HOKLAS 007 Annex II

Checklist

(Based on ISO/IEC 17025:2017)

The laboratory shall complete the following checklist, which will be used for the assessment of the laboratory's conformity with HKAS accreditation requirements.

The checklist consists of questions based on the requirements of ISO/IEC 17025:2017, HKAS 002, HKAS Supplementary Criteria No. 6 and HOKLAS Supplementary Criteria No. 33. For further information, please refer to the corresponding document and clause as listed in the second column.

The laboratory shall indicate in the 'MS Clause' column, for every question, the clause(s) in its management system manual, operation procedures manual or other related document which can demonstrate the laboratory's conformity with the requirement.

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

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

ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
4 General requirements					
4.1 Impartiality					
Are your laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality?	4.1.1		☐		
Is your laboratory management committed to impartiality?	4.1.2		☐		
Is your laboratory responsible for the impartiality of your laboratory activities and does your laboratory prohibit commercial, financial or other pressures from compromising impartiality?	4.1.3		☐		
Does your laboratory identify risks to your impartiality on an on-going basis? Do the risks include those that arise from its activities, or from its relationships, or from the relationships of its personnel? However, such relationships do not necessarily present a laboratory with a risk to impartiality. NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.	4.1.4		☐		
If a risk to impartiality is identified, is your laboratory able to demonstrate how it eliminates or minimises such risk?	4.1.5		☐		
4.2 Confidentiality					
Is your laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities?	4.2.1		☐		
Does your laboratory inform the customer in advance, of the information you intend to place in the public domain?	4.2.1		☐		
Except for information that the customer makes publicly available, or when agreed between your laboratory and the customer (e.g. for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?	4.2.1		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
When your laboratory is required by law or authorised by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, notified of the information provided?	4.2.2		☐		
Is the information about the customer obtained from sources other than the customer (e.g. complainant, regulators) confidential between the customer and the laboratory? Is the provider (source) of this information confidential to the laboratory and not shared with the customer, unless agreed by the source?	4.2.3		☐		
Do your personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities, except as required by law?	4.2.4		☐		
5 Structural requirements					
Is your laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for your laboratory activities? NOTE For the purposes of ISO/IEC 17025:2017, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.	5.1		☐		
Does your laboratory identify management that has overall responsibility for the laboratory?	5.2		☐		
Does your laboratory define and document the range of laboratory activities for which it conforms with ISO/IEC 17025:2017 and only claim conformity with ISO/IEC 17025:2017 for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?	5.3		☐		
Are your laboratory activities carried out in such a way as to meet the requirements of ISO/IEC 17025:2017, customers of your laboratory, regulatory authorities and organisations providing recognition? This shall include laboratory activities performed in all your permanent facilities, at sites away from your permanent facilities, in associated temporary or mobile facilities or at your customer's facility.	5.4		☐		
Does your laboratory - define the organisation and management structure of your laboratory, the place in any parent organisation, and the relationships between management, technical	5.5 a		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
operations and support services?					
- specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities?	5.5 b		☐		
- document the procedures to the extent necessary to ensure the consistent application of your laboratory activities and the validity of the results?	5.5 c		☐		
Does your laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including					
- implementation, maintenance and improvement of your laboratory's management system?	5.6 a		☐		
- identification of deviations from the management system or from the procedures for performing laboratory activities?	5.6 b		☐		
- initiation of actions to prevent or minimise such deviations?	5.6 c		☐		
- reporting to laboratory management on the performance of your laboratory's management system and any need for improvement?	5.6 d		☐		
- ensuring the effectiveness of laboratory activities?	5.6 e		☐		
Does your laboratory management ensure that:					
- communication takes place regarding the effectiveness of your laboratory's management system and the importance of meeting customers' and other requirements?	5.7 a		☐		
- the integrity of your laboratory's management system is maintained when changes to the management system are planned and implemented?	5.7 b		☐		
6 Resource requirements					
6.1 General					
Does your laboratory have available the personnel, facilities, equipment, systems	6.1	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
and support services necessary to manage and perform its laboratory activities?					
6.2 Personnel					
Do all personnel of your laboratory, either internal or external, that could influence your laboratory activities act impartially, being competent and work in accordance with your laboratory's management system?	6.2.1	●	☐		
Does your laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience?	6.2.2	●	☐		
Does your laboratory ensure that your personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations?	6.2.3	●	☐		
Does the management of your laboratory communicate to personnel on their duties, responsibilities and authorities?	6.2.4	●	☐		
Does your laboratory have procedure(s) and retain records for:					
- determining the competence requirements?	6.2.5 a	●	☐		
- selection of personnel?	6.2.5 b	●	☐		
- training of personnel?	6.2.5 c	●	☐		
- supervision of personnel?	6.2.5 d	●	☐		
- authorisation of personnel?	6.2.5 e	●	☐		
- monitoring competence of personnel?	6.2.5 f	●	☐		
Does your laboratory authorise personnel to perform specific laboratory activities, including but not limited to, the following:					
- development, modification, verification and validation of methods?	6.2.6 a		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- analysis of results, including statements of conformity or opinions and interpretations?	6.2.6 b		☐		
- report, review and authorisation of results?	6.2.6 c		☐		
6.3 Facilities and environmental conditions					
Are the facilities and environmental conditions suitable for the laboratory activities? Do they adversely affect the validity of results? NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.	6.3.1	●	☐		
Are the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities documented?	6.3.2	●	☐		
Does your laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results?	6.3.3	●	☐		
Are measures to control facilities, including but not limited to the following, implemented, monitored and periodically reviewed:					
- access to and use of areas affecting laboratory activities?	6.3.4 a	●	☐		
- prevention of contamination, interference or adverse influences on laboratory activities?	6.3.4 b	●	☐		
- effective separation between areas with incompatible laboratory activities?	6.3.4 c	●	☐		
When your laboratory performs laboratory activities at sites or facilities outside it permanent control, does your laboratory ensure that the requirements related to facilities and environmental conditions of ISO/IEC 17025:2017 are met?	6.3.5	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
6.4 Equipment					
Does your laboratory have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results?	6.4.1	●	☐		
NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.					
NOTE 2 ISO 33403 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.					
When your laboratory uses equipment outside its permanent control, does your laboratory ensure that the requirements for equipment of ISO/IEC 17025:2017 are met?	6.4.2	●	☐		
Does your laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration?	6.4.3	●	☐		
Does your laboratory verify that equipment conforms to specified requirements before being placed or returned into service?	6.4.4	●	☐		
Is the equipment used for measurement capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result?	6.4.5	●	☐		
Is measuring equipment calibrated when:					
- the measurement accuracy or measurement uncertainty affects the validity of the reported results?	6.4.6	●	☐		
- calibration of the equipment is required to establish the metrological traceability of the reported results?	6.4.6	●	☐		

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NOTE Types of equipment having an effect on the validity of the reported results can include: - those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; - those used to make corrections to the measured value, e.g. temperature measurements; - those used to obtain a measurement result calculated from multiple quantities.					
Does your laboratory establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration?	6.4.7	●	☐		
Is all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity?	6.4.8	●	☐		
Is equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service and isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly?	6.4.9	●	☐		
Does your laboratory examine the effect of the defect or deviation from specified requirements and initiate the management of nonconforming work procedure? (See also 7.10 of ISO/IEC 17025:2017)	6.4.9	●	☐		
When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks carried out according to a procedure?	6.4.10	●	☐		
When calibration and reference material data include reference values or correction factors, does your laboratory ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements?	6.4.11	●	☐		
Does your laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results?	6.4.12	●	☐		
Are records for equipment which can influence laboratory activities retained? Do the records include at least the following, where applicable:	6.4.13	●	☐		
- the identity of equipment, including software and firmware version?	6.4.13 a	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- the manufacturer's name, type identification, and serial number or other unique identification?	6.4.13 b	●	☐		
- evidence of verification that equipment conforms with specified requirements?	6.4.13 c	●	☐		
- the current location?	6.4.13 d	●	☐		
- calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval?	6.4.13 e	●	☐		
- documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity?	6.4.13 f	●	☐		
- the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment?	6.4.13 g	●	☐		
- details of any damage, malfunction, modification to, or repair of, the equipment?	6.4.13 h	●	☐		
6.5 Metrological traceability					
Does your laboratory establish and maintain metrological traceability of your measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the 'property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty''. NOTE 2 See Annex A of ISO/IEC 17025:2017 for additional information on metrological traceability.	6.5.1	●	☐		
Does your laboratory ensure that measurement results are traceable to the International System of Units (SI) through:					
- calibration provided by a competent laboratory? or NOTE 1 Laboratories fulfilling the requirements of ISO/IEC 17025:2017 are considered to be competent.	6.5.2 a	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI? or NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.	6.5.2 b	●	☐		
- direct realisation of the SI units ensured by comparison, directly or indirectly, with national or international standards? NOTE 3 Details of practical realisation of the definitions of some important units are given in the SI brochure.	6.5.2 c	●	☐		
When metrological traceability to the SI units is not technically possible, does your laboratory demonstrate metrological traceability to an appropriate reference, e.g.:					
- certified values of certified reference materials provided by a competent producer?	6.5.3a	●	☐		
- results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison?	6.5.3b	●	☐		
6.6 Externally provided products and services					
Does your laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:					
- are intended for incorporation into the laboratory's own activities?	6.6.1 a	●	☐		
- are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider?	6.6.1 b	●	☐		
- are used to support the operation of the laboratory? NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services	6.6.1 c	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Does your laboratory have a procedure and retain records for:					
- defining, reviewing and approving the laboratory's requirements for externally provided products and services?	6.6.2 a	●	☐		
- defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers?	6.6.2 b	●	☐		
- ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025:2017, before they are used or directly provided to the customer?	6.6.2 c	●	☐		
- taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers?	6.6.2 d	●	☐		
Does your laboratory communicate the requirements to external providers for:					
- the products and services to be provided?	6.6.3 a	●	☐		
- the acceptance criteria?	6.6.3 b	●	☐		
- competence, including any required qualification of personnel?	6.6.3 c	●	☐		
- activities that your laboratory, or your customer, intends to perform at the external provider's premises?	6.6.3 d	●	☐		
7 Process requirements					
7.1 Review of requests, tenders and contracts					
Does your laboratory have a procedure for the review of requests, tenders and contracts to ensure that:					
- the requirements are adequately defined, documented and understood?	7.1.1 a	●	☐		
- the laboratory has the capability and resources to meet the requirements?	7.1.1 b	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- where external providers are used, the requirements of 6.6 of ISO/IEC 17025:2017 are applied and your laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval? NOTE 1 It is recognised that externally provided laboratory activities can occur when: - your laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full; - your laboratory does not have the resources or competence to perform the activities.	7.1.1 c	●	☐		
- the appropriate methods or procedures are selected and are capable of meeting the customers' requirements? NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.	7.1.1 d	●	☐		
Does your laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date?	7.1.2		☐		
When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), are the specification or standard and the decision rule clearly defined?	7.1.3	●	☐		
Unless inherent in the requested specification or standard, is the decision rule selected communicated to, and agreed with, the customer? NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.	7.1.3	●	☐		
Are any differences between the request or tender and the contract resolved before laboratory activities commence?	7.1.4		☐		
Is each contract acceptable both to the laboratory and the customer?	7.1.4		☐		
Do deviations requested by the customer not impact the integrity of the laboratory or the validity of the results?	7.1.4		☐		
Is the customer informed of any deviation from the contract?	7.1.5		☐		
If a contract is amended after work has commenced, is the contract review repeated and any amendments communicated to all affected personnel?	7.1.6		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Does your laboratory cooperate with customers or their representatives in clarifying the customer's request and in monitoring your laboratory's performance in relation to the work performed? NOTE Such cooperation can include: a) providing reasonable access to relevant areas of your laboratory to witness customer-specific laboratory activities; b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.	7.1.7		☐		
Are records of reviews, including any significant changes, retained?	7.1.8		☐		
Are records of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities retained?	7.1.8		☐		
7.2 Selection, verification and validation of methods					
7.2.1 Selection and verification of methods					
Does your laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data? NOTE 'Method' as used in ISO/IEC 17025:2017 can be considered synonymous with the term 'measurement procedure' as defined in ISO/IEC Guide 99.	7.2.1.1	●	☐		
Are all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and made readily available to personnel (see also 8.3 of ISO/IEC 17025:2017)?	7.2.1.2	●	☐		
Does your laboratory ensure that the latest valid version of a method is used unless it is not appropriate or possible to do so?	7.2.1.3	●	☐		
When necessary, is the application of the method supplemented with additional details to ensure consistent application? NOTE International, regional or national standards or other recognised specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in your laboratory. It can be	7.2.1.3	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
necessary to provide additional documentation for optional steps in the method or additional details.					
When the customer does not specify the method to be used, does your laboratory select an appropriate method and inform the customer of the method chosen? Methods published either in international, regional or national standards, or by reputable technical organisations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.	7.2.1.4	●	☐		
Does your laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance?	7.2.1.5	●	☐		
Are records of the verification retained?	7.2.1.5	●	☐		
If the method is revised by the issuing body, are verification repeated to the extent necessary?	7.2.1.5	●	☐		
When method development is required, is it a planned activity and assigned to competent personnel equipped with adequate resources?	7.2.1.6	●	☐		
As method development proceeds, is periodic review carried out to confirm that the needs of the customer are still being fulfilled?	7.2.1.6	●	☐		
Are any modifications to the development plan approved and authorised?	7.2.1.6	●	☐		
Do deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorised, and accepted by the customer? NOTE Customer acceptance of deviations can be agreed in advance in the contract.	7.2.1.7	●	☐		
7.2.2 Validation of methods					
Does your laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified?	7.2.2.1	●	☐		
Is the validation as extensive as is necessary to meet the needs of the given application or field of application?	7.2.2.1	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.					
When changes are made to a validated method, is the influence of such changes determined? and where they are found to affect the original validation, is a new method validation performed?	7.2.2.2	●	☐		
Are the performance characteristics of validated methods, as assessed for the intended use, relevant to the customers' needs and consistent with specified requirements? NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.	7.2.2.3	●	☐		
Does your laboratory retain the following records of validation:					
- the validation procedure used?	7.2.2.4 a	●	☐		
- specification of the requirements?	7.2.2.4 b	●	☐		
- determination of the performance characteristics of the method?	7.2.2.4 c	●	☐		
- results obtained?	7.2.2.4 d	●	☐		
- a statement on the validity of the method, detailing its fitness for the intended	7.2.2.4 e	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
use?					
7.3 Sampling					
Does your laboratory have a sampling plan and method when you carry out sampling of substances, materials or products for subsequent testing or calibration?	7.3.1	●	☐		
Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results?	7.3.1	●	☐		
Are the sampling plan and method available at the site where sampling is undertaken?	7.3.1	●	☐		
Are the sampling plans, whenever reasonable, based on appropriate statistical methods?	7.3.1	●	☐		
Does the sampling method describe:					
- the selection of samples or sites?	7.3.2 a	●	☐		
- the sampling plan?	7.3.2 b	●	☐		
- the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration?	7.3.2 c	●	☐		
NOTE When received into the laboratory, further handling can be required as specified in 7.4 of ISO/IEC 17025:2017					
Does your laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken? Do these records include, where relevant:	7.3.3	●	☐		
- reference to the sampling method used?	7.3.3 a	●	☐		
- date and time of sampling?	7.3.3 b	●	☐		
- data to identify and describe the sample (e.g. number, amount, name)?	7.3.3 c	●	☐		
- identification of the personnel performing sampling?	7.3.3 d	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- identification of the equipment used?	7.3.3 e	●	☐		
- environmental or transport conditions?	7.3.3 f	●	☐		
- diagrams or other equivalent means to identify the sampling location, when appropriate?	7.3.3 g	●	☐		
- deviations, additions to or exclusions from the sampling method and sampling plan?	7.3.3 h	●	☐		
7.4 Handling of test or calibration items					
Does your laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer?	7.4.1	●	☐		
Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration?	7.4.1	●	☐		
Are the handling instructions provided with the item followed?	7.4.1	●	☐		
Does your laboratory have a system for the unambiguous identification of test or calibration items?	7.4.2	●	☐		
Is the identification retained while the item is under the responsibility of your laboratory?	7.4.2	●	☐		
Does the system ensure that items will not be confused physically or when referred to in records or other documents?	7.4.2	●	☐		
Does the system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items?	7.4.2	●	☐		
Upon receipt of the test or calibration item, are deviations from specified conditions recorded?	7.4.3	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does your laboratory consult the customer for further instructions before proceeding and record the results of this consultation?	7.4.3	●	☐		
When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does your laboratory include a disclaimer in the report indicating which results may be affected by the deviation?	7.4.3	●	☐		
When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?	7.4.4	●	☐		
7.5 Technical records					
Does your laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original?	7.5.1	●	☐		
Do the technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results?	7.5.1	●	☐		
Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task?	7.5.1	●	☐		
Does your laboratory ensure that amendments to technical records can be tracked to previous versions or to original observations?	7.5.2	●	☐		
Are the original and amended data and files retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations?	7.5.2	●	☐		
7.6 Evaluation of measurement uncertainty					
Does your laboratory identify the contributions to measurement uncertainty?	7.6.1	●	☐		
When evaluating measurement uncertainty, are all contributions that are of significance, including those arising from sampling, taken into account using	7.6.1	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
appropriate methods of analysis?					
If your laboratory performs calibrations, including of your own equipment, does your laboratory evaluate the measurement uncertainty for all calibrations?	7.6.2	●	☐		
If your laboratory performs testing, is measurement uncertainty evaluated?	7.6.3	●	☐		
Where the test method precludes rigorous evaluation of measurement uncertainty, is estimation made based on an understanding of the theoretical principles or practical experience of the performance of the method?	7.6.3	●	☐		
NOTE 1 In those cases where a well-recognised test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 of ISO/IEC 17025:2017 by following the test method and reporting instructions.					
NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.					
NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.					
7.7 Ensuring the validity of results					
Does your laboratory have a procedure for monitoring the validity of results?	7.7.1	●	☐		
Are the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results?	7.7.1	●	☐		
Is this monitoring planned and reviewed and does it include, where appropriate, but not be limited to:					
- use of reference materials or quality control materials?	7.7.1 a	●	☐		
- use of alternative instrumentation that has been calibrated to provide traceable results?	7.7.1 b	●	☐		
- functional check(s) of measuring and testing equipment?	7.7.1 c	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- use of check or working standards with control charts, where applicable?	7.7.1 d	●	☐		
- intermediate checks on measuring equipment?	7.7.1 e	●	☐		
- replicate tests or calibrations using the same or different methods?	7.7.1 f	●	☐		
- retesting or recalibration of retained items?	7.7.1 g	●	☐		
- correlation of results for different characteristics of an item?	7.7.1 h	●	☐		
- review of reported results?	7.7.1 i	●	☐		
- intralaboratory comparisons?	7.7.1 j	●	☐		
- testing of blind sample(s)?	7.7.1 k	●	☐		
Does your laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate?	7.7.2	●	☐		
Is this monitoring planned and reviewed and does it include, but not be limited to, either or both of the following:					
- participation in proficiency testing?	7.7.2 a	●	☐		
NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.					
- participation in interlaboratory comparisons other than proficiency testing?	7.7.2 b	●	☐		
Are data from monitoring activities analysed, used to control and, if applicable, improve the laboratory's activities?	7.7.3	●	☐		
If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, is appropriate action taken to prevent incorrect results from being reported?	7.7.3	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
7.8 Reporting of results					
7.8.1 General					
Are the results reviewed and authorised prior to release?	7.8.1.1	●	☐		
Are the results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and do they include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used?	7.8.1.2	●	☐		
Are all issued reports retained as technical records?	7.8.1.2	●	☐		
NOTE 1 For the purposes of ISO/IEC 17025:2017, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.					
NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of ISO/IEC 17025:2017 are met.					
If the results are reported in a simplified way as agreed with the customer, is any information listed in 7.8.2 to 7.8.7 of ISO/IEC 17025:2017 that is not reported to the customer readily available?	7.8.1.3	●	☐		
7.8.2 Common requirements for reports (test, calibration or sampling)					
Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimising any possibility of misunderstanding or misuse:					
- a title (e.g. 'Test Report', 'Calibration Certificate' or 'Report of Sampling')?	7.8.2.1 a		☐		
- the name and address of the laboratory?	7.8.2.1 b		☐		
- the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities?	7.8.2.1 c		☐		
- unique identification that all its components are recognised as a portion of a	7.8.2.1 d		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
complete report and a clear identification of the end?					
- the name and contact information of the customer?	7.8.2.1 e		☐		
- identification of the method used?	7.8.2.1 f		☐		
- a description, unambiguous identification, and, when necessary, the condition of the item?	7.8.2.1 g		☐		
- the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results?	7.8.2.1 h		☐		
- the date(s) of performance of the laboratory activity?	7.8.2.1 i		☐		
- the date of issue of the report?	7.8.2.1 j		☐		
- reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results?	7.8.2.1 k		☐		
- a statement to the effect that the results relate only to the items tested, calibrated or sampled?	7.8.2.1 l		☐		
- the results with, where appropriate, the units of measurement?	7.8.2.1 m		☐		
- additions to, deviations, or exclusions from the method?	7.8.2.1 n		☐		
- identification of the person(s) authorisng the report?	7.8.2.1 o		☐		
- clear identification when results are from external providers?	7.8.2.1 p		☐		
NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.					
Is your laboratory responsible for all the information provided in the report, except when information is provided by the customer?	7.8.2.2		☐		
Are data provided by a customer clearly identified?	7.8.2.2		☐		
Is a disclaimer put on the report when the information is supplied by the customer	7.8.2.2		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
and can affect the validity of results?					
Where your laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), does it state in the report that the results apply to the sample as received?	7.8.2.2		☐		
7.8.3 Specific requirements for test reports					
In addition to the requirements listed in 7.8.2 of ISO/IEC 17025:2017, do test reports, where necessary for the interpretation of the test results, include the following:					
- information on specific test conditions, such as environmental conditions?	7.8.3.1 a		☐		
- where relevant, a statement of conformity with requirements or specifications (see also 7.8.6 of ISO/IEC 17025:2017)?	7.8.3.1 b		☐		
- where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:					
■ it is relevant to the validity or application of the test results?	7.8.3.1 c		☐		
■ a customer's instruction so requires?	7.8.3.1 c		☐		
■ the measurement uncertainty affects conformity to a specification limit?	7.8.3.1 c		☐		
- where appropriate, opinions and interpretations (see also 7.8.7 of ISO/IEC 17025:2017)?	7.8.3.1 d		☐		
- additional information that may be required by specific methods, authorities, customers or groups of customers?	7.8.3.1 e		☐		
Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 of ISO/IEC 17025:2017 where necessary for the interpretation of test results?	7.8.3.2		☐		
7.8.4 Specific requirements for calibration certificates					
In addition to the requirements listed in 7.8.2 of ISO/IEC 17025:2017, do					

ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
calibration certificates include the following:					
- the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)? NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.	7.8.4.1 a		☐		
- the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?	7.8.4.1 b		☐		
- a statement identifying how the measurements are metrologically traceable (see also Annex A of ISO/IEC 17025:2017)?	7.8.4.1 c		☐		
- the results before and after any adjustment or repair, if available?	7.8.4.1 d		☐		
- where relevant, a statement of conformity with requirements or specifications (see also 7.8.6 of ISO/IEC 17025:2017)?	7.8.4.1 e		☐		
- where appropriate, opinions and interpretations (see also 7.8.7 of ISO/IEC 17025:2017)?	7.8.4.1 f		☐		
Where the laboratory is responsible for the sampling activity, do calibration certificates meet the requirements listed in 7.8.5 of ISO/IEC 17025:2017 where necessary for the interpretation of calibration results?	7.8.4.2		☐		
Does a calibration certificate or calibration label not contain any recommendation on the calibration interval, except where this has been agreed with the customer?	7.8.4.3		☐		
7.8.5 Reporting sampling - specific requirements					
Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2 of ISO/IEC 17025:2017, do reports include the following, where necessary for the interpretation of results:					
- the date of sampling?	7.8.5 a		☐		
- unique identification of the item or material sampled (including the name of the	7.8.5 b		☐		

ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
manufacturer, the model or type of designation and serial numbers, as appropriate)?					
- the location of sampling, including any diagrams, sketches or photographs?	7.8.5 c		☐		
- a reference to the sampling plan and sampling method?	7.8.5 d		☐		
- details of any environmental conditions during sampling that affect the interpretation of the results?	7.8.5 e		☐		
- information required to evaluate measurement uncertainty for subsequent testing or calibration?	7.8.5 f		☐		
7.8.6 Reporting statements of conformity					
When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule?	7.8.6.1		☐		
NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.					
Does the laboratory report on the statement of conformity, such that the statement clearly identifies:					
- to which results the statement of conformity applies?	7.8.6.2 a		☐		
- which specifications, standards or parts thereof are met or not met?	7.8.6.2 b		☐		
- the decision rule applied (unless it is inherent in the requested specification or standard)?	7.8.6.2 c		☐		
NOTE For further information, see ISO/IEC Guide 98-4.					
7.8.7 Reporting opinions and interpretations					
When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorised for the expression of opinions and interpretations release	7.8.7.1		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
the respective statement?					
Does the laboratory document the basis upon which the opinions and interpretations have been made?	7.8.7.1		☐		
NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6 of ISO/IEC 17025:2017.					
Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and are clearly identified as such?	7.8.7.2		☐		
When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue retained?	7.8.7.3		☐		
7.8.8 Amendments to reports					
When an issued report needs to be changed, amended or re-issued, is any change of information clearly identified and, where appropriate, the reason for the change included in the report?	7.8.8.1		☐		
Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement 'Amendment to Report, serial number ... [or as otherwise identified]', or an equivalent form of wording?	7.8.8.2		☐		
Do such amendments meet all the requirements of ISO/IEC 17025:2017?	7.8.8.2		☐		
When it is necessary to issue a complete new report, is this uniquely identified and does it contain a reference to the original that it replaces?	7.8.8.3		☐		
7.9 Complaints					
Does your laboratory have a documented process to receive, evaluate and make decisions on complaints?	7.9.1		☐		
Is a description of the handling process for complaints available to any interested party on request?	7.9.2		☐		
Upon receipt of a complaint, does your laboratory confirm whether the complaint	7.9.2		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
relates to laboratory activities that it is responsible for and, if so, deal with it?					
Is your laboratory responsible for all decisions at all levels of the handling process for complaints?	7.9.2		☐		
Does the process for handling complaints include at least the following elements and methods:					
- description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it?	7.9.3 a		☐		
- tracking and recording complaints, including actions undertaken to resolve them?	7.9.3 b		☐		
- ensuring that any appropriate action is taken?	7.9.3 c		☐		
Is your laboratory responsible for gathering and verifying all necessary information to validate the complaint recieved?	7.9.4		☐		
Whenever possible, does your laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?	7.9.5		☐		
Are the outcomes to be communicated to the complainant made by, or reviewed and approved by; individual(s) not involved in the original laboratory activities in question? NOTE This can be performed by external personnel.	7.9.6		☐		
Whenever possible, does your laboratory give formal notice of the end of the complaint handling to the complainant?	7.9.7		☐		
7.10 Nonconforming work					
Does your laboratory have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)?	7.10.1		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Does the procedure ensure that:					
- the responsibilities and authorities for the management of nonconforming work are defined?	7.10.1 a		☐		
- actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory?	7.10.1 b	●	☐		
- an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results?	7.10.1 c	●	☐		
- a decision is taken on the acceptability of the nonconforming work?	7.10.1 d		☐		
- where necessary, the customer is notified and work is recalled?	7.10.1 e		☐		
- the responsibility for authorising the resumption of work is defined?	7.10.1 f		☐		
Does your laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f) of ISO/IEC 17025:2017?	7.10.2		☐		
Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, does your laboratory implement corrective action?	7.10.3		☐		
7.11 Control of data and information management					
Does your laboratory have access to the data and information needed to perform laboratory activities?	7.11.1		☐		
Does the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by your laboratory before introduction?	7.11.2		☐		
Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorised, documented and validated before implementation?	7.11.2		☐		
NOTE 1 In ISO/IEC 17025:2017, 'laboratory information management system(s)' includes the management of data and information contained in both computerised and					

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
non-computerised systems. Some of the requirements can be more applicable to computerised systems than to non-computerised systems. NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated. Is your laboratory information management system(s):					
- protected from unauthorised access?	7.11.3 a		☐		
- safeguarded against tampering and loss?	7.11.3 b		☐		
- operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription?	7.11.3 c		☐		
- maintained in a manner that ensures the integrity of the data and information?	7.11.3 d		☐		
- capable of recording system failures and the appropriate immediate and corrective actions?	7.11.3 e		☐		
When the laboratory information management system is managed and maintained off-site or through an external provider, does your laboratory ensure that the provider or operator of the system complies with all applicable requirements of ISO/IEC 17025:2017?	7.11.4		☐		
Does your laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel?	7.11.5		☐		
Are calculations and data transfers checked in an appropriate and systematic manner?	7.11.6		☐		
8 Management system requirements					
8.1 Options					
8.1.1 General					

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Does your laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 and assuring the quality of the laboratory results?	8.1.1		☐		
In addition to meeting the requirements of Clauses 4 to 7 of ISO/IEC 17025:2017, does your laboratory implement a management system in accordance with Option A or Option B? NOTE See Annex B of ISO/IEC 17025:2017 for more information.	8.1.1		☐		
8.1.2 Option A					
Does the management system of your laboratory, as a minimum, address the following:					
- management system documentation (see also 8.2 of ISO/IEC 17025:2017)?	8.1.2		☐		
- control of management system documents (see also 8.3 of ISO/IEC 17025:2017)?	8.1.2		☐		
- control of records (see also 8.4 of ISO/IEC 17025:2017)?	8.1.2		☐		
- actions to address risks and opportunities (see also 8.5 of ISO/IEC 17025:2017)?	8.1.2		☐		
- improvement (see also 8.6 of ISO/IEC 17025:2017)?	8.1.2		☐		
- corrective actions (see also 8.7 of ISO/IEC 17025:2017)?	8.1.2		☐		
- internal audits (see also 8.8 of ISO/IEC 17025:2017)?	8.1.2		☐		
- management reviews (see also 8.9 of ISO/IEC 17025:2017)?	8.1.2		☐		
8.1.3 Option B					
If Option B is adopted, has your laboratory established and maintained a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of ISO/IEC 17025:2017 also fulfils at least the	8.1.3		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
intent of the management system requirements specified in 8.2 to 8.9 of ISO/IEC 17025:2017?					
8.2 Management system documentation (Option A)					
Does your laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of ISO/IEC 17025:2017 and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organisation?	8.2.1		☐		
Do the policies and objectives address the competence, impartiality and consistent operation of your laboratory?	8.2.2		☐		
Does your laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?	8.2.3		☐		
Are all documentation, processes, systems, records, related to the fulfilment of the requirements of ISO/IEC 17025:2017 included in, referenced from, or linked to the management system?	8.2.4		☐		
Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?	8.2.5		☐		
8.3 Control of management system documents (Option A)					
Does your laboratory control the documents (internal and external) that relate to the fulfilment of ISO/IEC 17025:2017?	8.3.1		☐		
NOTE In this context, 'documents' can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.					
Does your laboratory ensure that:					
- documents are approved for adequacy prior to issue by authorised personnel?	8.3.2 a		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- documents are periodically reviewed, and updated as necessary?	8.3.2 b		☐		
- changes and the current revision status of documents are identified?	8.3.2 c		☐		
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled?	8.3.2 d		☐		
- documents are uniquely identified?	8.3.2 e		☐		
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?	8.3.2 f		☐		
8.4 Control of records (Option A)					
Does your laboratory establish and retain legible records to demonstrate fulfilment of the requirements in ISO/IEC 17025:2017?	8.4.1		☐		
Does your laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records?	8.4.2		☐		
Does your laboratory retain records for a period consistent with its contractual obligations?	8.4.2	●	☐		
Is the access to these records consistent with the confidentiality commitments, and are the records readily available?	8.4.2		☐		
NOTE Additional requirements regarding technical records are given in 7.5 of ISO/IEC 17025:2017.					
8.5 Actions to address risks and opportunities (Option A)					
Does your laboratory consider the risks and opportunities associated with the laboratory activities in order to:					
- give assurance that the management system achieves its intended results?	8.5.1 a		☐		
- enhance opportunities to achieve the purpose and objectives of the laboratory?	8.5.1 b		☐		
- prevent, or reduce, undesired impacts and potential failures in the laboratory	8.5.1 c		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
activities?					
- achieve improvement?	8.5.1 d		☐		
Does your laboratory plan:					
- actions to address these risks and opportunities?	8.5.2 a		☐		
- how to:					
■ integrate and implement these actions into its management system?	8.5.2 b		☐		
■ evaluate the effectiveness of these actions?	8.5.2 b		☐		
NOTE Although ISO/IEC 17025:2017 specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by ISO/IEC 17025:2017, e.g. through the application of other guidance or standards.					
Are the actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results?	8.5.3	●	☐		
NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.					
NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.					
8.6 Improvement (Option A)					
Does your laboratory identify and select opportunities for improvement and implement any necessary actions?	8.6.1	●	☐		
NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.					
Does your laboratory seek feedback, both positive and negative, from its customers?	8.6.2		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Is the feedback analysed and used to improve the management system, laboratory activities and customer service? NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.	8.6.2		☐		
8.7 Corrective actions (Option A)					
When a nonconformity occurs, does your laboratory:					
- react to the nonconformity and, as applicable:					
■ take action to control and correct it?	8.7.1 a	●	☐		
■ address the consequences?	8.7.1 a	●	☐		
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:					
■ reviewing and analysing the nonconformity?	8.7.1 b	●	☐		
■ determining the causes of the nonconformity?	8.7.1 b	●	☐		
■ determining if similar nonconformities exist, or could potentially occur?	8.7.1 b	●	☐		
- implement any action needed?	8.7.1 c	●	☐		
- review the effectiveness of any corrective action taken?	8.7.1 d	●	☐		
- update risks and opportunities determined during planning, if necessary?	8.7.1 e	●	☐		
- make changes to the management system, if necessary?	8.7.1 f	●	☐		
Are corrective actions appropriate to the effects of the nonconformities encountered?	8.7.2	●	☐		
Does your laboratory retain records as evidence of:					
- the nature of the nonconformities, cause(s) and any subsequent actions taken?	8.7.3 a	●	☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
- the results of any corrective action?	8.7.3 b	●	☐		
8.8 Internal audits (Option A)					
Does your laboratory conduct internal audits at planned intervals to provide information on whether the management system:					
- conforms to:					
■ your laboratory's own requirements for its management system, including the laboratory activities?	8.8.1 a		☐		
■ the requirements of ISO/IEC 17025:2017?	8.8.1 a		☐		
- is effectively implemented and maintained?	8.8.1 b		☐		
Does your laboratory:					
- plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which take the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits into consideration?	8.8.2 a		☐		
- define the audit criteria and scope for each audit?	8.8.2 b		☐		
- ensure that the results of the audits are reported to relevant management?	8.8.2 c		☐		
- implement appropriate correction and corrective actions without undue delay?	8.8.2 d		☐		
- retain records as evidence of the implementation of the audit programme and the audit results?	8.8.2 e		☐		
NOTE ISO 19011 provides guidance for internal audits.					
8.9 Management reviews (Option A)					
Does your laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of ISO/IEC	8.9.1		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
17025:2017?					
Are the inputs to management review recorded and do they include information related to the following:					
- changes in internal and external issues that are relevant to the laboratory?	8.9.2 a		☐		
- fulfilment of objectives?	8.9.2 b		☐		
- suitability of policies and procedures?	8.9.2 c		☐		
- status of actions from previous management reviews?	8.9.2 d		☐		
- outcome of recent internal audits?	8.9.2 e		☐		
- corrective actions?	8.9.2 f		☐		
- assessments by external bodies?	8.9.2 g		☐		
- changes in the volume and type of the work or in the range of laboratory activities?	8.9.2 h		☐		
- customer and personnel feedback?	8.9.2 i		☐		
- complaints?	8.9.2 j		☐		
- effectiveness of any implemented improvements?	8.9.2 k		☐		
- adequacy of resources?	8.9.2 l		☐		
- results of risk identification?	8.9.2 m		☐		
- outcomes of the assurance of the validity of results?	8.9.2 n		☐		
- other relevant factors, such as monitoring activities and training?	8.9.2 o		☐		

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ISO/IEC 17025:2017 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at laboratory
Do the outputs from the management review record all decisions and actions related to at least:					
- the effectiveness of the management system and its processes?	8.9.3 a		☐		
- improvement of the laboratory activities related to the fulfilment of the requirements of ISO/IEC 17025:2017?	8.9.3 b		☐		
- provision of required resources?	8.9.3 c		☐		
- any need for change?	8.9.3 d		☐		

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

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
covering the result of such activity?					
When making any statement in relation to your laboratory's accreditation status in situation where non-accredited activities are mentioned, will your laboratory ensure that such a statement is accompanied by a statement indicating which activities are not accredited?	HKAS 002 5.3		☐		
Is your laboratory 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 laboratory cooperate with HKAS Executive and its assessment teams and provide them with full support during an on-site assessment and in any other situation such as to provide all necessary information for assessment of the laboratory's competence and its conformity with the accreditation criteria?	HKAS 002 5.5		☐		
Upon the request of HKAS Executive, will your laboratory 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 laboratory 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 laboratory maintain complete integrity and impartiality in all circumstances?	HKAS 002 5.7		☐		
Does your laboratory issue and implement a pertinent code of conduct for all its directors, officers, employees and other personnel involved in its operation?	HKAS 002 5.7		☐		
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 HKSAR)?	HKAS 002 5.7		☐		
Will the authorised representative further report any impropriety or unlawful act of the organisation or any iniquitous management and/or staff to HKAS Executive?	HKAS 002 5.7		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
Will your laboratory notify HKAS Executive within one calendar month if a new authorised representative has been appointed?	HKAS 002 5.8		☐		
Will the authorised representative or in his absence, other responsible person of the laboratory inform HKAS Executive in writing immediately of any changes or intended changes in the laboratory's circumstances which may affect its conformity with relevant accreditation criteria?	HKAS 002 5.9		☐		
Does your laboratory implement the following HKAS regulation on confidentiality: 'An applicant or 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 or accredited organisation shall obtain consent from their customers for the disclosure of any relevant information to HKAS.'?	HKAS 002 5.10		☐		
Does your laboratory 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 laboratory's assessment made between the authorised representative or his/her representative or its chief executive or his/her representative and HKAS Executive?	HKAS 002 5.11		☐		
Does your laboratory have a clear policy in writing concerning offering, solicitation and acceptance of advantages as stipulated in the Prevention of Bribery Ordinance by its personnel?	HKAS 002 5.12		☐		
Does the policy document contain a statement notifying its personnel of the law under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)?	HKAS 002 5.12		☐		
Does your laboratory further ensure that the policy is made known to all its	HKAS 002		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
personnel?	5.12				
Does your laboratory 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 laboratory 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 compliance with your laboratory's polices or procedures, will your laboratory 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 laboratory notify HKAS Executive in writing of this matter?	HKAS 002 5.15		☐		
Is your laboratory aware that any concerned party may lodge complaints with HKAS on any of your accredited activities?	HKAS 002 5.16		☐		
Will your laboratory cooperate with HKAS Executive and provide them with full support for investigation of those complaint upon request?	HKAS 002 5.16		☐		
Is your laboratory 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		☐		
Is your laboratory aware of the following HKAS regulation? 'An applicant or 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	HKAS 002 5.18		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
organisation in violation of this requirement.'					
Use of HKAS accreditation symbols and claims of accreditation status					
Does your laboratory implement the following HKAS regulation:-			☐		
'An accredited organisation may use the relevant HKAS accreditation symbols and claim its accreditation status as described in HKAS Supplementary Criteria No. 1 – 'Use of HKAS accreditation symbols and claims of 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 8.1 a		☐		
(b) HKAS Supplementary Criteria No. 1 – 'Use of HKAS accreditation symbols and claims of accreditation status' and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations, are conformed with at all times; and	HKAS 002 8.1 b		☐		
(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 8.1 c		☐		
Is your laboratory aware 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 laboratory ensure that its customers, on receiving any HKAS endorsed report, 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 or certificate is in no way approved nor disapproved by HKAS or HKAS Executive?	HKAS 002 8.2		☐		
Upon suspension or termination of the accreditation of any activities carried out by an organisation, regardless of whether it is voluntarily made, will your organisation discontinue to make reference to the accreditation in any report, certificate, and other document reporting conformity assessment results, letterhead, brochure,	HKAS 002 8.3		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
advertising material, stationery, and Internet websites, etc., immediately?					
Specific regulations for HKAS					
Has your laboratory documented a code of conduct within its management system for stating its policies on impartiality, confidentiality, professionalism, integrity, conflict of interest, and the organisation's commitment to complying with the Prevention of Bribery Ordinance (Cap 201) of Hong Kong or applicable laws and regulations of the country where the accredited organisation is located?	HKAS SC-06 2.1		☐		
Does the code of conduct cover at least the following aspects:					
- Solicitation and acceptance of advantage	HKAS SC-06 2.2 a		☐		
- offer of advantage?	HKAS SC-06 2.2 b		☐		
- entertainment?	HKAS SC-06 2.2 c		☐		
- compliance with laws of Hong Kong or of relevant jurisdictions?	HKAS SC-06 2.2 d		☐		
- conformity with relevant requirements of applicable professional standards?	HKAS SC-06 2.2 e		☐		
- conflict of interest?	HKAS SC-06 2.2 f		☐		
- use of company assets?	HKAS SC-06 2.2 g		☐		
- confidentiality of company information?	HKAS SC-06 2.2 h		☐		
- outside employment?	HKAS SC-06 2.2 i		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
- relationship with customers, suppliers and contractors?	HKAS SC-06 2.2 j		☐		
- procedures for reporting suspected violation and established mechanism for the prompt and fair adjudication of alleged violations?	HKAS SC-06 2.2 k		☐		
- disciplinary actions to be taken against violations?	HKAS SC-06 2.2 l		☐		
Does your laboratory determine the contents of the code of conduct in accordance with its circumstances to ensure that all personnel working for it act lawfully, ethically, professionally, and honestly and protect the impartiality, independence and integrity of the organisation?	HKAS SC-06 2.3		☐		
Does your laboratory ensure that all personnel including its directors, staff and other personnel working for it understand and implement the code of conduct?	HKAS SC-06 3.1		☐		
Has your laboratory provided training to all personnel as part of the orientation training when they join the organisation and refresher training to all personnel periodically thereafter?	HKAS SC-06 3.2		☐		
Does your laboratory periodically remind all personnel working for it the code of conduct?	HKAS SC-06 3.3		☐		
Is the code of conduct accessible to all personnel working for the organisation?	HKAS SC-06 3.4		☐		
Is the authorised representative aware that he/she shall report any impropriety or unlawful act of the organisation or any iniquitous management and/or staff to HKAS Executive in accordance with HKAS 002 clause 5.7?	HKAS SC-06 3.5		☐		
Does your laboratory periodically review the code's suitability and adequacy; and implement improvement as appropriate?	HKAS SC-06 3.6		☐		
Specific regulations for HOKLAS					
Is your laboratory aware of the following accreditation regulation on accreditation procedure:	HOKLAS SC-33 2.1		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
'An assessment team may require a laboratory to demonstrate a test, a calibration or other laboratory activities as part of an assessment. It may also require the laboratory to participate in proficiency testing in order to evaluate its standard and competence. The specific laboratory activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team.'?					
Does your laboratory have, where appropriate, legally enforceable arrangements with its customers that commit the customers to provide, on request, access to HKAS assessment teams to assess the laboratory's performance when carrying out laboratory activities at its customers' site?	HOKLAS SC-33 2.1		☐		
Is your laboratory aware of the following accreditation regulation on accreditation procedure:					
'HKAS Executive shall conduct a reassessment on the accredited activities of a laboratory:-					
(a) within twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the laboratory;	HOKLAS SC-33 2.2 a		☐		
(b) every two years after the due date of the first reassessment or at such time intervals as specified for the Monitoring Plan adopted by the laboratory;	HOKLAS SC-33 2.2 b		☐		
(c) at such other times as may be specified in the terms of accreditation;	HOKLAS SC-33 2.2 c		☐		
(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited laboratory, of any change in the structure and circumstances of the laboratory since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the laboratory's competence or conformity with the accreditation criteria; and	HOKLAS SC-33 2.2 d		☐		
(e) HKAS Executive may, at its discretion, vary the reassessment schedule.'?	HOKLAS SC-33		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
	2.2 e				
Is your laboratory aware of the following accreditation regulation on accreditation procedure: 'HKAS Executive shall conduct a surveillance visit to an accredited laboratory if neither reassessment, assessment for extension of accreditation, nor surveillance visit to it has been conducted within the past twelve months' period or at such time intervals as specified for the Monitoring Plan adopted by the laboratory. HKAS Executive may, at its discretion, vary the surveillance visit schedule.'?	HOKLAS SC-33 2.3		☐		
Is your laboratory aware of the following HKAS regulation: 'Upon granting of accreditation for a test category to a laboratory, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for such test category.'?	HOKLAS SC-33 2.4		☐		
Does your laboratory at all times comply with the following HOKLAS accreditation criteria? HKAS 002, ISO/IEC 17025:2017, HKAS Policy Document No. 1, relevant HOKLAS Supplementary Criteria and relevant HKAS Supplementary Criteria.	HOKLAS SC-33 3.1		☐		
Does your laboratory ensure that its accreditation status will not be used 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 approved or disapproved by HKAS or HKAS Executive? Will your laboratory further endeavour to ensure that no person will use any certificate, report, statement or documentation issued by it for such activity in a misleading manner?	HOKLAS SC-33 3.2		☐		
Is your laboratory aware of the following HKAS regulation on cooperation with customers: 'A laboratory accredited under HOKLAS shall afford its customers or their representative reasonable cooperation to monitor the laboratory's performance (in so far as to their respective contracts are concerned). This cooperation shall include: (a) performing any reasonable check tests or calibrations or checks for other laboratory activities, including to prepare, pack and dispatch the test pieces, samples and other items for such check activities, which serve to verify its capability or standard of service as requested by the customer;	HOKLAS SC-33 3.3 a		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
(b) allowing each of its customers or their representatives reasonable access to the laboratory in order to observe any test, calibration or other activity performed by it for the customer. However, the laboratory shall ensure that the confidentiality of its other customers will be protected and their information will not be divulged to any third party (subject to clause 5.10 of HKAS 002). For avoidance of doubt, the laboratory may also take reasonable steps to protect its proprietary information and agree with its customers the cost they have to pay to the laboratory for performing or taking part in such monitoring activities.'?	HOKLAS SC-33 3.3 b		☐		
Is your laboratory aware of the following HKAS regulation on subcontracting: 'If an accredited laboratory intends to subcontract any part of its activities for which HOKLAS accreditation has been granted, it shall ensure that the activities of the laboratory to which the activities will be subcontracted have been accredited by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement. A list of such accreditation bodies is available at the HKAS website. The accredited laboratory shall also - document its policy and procedures for subcontracting; - require its subcontractor to perform the subcontracted test or calibration by itself, and not to further subcontract the test or calibration to another laboratory; - notify its customer concerned in writing of its intention to subcontract the activities and the extent of such subcontracting. It shall obtain agreement from the customer regarding such arrangement and shall further keep records of such agreement; - identify the activities performed and the results obtained by such subcontractor in the report or certificate.'?	HOKLAS SC-33 3.4		☐		
Does your laboratory participate in proficiency testing (PT) activities (either PT or inter-laboratory comparison (ILC) other than PT, if PT is not available) which are relevant to its scope of accreditation, taking into consideration of the outcome of the laboratory's risk assessment?	HOKLAS SC-33 3.5		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
Is the performance of your laboratory in any PT activity relevant to its scope of accreditation acceptable to HKAS Executive?	HOKLAS SC-33 3.5		☐		
Is your laboratory aware of the following HKAS regulation on proficiency testing: 'An applicant laboratory shall have taken part in appropriate PT activities, representative of each test area of the laboratory's scope of accreditation to demonstrate its competence in each test area, and obtain satisfactory result before initial accreditation or accreditation extended to a new test area will be granted.'?	HOKLAS SC-33 3.6		☐		
Does your laboratory maintain appropriate evidence of the competence of its PT providers or ILC organisers?	HOKLAS SC-33 3.7		☐		
Does your laboratory establish a one-year PT participation plan with the coverage being representative and adequate to demonstrate your laboratory's competence in performing tests under its scope of accreditation?	HOKLAS SC-33 3.8		☐		
Where suitable PT activities do not exist or are not practical, has your laboratory included suitable alternative means aiming to demonstrate the laboratory's competence in the plan?	HOKLAS SC-33 3.8		☐		
Has the plan been regularly reviewed and updated where necessary (for example, in response to changes of the scope of accreditation, staffing, methodology, instrumentation, outcome of the laboratory's risk assessment and other factors that may affect the quality of the laboratory's test or calibration results)?	HOKLAS SC-33 3.8		☐		
Has any change to the plan been documented and justified?	HOKLAS SC-33 3.8		☐		
When the laboratory updates its PT plan, does your laboratory ensure its continual suitability in relation to its scope of accreditation?	HOKLAS SC-33 3.8		☐		
Is your laboratory aware of the following HKAS regulation on PT: 'Records of PT participation for the past four years shall be available to show that the laboratory participated in PT activities representative of the accredited	HOKLAS SC-33 3.9		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
tests/calibration activities under each test area of its scope of accreditation. PT activities participated to represent a group of tests in a test area are expected to vary in subsequent cycles. It should be noted that the necessary level of participation in PT for certain technical disciplines may be specifically defined in the relevant HOKLAS Supplementary Criteria. Where defined, the laboratory shall ensure that the planned participation fulfils the respective PT requirements as stated in the relevant supplementary criteria. Where more stringent PT requirements are stipulated in the relevant supplementary criteria, the more stringent requirements shall be followed.'?					
Is your laboratory aware of the following HKAS regulation on proficiency testing: 'An assessment team shall determine the adequacy of the PT participation plan and the appropriateness of any PT activities and may, at its discretion, require the laboratory to participate in other forms of PT activity so as to evaluate its competence in performing specific tests, calibrations or other laboratory activities. Where an applicant or an accredited laboratory is unable to participate in any appropriate PT activity because it fails to identify a suitable PT programme or ILC, it shall demonstrate to the satisfaction of the assessment team that it has taken all reasonable steps to identify such PT programme or ILC and any justification to use alternative suitable means shall be documented. In this clause, PT activity includes any international, regional and national interlaboratory comparisons as well as measurement audits and check samples acceptable to HKAS.'?	HOKLAS SC-33 3.10		☐		
Where the performance of an accredited laboratory in a PT activity is unsatisfactory, has your laboratory investigated the cause and take effective corrective actions?	HOKLAS SC-33 3.11		☐		
Are relevant records of corrective actions kept?	HOKLAS SC-33 3.11		☐		
Has your laboratory demonstrated promptly the effectiveness of its corrective actions and that it can achieve satisfactory PT performance for the activity in question?	HOKLAS SC-33 3.11		☐		
If your laboratory cannot rectify the unsatisfactory PT performance for an accredited activity within a reasonable timeframe (e.g. three months), has your laboratory notified HKAS Executive in writing of the actions taken to address the	HOKLAS SC-33 3.11		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
problem and the measures taken to deal with request for the problematic activity?					
Is your laboratory aware of the following HKAS regulation on approved signatory: 'An applicant laboratory shall nominate person(s) to HKAS Executive for signing endorsed reports and certificates for every test, calibration or other activity in the scope of accreditation. Accreditation for such activity will not be granted unless HKAS Executive is satisfied that at least one nominee meets the requirements for approved signatories as laid down in the accreditation criteria. An accredited laboratory shall maintain at least one approved signatory for each accredited activity. Additional persons may be nominated by an accredited laboratory to HKAS Executive for approval as approved signatories at any time.'?	HOKLAS SC-33 3.12		☐		
'A person nominated for approved signatory shall: - be an employee of or under contract to the laboratory and has been authorised by the accredited laboratory to sign reports or certificates issued by the laboratory for specific activities; - be familiar with the management system and operation of the laboratory; - have sufficient contact with the laboratory to enable him to have an in-depth understanding on the operation of the laboratory and have confidence in the validity of the test results which are obtained in accordance with the laboratory's documented procedures; - be competent to make critical evaluation of the reported results with adequate knowledge of the technical procedures and understanding of their underlying principles, interpretations and limitations; - occupy a position in his/her organisation's staff structure that makes him/her responsible for the accuracy of such results; - be fully aware of the HOKLAS Accreditation Criteria as specified in clause 3.1 of HOKLAS SC-33; - have the necessary qualifications and experience.'?	HOKLAS SC-33 3.13		☐		
'As signatory approval is granted in the context of the work being performed in a particular laboratory, such approval shall not be considered as a personal qualification.'?	HOKLAS SC-33 3.14		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
Is your laboratory aware of the following HKAS regulation on approved signatory: 'An accredited laboratory shall inform HKAS Executive forthwith of any change in the availability and duties of any of its HOKLAS approved signatories. HKAS Executive shall withdraw the approval concerning such approved signatory who no longer meets the requirements for approved signatories as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a laboratory for a test, calibration or other laboratory activity if it does not have any approved signatory for such activity 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 activity.'?	HOKLAS SC-33 3.15		☐		
Is your laboratory aware of the following HKAS regulation on integrity: 'An applicant laboratory shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant laboratory intentionally provides false information or if the applicant laboratory 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-33 3.16		☐		
Will the authorised representative of your laboratory, within 14 days from the effective date of any suspension or termination (voluntarily or by HKAS Executive), identify the customers to whom the laboratory has issued results for tests, calibrations or other activities which are found to be unreliable because of the deficiencies discovered during the investigation of the suspension and termination, and inform them that the results are unreliable?	HOKLAS SC-33 4.1		☐		
Is your laboratory aware of the following HKAS regulation on suspension: 'The laboratory 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-33 4.1		☐		
Is your laboratory aware of the following HKAS regulation on suspension and termination: 'HKAS Executive may publish information relating to any suspension and termination of accreditation granted by HKAS in any HKAS publications and in	HKAS 002 2.10		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
the website of HKAS.'?					
Is your laboratory aware of the following HKAS regulation: 'An accredited laboratory may display the appropriate HOKLAS accreditation symbol in a report or certificate issued by it for reporting the result(s) of an activity accredited under HOKLAS. Such a document is referred to hereafter as a HOKLAS endorsed report or certificate.'?	HOKLAS SC-33 5.1		☐		
Is your laboratory aware of the following HKAS regulation: 'An accredited laboratory shall include in a HOKLAS endorsed report or certificate the following:-					
(a) the HOKLAS accreditation symbol (which includes the laboratory's registration number and identification code of the accreditation programme) at the top right hand corner of the front page;	HOKLAS SC-33 5.2 a		☐		
(b) on the same page the following statements:-					
(i) for non-medical laboratories 'HKAS has accredited this laboratory (Reg. No. HOKLAS 999) under HOKLAS for specific laboratory activities as listed in the HOKLAS directory of accredited laboratories.'	HOKLAS SC-33 5.2 b(i)		☐		
(ii) for calibration laboratories 'HKAS has accredited this laboratory (Reg. No. HOKLAS 999) under HOKLAS for specific calibration activities as listed in the HOKLAS directory of accredited laboratories. The results shown in this report (or certificate, where appropriate) are traceable to the International System of Units (SI) or recognised measurement standards.'	HOKLAS SC-33 5.2 b(ii)		☐		
The word 'this laboratory' in the first sentence of the above statement may be replaced by the full identity of the laboratory as listed in the scope of accreditation. When the statement is used alone to claim a laboratory's accreditation status without displaying the accreditation symbol (See clause 5.3 of HOKLAS SC-33), the same words shall be replaced by the full identity, registration number and identification code of the accreditation programme (in form of e.g., ABC Testing Limited, Registration Number HOKLAS 999 and the appropriate Identification Code such as 'TEST', 'CAL' etc.).			☐		
(c) A HOKLAS endorsed report or certificate shall also bear either:-					

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
(i) a statement indicating that such report or certificate shall not be reproduced except in full, or	HOKLAS SC-33 5.2 c(i)		☐		
(ii) a statement indicating the conditions under which such report or certificate may be reproduced either in full or in part. Any extract or abstract of a HOKLAS endorsed report or certificate shall not contain the HOKLAS accreditation symbol nor other details as specified in clause 5.2 (b) above unless the authorised representative of the accredited laboratory which issues the report or certificate 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-33 5.2 c(ii)		☐		
Is your laboratory aware of the following HKAS regulation: 'For reports and certificates issued for internal use and where it is technically not possible or very difficult to display the accreditation symbol on a report or certificate, claiming of accreditation status may be made with the statements in 5.2 (b) without displaying the accreditation symbol. Such claim without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive. The laboratory should note that an endorsed report or certificate shall bear the accreditation symbol. It should also note that if it selects to claim the accreditation status with one of the statements in 5.2 (b) without displaying the accreditation symbol, requirements that govern the issue of HOKLAS endorsed report as detailed in HOKLAS SC-33 and HKAS 002 shall also apply to such reports or certificates.'?	HOKLAS SC-33 5.3		☐		
Does your laboratory ensure that the term 'HOKLAS', the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS will not be used in any report or certificate of laboratory activities except as described above in clause 5.2 and 5.3 of HOKLAS SC-33?	HOKLAS SC-33 5.4		☐		
Does your laboratory ensure that the form, size, colour and usage of the HOKLAS accreditation symbol are in accordance with Supplementary Criteria No. 1?	HOKLAS SC-33		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
	5.5				
Is your laboratory aware of the following HKAS regulation: 'A HOKLAS endorsed report or certificate shall be signed by a HOKLAS approved signatory of the issuing laboratory. For printed reports or certificates, such signature shall be made in hand-written form. For reports or certificates in an electronic form, the electronic signature shall be in a form acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identity document such as identity card or passport) shall be clearly shown alongside the signature. Other arrangements of signing HOKLAS endorsed reports or certificates may be acceptable 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-33 5.6		☐		
Is your laboratory aware of the following HKAS regulation: 'A HOKLAS endorsed report or certificate may contain signatures of others provided that one of the laboratory's HOKLAS approved signatories has signed the report or certificate. Where signatures other than the approved signatory also appear on the report or certificate, the capacity of the one who signed (such as his capacity as the quality manager) shall appear on the report or certificate.'?	HOKLAS SC-33 5.7		☐		
Do HOKLAS endorsed reports or certificates issued by your laboratory contain only the results of the tests, calibrations or other laboratory activities for which your laboratory is holding valid HOKLAS accreditation?	HOKLAS SC-33 5.8		☐		
Is your laboratory aware of the following HKAS regulation: 'The results of any activity, including sampling activity, which has not been accredited (whether obtained by the laboratory or its subcontractor) can only be included in a HOKLAS endorsed report or certificate if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed report and certificate which contains the said results shall clearly state therein that the activities are not covered by the laboratory's HOKLAS accreditation, unless the activities have been explicitly excluded in the scope of accreditation of the	HOKLAS SC-33 5.9		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
laboratory'?					
Does your laboratory keep at least one exact copy of the test report or certificate for any accredited activities issued by it for record? Does your laboratory also keep such copies of report or certificate, all original observations and records in relation to any accredited activity performed by it for a period of not less than four years or for a period specified by the HKAS Executive?	HOKLAS SC-33 5.10		☐		
Does your laboratory ensure that each HOKLAS endorsed report/certificate, or any report/certificate with the accreditation status claimed, comply with all relevant accreditation criteria as specified by HKAS Executive from time to time?	HOKLAS SC-33 5.11		☐		
Is your laboratory aware of the following HKAS regulation:					
'An accredited laboratory may issue a HOKLAS endorsed report or certificate which extends the results of a test, a calibration or another laboratory activity on a sample or samples to the properties or qualities of the inspected lot, batch or consignment from which the sample(s) was drawn provided that:					
(a) the accredited laboratory's scope of accreditation covers the sampling involved; and	HOKLAS SC-33 5.12 a		☐		
(b) the sample or samples concerned were taken by staff of the accredited laboratory using the accredited sampling procedure.'?	HOKLAS SC-33 5.12 b		☐		
Is your laboratory aware of the following HKAS regulation:					
'A HOKLAS endorsed report or certificate may include statements in amplification of results reported therein provided that:-					
(a) where a sample, batch or consignment is tested, calibrated or examined to specification requirements, such statements shall be limited to information as to whether or not the sample, batch or consignment conforms to the specification requirements and the manner or degree in which it departs from such specification requirements;	HOKLAS SC-33 5.13 a		☐		
(b) where a sample is not tested, calibrated or examined to specification requirements, such statements shall be limited to explanation of the results as is necessary for interpretation of their meaning; and	HOKLAS SC-33 5.13 b		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at laboratory
(c) where an instrument or measuring device is calibrated, such statements shall be limited to:- (i) the uncertainty to be associated with its use, or (ii) the information referred to in (a) or (b) above as appropriate.'?	HOKLAS SC-33 5.13 c		☐		
Is your laboratory aware of the following HKAS regulation: 'Opinions or interpretations for which a laboratory is not accredited for providing can only be included in a HOKLAS endorsed report or certificate if HKAS Executive has given its approval for such inclusion in writing. An endorsed report or certificate containing such opinions or interpretations shall in all cases clearly state that the laboratory is not accredited for providing such opinions or interpretations.'?	HOKLAS SC-33 5.14		☐		
Is your laboratory aware of the following HKAS regulation: 'Application for any accreditation service from HKAS shall be made in appropriate forms. These forms can be downloaded at the HKAS website.'?	HOKLAS SC-33 6.1		☐		
Is your laboratory aware that you shall submit the letterhead and formats of HOKLAS endorsed report and certificate, or formats of reports claiming accreditation status but without the use of the accreditation symbol as per HOKLAS SC-33 clause 5.3 to HKAS Executive for approval before use?	HOKLAS SC-33 7.1		☐		
Is your laboratory aware that you shall not issue any test report or calibration certificate containing any logo, symbol or statement that may be interpreted by any person that the activities or results reported are covered by certification?	HOKLAS SC-33 7.2		☐		

End

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