HOKLAS018 Annex II

Checklist

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

The checklist consists of questions based on the requirements of ISO/IEC 17043:2010, HKAS 002 and HOKLAS Supplementary Criteria No. 34. For further information, please refer to the corresponding document and clause as listed in the second column.

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

The columns headed '*', 'Y', 'N', 'NA' are for internal use of HKAS Executive.

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

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Technical Requirements							
General	4.1						
Is your laboratory or your subcontractor's laboratory accredited to ISO/IEC 17025 or ISO 15189?							
If your proficiency test items are reference materials, is the producer of the reference materials that provide proficiency test items accredited to ISO 17034?							
Personnel	4.2						
Do the managerial and technical personnel have the necessary authority, resources and technical competence required to perform their duties?	4.2.1						
Has the proficiency testing provider's management defined the minimum levels of qualification and experience necessary for the key positions within its organisation and ensured those qualifications are met?	4.2.2						
Are the personnel employed by, or under contract to the proficiency testing provider? Where contracted and additional technical and key support personnel are used, are they supervised and competent and do they work in accordance with the management system?	4.2.3						
NOTE Where technical experts are used on an ad-hoc basis or as part of an advisory or steering group (see 4.4.1.4), the existence of formal agreements through, for example, group terms of reference or other means, can be considered to satisfy this requirement.							
Are specific personnel authorized by the proficiency testing provider to:	4.2.4						
- select appropriate proficiency test items?	4.2.4a						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- plan proficiency testing schemes?	4.2.4b						
- perform particular types of sampling?	4.2.4c						
- operate specific equipment?	4.2.4d						
 conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the proficiency test item? 	4.2.4e						
- prepare, handle and distribute proficiency test items?	4.2.4f						
- operate the data processing system?	4.2.4g						
- conduct statistical analysis?	4.2.4h						
- evaluate the performance of proficiency testing participants?	4.2.4i						
- give opinions and interpretations?	4.2.4j						
- authorize the issue of proficiency testing reports?	4.2.4k						
Are up-to-date records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel maintained? Are these information readily available and do they include the date on which competence to perform their assigned tasks was assessed and confirmed?	4.2.5						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are the objectives with respect to the education, training, and skills for each staff member involved with the operation of the proficiency testing scheme formulated? Are there policy and procedures for identifying training needs and providing training of personnel? Is the training programme relevant to the present and anticipated needs of the proficiency testing provider?	4.2.6						
NOTE It is advisable to consider the need to retrain staff periodically. Staff training policies can take account of technological change, the need to demonstrate ongoing competence and aim at continual skills upgrading.							
Are staff trained to ensure their competent performance of measurements, operation of equipment and any other activities which affect the quality of the proficiency testing scheme? Is the effectiveness of training activities evaluated?	4.2.7						
NOTE Objective measures can be used to assess the attainment of competence.							
Equipment, accommodation and environment	4.3						
Is there appropriate accommodation for the operation of the proficiency testing scheme? This includes facilities and equipment for proficiency test item manufacturing, handling, calibration, testing, storage and despatch, for data processing, for communications, and for retrieval of materials and records.	4.3.1	•					
Do the environmental conditions not compromise the proficiency testing scheme or the required quality of operations? Is particular care taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by subcontractors? Are the technical requirements for accommodation and environmental conditions that can affect the proficiency testing documented?	4.3.2	•					
Is access to and use of areas affecting the quality of proficiency testing schemes controlled? Does the proficiency testing provider determine the extent of control based on its particular circumstances?	4.3.3	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are environmental conditions that can significantly influence the quality of the proficiency test items and any testing and calibration carried out, including conditions that are required by relevant specifications and measurement procedures identified, controlled and monitored and all relevant monitoring activities recorded? When the environmental conditions jeopardize the quality or the operations of the proficiency testing scheme, are the relevant proficiency testing activities stopped?	4.3.4	•					
NOTE Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.							
Are there effective separation between neighbouring areas in which there are incompatible activities? Are action taken to prevent cross-contamination?	4.3.5	•					
Are the performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of proficiency testing items appropriately validated and maintained?	4.3.6	•					
Design of proficiency testing schemes	4.4						
Planning	4.4.1						
Are those processes which directly affect the quality of the proficiency testing scheme identified and planned? Are they carried out in accordance with prescribed procedures?	4.4.1.1	•					
NOTE Stakeholders' interests can be considered in developing a plan and relevant information.							
Does the proficiency testing provider plan the proficiency testing scheme by itself? (see 5.5.2).	4.4.1.2	•					
NOTE The proficiency testing provider can utilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4).							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Is a plan documented before commencement of the proficiency testing scheme? Does the plan address the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:	4.4.1.3	•					
- the name and address of the proficiency testing provider?	4.4.1.3a						
- the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the proficiency testing scheme?	4.4.1.3b						
- the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the proficiency testing scheme?	4.4.1.3c						
- criteria to be met for participation?	4.4.1.3d						
- the number and type of expected participants in the proficiency testing scheme?	4.4.1.3e						
- selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round?	4.4.1.3f						
- a description of the range of values or characteristics, or both, to be expected for the proficiency test items?	4.4.1.3g						
- the potential major sources of errors involved in the area of proficiency testing offered?	4.4.1.3h						
- requirements for the production, quality control, storage and distribution of proficiency test items?	4.4.1.3i						
 reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected? 	4.4.1.3j						

HOKLA	S 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
	a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme?	4.4.1.3k						
	for continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants?	4.4.1.31						
	any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements?	4.4.1.3m						
	procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability?	4.4.1.3n						
	preparation of any standardized reporting formats to be used by participants?	4.4.1.30						
-	a detailed description of the statistical analysis to be used?	4.4.1.3p						
	the origin, metrological traceability and measurement uncertainty of any assigned values?	4.4.1.3q						
-	criteria for the evaluation of performance of participants?	4.4.1.3r						
	a description of the data, interim reports or information to be returned to participants?	4.4.1.3s						
	a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public?	4.4.1.3t						
-	actions to be taken in the case of lost or damaged proficiency test items?	4.4.1.3u						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Does the proficiency testing provider have access to the necessary technical expertise and experience in the relevant field of testing, calibration, sampling or inspection, as well as statistics? This may be achieved, if necessary, by establishing an advisory group (named as appropriate).	4.4.1.4	•					
Are technical expertise used, as appropriate, to determine matters such as the following:	4.4.1.5	•					
- planning requirements as listed in 4.4.1.3?	4.4.1.5a						
- identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items, or in the provision of a stable assigned value for a proficiency test item?	4.4.1.5b						
- preparation of detailed instructions for participants?	4.4.1.5c						
- comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds?	4.4.1.5d						
- provision of advice in evaluating the performance of participants?	4.4.1.5e						
- comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants?	4.4.1.5f						
- provision of advice for participants (within limits of confidentiality), either individually or within the report?	4.4.1.5g						
- responding to feedback from participants?	4.4.1.5h						
- planning or participating in technical meetings with participants?	4.4.1.5i						
Preparation of proficiency test items	4.4.2						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are procedures established and implemented to ensure that proficiency test items are prepared in accordance with the plan described in 4.4.1?	4.4.2.1	•					
NOTE It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.							
Are procedures established and implemented to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. Do the procedures ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements?	4.4.2.2	•					
Do the proficiency test items match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration?	4.4.2.3	•					
In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, are instructions for preparation, packaging and transport of the proficiency test item issued?	4.4.2.4	•					
Homogeneity and stability	4.4.3						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are criteria for suitable homogeneity and stability established and based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance?	4.4.3.1	•					
NOTE 1 The requirements in this subclause are intended to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. Careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.							
NOTE 2 In some cases, it is not feasible for proficiency test items to be subjected to homogeneity and stability testing. Such cases would include, for example, when limited material is available to prepare proficiency testing items.							
NOTE 3 In some cases, materials that are not sufficiently homogeneous or stable are the best available; in such cases, they can still be useful as proficiency test items, provided that the uncertainties of the assigned values or the evaluation of results take due account of this (see B.3.1.3 and ISO 13528:2005, Annex B).							
NOTE 4 Considerations for homogeneity and stability are further discussed in ISO 17034, ISO Guide 35 and ISO 13528.							
Are procedures for the assessment of homogeneity and stability documented and conducted, where applicable, in accordance with appropriate statistical designs? Does the proficiency testing provider use a statistically random selection of a representative number of proficiency test items from the whole batch of test material in order to assess the homogeneity of the material, where possible?	4.4.3.2	•					
NOTE In some cases, the use of a random stratified or systematic selection of proficiency test items from the whole batch is more appropriate.							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Is the assessment of homogeneity performed after the proficiency test items have been packaged in the final form and before distribution to participants unless, for example, stability studies indicate that they should be stored in bulk form?	4.4.3.3	•					
NOTE 1 Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.							
NOTE 2 On some occasions, homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons.							
Are proficiency test items demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency testing, including storage and transport conditions? When this is not possible, is the stability quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the proficiency test item, and/or taken into account in the evaluation criteria?	4.4.3.4	•					
When proficiency test items from previous rounds are retained for future use, are the property values to be determined in the proficiency testing scheme confirmed by the proficiency testing provider prior to distribution?	4.4.3.5	•					
In circumstances where homogeneity and stability testing is not feasible, are the procedures used to collect, produce, package and distribute the proficiency test items demonstrated to be sufficient for the purpose of the proficiency testing?	4.4.3.6	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Statistical design	4.4.4						
Are statistical designs developed to meet the objectives of the scheme, based on the nature of the data (quantitative or qualitative, including ordinal and categorical), statistical assumptions, the nature of errors, and the expected number of results (see B.3.2.2)?	4.4.4.1	•					
NOTE 1 Statistical design covers the process of planning, collection, analysis and reporting of the proficiency testing scheme data. Statistical designs are often based on stated objectives for the proficiency testing scheme, such as detection of certain types of errors with specified power or determination of assigned values with specified measurement uncertainty							
NOTE 2 Data analysis methods could vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different proficiency test items.							
NOTE 3 In cases where the proficiency testing scheme design is mandated by a specification given by, for example, a customer, regulatory authority or accreditation body, the statistical design and data analysis methods can be taken directly from the specification.							
NOTE 4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.							
Are the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results documented? Is a description of the reasons for their selection and assumptions upon which they are based provided? Does the proficiency testing provider able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures?	4.4.4.2	•					
In designing a statistical analysis, has careful consideration been given by the proficiency testing provider to the following:	4.4.4.3	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
 the accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measurand or characteristic in the proficiency testing? 	4.4.4.3a						
- the minimum number of participants in the proficiency testing scheme needed to meet the objectives of the statistical design; in cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of results, the proficiency testing provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance?	4.4.4.3b						
- the relevance of significant figures to the reported result, including the number of decimal places?	4.4.4.3c						
- the number of proficiency test items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each proficiency test item or for each determination?	4.4.4.3d						
- the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria?	4.4.4.3e						
- procedures to be used to identify or handle outliers, or both?	4.4.4.3f						
- where relevant, the procedures for the evaluation of values excluded from statistical analysis?	4.4.4.3g						
- where appropriate, the objectives to be met for the design and the frequency of proficiency testing rounds?	4.4.4.3h						
Assigned values	4.4.5						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are the procedures for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme documented? Does this procedure take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose?	4.4.5.1	•					
NOTE Metrological traceability is not always possible or appropriate.							
Do assigned values for proficiency testing schemes in the area of calibration have metrological traceability, including measurement uncertainty?	4.4.5.2	•					
For proficiency testing schemes in areas other than calibration, have the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value been determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme?	4.4.5.3	•					
NOTE The required metrological traceability chain can differ depending on the type of proficiency test item, the measurand or characteristic, and the availability of traceable calibrations and reference materials.							
When a consensus value is used as the assigned value (see Annex B), is the reason for that selection documented and the uncertainty of the assigned value as described in the plan for the proficiency testing scheme estimated?	4.4.5.4	•					
Is there a policy regarding the disclosure of assigned values? Does the policy ensure that participants cannot gain advantage from early disclosure?	4.4.5.5	•					
Choice of method or procedure	4.5						
Are participants normally expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with their routine procedures? The proficiency testing provider may instruct participants to use a specified method in accordance with the design of the proficiency testing scheme.	4.5.1	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Where participants are permitted to use a method of their choice,	4.5.2						
 does the proficiency testing provider have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods? 	4.5.2a	•					
 is the proficiency testing provider aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly? 	4.5.2b	•					
Operation of proficiency testing schemes	4.6						
Instructions for participants	4.6.1						
Are the participants given sufficient prior notices before sending proficiency test items? Is the date on which the proficiency test items are likely to arrive or to be despatched provided, unless the design of the proficiency testing scheme makes it inappropriate to do so?	4.6.1.1	•					
Are detailed documented instructions to all participants given? Do instructions to participants include:	4.6.1.2	•					
- the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the proficiency testing scheme which require departure from this principle)?	4.6.1.2a						
details of factors which could influence the testing or calibration of the proficiency test items, e.g. the nature of the proficiency test items, conditions of storage, whether the proficiency testing scheme is limited to selected test methods, and the timing of the testing or measurement?	4.6.1.2b						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
 detailed procedure for preparing or conditioning, or both preparing and conditioning, of the proficiency test items before conducting the tests or calibrations? 	4.6.1.2c						
- any appropriate instructions on handling the proficiency test items, including any safety requirements?	4.6.1.2d						
 any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement? 	4.6.1.2e						
 specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability? 	4.6.1.2f						
NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places and reporting basis (e.g. on dry weight, or "as received").							
- the latest date for the provider to receive the proficiency testing or measurement results for analysis?	4.6.1.2g						
- information on the contact details of the proficiency testing provider for enquiries?	4.6.1.2h						
- instructions on return of the proficiency test items, when applicable?	4.6.1.2i						
Proficiency test items handling and storage	4.6.2						
Are proficiency test items appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants?	4.6.2.1	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are secure storage areas or stock rooms, or both, which prevent damage or deterioration of any proficiency test item between preparation and distribution provided? Are there appropriate procedures for authorizing despatch to, and receipt from, such areas defined?	4.6.2.2	•					
When appropriate, are the condition of stored or stocked proficiency test items, chemicals and materials assessed at specified intervals during their storage life in order to detect possible deterioration?	4.6.2.3	•					
Where potentially hazardous proficiency test items, chemicals and materials are used, are facilities available to ensure their safe handling, decontamination and disposal?	4.6.2.4	•					
Packaging, labelling and distribution of proficiency test items	4.6.3						
Are packaging and labelling processes controlled to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements?	4.6.3.1	•					
NOTE The proper distribution of proficiency test items can present severe problems for some types of material, e.g. those which require uninterrupted storage in cold conditions or which should not be exposed to X-rays, shock or vibration. Most types of chemical materials would benefit from air-tight packaging to avoid contamination by atmospheric contaminants, e.g. fuel vapours or engine exhaust gases which can be encountered during transport.							
Does the proficiency testing provider specify relevant environmental conditions for the transport of proficiency test items? Where relevant, are the pertinent environmental conditions of the proficiency test item during transport monitored and is the impact of environmental influences on the proficiency test item assessed?	4.6.3.2	•					
In proficiency testing schemes where participants are required to transport the proficiency test items to other participants, are documented instructions for this transport supplied?	4.6.3.3	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are labels securely attached to the packaging of individual proficiency test items? Are they designed to remain legible and intact throughout the proficiency testing round?	4.6.3.4	•					
Does the proficiency testing provider follow a procedure to enable the confirmation of delivery of the proficiency test items?	4.6.3.5	•					
NOTE This could be achieved in accordance with 4.6.1.1 by asking participants to inform the proficiency testing provider if proficiency test items have not been received in line with the schedule of dates provided.							
Data analysis and evaluation of proficiency testing scheme results	4.7						
Data analysis and records	4.7.1						
Are all data processing equipment and software validated in accordance with procedures before being brought into use? Does computer system maintenance include a back-up process and system recovery plan? Are the results of such maintenance and operational checks recorded?	4.7.1.1	•					
Are results received from participants recorded and analysed by appropriate methods? Are procedures established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting?	4.7.1.2	•					
Are the summary and performance statistics and the associated information generated from data analysis consistent with the statistical design of the proficiency testing scheme?	4.7.1.3	•					
Are robust statistical methods or appropriate tests to detect statistical outliers used to minimize the influence of outliers on summary statistics?	4.7.1.4	•					
Are criteria and procedures documented for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors?	4.7.1.5	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are criteria and procedures documented to identify and manage proficiency test items that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination?	4.7.1.6	•					
Evaluation of performance	4.7.2						
Does the proficiency testing provider use valid methods of evaluation which meet the purpose of the proficiency testing scheme? Are the methods documented and do they include a description of the basis for the evaluation?	4.7.2.1	•					
Does the proficiency testing provider evaluate the performance itself? (see 5.5.2).	4.7.2.1	•					
Where appropriate for the purpose of the proficiency testing scheme, does the proficiency testing provider provide expert commentary on the performance of participants with regard to the following:	4.7.2.2	•					
- overall performance against prior expectations, taking measurement uncertainties into account?	4.7.2.2a						
 variation within and between participants, and comparisons with any previous proficiency testing rounds, similar proficiency testing schemes, or published precision data? 	4.7.2.2b						
- variation between methods or procedures?	4.7.2.2c						
- possible sources of error (with reference to outliers) and suggestions for improving performance?	4.7.2.2d						
- advice and educational feedback to participants as part of the continual improvement procedures of participants?	4.7.2.2e						
- situations where unusual factors make evaluation of results and commentary on performance impossible?	4.7.2.2f						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- any other suggestions, recommendations or general comments?	4.7.2.2g						
- conclusions?	4.7.2.2h						
NOTE It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular proficiency testing scheme. These can include updated summaries of performance for individual participants over successive proficiency testing rounds of a continuous proficiency testing scheme. Such summaries can be further analysed and trends highlighted, if required.							
Reports	4.8						
Are proficiency test reports clear and comprehensive and do they include data covering the results of all participants, together with an indication of the performance of individual participants?	4.8.1	•					
NOTE Where all original data cannot be reported to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied.							
Does the proficiency testing provider authorize the final report itself (see 5.5.2)?		•					
Do reports include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:	4.8.2	•					
- the name and contact details for the proficiency testing provider?	4.8.2a						
- the name and contact details for the coordinator?	4.8.2b						
- the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report?	4.8.2c						
 an indication of which activities are subcontracted by the proficiency testing provider? 	4.8.2d						

HOKL	AS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
-	the date of issue and status (e.g. preliminary, interim, or final) of the report?	4.8.2e						
-	page numbers and a clear indication of the end of the report?	4.8.2f						
-	a statement of the extent to which results are confidential?	4.8.2g						
-	the report number and clear identification of the proficiency testing scheme?	4.8.2h						
-	a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment?	4.8.2i						
-	the participants' results?	4.8.2j						
-	statistical data and summaries, including assigned values and range of acceptable results and graphical displays?	4.8.2k						
-	procedures used to establish any assigned value?	4.8.21						
-	details of the metrological traceability and measurement uncertainty of any assigned value?	4.8.2m						
-	procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation?	4.8.2n						
-	assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants)?	4.8.20						
-	comments on participants' performance by the proficiency testing provider and technical advisers?	4.8.2p						
-	information about the design and implementation of the proficiency testing scheme?	4.8.2q						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- procedures used to statistically analyse the data?	4.8.2r						
- advice on the interpretation of the statistical analysis?	4.8.2s						
- comments or recommendations, based on the outcomes of the proficiency testing round?	4.8.2t						
NOTE For continuous proficiency testing schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause could be excluded from routine reports, but included in proficiency testing scheme protocols or in periodic summary reports that are available to participants.							
Are reports made available to participants within planned timescales? In sequential proficiency testing schemes, e.g. where the turn-around time may be very long, and in schemes involving perishable materials, are preliminary or anticipated results provided before final results are disclosed?	4.8.3	•					
NOTE This allows for early investigation of possible error.							
Is there a policy for the use of reports by individuals and organisations?	4.8.4	•					
When it is necessary to issue a new or amended report for a proficiency testing scheme, does it include the following:	4.8.5	•					
- a unique identification?	4.8.5a						
- a reference to the original report that it replaces or amends?	4.8.5b						
- a statement concerning the reason for the amendment or re-issue?	4.8.5c						
Communication with participants	4.9						
Is detailed information about the proficiency testing scheme available to participants? Does it include:	4.9.1	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- relevant details of the scope of the proficiency testing scheme?	4.9.1a						
- any fees for participation?	4.9.1b						
- documented eligibility criteria for participation?	4.9.1c						
- confidentiality arrangements?	4.9.1d						
- details of how to apply?	4.9.1e						
Are participants advised promptly of any changes in proficiency testing scheme design or operation?	4.9.2	•					
Are there documented procedures for enabling participants to appeal against the evaluation of their performance in a proficiency testing scheme? Is the availability of this process communicated to proficiency testing scheme participants?	4.9.3	•					
Are relevant records of communications with participants maintained and retained, as appropriate?	4.9.4	•					
If the proficiency testing provider issues statements of participation or performance, do they contain sufficient information to not be misleading?	4.9.5	•					
Confidentiality	4.10						
Are the identities of participants in a proficiency testing scheme confidential and known only to persons involved in the operation of the proficiency testing scheme, unless the participant waives confidentiality?	4.10.1	•					

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Is all information supplied by a participant treated as confidential?	4.10.2	•					
NOTE Participants can elect to waive confidentiality within the proficiency testing scheme for the purposes of discussion and mutual assistance, e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In most instances, the proficiency testing results can be provided to the relevant authority by the participants themselves.							
When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, are the participants made aware of the arrangement in advance of participation?	4.10.3	•					
In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, are the affected participants notified of this action in writing?	4.10.4	•					
Management requirements	5						
Organisation	5.1						
Is the proficiency testing provider, or the organisation of which it is part, an entity that is legally identifiable and accountable?	5.1.1						
Are proficiency testing operations carried out in such a way as to meet the requirements of this International Standard and to satisfy the needs of the participants, regulatory authorities and organisations providing recognition?	5.1.2						
Does the management system cover work carried out in the proficiency testing provider's permanent facilities, at sites away from its permanent facilities, and in associated temporary facilities?	5.1.3						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
If the proficiency testing provider is part of an organisation performing other activities, are the responsibilities of key personnel in the organisation that have an involvement in or could have influence on the proficiency test activities identified, in order to identify potential conflicts of interest? Where potential conflicts of interest are identified, are procedures put in place to ensure that all activities of the proficiency testing provider are conducted with impartiality?	5.1.4						
Does the proficiency testing provider:	5.1.5						
- have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for providing proficiency testing schemes, and to initiate actions to prevent or minimize such departures?	5.1.5a						
- have arrangements to ensure that its management and personnel are free from any undue internal or external commercial, financial and other pressures that may adversely affect the quality of their work?	5.1.5b						
 have policies and procedures to ensure the protection of its participants' confidential information and proprietary rights, including procedures for their protection during electronic storage and transmission? 	5.1.5c						
 have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity? 	5.1.5d						
 define the organisation and management structure, its place in any parent organisation, and the relationships between quality management, technical operations and support services? 	5.1.5e						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- specify the responsibility, authority, interrelationships and required competence of all personnel who manage, perform or verify work affecting the quality of the operation of proficiency testing schemes?	5.1.5f						
 ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system? 	5.1.5g						
- provide adequate supervision of technical staff, including trainees, by persons familiar with procedures for each activity?	5.1.5h						
- have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of proficiency testing schemes, including access to the necessary technical expertise and experience in the relevant field of testing, calibration or inspection, as well as statistics, as indicated in 4.4.1.4?	5.1.5i						
- appoint a member of staff as quality manager (named as appropriate) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on the proficiency testing provider's policies or resources?	5.1.5j						
- appoint deputies for key managerial personnel?	5.1.5k						
NOTE Where proficiency testing providers have a small number of personnel, individuals can have more than one function and it can be impractical to appoint deputies for all major functions.							
Does top management ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the management system?	5.1.6						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Management system	5.2						
Is a management system appropriate to its scope of activities, including the type, range and volume of proficiency testing that it provides established, implemented and maintained?	5.2.1						
Are policies, schemes, procedures and instructions defined and documented to the extent necessary to assure the quality of all aspects of proficiency testing? Is the system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel?	5.2.2						
NOTE These aspects include, but are not limited to, proficiency test item quality (e.g. homogeneity and stability), characterization (e.g. equipment calibration and method validation), assignment of property values (e.g. use of appropriate statistical procedures), evaluation of participant performance, distribution of proficiency test items, storage and transport procedures, statistical treatment of test results, and reporting.							
Are management system policies related to quality, including a quality policy statement, defined in a quality manual (named as appropriate)?	5.2.3						
Are the overall objectives established and reviewed during management review?	5.2.3						
Does the quality policy statement issued under the authority of top management include at least the following:							
- the management's commitment to the quality of its proficiency testing services to participants and other customers?	5.2.3a						
- the management's statement of the standard of service?	5.2.3b						
- the purpose of the management system related to quality?	5.2.3c						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- a requirement that all personnel concerned with the proficiency testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work?	5.2.3d						
- the management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system?	5.2.3e						
Does top management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?	5.2.4						
Does top management communicate to the organisation the importance of meeting customer requirements, as well as statutory and regulatory requirements?	5.2.5						
Does the quality manual include or make reference to the supporting procedures, including technical procedures? Does it outline the structure of the documentation used in the management system?	5.2.6						
Are the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, defined in the quality manual?	5.2.7						
Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?	5.2.8						
Document control	5.3						
General	5.3.1						
Are procedures established and maintained to control all documents that form part of the management system (internally generated, or from external sources), such as regulations, standards, other normative documents, proficiency testing scheme protocols, test or calibration methods, or both test and calibration methods, as well as drawings, software specifications, instructions and manuals?							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Document approval and issue	5.3.2						
Are all documents issued as part of the management system reviewed and approved for use by authorized personnel prior to issue? Is a master list or equivalent document control procedure identifying the current revision status and distribution of documents in the management system established and readily available, in order to prevent the use of invalid or obsolete documents, or both?	5.3.2.1						
Do the procedures adopted ensure that:	5.3.2.2						
 authorized editions of appropriate documents are available at all locations where activities essential to the effective operation of proficiency testing schemes are performed? 	5.3.2.2a						
- documents are periodically reviewed and updated, as necessary, to ensure continuing suitability and compliance with applicable requirements?	5.3.2.2b						
- invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?	5.3.2.2c						
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?	5.3.2.2d						
Are management system documents generated by the proficiency testing provider uniquely identified? Does such identification include the date of issue or revision identification, or both, page numbering, the total number of pages or a mark to signify the end of a document, and the issuing authority/authorities?	5.3.2.3						
Document changes	5.3.3						
Are changes to documents reviewed and approved by the same function that performed the original review and approval, unless specifically designated otherwise? Does the designated personnel have access to pertinent background information upon which to base their review and approval?	5.3.3.1						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Where practicable, are the altered or new text identified in the document or the appropriate attachments?	5.3.3.2						
If the document control system allows for the amendment of documents by hand, pending re-issue of the documents, are the procedures and authorities for such amendments defined? Are amendments clearly marked, initialed and dated? Is a revised document issued as soon as practicable?	5.3.3.3						
Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?	5.3.3.4						
Reviewed of requests, tenders and contracts	5.4						
Are policies and procedures for the review of requests, tenders and contracts established and maintained? Do these reviews ensure that:	5.4.1						
 the requirements, including those for test and calibration methods, measuring equipment and proficiency test items to be used, are adequately defined, documented and understood? 	5.4.1a						
- the proficiency testing provider has the capability and resources to meet the requirements?	5.4.1b						
- the proficiency testing scheme is technically appropriate?	5.4.1c						
NOTE 1 This review is particularly important when a customer requests a proficiency testing scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.							
NOTE 2 This review can be simplified when the proficiency test scheme is fully described in a catalogue or other notice, and the participant is enrolling for a routine shipment.							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are records of such reviews, including any changes, maintained? Are records also maintained of pertinent discussions with a customer relating to the customer's requirements, or the results of the work during the period of execution of the contract, or both?	5.4.2						
Does the review cover all aspects of the request, including any work that is subcontracted by the proficiency testing provider?	5.4.3						
Are the participants and other customers, as appropriate, informed of any deviation in the contract or agreed proficiency testing scheme design?	5.4.4						
If a request or contract is amended after the proficiency testing scheme is underway, is the same review process repeated and are the amendments communicated to all affected personnel?	5.4.5						
Subcontracting services	5.5						
When a proficiency testing provider subcontracts work, does the proficiency testing provider demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards?	5.5.1						
Does the proficiency testing provider plan the proficiency test scheme (see 4.4.1.2), evaluate performance (see 4.7.2.1) and authorize the final report (see 4.8.1) by itself?	5.5.2						
NOTE This does not preclude the proficiency testing provider utilizing advice or assistance from any advisors, experts or steering group.							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are participants informed, in advance and in writing, of services that are, or may be, subcontracted?	5.5.3						
NOTE This notification can, for example, take the form of a statement in the proficiency testing scheme documentation, such as the following: "Various aspects of the proficiency testing scheme can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the proficiency testing provider is responsible for this work."							
Is the proficiency testing provider responsible to the participants and other customers for the subcontractor's work, except in the case where a regulatory authority specifies which subcontractor is to be used?	5.5.4						
Is a register of all subcontractors used in the operation of proficiency testing schemes, including the scope of subcontracting and a record of the competence assessment against relevant parts of this International Standard and other appropriate standards for the work in question maintained?	5.5.5						
Purchasing services and supplies	5.6						
Are there a policy and procedure(s) for the selection of services and supplies to be used and that affect the quality of the proficiency testing schemes? Do procedures exist for the purchase, reception and storage of reagents, proficiency test items, reference materials and other consumable materials relevant for the proficiency testing schemes?	5.6.1						
Are purchased supplies, equipment and consumable materials that affect the quality of proficiency testing schemes not used until they have been inspected or otherwise verified as complying with specifications or requirements? Are records of actions taken to check compliance maintained?	5.6.2	•					
Do purchasing documents for items affecting the quality of proficiency testing schemes contain data describing the services and supplies ordered? Are these purchasing documents reviewed and approved for technical content prior to release?	5.6.3						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are suppliers of critical supplies and services which affect the quality of proficiency testing schemes evaluated? Does it maintain records of these evaluations, and list those suppliers that are approved?	5.6.4						
NOTE It is understood that some proficiency testing providers can be required to implement their purchasing procedures in accordance with policies defined by their parent company or a host organisation.							
Service to the customer	5.7						
Is the proficiency testing provider willing to cooperate with participants and other customers in clarifying customers' requests and in monitoring the proficiency testing provider's performance in relation to the work performed, provided that the proficiency testing provider assures confidentiality to its participants?	5.7.1						
Is feedback, both positive and negative, sought from its customers? Is the feedback used and analysed to improve the management system, proficiency testing schemes, and customer service?	5.7.2						
NOTE Examples of the types of feedback include customer satisfaction surveys and review of proficiency testing reports with customers.							
Complaints and appears	5.8						
Does the proficiency testing provider have a policy and follow a procedure for the resolution of complaints and appeals received from participants, customers or other parties? Are records maintained of all complaints, appeals, investigations and corrective actions taken by the proficiency testing provider?							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Control of nonconforming work	5.9						
Does the proficiency testing provider have a policy and procedure(s) that shall be implemented when any aspect of its activities does not conform to its own procedures or the agreed requirements of its customers? Do the policy and procedure(s) ensure that:	5.9.1						
 the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting work of ongoing schemes and withholding reports, as necessary) are defined and taken when nonconforming work is identified? 	5.9.1a						
- an evaluation of the significance of the nonconforming work is made?	5.9.1b						
 a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work? 	5.9.1c						
- proficiency testing scheme participants and other customers, as appropriate, are informed and the nonconforming proficiency test items or reports already sent to participants are recalled or disregarded?	5.9.1d						
- the responsibility for authorization of the resumption of work is defined?	5.9.1e						
NOTE Identification of nonconforming work or problems with the management system or with technical activities can occur at various places within the management system and technical operations. Examples are participant complaints, management reviews and internal or external audits, quality control, preparations of proficiency test items, homogeneity and stability tests, data analysis, instructions to participants, and materials handling and storage.							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the proficiency testing provider or subcontractor with their own policies and procedures, is the corrective action procedure in 5.11 promptly followed?	5.9.2						
Improvement	5.10						
Is the effectiveness of the management system continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?							
Corrective actions	5.11						
General	5.11.1						
Does the proficiency testing provider establish a policy and procedure(s) and designate appropriate personnel for implementing corrective actions when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?							
NOTE See 5.9.1, Note.							
Cause analysis	5.11.2						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?							
NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often, the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, proficiency test items and their specifications, methods and procedures, staff skills and training, consumable supplies, preparations of proficiency test items, homogeneity and stability tests, statistical design, instructions to participants, and materials handling and storage.							
Selection and implementation of corrective actions	5.11.3						
Where corrective action is needed, are potential corrective actions identified? Are the action(s) most likely to eliminate the problem and to prevent recurrence selected and implemented?	5.11.3.1						
Are corrective actions appropriate to the magnitude and risk of the problem?	5.11.3.2						
Does the proficiency testing provider document and implement any required changes resulting from corrective action investigations?	5.11.3.3						
Monitoring of corrective actions Does the proficiency testing provider monitor the results to ensure that the corrective	5.11.4						
actions taken have been effective? Additional audits	5.11.5						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Where the identification of nonconforming activities or departures from authorized procedures cast doubts on the compliance of the proficiency testing provider with its own policies and procedures, or on its compliance with this International Standard, are the appropriate areas of activity audited in accordance with 5.14 as soon as possible?							
NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit can be necessary only when a serious issue or risk to the proficiency testing scheme is identified.							
Preventive actions	5.12						
Are areas for improvements and potential sources of nonconforming work, either technical or concerning the management system, identified? When improvement opportunities are identified, or if preventive action is required, are action plans developed, implemented and monitored, to reduce the likelihood of such nonconforming work and to take advantage of the opportunities for improvement?	5.12.1						
Does the procedure for preventive action include the initiation of such actions and application of controls to ensure that they are effective?	5.12.2						
Control of records	5.13						
General	5.13.1						
Are procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of records established and maintained? Do quality records include reports from internal audits and management reviews, as well as records of corrective and preventive actions?	5.13.1.1						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are all records legible, stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss? Are retention times of records established?	5.13.1.2						
NOTE Records can be in the form of any type of media, such as hard copy or electronic storage media.							
Are all records kept secure and confidential, and in accordance with relevant regulatory requirements?	5.13.1.3						
Does the proficiency testing provider follow procedures to protect and back-up records stored electronically and to prevent unauthorized access or amendment of these records?	5.13.1.4						
Technical records	5.13.2						
Are records of all technical data relating to each proficiency testing round retained for a defined period, including, but not necessarily limited to:	5.13.2.1	•					
- results of homogeneity and stability testing?	5.13.2.1a						
- instructions to participants?	5.13.2.1b						
- participants' original responses?	5.13.2.1c						
- collated data for statistical analysis?	5.13.2.1d						
- information required for reports (see 4.8)?	5.13.2.1e						
- final reports (summary or individual, or both)?	5.13.1f						
NOTE 1 It is advisable to retain sufficient information to establish an audit trail for the processing of results from proficiency testing rounds.							

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
NOTE 2 Technical records are accumulations of data and information which result from carrying out all proficiency testing activities. They can include forms, contracts, work sheets, work books, check sheets, work notes, sub-contractor reports and participant feedback.							
Are data entry, checking and calculations recorded at the time they are made and are they identifiable to the specific task and to the personnel responsible?	5.13.2.2	•					
When mistakes occur in records and alterations are made, are actions taken to:	5.13.2.3	•					
- identify the change and date of alteration?	5.13.2.3a						
- avoid loss of original data?	5.13.2.3b						
- identify the person making the alteration?	5.13.2.3c						
Internal audits	5.14						
Does the proficiency testing provider conduct internal audits of its activities periodically, and in accordance with a predetermined schedule and procedure, in order to verify that its operations continue to comply with the requirements of the management system and this International Standard?	5.14.1						
Does the internal audit programme address all elements of the management system, including the technical procedures and proficiency test item preparation, storage and distribution, as well as reporting activities for the operation of a proficiency testing scheme?	5.14.1						
Is the quality manager responsible for planning and organizing audits as required by the schedule and requested by management?	5.14.1						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are internal audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited?	5.14.1						
NOTE It is advisable that the programme for internal auditing of the management system be completed every 12 months.							
When audit findings cast doubt upon the effectiveness of the operations, including the suitability and correctness of proficiency test items, procedures, statistical evaluations and data presentation, is take timely corrective action taken by the proficiency testing provider and are its customers or participants, or both, in proficiency testing schemes whose activities may have been affected notified?	5.14.2						
Are the area of audited activity, the audit findings and any corrective actions that arise from them recorded?	5.14.3						
Do follow-up audit activities verify and record the implementation and effectiveness of any corrective actions taken?	5.14.5						
Management reviews	5.15						
In accordance with a pre-determined schedule and procedure, is a review of the management system and proficiency testing activities periodically conducted by the top management, in order to ensure their continued suitability and effectiveness and to introduce any necessary changes or improvements?	5.15.1						
Does the review take account of:							
- the suitability of policies and procedures?	5.15.1a						
- reports from management and supervisory personnel?	5.15.1b						
- the outcome of recent internal audits?	5.15.1c						
- corrective and preventive actions?	5.15.1d						

HOKLAS 017: 2016 Requirements	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
- assessments by external bodies?	5.15.1e						
- changes in the volume and type of work?	5.15.1f						
- customer, advisory group or participant feedback?	5.15.1g						
- complaints and appeals?	5.15.1h						
- recommendations for improvement?	5.15.1i						
- other relevant factors, such as resources and staff training?	5.15.1j						
NOTE 1 A typical period for conducting a management review is once every 12 months.							
NOTE 2 Results can feed into the proficiency testing provider's planning system and can include the objectives and action plans.							
NOTE 3 A management review includes consideration of related subjects at regular management meetings.							
NOTE 4 Where the proficiency testing provider is part of a larger organisation, it can be appropriate to hold a separate review meeting to cover proficiency testing activities.							
Are findings from management reviews, and the actions that arise from them, recorded? Are those actions discharged within an appropriate and agreed timescale?	5.15.2						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Regulations for HKAS Accreditation (as required under HKAS 002)	HKAS 002						
The obligations of an accredited or applicant organisation	5						
After obtaining accreditation, will you as the PT provider 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 its 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 such 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; and	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, does 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)						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
♦ For each location (except location of on-site activities) where accredited activities are performed, is 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)						
Do you (as the accredited PT provider) maintain a quality standard in compliance with the accreditation criteria as set by HKAS for an accredited activity performed for any customers?	HKAS 002 5.2						
Do you (as the accredited PT provider) maintain the same quality standard at all times whether or not the HKAS accreditation symbol is used in the proficiency testing report covering the result of such activity?	HKAS 002 5.2						
When making any statement in relation to your accreditation status as an accredited proficiency testing provider in situation where non-accredited activities are mentioned, will you ensure that a statement indicating which activities are not accredited is included?	HKAS 002 5.3						
Are you (as the accredited PT provider) 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 you cooperate with HKAS Executive and its assessment teams and provide them with full support during assessment and in any other situation access to your personnel, locations, equipment, information, documents and records for assessment of the provider's competence and its conformity with the accreditation criteria?	HKAS 002 5.5						
Upon the request of HKAS Executive, will you and your subcontractor be able to 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						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Do you (as the accredited PT provider) ensure that you will use your accreditation status only in a manner that will not bring HKAS or any of its accreditation schemes into disrepute and will not make any statement regarding your accreditation status which HKAS Executive may reasonably consider it to be misleading?	HKAS 002 5.6						
Do you (as the accredited PT provider) maintain complete integrity and impartiality in all circumstances?	HKAS 002 5.7						
Do you (as the accredited PT provider) 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						
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						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Are you (as the accredited PT provider) aware of the following HKAS regulation on confidentiality:							
♦ "An accredited organisation shall pay due regard to the confidentially of its customer's information and shall make internal rules and guidelines in order to ensure protection of its customer's information. Confidential information about a particular customer shall not be disclosed to a third party without the consent of the customer, except where the law requires such information to be so disclosed. However, an applicant organisation or an accredited organisation shall allow HKAS Executive to examine all its records which are relevant to the scope of accreditation in order to assess its competence and conformity with the relevant accreditation criteria. An applicant organisation and an accredited organisation shall obtain consent from their customers for the disclosure of any relevant information to HKAS."?	HKAS 002 5.10						
Do you (as the accredited PT provider) 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 PT provider's assessment and accreditation only made between the authorised representative, his/her representative, or your Chief Executive or his/her representative and HKAS Executive?	HKAS 002 5.11						
Does the PT provider have a clear policy in writing concerning the 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 staff the law under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)?	HKAS 002 5.12						
Does the PT provider further ensure that the policy is made known to all its personnel?	HKAS 002 5.12						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Does the PT provider 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 the PT provider 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 made to the PT provider by its customers or other parties raise any doubt on its compliance with its policies or procedures, will the PT provider ensure that the relevant areas of its accredited activities are promptly audited?	HKAS 002 5.14						
If a complaint, dispute or appeal made to the PT provider by its customers or other parties relating to any of its accredited activities is not satisfactorily resolved within 60 days from the date of receipt, will the PT provider notify HKAS Executive in writing of this matter?	HKAS 002 5.15						
Are you (as the accredited PT provider) aware of the following HKAS regulation? • "Any concerned party may lodge complaints with HKAS on any accredited activities carried out by an accredited organisation. The accredited organisation shall cooperate with HKAS Executive and provide them with full support for investigation of those complaints upon request."	HKAS 002 5.16						
♦ "Upon the request of HKAS Executive, an accredited proficiency testing provider shall confirm the authenticity or otherwise of a proficiency testing report other document purporting to have been issued by it for an accredited activity. Where such a report document is found to be a forged document, the proficiency testing provider shall cooperate with HKAS Executive in the investigation of its cause and taking mutually agreeable steps to prevent recurrence."	HKAS 002 5.17						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
◆ "An applicant or accredited proficiency testing provider shall not provide certification to any standard that is used by HKAS as accreditation criteria. HKAS Executive will take immediate action to suspend the accreditation of an accredited organisation in violation of this requirement."	HKAS 002 5.18						
Use of HKAS accreditation symbols and claims of accreditation status	8						
Are you (as the accredited PT provider) aware of the following HKAS regulation?							
♦ "An accredited organisation may use the relevant HKAS accreditation symbol of its accreditation as described in HKAS Supplementary Criteria No. 1 and claim its accreditation status provided that the following conditions are complied 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 an organisation;	HKAS 002 8.1 (a)						
(b) HKAS Supplementary Criteria No. 1 and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations are conformed with at all times; and	HKAS 002 8.1 (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)						
Have you (as the accredited PT provider) ensure that your accreditation is not used to imply that any subject of your accredited activities for example, a product, process, system or person is approved by HKAS? Are actions taken to stop any incorrect reference to accreditation?	HKAS 002 8.2						

Regulations for HKAS Accreditation	Clause	*	Y	N	NA	MS Clause	Remarks / Questions to be asked
Have you (as the accredited PT provider) ensured that your customers, on receiving any report or certificate which bears a HOKLAS accreditation symbol, 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 accredited PT provider, whether or not voluntarily made, are you (as the PT provider) aware that all references to the accreditation status of the provider in any report, certificate, letterhead, brochure, advertising material, stationery, and Internet websites, etc. have to be discontinued immediately?	HKAS 002 8.3						

Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	HOKLAS SC 34					
Proficiency testing provider accreditation procedures Are you aware of the following accreditation regulation on accreditation procedure? ◆ "An assessment team may require a proficiency testing provider or its subcontractor to demonstrate an activity as part of an assessment in order to evaluate its standard and competence. The specific activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team."	HOKLAS SC-34 2.1					
◆ "HKAS Executive shall conduct a reassessment on the accredited activities of a proficiency testing provider:-						
(a) twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the proficiency testing provider;	HOKLAS SC-34 2.2 (a)					
(b) every two years after the due dates of the first reassessment;	HOKLAS SC-34 2.2 (b)					
(c) at such other times as may be specified in the terms of accreditation; and	HOKLAS SC-34 2.2 (c)					
(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited proficiency testing provider, of any change in the structure and circumstances of the proficiency testing provider since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the provider's competence or conformity with the accreditation criteria.	HOKLAS SC-34 2. 2 (d)					

(e) HKAS Executive may, at its discretion, vary the reassessment schedule."	HOKLAS SC-34 2.2 (e)				
♦ "HKAS Executive shall conduct a surveillance visit to an accredited proficiency testing provider if neither reassessment, assessment for extension of accreditation nor surveillance visit to the provider has been conducted for the past twelve months' period or at such time intervals as specified for the Monitoring Plan adopted by the proficiency testing provider. HKAS Executive may, at its discretion, vary the surveillance visit schedule."	HOKLAS SC-34 2.3				
♦ "Upon granting of accreditation to a proficiency testing provider, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for proficiency testing provider."	HOKLAS SC-34 2.4				
Obligations of accredited or applicant proficiency testing providers	3				
Does the proficiency testing provider at all times comply with the accreditation criteria as documented in HKAS 002, HOKLAS 017, relevant HOKLAS Supplementary Criteria and relevant HKAS Supplementary Criteria?	HOKLAS SC-34 3.1				
Does the proficiency testing provider 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 accreditation has been granted has been approved or disapproved by HKAS or HKAS Executive?	HOKLAS SC-34 3.2				
Does the proficiency testing provider ensure that no person uses any certificate or report issued by it for such an activity in a misleading manner?	HOKLAS SC-34 3.2				
Are you (as the accredited PT provider) aware of the following HKAS regulation on cooperation?					

HOKLAS SC-34 3.3									
HOKLAS SC-34 3.3									
HOKLAS SC-34 3.4									
HOKLAS SC-34 3.5									
	SC-34 3.3 HOKLAS SC-34 3.3 HOKLAS SC-34 3.4	SC-34 3.3 HOKLAS SC-34 3.3 HOKLAS SC-34 3.4	HOKLAS SC-34 3.3 HOKLAS SC-34 3.4 HOKLAS SC-34 SC-34 GROWN DEEP COMMENT OF THE PROPERTY OF THE	SC-34 3.3 HOKLAS SC-34 3.3 HOKLAS SC-34 3.4 □ □ HOKLAS SC-34 □ □	SC-34 3.3 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4	SC-34 3.3 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4	HOKLAS SC-34 3.4	SC-34 3.3 HOKLAS SC-34 3.3 HOKLAS SC-34 3.4 HOKLAS SC-34 HOKLAS SC-34	SC-34 3.3 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4 HOKLAS SC-34 3.4

♦ "An accredited proficiency testing provider shall inform HKAS Executive forthwith of any change in the availability and duties of any of its approved signatories. HKAS shall withdraw the approval concerning such an approved signatory who no longer meets the requirements as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a proficiency testing provider for a proficiency testing scheme, if it does not have any approved signatory for such a scheme 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 a scheme."	HOKLAS SC-34 3.6					
Are you (as the PT provider) aware of the following HKAS regulation on integrity?						
◆ "An applicant proficiency testing provider shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant proficiency testing provider intentionally provides false information or if the applicant proficiency testing provider 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-34 3.7					
Suspension and cancellation of accreditation	4					
Will the authorised representative of the accredited proficiency testing provider, within 14 days from the effective date of any suspension or cancellation (voluntarily or by HKAS Executive) of the accreditation of a proficiency testing scheme, identify the customers to whom the proficiency testing provider has issued proficiency testing reports with results for such a proficiency testing scheme, which are found to be unreliable because of the deficiencies discovered during the investigation of the suspension or cancellation, and inform them that the results are unreliable?	HOKLAS SC-34 4.1					
Use of HOKLAS accreditation symbols for proficiency testing providers and claims of accreditation status	5					
Are you (as an accredited PT provider) aware of the following HKAS regulation on the use of HOKLAS accreditation symbols and claims of accreditation status?						

♦ "An accredited proficiency testing provider may display the HOKLAS accreditation symbol for proficiency testing providers in a report issued by it for reporting the result(s) of a proficiency testing scheme in its scope of accreditation. Such a report is referred to hereafter as a HOKLAS endorsed proficiency testing report."	HOKLAS SC-34 5.1					
♦ An accredited PT provider shall include in a HOKLAS endorsed proficiency testing report the following:-						
(a) the HOKLAS accreditation symbol (which includes the proficiency testing provider's registration number and the identification code of the accreditation program) at the top right hand corner of the front page; and	HOKLAS SC-34 5.2 (a)					
(b) on the front page the following statements for a proficiency testing scheme within its scope of accreditation:	HOKLAS SC-34 5.2 (b)					
'HKAS has accredited this proficiency testing provider (Reg. No.) under HOKLAS for specific proficiency testing schemes as listed in the scope of accreditation.'	3.2 (0)					
The word 'this proficiency testing provider' in the first sentence of the above endorsement statement may be replaced by the full identity of the proficiency testing provider as it appears on the scope of accreditation.						
Are the form, size, colour and usage of the HOKLAS accreditation symbol for proficiency testing providers in accordance with HKAS Supplementary Criteria No. 1?	HOKLAS SC-34 5.3					
Are you (as an accredited PT provider) aware of the following HKAS regulation on the use of HOKLAS accreditation symbols and claims of accreditation status?						
◆ "An accredited proficiency testing provider may also claim its accreditation status by including the statement described in 5.2 (b) in a proficiency testing report of an accredited scheme, but such a report is not considered as a HOKLAS endorsed proficiency testing report."	HOKLAS SC-34 5.4					

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♦ "the HOKLAS accreditation symbol shall not be used alone to claim the accreditation status."	HOKLAS SC-34 5.4					
Are the term 'HKAS'/'HOKLAS', the HOKLAS accreditation symbol for a proficiency testing provider and/or a statement claiming accreditation status under HOKLAS only used in a HOKLAS endorsed proficiency testing report and not in any other proficiency testing report of a proficiency testing scheme not within its scope of accreditation?	HOKLAS SC-34 5.5					
Are you (as an accredited PT provider) aware of the following HKAS regulation on the use of HOKLAS accreditation symbols and claims of accreditation status?						
◆ Claiming of accreditation status without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive.	HOKLAS SC-34 5.6					
♦ if you select to claim the accreditation status with the statement described in 5.2(b) without displaying the accreditation symbol, requirements that govern the issue of HKAS endorsed report as detailed in HOKLAS Supplementary Criteria No. 34 and HKAS 002 shall also apply to such reports.	HOKLAS SC-34 5.6					
Is a HOKLAS endorsed proficiency testing report or a report with accreditation status claimed by a statement signed by an approved signatory of the issuing proficiency testing provider?	HOKLAS SC-34 5.7					
Is the signature made in hand-written form for printed report? Is the signatory made in electronic form acceptable to the Electronic Transactions Ordinance (Cap. 553) for an electronic report?	HOKLAS SC-34 5.7					
Is the full name of the approved signatory (as in his/her identify document such as identity card or passport) clearly shown alongside the signature?	HOKLAS SC-34 5.7					

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Other arrangements of signing HOKLAS endorsed reports 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.		
Are you (as an accredited PT provider) aware of the following HKAS regulation on signature?		
♦ "A HOKLAS endorsed proficiency testing report may contain signatures of others provided that an HKAS approved signatory of the accredited proficiency testing provider has signed the proficiency testing report. Where signatures other than the approved signatory also appear on the report, the capacity of the one who signed (such as his capacity as reviewer) shall appear on the report."	HOKLAS SC-34 5.8	
Does the HOKLAS endorsed proficiency testing report contain only results of proficiency testing activities for which the proficiency testing provider is holding valid HKAS accreditation unless otherwise approved?	HOKLAS SC-34 5.9	
If results of any non-accredited activities are included in a HOKLAS endorsed proficiency testing report, has explicit approval for such inclusion been obtained from HKAS Executive in writing?	HOKLAS SC-34 5.10	
Does the HOKLAS endorsed proficiency testing report which contains the said non-accredited results clearly state therein that the activities are not covered by the proficiency testing provider's HKAS accreditation?	HOKLAS SC-34 5.10	
Does the accredited proficiency testing provider keep at least one exact copy of each HOKLAS endorsed proficiency testing report issued by it for record? Does the provider also keep such copies, all original observations and records in relation to any accredited activity performed by it for a period of not less than three years or for a period specified by HKAS Executive?	HOKLAS SC-34 5.11	
Does every HOKLAS endorsed proficiency testing report comply with all relevant accreditation criteria as specified by HKAS Executive from time to time?	HOKLAS SC-34 5.12	

Does a HOKLAS endorsed proficiency testing report issued by the accredited proficiency testing provider bear either:-						
(a) a statement indicating that such a report shall not be reproduced except in full, or	HOKLAS SC-34 5.13 (a)					
(b) a statement indicating the conditions under which such a report may be reproduced either in full or in part?	HOKLAS SC-34 5.13 (b)					
Are you aware that an extract or abstract of a HOKLAS endorsed proficiency testing report shall not contain the HOKLAS accreditation symbol for proficiency testing providers nor other details as specified in clause 5.2 above unless the authorised representative of the accredited proficiency testing provider has approved in writing of such inclusion in the extract or abstract; and that 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-34 5.13					
If technical comments other than those on the performance of participants, and opinions or interpretations for which a proficiency testing provider is not accredited for providing are included in a HOKLAS endorsed proficiency testing report, has HKAS Executive given its approval for such inclusion in writing?	HOKLAS SC-34 5.14					
If an endorsed proficiency testing report contains such comments, opinions or interpretations, has it clearly stated in all cases that the proficiency testing provider is not accredited for providing such comments, opinions or interpretations?	HOKLAS SC-34 5.14					
Are you aware that an accredited proficiency testing provider shall not issue any proficiency testing report containing any logo, symbol or statement that may be interpreted by any person that the activities or results reported are covered by certification which does not convey any information on technical competence?	HOKLAS SC-34 5.15					

End