HOKLAS 023 Annex II

Checklist

The Reference Material Producer (RMP) shall complete the following checklist, which will be used for the assessment of the RMP's conformity with HOKLAS requirements.

The checklist consists of questions based on the requirements of HKAS 002, HOKLAS 022:2017 and HOKLAS Supplementary Criteria No. 39. For further information, please refer to the clause as listed in the column for the corresponding document.

The RMP should indicate under the "QM Clause" column, for every question, the relevant clause(s) in their management system manual and operation procedures manual or other related documents that cover that requirement.

The columns headed '*' and 'OK' for internal use of HKAS Executive.

A softcopy of this completed checklist shall be provided to HKAS Executive by email or other means.

HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
General requirements					
Contractual matters					
Has your RMP reviewed request, tender or contract concerning the production of an RM, following documented policies and procedures established, to ensure that: a) the requirements for RMs and their production are adequately defined, documented and understood; and b) your RMP has the capability and resources to meet the requirements?	4.1.1		☐		
Have these reviews included any work that needs to be subcontracted?	4.1.2		☐		
Has your RMP maintained records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work?	4.1.3		☐		
Impartiality					
Is your RMP structured and managed so as to safeguard impartiality?	4.2.1		☐		
Does your RMP have arrangements to ensure that your management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of its work?	4.2.2a		☐		
Has your RMP identified risks to impartiality on an on-going basis? Has your RMP included those risks that arise from its activities, or from its relationships, or from the relationships of its personnel; however, such relationships do not necessarily present your RMP with a risk to impartiality.	4.2.2b		☐		
Is your RMP able to demonstrate, if a risk to impartiality is identified, how such risk is eliminated or minimized?	4.2.2c		☐		
Does your RMP have top management commitment to impartiality?	4.2.2d		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
General requirements (continued)					
Confidentiality					
Is your RMP responsible for and does it treat in an appropriate manner all information obtained, including confidential information? Where information is received from another individual or body, have your RMP regarded such information as confidential unless the individual or body concerned places the information in the public domain or agrees to its disclosure to others?	4.3.1		☐		
When your RMP is required by law or authorised by contractual arrangements to release confidential information, has the individual or the body concerned, unless prohibited by law, been notified of the information provided?	4.3.2		☐		
Structural requirements					
Is your RMP a legal entity, or a defined part of a legal entity, that can be held responsible for all your activities related to the production of RMs?	5.1		☐		
Is your RMP organised and operated in such a way that it meets all the applicable requirements of HOKLAS 022, whether carrying out work at its permanent facilities or at other sites (including associated temporary or mobile facilities)?	5.2		☐		
Does your RMP have a description of its legal status, define its organisational and management structure, its place in any parent organisation and the relations between management, technical operations, support services and subcontractors?	5.3a		☐		
Has your RMP defined the parts of the organisation covered by the management system for the production of RMs?	5.3b		☐		
Has your RMP specified the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of RMs produced?	5.3c		☐		
Does your RMP have managerial personnel, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures?	5.3d		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Structural requirements (continued)					
Does your RMP have technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production?	5.3e		☐		
Has your RMP appointed personnel (however named) who, irrespective of other duties and responsibilities, have defined responsibility and authority for ensuring that the requirements of HOKLAS 022 are implemented and followed at all times? Do these appointed personnel have direct access to the highest level of management at which decisions are taken on RM production policy or resources?	5.3f		☐		
Does your RMP have adequate provision (e.g. insurance or reserves) to cover liabilities arising from your activities?	5.3g		☐		
Has your RMP management ensured that internal and external communication mechanisms are established?	5.4a		☐		
Has your RMP management ensured that communication takes place regarding the effectiveness of the management system?	5.4b		☐		
Has your RMP management ensured that the importance of meeting customer and other requirements is communicated to the RMP personnel?	5.4c		☐		
Resource requirements					
Personnel					
Has your RMP ensured that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system?	6.1.1		☐		
Have personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf, complied with the policies and procedures for management of confidential information that are set by the RMP?	6.1.2		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Resource requirements (continued)					
Personnel (continued)					
Has your RMP ensured the competence of all personnel operating under its management system, including technical management personnel, who undertake activities relating to the production of each particular type of RM? Are there sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions?	6.1.3	●	☐		
Does your RMP have procedures for identifying training needs and providing training of personnel? Is the training programme relevant to the present and anticipated tasks of your RMP?	6.1.4	●	☐		
Has your RMP maintained records of job description for its personnel involved in RM production activities?	6.1.5	●	☐		
Has your RMP authorised competent personnel to perform particular activities relating to RM production? Has your RMP maintained records of the authorizations, competence, educational and professional qualifications of those personnel? These records shall provide evidence that individuals have been adequately trained and that their competence to perform particular activities in the RM production has been assessed. Is this information readily available and does it include the date on which the authorisation and/or competence has been confirmed?	6.1.6	●	☐		
Subcontracting					
Where subcontractors are used to undertake part of the production, including sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM, does your RMP have procedures to ensure that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of HOKLAS 022 and other appropriate standards?	6.2.1	●	☐		
Does your RMP select subcontractors on the basis of their ability to meet the requirements stipulated by your RMP?	6.2.2	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Resource requirements (continued)					
Subcontracting (continued)					
Has your RMP ensured that the following processes are not subcontracted? - the production planning; - the selection of subcontractors; - the assignment of property values and their uncertainties; - the authorization of property values and their uncertainties; - the authorization of RM documents.	6.2.3	●	☐		
Has your RMP established and maintained procedures to assess that all tasks performed by subcontractors comply with the requirements set by your RMP and with any relevant clauses of HOKLAS 022?	6.2.4	●	☐		
Has your RMP established and maintained evidence of the subcontractor's competence, including records of evaluations and any audits made of their capability to carry out contracted tasks?	6.2.5	●	☐		
Where the competence of subcontractors cannot be ascertained via provision of documentary evidence, has your RMP evaluated the competence of the subcontractor or supervised the operations carried out by the subcontractor?	6.2.6	●	☐		
Has your RMP ensured that results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data?	6.2.7	●	☐		
When working with subcontractors, does your RMP have personnel operating under your RMP's management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity?	6.2.8	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Resource requirements (continued)					
Provision of equipment, services and supplies					
Does your RMP have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced?	6.3.1	●	☐		
Has your RMP used only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs produced?	6.3.2	●	☐		
Has your RMP ensured that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RMP production activities?	6.3.3	●	☐		
Has your RMP maintained records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data?	6.3.4	●	☐		
Facilities and environmental conditions					
Has your RMP ensured that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable)?	6.4.1	●	☐		
When the environmental conditions could have an adverse effect on the RM, have the environmental conditions in which the RM production activities are undertaken been monitored with appropriately calibrated equipment, controlled and recorded, such that results and processes are not adversely affected?	6.4.2	●	☐		
Have RM processing and calibration and testing areas, in addition to satisfying requirements for humidity and temperature, been protected from other environmental factors such as incompatible activities, vibration, aerosols, airborne dust and microbiological contamination, magnetic fields, light and electromagnetic and/or ionising radiation , where appropriate,?	6.4.3	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Resource requirements (continued)					
Facilities and environmental conditions (continued)					
Have access to and use of areas been controlled as appropriate to maintain the quality of the RMs?	6.4.4	●	☐		
Technical and production requirements					
General requirements					
Has your RMP addressed the requirements in clause 7 for the production of RMs, including CRMs?	7.1	●	☐		
Production planning					
Has your RMP identified and planned those processes that directly affect the quality of RM production, and is the production plan documented?	7.2.1	●	☐		
Has technical input of subcontractors involved specified and the required information been documented and regularly reviewed?	7.2.2	●	☐		
Has your RMP addressed the following during the planning stage?					
a) material selection (including, where appropriate, sampling);	7.2.3a	●	☐		
b) verification of the identity of the material;	7.2.3b	●	☐		
c) maintaining suitable environments for all aspects of production;	7.2.3c	●	☐		
d) material processing;	7.2.3d	●	☐		
e) choice of measurement procedures;	7.2.3e	●	☐		
f) validation of measurement procedures;	7.2.3f	●	☐		
g) verification and calibration of measuring equipment;	7.2.3g	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Production planning (continued)					
h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling;	7.2.3h	●	☐		
i) specification of acceptance criteria for, and assessment and monitoring of, stability, including sampling;	7.2.3i	●	☐		
j) designing and organising appropriate characterization, including sampling;	7.2.3j	●	☐		
k) assessing commutability (where appropriate);	7.2.3k	●	☐		
l) assigning property values;	7.2.3l	●	☐		
m) establishing uncertainty budgets and estimating uncertainties of certified value(s);	7.2.3m	●	☐		
n) defining acceptance criteria for measurand levels and their uncertainties;	7.2.3n	●	☐		
o) establishing metrological traceability of measurement result(s) and certified value(s);	7.2.3o	●	☐		
p) issuing RM documents;	7.2.3p	●	☐		
q) ensuring adequate storage facilities and conditions;	7.2.3q	●	☐		
r) ensuring appropriate labelling and packaging of the RMs;	7.2.3r	●	☐		
s) ensuring appropriate transport arrangements;	7.2.3s	●	☐		
t) ensuring post-production stability monitoring, if applicable; and	7.2.3t	●	☐		
u) ensuring an adequate post-distribution service for RM users.	7.2.3u	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Production planning (continued)					
Where multiple batches of RMs with equivalent properties are produced by using similar starting materials and by applying the sample procedures, has any verification been done to ensure that information obtained from previous batches remains applicable for the new batch?	7.2.4	●	☐		
Production control					
Has your RMP verified that the production plan has been implemented as specified, and are deviations from the plan documented and approved?	7.3	●	☐		
Material handling and storage					
Has your RMP made arrangements to ensure the integrity of its candidate RMs and RMs throughout the production process? Are precautions taken against adverse environmental influences and possible contamination of the candidate RM during its processing?	7.4.1	●	☐		
Has your RMP identified, preserved and separated candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution to users?	7.4.2	●	☐		
Has your RMP ensured adequate packaging of all RMs (e.g. where appropriate, use light-shielding, air-free, moisture-free or inert-gas packaging) and provided secure storage areas/stock rooms which prevent damage or deterioration of any item or material between characterization and distribution?	7.4.3	●	☐		
Is the condition of all RMs assessed at appropriate intervals throughout the storage period, in order to detect possible deterioration?	7.4.4	●	☐		
Has your RMP controlled packaging and labelling processes to the extent necessary to ensure conformity with safety and transport requirements? Have procedures for transport to the customer been defined?	7.4.5	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Material handling and storage (continued)					
Has your RMP taken measures to ensure that the integrity of each individual RM unit is maintained until the seal, if any, has been broken or up to the point when first used?	7.4.6	●	☐		
Material processing					
Has your RMP established procedures to ensure that the material has undergone adequate processing for its intended use? Have your RMP's procedures for material processing addressed at least the following:	7.5.1	●	☐		
a) qualitative analysis for verification of material type and/or identity;	7.5.1a	●	☐		
b) synthesis, purification (e.g. distillation, extraction), incubation, and transformation into the final form (e.g. machining, grinding, blending, sieving and riffling, extrusion, melting);	7.5.1b	●	☐		
c) homogenization;	7.5.1c	●	☐		
d) proper handling (e.g. protection from contamination and use of insert equipment)	7.5.1d	●	☐		
e) measurements for control of material processing (e.g. particle size distribution, moisture content);	7.5.1e	●	☐		
f) pre-treatment, cleaning or sterilization of processing equipment and sample containers;	7.5.1f	●	☐		
g) stabilization of material (e.g. drying, irradiation, sterilization);	7.5.1g	●	☐		
h) packaging (e.g. bottling, ampouling) of the material; and	7.5.1h	●	☐		
i) safety precautions?	7.5.1i	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Material processing (continued)					
Has eequipment used in material processing been operated in accordance with documented procedures?	7.5.2	●	☐		
Measurement procedures					
Has your RMP ensured that the relevant requirements of ISO/IEC 17025 (or ISO 15189 in case of tests performed in the medical field) are met with respect to calibration and testing? Are these activities, where appropriate, consistent with the required accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned?	7.6	●	☐		
Measuring equipment					
Has your RMP ensured that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025 (or ISO 15189 in case of tests performed in the medical field)?	7.7	●	☐		
Data integrity and evaluation					
Has your RMP ensured that all calculations and data transfers are subject to appropriate checks?	7.8.1	●	☐		
Has your RMP ensured that:					
a) a computer software developed in-house or off-the-shelf software further developed for specific use is validated and shown to be adequate for use;	7.8.2a	●	☐		
b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing;	7.8.2b	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Data integrity and evaluation (continued)					
c) equipment and software are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain data integrity; and	7.8.2c	●	☐		
d) appropriate procedures are established and implemented for the maintenance of data security, including prevention of unauthorized access and changes to records, including computer records?	7.8.2d	●	☐		
Have statistical procedures used in monitoring, testing, calibration or value assignment of RMs been appropriate for their application?	7.8.3	●	☐		
Metrological traceability of certified values					
When producing CRMs, has the metrological traceability of the certified values been established in compliance with the relevant requirements of ISO/IEC 17025 (or ISO 15189 in case of tests performed in the medical field)? Has your RMP provided evidence of the metrological traceability of the certified value to a stated reference?	7.9.1	●	☐		
Is the stated reference a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard?	7.9.2	●	☐		
Where it is technically possible, has your RMP demonstrated that the stated reference is traceable to the International System of Units (SI).	7.9.3	●	☐		
Where metrological traceability to the SI units is not technically possible, has your RMP demonstrated metrological traceability to an appropriate reference (see traceability requirements in ISO/IEC 17025)?	7.9.4	●	☐		
For studies in which the values need to be traceable to a higher order reference system (e.g. characterization studies with measurements under reproducibility conditions), has it been ensured that the measurements are calibrated with standards with metrologically traceable values?	7.9.5	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Metrological traceability of certified values (continued)					
Do secondary parameters that have a significant influence on the certified value or its uncertainty (e.g. temperature and humidity) have evidence of metrological traceability?	7.9.6	●	☐		
Assessment of homogeneity					
Has your RMP carried out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose?	7.10.1	●	☐		
When the material is produced in multiple batches, has the equivalence of the batches been demonstrated or the homogeneity of each batch been evaluated separately?	7.10.2	●	☐		
Have validated measurement procedures been selected so that the precision and selectively are fit for the purpose required?	7.10.3	●	☐		
Where homogeneity needs to be determined experimentally, has your RMP determined the homogeneity for every property of interest unless it can be shown, using scientific evidence or previous experience, that particular groups of properties are sufficiently closely associated that measurement of one property in such a group furnishes evidence of homogeneity for other properties in the same group?	7.10.4	●	☐		
For certified values, has homogeneity been quantified as an uncertainty contribution to the certified value or shown to be a negligible contribution to the uncertainty of the certified value?	7.10.5	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Assessment and monitoring of stability					
Has your RMP					
a) assessed, by experimentation if necessary, the stability of all relevant properties of an RM under proposed storage conditions and choose pre-treatment, packaging and storage conditions in accordance with the results of the assessment;	7.11.1a	●	☐		
b) assessed, by experimentation if necessary, the stability of all relevant properties of an RM under proposed conditions of transport, and choose transport conditions to maintain stability during transport;	7.11.1b	●	☐		
c) established any necessary advice on storage and use of the material to maintain stability at the user's premises;	7.11.1c	●	☐		
d) selected a scheme for monitoring the stability of materials held in long term storage that permits prompt detection of change, taking into account the possible rate of change;	7.11.1d	●	☐		
e) where the stability of a certified value cannot be ensured, made due allowance in the stated uncertainty for possible change in the value prior to use or, where the change with time can be predicted, provided a means of correcting the certified value and its uncertainty for the expected change over time;	7.11.1e	●	☐		
f) where repeated sampling from an RM unit or repeated use of an entire RM unit is permitted by the instructions for use, assessed the possible effects on the stability of the material and take appropriate action?	7.11.1f	●	☐		
Has your RMP conducted an experimental assessment of stability before release unless there is evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions?	7.11.2	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Assessment and monitoring of stability (continued)					
Where an RM is produced in multiple batches that are not individually tested for stability, has your RMP verified the stability of a sufficient number of different batches experimentally to provide confidence in the stability of all batches?	7.11.3	●	☐		
Characterisation					
Where property values are assigned, has characterisation of the RM been carried out?	7.12.1	●	☐		
Has your RMP clearly defined whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure?	7.12.2	●	☐		
Has your RMP selected a characterisation strategy appropriate for the intended use of the RM?	7.12.3	●	☐		
Has your RMP specified the characterization study so that the properties of interest are each characterised with appropriate traceability and sufficient reliability whether or not traceability and measurement uncertainty are reported on the RM documentation? To this end, the RMP shall:	7.12.4	●	☐		
Has your RMP documented a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterisation?	7.12.4a	●	☐		
For certified values, has your RMP demonstrated the competence of each involved laboratory by using data from each laboratory that was not obtained on the material to be characterised?	7.12.4b	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Characterisation (continued)					
When evaluating the characterisation data, has your RMP performed a technical evaluation of the data and documents involved in characterisation to confirm adherence to the measurement plan as defined in HOKLAS 022 7.12.4, bullet a), and, in the case of deviations from the plan, assessed whether the deviation necessitates exclusion of the data from characterization.	7.12.5	●	☐		
Assignment of property values and their uncertainties					
Has your RMP used documented procedures for the assignment of property values?	7.13.1	●	☐		
Have these procedures included, as appropriate:					
a) details of the experimental designs and statistical techniques used;	7.13.2a	●	☐		
b) policies on treatment and investigation of anomalous results, including outliers;	7.13.2b	●	☐		
c) whether weighting techniques are used for contributions to assigned property values derived from different procedures or laboratories with different measurement uncertainties;	7.13.2c	●	☐		
d) the approach used to assign uncertainties to the property values;	7.13.2d	●	☐		
e) any other significant factors that may affect the assignment of property values?	7.13.2e	●	☐		
Has your RMP taken due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest?	7.13.3	●	☐		
Have outliers not excluded solely based on statistical evidence until they have been investigated and, where possible, the reasons for the discrepancies identified? Were robust statistical methods applied where appropriate?	7.13.4	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Assignment of property values and their uncertainties (continued)					
For certified values, has your RMP identified the uncertainty contributions to be included in the assigned uncertainty?	7.13.5	●	☐		
For certified values, has your RMP considered, at a minimum, uncertainty contributions of each of the following:					
a) characterization, including any difference between multiple procedures used for characterization;	7.13.6a	●	☐		
b) between-unit and within-unit inhomogeneity;	7.13.6b	●	☐		
c) changes of property values during storage;	7.13.6c	●	☐		
d) changes of property values during transport?	7.13.6d	●	☐		
RM documents and labels					
Has your RMP issued and made available an RM certificate for CRMs and product information sheet for other RMs?	7.14.1	●	☐		
Have the contents of RM certificates and product information sheets included the following:					
a) title of the document;	7.14.2a	●	☐		
b) unique identifier of the RM;	7.14.2b	●	☐		
c) the name of the RM;	7.14.2c	●	☐		
d) name and contact details of the RMP;	7.14.2d	●	☐		
e) intended use;	7.14.2e	●	☐		

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Technical and production requirements (continued)					
RM documents and labels (continued)					
f) minimum sample size (whenever applicable);	7.14.2f	●	☐		
g) period of validity;	7.14.2g	●	☐		
h) storage information;	7.14.2h	●	☐		
i) instructions for handling and use that are sufficient to ensure the integrity of the material;	7.14.2i	●	☐		
j) page number and the total number of pages;	7.14.2j	●	☐		
k) document version;	7.14.2k	●	☐		
l) information on commutability of the material (where appropriate)?	7.14.2l	●	☐		
In addition to the above, have RM certificates contained the following additional information:					
a) description of the CRM;	7.14.3a	●	☐		
b) property of interest, property value and associated uncertainty;	7.14.3b	●	☐		
c) measurement procedure for operationally defined measurands;	7.14.3c	●	☐		
d) metrological traceability of the certified values;	7.14.3d	●	☐		
e) name and function of RMP's approving officer?	7.14.3e	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
RM documents and labels (continued)					
Has the RM label been securely attached to the product container of an individual RM unit, and designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM, i.e. the period during which the RM is available from the RMP extended by the period of validity of its certificate?	7.14.4	●	☐		
Has the RM label identified the material, the RMP, its batch, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as the individual sample number), where appropriate, to its product information sheet or RM certificate?	7.14.4	●	☐		
Where the physical size of the RM unit limits the amount of information that can be contained on the label, has the information been included elsewhere (e.g. in an RM document) and a unique identifier has been given?	7.14.5	●	☐		
Distribution service					
Has the distribution process been specified including precautions needed to avoid deterioration of the RM (see HOKLAS 022 7.11.1)? Has your RMP determined the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance?	7.15.1	●	☐		
Has your RMP maintained up-to-date records of all RM sales and distribution?	7.15.2	●	☐		
Has your RMP offered to users reasonable guidance and technical support related to the RMs produced?	7.15.3	●	☐		
Has your RMP employed best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet?	7.15.4	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Distribution service (continued)					
Where RMs subject to resale through a distributor with whom your RMP has a contractual relationship, has your RMP passed on to the authorised distributor all necessary information to ensure that an effective post-distribution service is maintained and made arrangements with the distributor to ensure that its activities are executed in accordance with the relevant clauses of HOKLAS 022?	7.15.5	●	☐		
Control of quality and technical records					
Has your RMP established and maintained procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records?	7.16.1	●	☐		
Has your RMP ensured that it has recorded such information that might be needed in a future dispute situation?	7.16.2	●	☐		
Are all records legible and have been stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss? Has retention time of records been established in accordance with customer or other relevant requirements, and has been documented?	7.16.3	●	☐		
When mistakes occur in records, has each mistake been crossed out, not erased, made illegible or deleted, and the correct information entered alongside? Have all such alterations to records been signed or initialled, and dated by the person making the correction? In the case of records stored electronically, have equivalent measures been taken to avoid the loss or change of original information?	7.16.4	●	☐		
Have all records been held securely and, where appropriate, in confidence?	7.16.5	●	☐		
Has your RMP had procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data?	7.16.6	●	☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Control of quality and technical records (continued)					
Has your RMP arranged for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the RM remains valid?	7.16.7	●	☐		
Have the results of each calibration or measurement (or series of either) carried out by your RMP or by a subcontractor reported in accordance with ISO/IEC 17025?	7.16.8	●	☐		
Management of non-conforming work					
Has your RMP had procedures that shall be implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer?	7.17.1		☐		
Have the procedures ensured that:					
a) responsibilities and authorities for the management of non-conforming work are designated;	7.17.2a		☐		
b) the actions to be taken when any non-conforming work and/or RMs are identified including root-cause analysis and a system that ensures that they are effectively implemented;	7.17.2b		☐		
c) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action;	7.17.2c		☐		
d) where necessary, work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld;	7.17.2d		☐		
e) remedial actions such as customer notifications are taken within a defined time-frame;	7.17.2e		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Management of non-conforming work (continued)					
f) where necessary, best efforts are employed to notify the users of the possible effects, within an appropriate period and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled;	7.17.2f		☐		
g) the responsibility for authorization of the resumption of work is defined;	7.17.2g		☐		
h) where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken?	7.17.2h		☐		
Has the decision on recall of RMs been taken in a timely manner to limit the use of non-conforming RMs?	7.17.3		☐		
Complaints					
Has the RMP hed a documented process to receive, evaluate and make decisions on complaints?	7.18.1		☐		
Is a description of the handling process for complaints available to any interested party on request?	7.18.2		☐		
Upon receipt of a complaint, has your RMP confirmed whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it?	7.18.3		☐		
Is your RMP responsible for all decisions at all levels of the handling process for complaints?	7.18.4		☐		
Have investigation and decision on complaints not resulted in any discriminatory actions?	7.18.5		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Technical and production requirements (continued)					
Complaints (Continued)					
Has the process for handling complaints included at least the following elements and methods:					
a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;	7.18.6a		☐		
b) tracking and recording complaints, including actions undertaken to resolve them;	7.18.6b		☐		
c) ensuring that any appropriate action is taken?	7.18.6c		☐		
When receiving the complaint, has your RMP been responsible for gathering and verifying all necessary information to validate the complaint?	7.18.7		☐		
Whenever possible, has your RMP acknowledged receipt of the complaint, and provide the complainant with progress reports and the outcome?	7.18.8		☐		
Has the decision to be communicated to the complainant been made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question?	7.18.9		☐		
Has your RMP given formal notice of the end of the complaint handling process to the complainant whenever possible?	7.18.10		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements					
Options - General					
Has your RMP established and maintained a management system that is capable of achieving the consistent fulfilment of the requirements of HOKLAS 022 in accordance with either Option A or Option B below?	8.1.1		☐		
Option A					
Has your RMP established, implemented and maintained a documented management system that addresses the scope of its RM production activities, which covers the type, range and scale of the RM production it undertakes?	8.1.2.1		☐		
Has your RMP defined and documented its scope of activities?	8.1.2.2		☐		
Has your management system addressed the following: - quality policy (see 8.2); - general management system documentation (see 8.3); - control of management system documents (see 8.4); - control of records (see 8.5); - management review (see 8.6); - internal audit (see 8.7); - actions to address risks and opportunities (see 8.8); - corrective actions (see 8.9); - improvement (see 8.10); - feedback from customers (see 8.11)?	8.1.2.3		☐		
Option B					
Has your RMP established and maintained a management system, in accordance with the requirements of ISO 9001, and is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of HOKLAS 022?	8.1.3		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Quality policy (Option A)					
Has your RMP defined and documented its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production, storage and distribution procedures?	8.2.1		☐		
Has your RMP's management system policies related to quality, including a quality policy statement, been documented under the authority of the top management?	8.2.2		☐		
Has your quality policy included the following commitments:					
a) to produce RMs which conform to the requirements of this International Standard;	8.2.3a		☐		
b) to conduct all testing and calibration in support of the production of RMs in compliance with the requirements of ISO/IEC 17025;	8.2.3b		☐		
c) to require that all personnel concerned with the quality of any aspect of RM production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work;	8.2.3c		☐		
d) for the management to continually improve the effectiveness of the management system and to be committed to good professional practice and to the quality of its RMs?	8.2.3d		☐		
Have the overall objectives sbeen reviewed during the management reviews?	8.2.4		☐		
General management system documentation (Option A)					
Has your RMP documented all of its systems, programmes, procedures, instructions, findings, etc., to the extent necessary to ensure the quality of the RMs produced? Has documentation used in this management system been communicated to, understood by, available to and implemented by all personnel concerned?	8.3		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Control of management system documents (Option A)					
Has your RMP controlled the documents (internal and external) that relate to the fulfilment of HOKLAS 022?	8.4.1		☐		
Has your RMP ensured that:					
a) documents are approved for adequacy prior to issue by authorized personnel;	8.4.2a		☐		
b) documents are periodically reviewed and updated (as necessary);	8.4.2b		☐		
c) changes and the current revision status of documents are identified;	8.4.2c		☐		
d) relevant versions of applicable documents are available at points of use;	8.4.2d		☐		
e) documents are uniquely identified and where necessary their distribution controlled;	8.4.2e		☐		
f) the unintended use of obsolete documents is prevented, and suitable identification applied to them if they are retained for any purpose?	8.4.2f		☐		
Control of records (Option A)					
Has your RMP established procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of HOKLAS 022?	8.5.1		☐		
Has your RMP established procedures for retaining records for a period consistent with its contractual and legal obligations? Has access to these records been consistent with the confidentiality arrangements?	8.5.2		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Management review (Option A)					
Has your RMP's top management, in accordance with a predetermined schedule and procedure, periodically conducted a review of its management system and production processes to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements?	8.6.1		☐		
Note: A typical period for conducting a management review is once every year.					
Has the review taken account of, but not be limited to:					
a) the suitability of policies and procedures;	8.6.1a		☐		
b) reports from managerial and supervisory personnel;	8.6.1b		☐		
c) the outcome of internal audits;	8.6.1c		☐		
d) corrective actions;	8.6.1d		☐		
e) result of risk identification;	8.6.1e		☐		
f) assessments by external bodies;	8.6.1f		☐		
g) changes in scale and type of work;	8.6.1g		☐		
h) feedback from customers	8.6.1h		☐		
i) recommendations for improvement including complaints;	8.6.1i		☐		
j) other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the RMs;	8.6.1j		☐		
k) the quality objectives (see 8.2)	8.6.1k		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Management review (Option A) (continued)					
Have findings from management reviews and the actions that arise from them been recorded? Has the management ensured that these actions are discharged within an appropriate and agreed timescale?	8.6.2		☐		
Internal audit (Option A)					
Has your RMP periodically and in accordance with a predetermined schedule and procedure conducted internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the requirements of HOKLAS 022? Has the internal audit programme addressed all elements of the management system, including the technical and production activities leading to the finished product (RM)? Has your RMP planned and organised audits as required by the schedule and requested by management? Have such audits been carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited? Have the personnel not audited their own activities?	8.7.1		☐		
When audit findings cast doubt on the effectiveness of the operations, or on the integrity of the RMs, or on the correctness of their documentation, has your RMP taken timely corrective actions and shall notify, in writing, its customers whose activities may have been adversely affected?	8.7.2		☐		
Have all audit findings and corrective actions that arise from them been recorded? Has your RMP's management ensured that these actions are discharged within an appropriate and agreed timescale?	8.7.3		☐		
Have follow-up activities verified and recorded the implementation and effectiveness of the corrective actions taken?	8.7.4		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Actions to address risks and opportunities (Option A)					
Has your RMP considered the risks and opportunities to:					
a) give assurance that the management system can achieve its intended result(s);	8.8.1a		☐		
b) enhance desirable effects;	8.8.1b		☐		
c) prevent, or reduce, undesired effects;	8.8.1c		☐		
d) achieve improvement?	8.8.1d		☐		
Has your RMP taken actions to:					
a) address these risks and opportunities;	8.8.2a		☐		
b) integrate and implement the actions into its management system processes;	8.8.2b		☐		
c) evaluate the effectiveness of these actions?	8.8.2c		☐		
Have actions taken to address risks and opportunities been proportionate to the potential impact on the quality of the RM production and service?	8.8.3		☐		
Corrective action (Option A)					
Has your RMP established a policy and procedure(s) and designated appropriate authorities for implementing corrective actions when non-conforming RMs, non-conforming work on the production of RMs, or departures from the policies and procedures in the management system have been identified?	8.9.1		☐		
Are corrective action procedures started with an investigation to identify the root causes of the problem? Has the investigation been conducted for both in-house production and, where required, any work performed by subcontractors?	8.9.2		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Corrective action (Option A) (continued)					
Where corrective actions are needed, has your RMP identified potential corrective actions? Has it selected and implemented the action(s) most likely to eliminate the problem and to prevent recurrence?	8.9.3.1		☐		
Has corrective action taken to eliminate the causes of non-conformities or other departures been appropriate to the magnitude of the problem and commensurate with the risks encountered?	8.9.3.2		☐		
Has your RMP documented and implemented any required changes to the operational procedures resulting from corrective action investigations?	8.9.3.3		☐		
After having implemented the corrective actions, has your RMP monitored the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems?	8.9.4		☐		
Where the identification of non-conformities or departures casts doubt on the RMP's compliance with its own policies and procedures, or on its compliance with HOKLAS 022, has your RMP ensured that the appropriate areas of activity are audited in accordance with 7.17, as soon as possible?	8.9.5		☐		
Improvement (Option A)					
Has your RMP continually improved the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	8.10.1		☐		
Have required improvements and potential sources of non-conformities, either technical or concerning the management system, been identified? When improvement opportunities are identified or if improvement is required, have action plans been developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement.	8.10.2		☐		

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HOKLAS 022:2017 Requirement	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Management system requirements (continued)					
Improvement (Option A) (continued)					
After the implementation of the improvement, has your RMP monitored the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action?	8.10.3		☐		
Feedback from customers (Option A)					
Has your RMP sought feedback, both positive and negative, from its customers? Has the feedback beene used and analysed to improve the management system, RM production activities and customer service?	8.11		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
The obligations of an accredited organisation					
After obtaining accreditation, will your organisation at all times:-					
(a) conform with the accreditation criteria, including accreditation regulations specified in HKAS 002 and HOKLAS Supplementary Criteria No.39, technical and non-technical requirements and other conditions as specified by HKAS Executive under your terms of accreditation;	HKAS 002 5.1a		☐		
(b) represent honestly and truthfully to any person concerned that it is only accredited for activities stated in the scope of accreditation;	HKAS 002 5.1b		☐		
(c) pay such fees and charges as determined by HKAS Executive;	HKAS 002 5.1c		☐		
(d) endeavor to ensure the accreditation granted by HKAS is not used in a misleading manner; and	HKAS 002 5.1d		☐		
(e) be a legal entity?	HKAS 002 5.1e		☐		
(f) conform to the Business Registration Ordinance (Cap. 310) and provide a copy-of its business registration certificate to HKAS Executive if such legislation is applicable to the organisation. If your organisation is incorporated or registered outside HKSAR, provide a copy of official document showing its name and registered address under the laws of its place of incorporation or registration. For each permanent location where accredited activities are performed, your organisation shall provide proof that the organisation has the right to access and perform accredited activities at that permanent location.	HKAS 002 5.1f		☐		
For any customers for which your organisation performs any accredited activity, does your organisation maintain for such activity a quality standard which is in conformity with the accreditation criteria as set by HKAS?	HKAS 002 5.2		☐		
Will your organisation maintain the same quality standard at all times, no matter whether or not the HKAS accreditation symbol is used in the report/certificate/ statement covering the result of such activity?	HKAS 002 5.2		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
When making any statement in relation to your organisation's accreditation status in situation where non-accredited activities are mentioned, will your organisation ensure that such a statement is accompanied by a statement indicating which activities are not accredited?	HKAS 002 5.3		☐		
Is your organisation aware of the following accreditation regulation: "Upon termination of accreditation for all activities of an organisation as specified in a certificate of accreditation, the organisation shall return such certificate of accreditation to HKAS Executive forthwith."?	HKAS 002 5.4		☐		
Will your organisation cooperate with HKAS Executive and its assessment teams and provide them with full support during an assessment and in any other situation such as to provide access to its personnel, locations, equipment, information documents and records for assessment of the organisation's competence and its conformity with the accreditation criteria?	HKAS 002 5.5		☐		
Upon the request of HKAS Executive, will your organisation provide HKAS Executive with a copy of the documentary standard for which it seeks HKAS accreditation for use during the assessment?	HKAS 002 5.5		☐		
Does your organisation ensure that it will use its accreditation status only in a manner that will not bring HKAS or any of its accreditation schemes into disputes and will not make any statement regarding its accreditation status that HKAS Executive may reasonably consider it to be misleading?	HKAS 002 5.6		☐		
Does your organisation maintain complete integrity and impartiality in all circumstances? Does your organisation issue and implement a pertinent code of conduct for all its directors, officers, employees and other personnel involved in its operation? Will the authorised representative report any impropriety or unlawful act of the organisation or any iniquitous management and/or staff to HKAS Executive? Will the authorised representative further report immediately any corrupt practice to the ICAC (or similar authority or the police when outside the jurisdiction of the HKASR)?	HKAS 002 5.7		☐		
Will your organisation notify HKAS Executive within one calendar month if a new authorised representative has been appointed?	HKAS 002 5.8		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Will the authorised representative or in his absence, other responsible person of the organisation inform HKAS Executive in writing immediately of any changes or intended changes in the organisation's circumstances which may affect its conformity with relevant accreditation criteria?	HKAS 002 5.9		☐		
Does your organisation implement the following HKAS regulation on confidentiality: "An accredited organisation shall pay due regard to the confidentially of its customer's information and shall make internal rules and guidelines in order to ensure protection of its customer's information. Confidential information about a particular customer shall not be disclosed to a third party without the consent of the customer, except where the law requires such information to be so disclosed. However, an applicant organisation or an accredited organisation shall allow HKAS Executive to examine all its records which are relevant to the scope of accreditation in order to assess its competence and compliance with the relevant accreditation criteria. An applicant organisation and an accredited organisation shall obtain consent from their customers for the disclosure of any relevant information to HKAS."?	HKAS 002 5.10		☐		
Does your organisation ensure that no unofficial contact with assessors, technical experts and/or AAB members will be made on any matter relating to or in connection with the assessment of any activity for the purpose of granting or maintaining accreditation?	HKAS 002 5.11		☐		
Are all communications concerning the organisation's assessment made between HKAS Executive and the organisation's authorised representative, or in his absence, the chief executive or other responsible persons nominated by the organisation?	HKAS 002 5.11		☐		
Does your organisation have a clear policy in writing concerning the offering, solicitation and acceptance of advantages by its personnel? Does the policy document contain a statement notifying its personnel the law under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)? Does your organisation further ensure that the policy is made known to all its personnel?	HKAS 002 5.12		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Does your organisation have a policy and procedure in writing for handling and resolving complaints, disputes and appeals made to it by its customers or other parties?	HKAS 002 5.13		☐		
Does your organisation keep records of all complaints, disputes and appeals and actions taken for a minimum of 3 years and make available to HKAS Executive for inspection upon request?	HKAS 002 5.13		☐		
Where a complaint, dispute or appeal received from your customers or other parties raise any doubt on your conformity with your polices or procedures, will your organisation ensure that the relevant areas of its accredited activities are promptly audited?	HKAS 002 5.14		☐		
If a complaint, dispute or appeal received from your customers or other parties relating to any of your accredited activities is not satisfactorily resolved within 60 days from the date of receipt, will your organisation notify HKAS Executive in writing of this matter?	HKAS 002 5.15		☐		
Is your organisation aware that any concerned party may lodge complaints with HKAS on any of your accredited activities, and your organisation shall cooperate with HKAS Executive and provide them with full support for investigation of those complaints upon request?	HKAS 002 5.16		☐		
Is your organisation aware of the following HKAS regulation?					
Upon the request of HKAS Executive, an accredited organisation shall confirm the authenticity or otherwise of a report, certificate or other document purporting to have been issued by it for an accredited activity. Where such a report, certificate or document is found to be a forged document, the organisation shall cooperate with HKAS Executive in the investigation of its cause and taking mutually agreeable steps to prevent recurrence.	HKAS 002 5.17		☐		
An accredited organisation shall not provide certification service to any other party for any standard used by HKAS as accreditation criteria. HKAS Executive will take immediate action to suspend the accreditation of an accredited organisation in violation of this requirement.	HKAS 002 5.18		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Use of HKAS accreditation marks and claims of accreditation status					
Does your organisation implement the following HKAS regulation:- "An accredited organisation may use the relevant HKAS accreditation symbol as described in HKAS Supplementary Criteria No. 1 and claim its accreditation status provided that the following conditions are conformed with:-					
(a) all advertising and promotional materials (including letterheads) shall not, in the opinion of HKAS Executive, give a false or misleading impression regarding the accreditation status of the organisation;	HKAS 002 8.1a		☐		
(b) HKAS Supplementary Criteria No. 1 and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations, are conformed with at all times; and	HKAS 002 8.1b		☐		
(c) any statement made by the organisation in connection with its accreditation status shall not, in the opinion of HKAS Executive, give a false or misleading impression to any third party of its accreditation status."?	HKAS 002 8.1c		☐		
Is your organisation aware of that an organisation shall not allow its accreditation be used to imply that any subject of its accredited activities, for example, a product, process, system or person is approved by HKAS or HKAS Executive and shall take suitable actions to stop any incorrect reference to accreditation.	HKAS 002 8.2		☐		
Does your organisation ensure that your customers, on receiving any report or certificate which bears a HOKLAS accreditation mark are aware that the subject of the activity (e.g. the sample, instrument, product, design or system tested, calibrated, certified or inspected) as referred to in such report/certificate/statement is in no way approved nor disapproved by HKAS or HKAS Executive?	HKAS 002 8.2		☐		
Upon termination of the accreditation of any activities carried out by an accredited organisation, regardless of whether it is voluntarily made, will your organisation discontinue to make reference to the accreditation in any report, certificate, statement and other document reporting conformity assessment results, letterhead, brochure, advertising material, stationery, and Internet websites, etc., immediately?	HKAS 002 8.3		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Specific regulations for HOKLAS					
Is your organisation aware of the following accreditation regulation on accreditation procedure: "An assessment team may require a reference material producer to demonstrate a test, a calibration or other activities as part of an assessment, or to participate in proficiency testing in order to evaluate its standard and competence. The specific activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team."?	HOKLAS SC-39 2.1		☐		
Is your organisation aware of the following accreditation regulation on accreditation procedure: "HKAS Executive shall conduct a reassessment on the accredited activities of a reference material producer:-					
(a) twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the reference material producer;	HOKLAS SC-39 2.2a		☐		
(b) every two years after the due date of the first reassessment;	HOKLAS SC-39 2.2b		☐		
(c) at such other times as may be specified in the terms of accreditation;	HOKLAS SC-39 2.2c		☐		
(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited reference material producer, of any change in the structure and circumstances of the reference material producer since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the reference material producer's competence or conformity with the accreditation criteria; and	HOKLAS SC-39 2.2d		☐		
(e) The reassessment schedule may be varied at the discretion of HKAS Executive.	HOKLAS SC-39 2.2e		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Is your organisation aware of the following accreditation regulation on accreditation procedure: "HKAS Executive shall conduct a surveillance visit to an accredited reference material producer if no reassessment nor assessment for extension of accreditation nor surveillance visit to it has been conducted for the past twelve months. HKAS Executive may, at its discretion, vary the surveillance visit schedule."?	HOKLAS SC-39 2.3		☐		
Is your organisation aware of the following HKAS regulation: "Upon granting of accreditation reference material producer, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for reference material producer."?	HOKLAS SC-39 2.4		☐		
Does your organisation at all times comply with the following HOKLAS accreditation criteria? HKAS002, HOKLAS022, ISO/IEC 17025 and other relevant requirements documents (for testing and calibration activities), and relevant HKAS and HOKLAS Supplementary Criteria.	HOKLAS SC-39 3.1		☐		
Does your organisation ensure that the accredited RMP does not use its accreditation status in a way that may be interpreted by any person that any product, material or any other subject of an activity for which HOKLAS accreditation has been granted has been produced, approved or disapproved by HKAS or HKAS Executive? Does your organsiation further endeavor to ensure that no person use any certificate or report, statement or documentation issued by it for such activity in a misleading manner?	HOKLAS SC-39 3.2		☐		
Is your organisation aware of the following HKAS regulation on coorperation: "A reference material producer accredited under HOKLAS shall afford its customers or their representatives reasonable cooperation to monitor the reference material producer's performance (in so far as to their respective contracts are concerned). However, the reference material producer shall ensure that the confidentiality of its other customers will be protected and their information will not be divulged to any third party.	HOKLAS SC-39 3.3		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
For avoidance of doubt, the reference material producer may also take reasonable steps to protect its proprietary information and agree with its customers the cost the customers have to pay to the reference material producer for performing or taking part in such monitoring activities."?	HOKLAS SC-39 3.3		☐		
Are the subcontractors for testing and calibration activities accredited by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement, and their scopes of accreditation cover the specific tests and/or calibrations performed in support of producing the reference materials concerned? Has your RMP documented the production process for each type of reference material included in the scope of accreditation or the proposed scope of accreditation to indicate which tasks are performed by itself and which tasks are performed by subcontractors and the identities of the subcontractors? If there is any change in the arrangement, will its authorised representative or in his absence, another responsible person inform HKAS Executive in writing immediately of the details of the change?	HOKLAS SC-39 3.4		☐		
Does your accredited RMP take part in proficiency testing programmes for testing and calibration activities which are relevant to the scope of accreditation ? Is the performance of your accredited RMP in any proficiency testing activity relevant to its scope of accreditation acceptable to HKAS Executive? Does your accredited RMP require its subcontractors for tests and calibrations to participate in suitable proficiency testing schemes? Where proficiency testing schemes are not available, have other means to demonstrate competence, e.g. use of measurement audits and check samples, been considered.	HOKLAS SC-39 3.5		☐		
Is your organisation aware of the following HKAS regulations on frequency of participation in proficiency testing activities. "The frequency of participation in proficiency testing activities stated in HOKLAS Supplementary Criteria No. 33 and relevant HOKLAS Supplementary Criteria apply to the tests and calibrations undertakes by the reference material producers.	HOKLAS SC-39 3.6		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Where the performance of an applicant reference material producer or an accredited reference material producer in a proficiency testing activity is unsatisfactory, the reference material producer shall take immediate remedial actions and shall investigate the cause of the unsatisfactory performance and take effective corrective actions."?	HOKLAS SC-39 3.7		☐		
Is your organisation aware of the following HKAS regulation on approved signatory: An accredited reference material producer shall inform HKAS Executive forthwith or any change in the availability and duties of any of its approved signatories. HKAS shall withdraw the approval concerning such approved signatory who no longer meets and the requirements for approved signatories as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation for producing a reference material if it does not have any approved signatory for such reference material and has failed to obtain approval from HKAS Executive for a new signatory within three months from the date when it ceased to have any approved signatory for such reference material."?	HOKLAS SC-39 3.9		☐		
Is your organisation aware of the following HKAS regulation on integrity: An applicant reference material producer shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, or if the applicant intentionally provides false information or conceals information, HKAS Executive shall reject the application or terminate the assessment process. The resulting application and assessment fees paid are not refundable.	HOKLAS SC-39 3.10		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Will the authorised representative of your reference material producer, which has its accreditation suspended or terminated (voluntarily or by HKAS Executive) shall employ best efforts to, within 14 days from the effective date of such suspension or termination, notify the customers who have purchased the affected reference materials which are found to be unreliable because of the deficiencies discovered during the investigation of the suspension and termination, and inform them that the reference materials are unreliable. Where the reference materials are subject to resale through an authorized distributor, with whom the producer has a contractual relationship, will the reference material producer pass on this information to its authorized distributor and require the distributor to pass on the information to the users of the reference materials?	HOKLAS SC-39 4.1		☐		
Is your organisation aware of the following HKAS regulations: "For voluntary suspension of accreditation, the effective date shall be advised by the reference material producer, or the same as the issue date of the notification letter confirming the suspension if the reference material producer does not provide one. For suspension imposed by HKAS Executive, the effective date shall be the issue date of the relevant notification letter. The reference material producer shall provide to HKAS Executive an action plan to solve the concerns related to the suspended activity(ies) within four weeks from the date of notice of suspension. Such actions shall be taken to the satisfaction of HKAS Executive within one year from the effective date of suspension"?	HOKLAS SC-39 4.2		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Is your organisation aware of the following HKAS regulations: "The reference material producer shall issue a certificate for certified reference materials and provide appropriate documentation for non-certified reference materials in the form of a statement, analysis report, or information sheet howsoever named. An accredited reference material producer may display the appropriate HOKLAS accreditation symbol in the certificate for certified reference material, or in the documentation issued by it for the reference materials it is accredited for producing. The claiming of accreditation in such a certificate and documentation for internal use may also be made in the form of a statement specified by HKAS Executive. Such a document is referred to hereafter as a HOKLAS endorsed certificate or documentation. A HOKLAS endorsed certificate or documentation shall contain the HOKLAS accreditation symbol and other details as described in clause 5.2 below. There are additional requirements for the use of HKAS accreditation symbols and claims of accreditation status given in HKAS Supplementary Criteria No. 1 that an accredited reference material producer need to comply with."?	HOKLAS SC No.39 5.1		☐		
Is your organisation aware of the following HKAS regulation on the use of HKAS accreditation marks and claims of accreditation status: "An accredited reference material producer shall include in a HOKLAS endorsed report or certificate the following:-					
(a) the HOKLAS accreditation symbol (which includes the reference material producer's registration number) at the top right hand corner of the front page.	HOKLAS SC-39 5.2a		☐		
(b) on the same page the following statement:- "HKAS has accredited this reference material producer (Reg. No. HOKLAS XXX) under HOKLAS for producing specific reference materials as listed in the scope of accreditation"'.	HOKLAS SC-39 5.2.b		☐		
The word "this reference material producer" in the first sentence of the above endorsement statement may be replaced by the full identity of the reference material producer as it appears on the scope of accreditation.					

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Is your organisation aware that the claiming of accreditation status in a certificate or documentation for internal use may also be made with the statement in 5.2 (b) alone but such claim without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive? Is your organisation aware that such a document without the HOKLAS accreditation symbol is not considered as a HOKLAS endorsed certificate or documentation, but requirements that govern the issue of HOKLAS endorsed certificate or documentation as detailed in HOKLAS Supplementary Criteria No. 39 and HKAS 002 apply? And the HOKLAS accreditation symbol shall not be used alone to claim the accreditation status?	HOKLAS SC-39 5.3		☐		
Does your organisation ensure that the term "HKAS"/"HOKLAS" and the HOKLAS accreditation symbol for reference material producer shall not be used in any certificate or documentation of reference materials except in a HOKLAS endorsed certificate or documentation?	HOKLAS SC-39 5.4		☐		
Does your organisation ensure that the form, size, colour and usage of the HOKLAS accreditation symbol shall be in accordance with HKAS Supplementary Criteria No. 1?	HOKLAS SC-39 5.5		☐		
Is your organisation aware of the following HKAS regulation: "A HOKLAS endorsed certificate or documentation shall be signed by a HOKLAS approved signatory of the issuing reference material producer. For printed certificates or documentation, such signature shall be made in hand-written form. For certificates or documentation in an electronic form, the signature shall be in the form of an electronic signature acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identify document such as identity card or passport) shall be clearly shown alongside the signature. Other arrangements of signing HOKLAS endorsed certificates or documentation may be accepted subject to agreement from HKAS Executive. When determining the acceptability of such an arrangement, HKAS Executive will consider all pertinent factors such as the reliability of the arrangement in ensuring proper and traceable authorisation by approved signatories and the demand of users of the accredited service."	HOKLAS SC-39 5.6		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
Is your organisation aware of the following HKAS regulation: "A HOKLAS endorsed certificate or documentation may contain signatures of others provided that the certificate or documentation has been signed by a HOKLAS approved signatory of the reference material producer."?	HOKLAS SC-39 5.7		☐		
Does HOKLAS endorsed certificate or documentation shall only contain information on reference material for which the reference material producer is holding valid HOKLAS accreditation? IS your organisation aware that any property values of a reference material that are outside the scope of accreditation, or an uncertainty of a property value that is less than or better than that stated in the scope of accreditation can only be included in a HOKLAS endorsed certificate or documentation if HKAS Executive has explicitly approved such inclusion in writing, and the HOKLAS endorsed certificate or documentation which contains such values shall clearly state therein that they are not covered by the reference material producer's HOKLAS accreditation?	HOKLAS SC-39 5.8		☐		
Does your reference material producer keep at least one exact copy of the HOKLAS endorsed certificate or documentation issued by it for record? It shall also keep such copies, all original observations and records in relation to any accredited activity performed by it for a period of not less than three years or for a period specified by the HKAS Executive, as counted from the expiration date of the reference material?	HOKLAS SC-39 5.9		☐		
Every HOKLAS endorsed certificate or documentation shall comply with all relevant accreditation criteria as specified by HKAS Executive from time to time.	HOKLAS SC-39 5.10		☐		
Is your organisation aware of the following HKAS regulation: "A HOKLAS endorsed certificate or documentation shall bear either:-					
(a) a statement indicating that such certificate or documentation may be reproduced except in full, or	HOKLAS SC-39 5.11a		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
(b) a statement indicating the conditions under which such certificate or documentation may be reproduced either in full or in part. Any extract or abstract of a HOKLAS endorsed certificate or documentation shall not contain the HOKLAS accreditation symbol nor other details as specified in clause 5.3 above unless the authorised representative of the accredited reference material producer which issues the certificate or documentation has approved in writing of such inclusion in the extract or abstract. The Authorised Representative, if granting approval under this clause, shall ensure that such extract or abstract will not be used for any purpose which HKAS Executive may consider it as having misleading effect."?	HOKLAS SC-39 5.11b		☐		
Is your organisation aware of the following HKAS regulation: "Opinions or interpretation for which a reference material producer is not accredited for providing can only be included in a HOKLAS endorsed certificate or documentation if HKAS Executive has given its approval for such inclusion in writing. An endorsed certificate or documentation containing such opinions or interpretations shall in all cases clearly state that the reference material producer is not accredited for providing such opinions or interpretation."?	HOKLAS SC-39 5.12		☐		
Is your organisation aware of the following HKAS regulation: "An accredited reference material producer shall not claim accreditation for HOKLAS accreditation for its testing and calibration activities even though such activities have been assessed in accordance with relevant requirements in ISO/IEC 17025. It shall also forbid its subcontractors to claim HKAS accreditation for the subcontracted activities even though such activities have been assessed by HKAS as part of the reference material production process.	HOKLAS SC-39 5.13		☐		
Is your organisation aware of the following HKAS regulation: "Accreditation symbol may be used on labels of reference materials produced within the scope of accreditation provided that the label meets the requirements of HKAS, Supplementary Criteria No. 1 and HOKLAS 022, and shall contain the following as a minimum:					
(a) HKAS accreditation symbol for reference material producers;	HOKLAS SC-39 5.14a		☐		
(b) Name of the accredited reference material producer;	HOKLAS SC-39 5.14b		☐		

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HKAS Regulations	Clause	*	OK	QM Clause	Remarks / Questions to be asked at the RMP
(c) Designation of the product and batch number; and	HOKLAS SC-39 5.14c		☐		
(d) Cross reference to the certificate of the CRM or documentation for non-certified RM.	HOKLAS SC-39 5.14d		☐		
The use of accreditation symbol on reference material label is voluntary."?					
Is your organisation aware of the following HKAS regulation: "Application for any HOKLAS service from HKAS shall be made in appropriate forms. These forms are obtainable from the office of HKAS Executive and have been uploaded to the HKAS website."?	HOKLAS SC-39 6.1		☐		

End

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