLAS accreditation regulations, criteria and requirements for laboratories. Accredited and applicant organisations 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.

Annex AB is a list of selected documents published by ISO, international and regional laboratory 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.

Introduction

(The main text of this clause is the text of the same clause of ISO 17034:2016)

1 Scope

(The main text of this clause is the text of the same clause of ISO 17034:2016)

2 Normative references

(The main text of this clause is the text of the same clause of ISO 17034:2016)

3 Terms and definitions

(The main text of this clause is the text of the same clause of ISO 17034:2016)

4 General requirements

4.1 Contractual matters

(The main text of this clause is the text of the same clause of ISO 17034:2016)

4.1.H HOKLAS Policy on Contractual requirements

When reviewing requests, tenders and contracts, RMPs shall ensure that the requested matrix, property values and their metrological traceability and measurement uncertainty, where applicable, meet the need of the customer. In some cases, the required validity period of the RM should also be included in the review. If necessary, the RMP should give advice to the customers and help them to determine their needs.

4.2 Impartiality

(The main text of this clause is the text of the same clause of ISO 17034:2016)

4.3 Confidentiality

(The main text of this clause is the text of the same clause of ISO 17034:2016)

5 Structural requirements

(The main text of this clause is the text of the same clause of ISO 17034:2016)

5.H HOKLAS Policy on Structural requirements

HKAS will grant accreditation to an RMP only for those activities for which it has competence to carry out. In this regard, the accredited RMP shall be fully responsible for and shall have the competence in project planning and management, assignment of and decision on property values and relevant uncertainties, authorisation of property values and issuance of RM certificate or other statements for the RMs it produces. Otherwise, it does not meet the definition of an RMP as given in clause 3.1 and cannot be regarded as an RMP accordingly. An organisation performing selected activities is not an RMP and cannot be accredited as such. For example, an organisation providing reference values for a candidate RM alone is not an RMP.

It is recognised that an RMP may operate in different modes at different times and/or for different RMs. This will be taken into account in the assessment. Accreditation is granted to an RMP based on the mode of operation of the RMP at the time of the assessment. If there is any change in the mode of operation, e.g. a key task such as characterisation of property value, which was originally performed by a competent subcontractor, is now performed by the RMP itself, the RMP is required to inform HKAS Executive immediately. In such case, the RMP shall not claim that it is accredited for producing the RM concerned, and cannot use an endorsed certificate/statement for such an RM until HKAS Executive has assessed the new mode of operation and concluded that accreditation requirements continue to be met by the RMP and that the RMP has been informed of this.

The officer-in-charge of an RMP, or section leaders in the case of large RMP, shall have sound knowledge of the principles of the technical field, provide adequate supervision of staff and have the ability to make critical evaluations of various stages of the RM production process.

The HKAS Executive considers each RMP on its merits and relates staff and management requirements to the range, complexity and frequency of production of RMs for which accreditation is sought. In some circumstances, adequate technical control may be achieved with a combination of staff. For example, an officer exercising technical control may be relatively inexperienced with respect to one facet of the RMP's work, but another officer working in close collaboration with him may complement him in that aspect. The accreditation in such a case will be reviewed if there is a major change in either person's duties.

HOKLAS assessments will pay particular attention to the mode of supervision of staff. The RMP management shall decide who can work under direction and who requires supervision. Each member of staff of the RMP shall be fully briefed or instructed. Adequate supervision shall be provided at each level of the staff structure to ensure strict adherence to RMP procedures and accepted techniques at all times.

There shall be clearly defined and recognisable lines of authority and responsibility within the RMP. All staff shall be aware of both the extent and limitations of their own responsibilities. A concise organisation chart should be documented (preferably in the quality manual) showing the RMP's overall organisation and lines of responsibility.

The technical management may be a designated technical manager or may consist of a combination of designated technical managerial personnel each of them responsible for specified areas. The responsibility of technical issues for all accredited activities shall be fully covered by the technical management.

When the testing or calibration tasks are performed by the RMP, clause 4.2 that covers impartiality shall be applied when assessing the in-house testing or calibration function and its relationship with the production department.

continued…….

It is the responsibility of the RMP to carry out its work in accordance with the applicable Laws and Regulations of Hong Kong, or of the country where the RMP is located. It should be emphasised that assessment of the RMP's compliance with the relevant regulatory requirements is outside the scope of HKAS accreditation schemes.

6 Resource requirements

6.1 Personnel

(The main text of this clause is the text of the same clause of ISO 17034:2016)

6.1.H HOKLAS Policy on Personnel

The appraisal of personnel is a major part of each assessment as the quality and standard of RMs produced depend largely on their professional knowledge and skills. The RMP personnel shall have knowledge and understanding of, at least, the production methods, analytical methods, matrices, stability, homogeneity, metrological traceability and measurement uncertainty with respect to all RMs it produces.

Three categories of personnel will be assessed. They are:-
(a) Technical personnel
(b) Supervisory personnel
(c) Management personnel

The RMP shall provide opportunities for all levels of its staff for continuing professional development.

HOKLAS Policy on Technical Personnel

Technical personnel shall have suitable qualifications and/or training and have sufficient experience and ability to perform their work. They may be asked to demonstrate specific techniques during an assessment.

An RMP shall have proper procedures for training new technical personnel and for developing the expertise of existing technical personnel in new or rarely used techniques. The criteria used to assess the competence of trainees shall form an integral part of the procedures. Records of training and assessments of competence shall be kept. These shall include or refer to records of results of productions, tests or calibrations performed during training and competence assessment. The continuing competence of technical personnel shall be assessed at suitable intervals and records of such assessment shall be kept.

The work of technical personnel, particularly in the early stages after completion of training in new techniques shall be monitored closely.

HKAS Executive may define minimum technical qualifications and work experience requirements for personnel involved in specific technical disciplines. For testing and calibration activities, requirements for personnel given in the relevant HOKLAS Supplementary Criteria for the testing discipline concerned apply.

Colour vision defects may prevent people from performing certain work satisfactorily. It is the responsibility of the management to ensure in such cases that colour vision problems will not affect validity of reference materials produced.

HOKLAS Policy on Supervisory and Management Personnel

The qualifications and experience of supervisory and management personnel will be carefully examined during the assessment of an RMP. Factors which will be considered include :

(a) the size of the RMP and the types and ranges of RM produced;

(b) the tasks performed by the RMP;

continued…….

(c) the technical complexity of the work involved;

(d) the involvement of the management personnel with the design, development and planning of reference material production.

Supervisory personnel shall have suitable qualifications or training and have sufficient authority, skills and experience to train, and supervise technical personnel properly. They shall demonstrate appropriate understanding of the technical areas in which they exercise supervision.

In assessing qualifications, the balance between relevant academic qualifications and practical experience will be examined in light of the range of work performed, and the complexity and the uncertainty of the reference materials produced.

HKAS places special emphasis on the adequacy of supervision. Supervisory staff members may have duties other than supervision of staff, but in all cases, the RMP has to provide evidence that the supervisory staff have spent sufficient amount of time in fulfilling the role of a supervisor. Supervision by solely vetting the records or reports of technical staff is considered by HKAS as not effective and sufficient. The supervisory staff shall spend sufficient time in the work areas to directly observe how the work is being carried out by the technical staff, particularly during critical stages of the work. Discussions on their work shall also be held as and when necessary.

Management personnel are not required to have in-depth understanding of every technical area but shall have adequate experience of production of reference materials. They shall have suitable qualifications or training, and have sufficient experience and ability to direct the operations of the RMP, and to accept responsibility for the implementation of the management system.

For an RMP seeking accreditation for a wide range of reference materials, management personnel will be expected to hold relevant professional and/or academic qualifications. In all cases, management personnel shall be able to demonstrate their competence and have adequate relevant experience to assume their responsibility and authority.

HOKLAS Policy on Approved Signatories for HOKLAS Endorsed RM Documents

HOKLAS endorsed certificates and product information sheets issued to users of CRMs and non-certified RMs respectively shall be signed by an approved signatory. An approved signatory for RM production is an individual who is an employee of or under contract to an accredited RMP and has been authorised by the accredited RMP to sign RM certificates or documents issued by the RMP for specific RMs and to whom HKAS Executive has given approval for signing endorsed RM certificates or documents for such reference materials.

A person nominated for approved signatory shall be familiar with the management system and operation of the RMP. There shall be objective evidence demonstrating that he/she has made sufficient contact with the RMP to enable him/her to have an in-depth understanding on the operation of the RMP and have confidence in the quality of the RMs produced. He/she shall be competent to make critical evaluation of technical content of the RM certificates and/or documents. He/she shall occupy a position in the RMP's staff structure which makes him/her responsible for the correctness of the RMs produced. The person shall be fully aware of the requirements detailed in this document, HKAS 002 and other relevant HKAS and HOKLAS Supplementary Criteria.

Signatory approval may be limited to specific RMs or may be granted for all RMs for which the RMP is accredited. As signatory approval is granted in the context of the work being performed in a particular RMP, it shall not be considered as a personal qualification.

Signatory approval may be granted to management personnel, provided that they have maintained sufficient contact with relevant operation of the RMP to retain the capability for critical evaluation of RMs produced.

continued……

The following attributes are taken into account when assessing the suitability of a staff member for approval as a reference material signatory :

(a) qualifications and experience;
(b) position in the staff structure;
(c) familiarity with technical procedures and understanding of their underlying principles and limitations;
(d) knowledge of the procedures for various steps of RM production;
(e) understanding of the HKAS regulations and accreditation criteria, particularly those referring to HOKLAS endorsed certificates and documentation.

6.2 Subcontracting

(The main text of this clause is the text of the same clause of ISO 17034:2016)

6.2.H HOKLAS Policy on Subcontracting

RMPs shall document, in the quality manual or related documents, their policy and procedures for sub-contracting. There are some processes that are not allowed to be subcontracted. Such processes are listed in clause 6.2.3.

During HKAS assessments, the assessment team will assess how the RMP determines the competence of its testing or calibration subcontractors if it does not require them to be accredited to ISO/IEC 17025. Documentation issued to subcontractors as a result of a successful assessment by the RMP shall state that it is only for the purpose of the contract and is not certification or accreditation. The RMP shall not allow serial subcontracting (i.e. subcontracting of subcontracted work), on an on-going basis, by its subcontractors.

For testing or calibration subcontractors, if they are accredited for the relevant tests and calibrations, an on-site assessment of the subcontractor by the RMP is not normally needed as long as the degree of review done by the RMP of the contract with the subcontractors is appropriate. Such contract review shall at a minimum includes, where relevant,

a) the measurand;
b) the test and/or calibration method(s) to be used;
c) the required measurement uncertainty;
d) metrological traceability;
e) reporting requirements, including, in addition to test or calibration results, other technical information necessary for subsequent data processing by the RMP;
f) performance of the subcontractor in proficiency testing activities (where suitable and applicable); and
g) whether the subcontractor performs the subcontracted work with the required degree of technical rigour.

In instances where subcontractors report major contributions to the uncertainty budget, the RMP shall provide evidence of their assessment of the subcontractor's technical competence including the subcontractors' claimed traceability and evaluation of the measurement uncertainty of these contributions. Where a subcontractor provides a reference value determination/characterisation, or provides testing as part of the material preparation, the requirements for measurement traceability as applicable in ISO/IEC 17025 and other relevant HOKLAS supplementary criteria shall be applied.

If considered necessary, HKAS may carry out on-site assessments of the RMP's subcontractors. Therefore, the RMP shall ensure that the arrangement with its subcontractors includes a provision that permits on-site assessments by HKAS. Such assessments will be arranged with the consent of the RMP and the subcontractors concerned. The assessment will normally be done in the presence of the RMP. Any nonconformity found during the assessments of the RMP's subcontractors will be raised to the RMP. The RMP is responsible for ensuring that actions are taken by its subcontractors to resolve the nonconformities. The RMP is responsible for responding to HKAS and for providing supporting evidence that its subcontractors have resolved the identified nonconformities satisfactorily. Granting of accreditation will be considered only when all nonconformities, including those related to its subcontractors, have been adequately addressed to the satisfaction of HKAS. The RMP is responsible for verifying the competence of its subcontractors at suitable intervals. Records of such verification shall be kept. Where there are difficulties in ensuring the competence of subcontractors, the RMP may consider using other means of determination of property values, e.g. by a collaborative study involving multiple laboratories.

continued…….

The RMP shall require its subcontractors for tests or calibrations to participate in suitable proficiency testing activities, when available. The frequency of participation shall be the same as that given in HOKLAS Supplementary Criteria No. 33 and other relevant HOKLAS Supplementary Criteria. When suitable proficiency testing programmes are not available, other means to demonstrate competence, e.g. use of measurement audits or check samples, should be considered.

Moreover, it should be emphasised that accreditation is granted to the RMP, and not to its subcontractors. In this regard, the RMP shall have a written agreement with its subcontractors which requires its subcontractors not to represent themselves to anybody that they are accredited for the subcontracted activities through the contractual relationship with the accredited RMP. It is an obligation of an accredited RMP to ensure that its subcontractors follow the relevant accreditation requirements and regulations that are applicable to its subcontractors. Documentation issued to subcontractors as a result of a successful assessment by the RMP shall state that it is only for the purpose of the contract and is not certification or accreditation. HKAS Executive may impose suspension of the accreditation when the RMP fails to ensure that its subcontractors follow any of the HKAS accreditation regulation or requirement relevant to the situation concerned.

As the assessment of the RMP's subcontractors is a part of the RMP assessment, the relevant policies, procedures, regulations and requirements for RMP assessment shall apply to the assessment of RMP's subcontractors.

The RMP's register of all subcontractors used shall include the following information,

a) name and address of the subcontractor;
b) the scope of tasks/activities performed by each subcontractor;
c) the testing, calibration and measurement activities performed by the subcontractors; and
d) evidence of the technical and/or quality competence of the subcontractors (e.g. certification to ISO 9001 for non-testing activities or accreditation to ISO/IEC 17025 for testing, calibration and measurement activities).

6.3 Provision of equipment, services and supplies

(The main text of this clause is the text of the same clause of ISO 17034:2016)

6.3.H HOKLAS Policy on Provision of equipment, services and supplies

Records of procurement of consumables or perishable items, e.g. media, chemical reagents and glassware, which bear a critical influence on the quality and validity of the RMs, shall be kept. The records should where appropriate include results of the acceptance tests on each new batch prior to use. Consideration should be given to excluding supplies from suppliers that are inappropriate/invalid or have a known history of supplying inappropriate/invalid materials.

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

It is further recommended that when choosing suppliers of service or products, priority should be given to 3rd party certified (refer to IAF Multilateral Recognitioin Arrangement) or accredited (refer to ILAC Mutual Recognition Arrangement) organisations.

For purchasing of candidate material for futher processing, requirements given in other sections such as clauses 7.2, 7.3. 7.5 etc. of this document shall be followed. Regarding testing and calibration service, the HOKLAS policy is given in 6.2.H.

6.4 Facilities and environmental conditions

(The main text of this clause is the text of the same clause of ISO 17034:2016)

6.4.H HOKLAS Policy on Facilities and environmental conditions

Suitability of the accommodation and environmental conditions for the production of a specific reference material will be assessed based on their effect on the quality and validity of the reference material being produced, including how they affect:

(a) the integrity of the RMs;
(b) the performance of laboratory equipment;
(c) the competent performance of laboratory staff;
(d) compliance with the conditions specified in the production plan.

Consideration of environmental effects on RMs includes precautions necessary to prevent contamination and degradation (refer to clause 6.4.3). The areas for the material preparation, preconditioning, testing or calibration and storage shall be of adequate size, free from dust, fumes and other factors (such as excessive temperature, humidity and direct sunlight) which may affect the integrity of the RMs. If the RMs produced require refrigeration, refrigerators or freezers of adequate capacity and capable of maintaining the required temperatures shall be available and temperature monitored.

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

Accommodation and environmental conditions should also be assessed based on their effects on staff competence in performing specific activities. There shall be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimise noise.

Adequate space shall also be provided for clerical functions (recording, reporting and documentation activities) and for separate amenity facilities. All necessary services for gas, water, power (suitably stabilised if necessary), waste disposal and for extraction of fumes shall be available and be conveniently located.

As regards requirements for accommodation and environmental conditions of testing and calibration activities, the requirements given in relevant Sections of ISO/IEC 17025 and HOKLAS Supplementary Criteria apply.

7 Technical and production requirements

7.1 General requirements

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.1.H HOKLAS Policy on General requirements

There are technical standards published by international organisations, or other well recognised professional bodies, that may be applicable to the production of certain reference materials. If such applicable technical standard exists, an RMP shall, as far as possible, follow such standard in its production of the RMs.

7.2 Production planning

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.2.H HOKLAS Policy on Production planning

It is critical that, before the start of the production of an RM, a detailed production plan is available. It is understood that pilot studies may sometimes need to be carried out but the need of any pilot study shall be considered at the planning stage. The production plan shall be documented. There are requirements for the production process given in this document and the RMP is required to provide evidence that, at the planning stage, these requirements are given full consideration, and if necessary, recommendations from advisory groups have been sought.

This plan may need to be reviewed during the production process. If it is necessary to make any change to the plan, the effects of the change on the conformity with the requirements of this document shall be evaluated. Changes shall be approved by the person authorised, in accordance with clause 6.1.6, to perform production planning of the RM. Changes shall be fully documented, and shall include the reasons and justifications for the changes. If the changes can affect the contract with the customer, the customer shall be consulted. Customer's agreement with the changes shall be obtained and records maintained as required by clause 4.1.3.

7.3 Production control

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.3.H HOKLAS Policy on Production control

Although effective control of each stage of the production process is needed, there are also certain critical steps in each stage where the quality of the RM can be significantly affected. An analysis of such critical control points can be carried out and a plan that is designed to ensure that these critical control points are effectively controlled, and monitored, is a useful means to ensure the quality of RMs.

Records shall be maintained to provide evidence that there is effective control of each stage of reference material production, e.g. records of inspection, testing, etc.

7.4 Material handling and storage

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.4.H HOKLAS Policy on Material handling and storage

It should be emphasised that the requirements of this section apply to all stages of the production - from the receipt of the raw material to the finished RM. If during some stages of production, the material has to go out of the direct control of the RMP, the RMP shall provide necessary instructions to the party responsible for handling the material. When storing the material, the storage environmental conditions shall be specified.

When the same equipment is used for different materials, the equipment shall be thoroughly cleaned between uses to prevent possible cross-contamination.

All persons handling the materials shall be trained on the proper handling procedures. They shall be aware of the precautions to be taken whilst handling the material.

It is the responsibility of the RMP to ensure that the packing and labelling of the RMs meet the safety and transport regulatory requirements. However, it should be emphasised that assessment of the compliance with the regulatory requirements is outside the scope of HKAS accreditation schemes.

7.5 Material processing

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.5.H HOKLAS Policy on Material processing

When the same equipment is used for processing different materials, the equipment shall be thoroughly cleaned between uses to prevent possible cross-contamination.

All material processing procedures shall be carried out by trained personnel and requirements of clause 6.1.3 of this document apply

Preparation of the material (such as drying, mixing of ingredient, spiking with analytes, etc) is a form of material process.

When candidate RMs are sent to subcontractors for testing, they shall be uniquely labelled, suitably packed and stored in suitable conditions during transport. Instructions on the storage conditions shall be given to the subcontractors.

In cases where the certified values are based on data obtained in the material processing procedure, the requirements relating to the assignment of property values and their uncertainties apply to the material processing procedures. In such cases, the material processing procedures shall comply with the requirements for measurement procedures and metrological traceability given in clauses 7.6 and 7.9. The requirements for measuring equipment given in clause 7.7 also apply to those items of equipment used in the material processing stage which contributes to the uncertainty of the assigned values of the reference materials.

7.6 Measurement procedures

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.6.H HOKLAS Policy on Measurement procedures

When tests and calibrations relating to the production of an RM are performed directly by the RMP being assessed, HKAS will assess these activities during the assessment. The requirements of ISO/IEC 17025 apply to these testing and calibration activities. Relevant HKAS and HOKLAS Supplementary Criteria shall also be complied with. It should also be noted that the requirements for participation in relevant proficiency testing activities are also applicable to the tests and calibrations performed by the RMP.

It should however be emphasized that an accredited RMP is accredited for the production of RMs, not for provision of testing or calibration services (i.e. as a laboratory), and as such, its scope of accreditation does not cover provision of testing and calibration for purpose other than the production of the reference materials stated in its scope of accreditation.

An organisation may however apply for accreditation as a laboratory to ISO/IEC 17025 for its testing and calibration. In such case, a separate application for laboratory accreditation is required. This accreditation will be processed in accordance with the procedure for laboratory accreditation and all relevant technical criteria and regulations for laboratory accreditation apply. A separate scope of accreditation and certification of accreditation for laboratory will be issued. Where the RMP is accredited to ISO/IEC 17025 by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement for the applicable testing and calibration activities, it can be considered as meeting the ISO/IEC 17025 requirements for competence in performing those activities.

When subcontractors are used for carrying out tests or calibrations, the requirements given in clause 6.2 apply.

7.7 Measuring equipment

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.7.H HOKLAS Policy on Measuring equipment

Requirements for measuring equipment given in ISO/IEC 17025 and other relevant HOKLAS Supplementary Criteria shall be complied with.

7.8 Data integrity and evaluation

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.8.H HOKLAS Policy on Data integrity and evaluation

Homogeneity and stability assessments, characterisation, assignment of property values and estimation of their uncertainties all involve evaluation of data. The RMP shall use appropriate statistical techniques for data evaluation. The general and statistical principles for certification of an RM given in ISO 33405, where appropriate, should be followed.

7.9 Metrological traceability of certified values

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.9.H HOKLAS Policy on Metrological traceability of certified values

For testing and calibration activities, the requirements for metrological (measurement) traceability given in ISO/IEC 17025 and other relevant HOKLAS Supplementary Criteria apply.

In cases where metrological traceability to the SI units is not technically possible, clause 7.9.4 requires metrological traceability to an appropriate reference. If a CRM is used for establishing metrological traceability, the CRM used shall have comparatively small uncertainty and is higher in the metrological traceability hierarchy. The uncertainties in the certified values of the CRM used shall be suitable for establishing metrological traceability appropriate to the CRMs being produced.

The RMP should consider the competence of the producer of any CRM it uses to provide the metrological traceability of the assigned value of its CRM. A competent producer may be a National Metrology Institute which is a signatory to the CIPM MRA, participates regularly in BIPM or Regional Key Comparisons, and has the relevant CMCs been included in Appendix C of the BIPM Key Comparison Database (KCDB); produces CRMs with assigned values covered by entries in the Joint Committee for Traceability in Laboratory Medicine database; or accredited RMPs under relevant mutual recognition arrangement with those CRMs listed on their scope of accreditation.

For biological CRMs, traceability can be established through the use of reference cultures kept in various economies such as American Type Culture Collection (ATCC), Type Culture Collection of Chinese Academy of Science (CGMCC), National Collection of Type Cultures (NCTC), UK, and European Collection of Animal Cell Culture. Biochemical tests, culturing techniques or DNA sequencing may be used to define the identity of the organisms. The traceability statement of these CRMs shall include which reference cultures, or which definition, is used as the reference.

More guidance on establishing and demonstrating traceability can be found in ISO 33405 and ISO/TR 16476 ‘Reference materials – Establishing and expressing metrological traceability of quantity values assigned to reference materials’. See also clause 7.12 of this document for approaches for characterising a reference material.

7.10 Assessment of homogeneity

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.10.H HOKLAS Policy on Assessment of homogeneity

When data from assessment of homogeneity are used for assigning the property values, the requirements for metrological traceability (clause 7.9) and characterisation (clause 7.12) apply to the test procedures used, where relevant.

When homogeneity data obtained in previous batches are used, the RMP shall demonstrate that the data are still applicable to the current batch. The RMP shall re-assess homogeneity if there is a change of procedure, or the source of the candidate materials, for producing the RMs. The RMP shall also re-assess homogeneity when any deviation from previous data has been observed. The extent of the check from batch to batch may vary depending on the type of the RM and the consistency of the process.

7.11 Assessment and monitoring of stability

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.11.H HOKLAS Policy on Assessment and monitoring of stability

Under normal circumstances, stability assessment for each and every property value shall be performed. It is not acceptable to assume the stability of a property value based on the assessment of another value unless correlation is demonstrated with analytes that are tested for stability.

Prediction of stability using a model is generally not acceptable unless such model is well established and widely accepted in the discipline concerned.

In case when data from assessment of stability are used for assigning the property values, the requirements for metrological traceability (clause 7.9) and characterisation (clause 7.12) apply to the test procedures used, where relevant.

Stability assessment should also include assessment of the effects of repeated use. This includes studies with multiple subsamples and any requirements for changed temperature for storage before subsampling. Any associated uncertainty could be expressed within the long term stability assessment or as considerations described in the certificate.

When stability data obtained in previous batches are used, the RMP shall demonstrate that the data are still applicable to the current batch. The RMP shall re-assess stability if there is a change of procedure, or the source of the candidate materials, for producing the RMs. The RMP shall also re-assess stability when any deviation from previous data has been observed. The extent of the check from batch to batch may vary depending on the type of the RM and the consistency of the process.

7.12 Characterization

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.12.H HOKLAS Policy on Characterisation

When the property value concerned is method-specific or operationally defined, the RMP shall use that specific method which defines the property value for characterisation. Details of the characterisation procedures used shall be recorded. When more than one laboratory is engaged for characterisation of operationally defined properties, all of them shall use the same method. Such property values are only meaningful when applied to the same method. Therefore, to be more useful, the methods used shall be those published by standard writing bodies or widely recognised professional bodies in the field concerned, clearly described and providing measurement results fit for their intended use and ensured by suitable comparison as appropriate.

7.13 Assignment of property values and their uncertainties

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.13.H HOKLAS Policy on Assignment of property values and their uncertainties

As CRMs are often used by laboratories for establishing their metrological traceability, it is important that the uncertainties of the assigned values are estimated using methods which are generally more rigorous than for other purposes. The uncertainties include not just the measurement uncertainty of the characterisation procedure but also other contributions.

Uncertainty in this clause covers both “measurement uncertainty” of a quantity value and “uncertainty” associated with a nominal property (i.e. property of a phenomenon, body, or substance, where the property has no magnitude e.g. colour chart, DNA sequence, etc).

The measurement model used to evaluate the measurement uncertainty of a property value shall cover all quantities that may contribute significantly to the uncertainty, and shall at least include contributions from characterisation, homogeneity, transportation stability and long term stability. If any of these contributions are known to be insignificant, such findings should be recorded.

Where practicable the measurement or characterisation model shall include contributions applicable to a best typical batch production. A best Reference Value Capability which includes the RMP’s estimate of its least uncertainty of measurement for each property value’s range is listed for each type of CRMs in the scope of accreditation of the RMP. RMPs shall maintain detailed records for these estimates and to review them periodically for currency. RMPs shall also have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment, a change of subcontractors, a change of material suppliers or other changes that would significantly affect the magnitude of relevant uncertainty components. RMPs shall be able to provide evidence that they can provide property values to customers with measurement uncertainties equal to those covered by the Reference Value Capability. Such evidence may typically include performance in proficiency testing, measurement audits or rigorous evaluation of the uncertainty of measurement.

7.14 RM documents and labels

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.14.H HOKLAS Policy on RM documents and labels

An RMP may perform tests or calibrations for the production of RMs. Such tests or calibration shall be performed in accordance with relevant requirements of ISO/IEC 17025. It should, however, be noted that requirements for reporting of results (as specified in ISO/IEC 17025) only apply to internal testing and calibration reports and do not apply to certificates and documentation of the RMs issued to users.

An RMP is allowed to contract out some of its tasks to competent subcontractors. It is not necessary to indicate which parts of the production process have been subcontracted in the certificate or documentation of RMs.

Certificates or documentation of RMs shall be traceable to its production process. This can be achieved by having a unique identification of the process, which may take the form of a reference number, the name of the process or in other suitable format.

For biological CRMs, if both DNA sequence and the identity of the organism are given on the certificate, it shall state clearly if only one of them, or both, is the certified property value. If DNA sequence is not the certified value but is used for characterising the organism only, it shall be stated in the certificate. In addition, if the CRM is produced by sub-culturing of a reference culture higher in the metrological hierarchy, clear indication of the reference culture used, as well as the number of passages and the sub-culturing techniques, shall be provided in the certificate. In cases where the biological CRMs are intended to be used for matching results of a certain test with that of test specimens, the tests used to characterise the organism as well as the test results shall be given in the certificate.

For those CRMs where the identity of a chemical compound is the certified property value, the certificate shall include both the identity as well as the purity of the compound and, if applicable, other information such as its molecular structure and the confirmatory technique(s) used to identify the compound.

7.15 Distribution service

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.16 Control of quality and technical records

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.16.H HOKLAS Policy on Control of quality and technical records

Each RMP shall maintain a record system designed to suit its particular requirements. The system shall be in conformity with this document but need not be an elaborate one.

Technical records shall include all original observations and raw data and provide a traceable link between the RMs produced and the information on the certificates or documentation of the RMs. This applies equally to electronic and paper record systems. If an RMP uses an Information Management System, the system shall meet all the relevant requirements, including audit trail, data security, safety and integrity, etc. It shall be fully validated and records of validation shall be maintained. RMPs shall keep back-up copies of electronic records within their retention period. They shall also have a system to ensure that electronic records remain accessible within that period even though the hardware and software of their computer system are being updated from time to time.

The record system shall allow for ready retrieval of original observations and data pertinent to any issued reports or certificates.

For each RM produced, the record system shall retain and provide ready access to the following detailed information :

(i) the full description of the RM;

(ii) the unique identification of the RM;

(iii) the test or calibration method or procedure used in the production process;

(iv) identification of equipment and RM s used in the production process;

(v) all data relating to the preparation and manufacturing of the candidate materials;

(vi) original observations during the test or calibration and calculations based on the observed data;

(vii) data and the statistical calculations for homogeneity and stabililty studies;

(viii) data used in the assignment of property values and their uncertainties, including those data which have been rejected and the reasons for rejection;

(vi) identification of persons performing the work;

(vii) an exact copy of the issued documentation or certificate of the RM produced.

Original observations shall be recorded immediately into bound notebooks, or onto properly designed proforma worksheets using indelible pen. Instrument printouts shall be kept when they are available. Where data processing systems are used, records of raw data shall be retained unless data are automated. Sheets of plain paper shall not be used.

Errors in calculations and incorrect transfer of data are major causes of incorrect results. Calculations and data transfers shall be checked by a second person and signed or initialled and dated by the reviewer except in the case when there is no other suitable person available for this purpose. Workbooks and worksheets shall have a dedicated place for the signature of the reviewer.

continued…….

The minimum period for retention of original test data, other technical records, HOKLAS endorsed RM certificates or documentation and distribution information records set by the HKAS Executive is four years after the RM ceases to be valid, 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 equipment records and laboratory operation procedures, the retention period of at least four years shall be counted from the date on which the use of the equipment or the operation procedures stopped. Similarly, the retention period of at least four years for personnel records shall be counted from the date of departure of the staff member concerned. In all cases, however, records shall be retained for a minimum of four years after the expiry date of the RMs produced.

7.17 Management of non-conforming work

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.17.H HOKLAS Policy on Management of non-conforming work

'Remedial actions' referred to in clause 7.17.2e) include both correction and corrective actions. In this regard, HOKLAS Policy on Corrective Actions given in 8.9.H also applies to this clause. Whilst corrections need to be taken as soon as possible, RMP should also take note of the requirement given in clause 8.9.2 for corrective actions.

Common examples of non-conforming work include environmental conditions in the testing or calibration areas exceeded the specified limits, tests performed using instruments with overdue calibration, acceptance criteria of quality control not met, unsatisfactory performance in proficiency testing programmes, etc. It is important that RMPs should not just correct the problem but shall initiate actions according to the requirements given in clause 7.17.2, which include a determination of whether the non-conforming work is an isolated incident or is due to some underlying causes with a possibility of recurrence. In the latter case, corrective actions, in addition to corrections, are needed. It should be emphasised that all personnel of the RMP need to be familiar with the procedures for handling non-conforming work. They should follow the documented procedures whenever non-conforming work is identified. Training on the procedures is essential to ensure relevant staff understands the procedures.

Records of nonconforming work shall be maintained as part of the RMP's quality records (see clause 7.16.1). The records shall include information on the nonconforming work, actions taken, results of evaluation of the significance and extent of the nonconforming work, etc. Internal audit should include checking the effectiveness of implementation of this aspect.

7.18 Complaints

(The main text of this clause is the text of the same clause of ISO 17034:2016)

7.18.H HOKLAS Policy on Complaints

An RMP shall note that when a complaint concerning activities covered under its scope of accreditation is not satisfactorily resolved within 60 days from the date of receipt, they shall notify HKAS Executive in writing of the matter. RMPs shall also comply with the regulations on the handling of complaints given in HKAS 002.

8 Management system requirements

8.1 Options

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.2 Quality policy (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.3 General management system documentation (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.3.H HOKLAS Policy on General Management system documentation

The management system of a RMP need not be complex and its format will depend on a number of factors including the size of the RMP, number of staff members and the range, volume and complexity of the work it performs.

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

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

The RMP shall retain information within its management system that clearly details the roles of and relationships with its subcontractors and other related parties.

8.4 Control of management system documents (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.5 Control of records (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.5.H HOKLAS Policy on Control of records

HOKLAS Policy on control of quality and technical records is given in 7.16.H.

8.6 Management review (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.7 Internal audit (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.8 Actions to address risks and opportunities (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.8.H HOKLAS Policy on Actions to address risks and opportunities

The requirement that actions shall be taken against risks and opportunities highlights the need to look out for potential problems and rooms for improvement. In other words, the RMP shall take a proactive approach rather than a passive and reactive approach. For example, in addition to checking for conformity, internal audits should also identify areas of risk and improvement opportunities. Whenever potential risk or areas for improvement is observed in an audit, the impact should be assessed and action should be recommended for addressing the risk or enhancing the system. Actions may also be taken in response to staff or customer feedback and complaints. It is unlikely that this kind of actions is not identified for an extended period of time. Management commitment to continually improve the effectiveness of the management system is often a key factor in the successful implementation of this requirement. Accordingly, the RMP management should show and provide full support to staff at all levels in identifying risks and opportunities. Taking actions to address risks and opportunities should not be regarded as additional work but a part of the responsibilities of all staff members. Management should initiate appropriate action if there has been no such actions identified for an extended period of time.

8.9 Corrective action (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.9.H HOKLAS Policy on Corrective actions

It must be emphasised that corrections and corrective actions are different. ISO 9000:2005 defines correction as "action to eliminate a detected nonconformity" whereas corrective action is defined as "action to eliminate the cause of a detected nonconformity or other undesirable situation". Hence, it is necessary to determine the cause(s) of a nonconformity before any corrective action can be taken. Without identifying the cause(s), actions cannot be taken to eliminate them. It is thus important to distinguish actions that are taken to eliminate the cause(s) of the nonconformity (corrective actions) from those which are just for eliminating the nonconformity (corrections). Carrying out correction without taking proper corrective action is ineffective as the cause of the nonconformity still exists and hence the nonconformity will recur. Making correction only without taking corrective action is rarely acceptable unless extensive investigation has demonstrated convincingly that there is no underlying cause and the nonconformity will not recur.

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

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

8.10 Improvement (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

8.10.H HOKLAS Policy on Improvement

The RMP management should show and provide full support to staff at all levels in identifying areas for improvement. All staff members shall be aware of the RMP's policy and objective on improvement. The idea of continual improvement should be ingrained in all aspects of operation of the RMP. The HOKLAS Policy on Actions to address risks and opportunities given in 8.8.H also applies to improvement.

8.11 Feedback from customers (Option A)

(The main text of this clause is the text of the same clause of ISO 17034:2016)

Annex A
(informative)

Summary of production requirements for RMs and CRMs

(The main text of this annex is the text of the same annex of ISO 17034:2016)

Bibliography

(The main text of this bibliography is the text of the same bibliography of ISO 17034:2016)

Annex AA

Procedures for HOKLAS Accreditation

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

STEP 1 - INITIAL CONTACT

(i) An organisation interested in seeking accreditation contacts HKAS Executive in writing.

(ii) Appropriate documents are provided including :

HKAS 002	Regulations for HKAS Accreditation
HOKLAS 005	Application Form for Laboratory Accreditation
HOKLAS 006	Schedule of Accreditation Fees for Hong Kong Laboratories
HOKLAS 022	Technical Criteria for Accreditation of Reference Material Producers
HOKLAS 023	Assessment/Reassessment Questionnaire for Reference Material Producers

Relevant HKAS and HOKLAS Supplementary Criteria

(iii) The RMP lodges the application by providing the following to HKAS Executive

(a) A completed Application Form for Laboratory Accreditation (HOKLAS 005)

(b) A completed Assessment/Reassessment Questionnaire for Reference Material Producers (HOKLAS 023)

(c) The documents specified in the HOKLAS 023

(d) Appropriate application fees as stated in HOKLAS 006

STEP 2 - PRELIMINARY VISIT TO APPLICANT

(i) Following examination of the documentation submitted by the applicant, HKAS Executive arranges a preliminary visit to :

(a) answer any questions relating to technical criteria and regulations.

(b) identify any improvements to existing practice necessary.

(c) comment on the acceptability of the management manual.

STEP 3 - PREPARATION FOR ASSESSMENT

(i) The applicant submits the final copies of its management manuals and operating procedures.

(ii) HKAS Executive seeks any further information required from the applicant.

(iii) HKAS Executive selects suitable technical assessors to undertake the on-site assessment of the applicant.

(iv) Arrangements are made with the applicant for a mutually agreed date or dates for an on-site assessment.

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

STEP 4 - ASSESSMENT OF APPLICANT

(i) An on-site assessment is undertaken at the applicant's premises.

NOTES : All key personnel shall be available for interview during the on-site assessment.
The applicant may be asked to undertake typical activities as part of the assessment process.

(ii) If necessary, an on-site assessment of the subcontractors carrying out testing and calibration activities of the applicant may be undertaken.

On completion of the on-site assessment, the applicant management is provided with an assessment report by the assessment team which includes

- the assessment team's recommendation regarding granting of accreditation for all or part of the scope of accreditation sought by the applicant;
- list of any action which may be necessary before accreditation for all or any of the activities can be further considered;
- details of follow-up actions.

STEP 5 - ASSESSMENT OUTCOME

For reassessments and assessments for extension of accreditation within a test category for which the applicant is already accredited, the assessment report will normally be reviewed by HKAS Executive. Any amendment to the assessment report will be issued to the applicant within 10 working days of the assessment.

For initial assessments or assessment for extension to another test category, the assessment report will be reviewed by HKAS Executive as well as the Accreditation Advisroy Board (AAB). The reviewed assessment results will be issued to the applicant in an outcome letter.

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

STEP 6 - REMEDIAL ACTIONS (if required)

(i) On receipt of written reply from an applicant that all required actions have been taken, the HKAS Executive will take follow-up action. If the matters are of a minor nature, remedial actions may be confirmed through submission of supporting documents or through a brief visit by a member of HKAS Executive and where necessary with an assessor, but in some cases, a further on-site assessment may be needed.

(ii) Assuming the remedial actions are found acceptable, a decision on granting of accreditation will normally follow. A formal notification letter and a certificate of accreditation will be issued.

(iii) The laboratory may lodge an appeal to HKAS Executive against the decision made by HKAS Executive. (See Chapter 7 Complaints and Appeals in HKAS 002).

STEP 7 - AFTER ACCREDITATION

(i) After accreditation has been granted, accredited RMPs are reassessed the following year and thereafter in accordance with a reassessment plan. Surveillance visits will also be conducted. The purpose is to ensure that the standards required for continued accreditation are being maintained.

(ii) Accredited RMPs may seek to have their scope of accreditation extended or reduced or they may seek changes to their HOKLAS approved signatories. Such changes may require on-site assessment.

(iii) Accredited RMPs are required to participate in proficiency testing programmes specified by HKAS (where appropriate).

(iv) Accredited RMPs are required under HKAS regulations to notify HKAS Executive immediately in writing of any changes which may affect their continued compliance with HKAS regulations or HOKLAS requirements.

The following list, which is not exhaustive, gives examples of such changes:

(a) change in ownership or name of the accredited organisation including the change in legal, commercial or organisational status, e.g. mergers, company dissolution, bankruptcies, compulsory or voluntary liquidation or any other matters concerning the Official Receiver;

(b) change in its organisational structure and managerial staff;

(c) change of the approved signatories;

(d) change in the organisational policies, where relevant;

(e) change in its registered address or any premises of the organisation where accredited activities are to be carried out;

(f) change in working procedures and resources including personnel, equipment, facilities, working environment, where significant;

(g) change in the nature of the work performed by an accredited organisation, e.g. a critical test which was performed by a subcontrator is now performed by the accredited RMP; and,

(h) any other matters that may affect the organisation's capability, or its scope of accreditation or its conformity with the accreditation criteria.

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 Regulations for HKAS Accreditation. However, an organisation shall note that it may be necessary to pass the HKAS's 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.

Annex AB
(informative**)**

List of references

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

A. ISO

ISO 5725-1	Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions
ISO 5725-2	Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
ISO 5725-3	Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate precision and alternative designs for collaborative studies
ISO 5725-4	Accuracy (trueness and precision) of measurement methods and results – Part 4: Basic methods for the determination of the trueness of a standard measurement method
ISO 5725-5	Accuracy (trueness and precision) of measurement methods and results - Part 5: Alternative methods for the determination of the precision of a standard measurement method
ISO 5725-6	Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values
ISO 9000	Quality management systems – Fundamentals and vocabulary
ISO 9001	Quality management systems – Requirements
ISO 10012	Measurement management systems – Requirements for measurement processes and measuring equipment
ISO/IEC 17011	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ISO 19011	Guidelines for auditing management systems
ISO Guide 30	Reference materials – Selected terms and definitions

ISO 33401	Reference materials – Contents of certificates, labels and accompanying documentation
ISO 33403	Reference materials – Requirements and recommendations for use
ISO 33405	Reference materials – Approaches for characterisation and assessment of homogeneity and stability
ISO/TR 16476	Reference materials – Establishing and expressing metrological traceability of quantity values assigned to reference materials
ISO/IEC 17043	Conformity assessment – General requirements for the competence of proficiency testing providers
ISO Guide 98-3	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement, jointly published by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML

B. International Laboratory Accreditation Cooperation (ILAC) (Website : ilac.org)

Guidance Series (G series)

ILAC G17	ILAC Guidelines for Measurement Uncertainty in Testing
ILAC G24	Guidelines for the Determination of Recalibration Intervals of Measuring Equipment

Policy Series (P series)

ILAC P5	ILAC Mutual Recognition Arrangement: Scope and Obligation
ILAC P8	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies
ILAC P9	ILAC Policy for Proficiency Testing and/or Interlaboratory Comparisons other than Proficiency Testing
ILAC P10	ILAC Policy on Metrological Traceability of Measurement Results

C. Asia Pacific Accreditation Cooperation (APAC) (Website : www.apac-accreditation.org)

APAC TEC1-008 APAC Guidance on Accreditation of RMPs

Annex AC
(informative)

Variations to ISO 17034:2016 for HOKLAS 022:2017

This Annex lists out all variations of this booklet to ISO 17034:2016 as follows:

Clause	**Modifications**
Foreword	Replaced by 'HKAS Introduction' and i, ii and iii under 'HKAS Introduction'.
4 Contractual requirements	Add 4.1.H 'HOKLAS Policy on Contractual requirements'
5 Structural requirements	Add 5.H 'HOKLAS Policy on Structural requirements'
6 Resource requirements	Add 6.1.H 'HOKLAS Policy on Personnel'
	Add 6.2.H 'HOKLAS Policy on Subcontracting'
	Add 6.3.H 'HOKLAS Policy on Provision of equipment, services and supplies'
	Add 6.4.H 'HOKLAS Policy on Facilities and environmental conditions'
7 Technical and production requirements	Add 7.1.H 'HOKLAS Policy on General requirements'
	Add 7.2.H 'HOKLAS Policy on Production planning'
	Add 7.3.H 'HOKLAS Policy on Production control'
	Add 7.4.H 'HOKLAS Policy on Material handling and storage'
	Add 7.5.H 'HOKLAS Policy on Material processing'
	Add 7.6.H 'HOKLAS Policy on Measurement procedures'
	Add 7.7.H 'HOKLAS Policy on Measuring equipment'
	Add 7.8.H 'HOKLAS Policy on Data Integrity and evaluation'
	Add 7.9.H 'HOKLAS Policy on Metrological traceability of certified values'
	Add 7.10.H 'HOKLAS Policy on Assessment of homogeneity'
	Add 7.11.H 'HOKLAS Policy on Assessment and monitoring of stability'
	Add 7.12.H 'HOKLAS Policy on Characterisation'
	Add 7.13.H 'HOKLAS Policy on Assignment of property values and their uncertainties'
	Add 7.14.H 'HOKLAS Policy on RM documents and labels'
	Add 7.16.H 'HOKLAS Policy on Control of quality and technical records'
	Add 7.17.H 'HOKLAS Policy on Management of nonconforming work'
	Add 7.18.H 'HOKLAS Policy on Complaints'

Clause	**Modifications**
8 Management system requirements	Add 8.3.H ‘HOKLAS Policy on General Management system documentation’
	Add 8.5.H ‘HOKLAS Policy on Control of records’
	Add 8.6.H ‘HOKLAS Policy on Management review’
	Add 8.7.H ‘HOKLAS Policy on Internal audits’
	Add 8.8.H ‘HOKLAS Policy on Actions to address risks and opportunities’
	Add 8.9.H ‘HOKLAS Policy on Corrective action’
	Add 8.10.H ‘HOKLAS Policy on Improvement’
--	Add Annex AA ‘Procedures for HOKLAS Accreditation’
--	Add Annex AB ‘List of references’
--	Add Annex AC ‘Variations to ISO 17034:2016 for HOKLAS 022:2017’

Explanation:

HOKLAS policies added serve as additional explanation of the requirements of ISO 17034:2016 and shall be regarded as mandatory under Hong Kong Laboratory Accreditation Scheme (HOKLAS).