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**CONFIDENTIAL**

**SINGAPORE ACCREDITATION COUNCIL**

**PROFICIENCY TESTING PROVIDERS (PTP) ACCREDITATION SCHEME**

|  |  |  |  |
| --- | --- | --- | --- |
| **Proficiency Testing Provider Assessment Checklist** | | | |
|  |  |  | |
| Type of Assessment | : | Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification | |
|  |  |  | |
| Facility | : |  | |
|  |  |  | |
| Address | : |  | |
|  |  |  | |
| Tel / Fax | : |  | |
|  |  |  | |
| Names of persons seen | : |  | |
|  |  |  | |
| Date of visit | : |  | |
|  |  |  | |
| Technical Assessor(s)/Expert(s) | : |  | |
|  |  |  | |
| Lead Assessor | : |  |  |
|  |  | Name & Signature | Date |

References

ISO/IEC 17043:2010, SAC-01, SAC-02, PTP 001

| **Clause No.** | **Description** | **Yes** | **No** | **N.A.** | **Remarks** | |
| --- | --- | --- | --- | --- | --- | --- |
| **4.** | **Technical Requirements** | | | | | |
| **4.1** | **General** |  |  |  |  | |
|  | Is the development and operation of PT schemes undertaken by PTP having the competence to conduct interlaboratory comparisons and access to expertise with the particular type of proficiency test items? |  |  |  |  | |
|  | Are the PTPs or their subcontractors also competent in the measurement of the properties being determined? |  |  |  |  | |
|  | Note: ISO/IEC 17025 or ISO 15189 can be used to determine the competence of a PTP’s laboratory or the laboratory subcontracted to perform tests or measurements related to the PT schemes. ISO 17034 can be used to demonstrate the competence of producers of reference materials that provide PT test items. |  |  |  |  | |
| PTP 001 2.1.1 | Do the testing and measurement activities carried out by a PTP meet the requirements of ISO/IEC 17025 or ISO 15189 (for medical tests)? |  |  |  |  | |
| PTP 001 2.1.2 | Are reference materials used by a PTP produced by competent reference material producers? (National Metrology Institutes, Designated Institutes, Reference material producer accredited to ISO 17034 in combination with ISO/IEC 17025)  Where such competent suppliers are not available for fields such as for Non-Destructive Testing, are reference test specimens manufactured by industry recognised organizations? |  |  |  |  | |
| PTP 001 2.1.3 | Does the applicant PTP submit a completed proficiency testing programme for each of the intended scope of application? |  |  |  |  | |
| **4.2** | **Personnel** |  |  |  |  | |
| 4.2.1 | Does the PTP have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties? |  |  |  |  | |
| 4.2.2 | Does the PTP’s management define the minimum levels of qualifications and experience necessary for the key positions within its organization and ensure those qualifications are met? |  |  |  |  | |
| 4.2.3 | Does the PTP use personnel who are either employed by, or under contract to it?  Where contracted and additional technical and key support personnel are used, does the PTP ensure that such personnel are supervised and competent and they work in accordance with the management system? |  |  |  |  | |
| 4.2.4 | Does the PTP authorize specific personnel for the following functions? |  |  |  |  | |
| a) | Select appropriate PT test items? |  |  |  |  | |
| b) | Plan PT schemes? |  |  |  |  | |
| c) | Perform particular types of sampling? |  |  |  |  | |
| d) | Operate specific equipment? |  |  |  |  | |
| e) | Conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the PT test item? |  |  |  |  | |
| f) | Prepare, handle and distribute PT test items? |  |  |  |  | |
| g) | Operate the data processing system? |  |  |  |  | |
| h) | Conduct statistical analysis? |  |  |  |  | |
| i) | Evaluate the performance of PT participants? |  |  |  |  | |
| j) | Give opinions and interpretations? |  |  |  |  | |
| k) | Authorize the issue of PT reports? |  |  |  |  | |
| 4.2.5 | Does the PTP maintain up-to-date records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all the technical personnel, including contracted personnel?  Is this information readily available and include the date on which competence to perform their assigned tasks was assessed and confirmed? |  |  |  |  | |
| 4.2.6 | Does the PTP formulate the objectives with respect to the education, training, and skills for each staff member involved with the operation of the PT scheme?  Does the PTP have 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 PTP? |  |  |  |  | |
| 4.2.7 | Does the PTP ensure that staff receives the necessary training to ensure competent performance of measurements, operation of equipment and any other activities which affect the quality of the PT scheme?  Is the effectiveness of the training activities evaluated? |  |  |  |  | |
| PTP 001 2.2.1 | Does the applicant or accredited PTP nominate an individual as the coordinator for each PT scheme included in its scope of accreditation?  Does the coordinator participate in the preparation and endorsement of the report(s) for the relevant scheme(s)? |  |  |  |  | |
| PTP 001 2.2.2 | Is the responsibility of the coordinator clearly documented?  In cases where external coordinator is used, is there written agreement between the coordinator and the PTP defining the tasks for which the coordinator shall be responsible?  Does the coordinator report directly to the PTP? |  |  |  |  | |
| PTP 001 2.2.3 | Does the nominated coordinator have appropriate training, qualifications and experience in the field of the specific scheme?  Does the nominated coordinator possess the following minimum qualifications and experience:   1. a bachelor’s degree in the relevant area; 2. Experience in the participation and/or organisation of PT in the past 3 years, and 3. working knowledge in the areas of statistical evaluation of data and measurement uncertainty.   Before appointing a potential coordinator, does the applicant or accredited PTP assess and confirm the competence of the candidate?  Are such assessment and their results recorded?  Is the coordinator available for SAC assessment?  Does the PTP inform SAC immediately when there is a change of coordinator for a particular scheme? |  |  |  |  | |
| PTP 001 2.2.4 | Is the person authorised to issue interim and final PT reports either employed by, or under contract to, the PTP?  Does this person ensure that the content of the report is endorsed by the coordinator, and there is adequate access to advice and assistance from experts or its advisory groups, where necessary, before authorising the issue of the reports(s)? |  |  |  |  | |
| **4.3** | **Equipment, accommodation and environment** |  |  |  |  | |
| 4.3.1 | Does the PTP ensure that there is appropriate accommodation for the operation of the PT scheme?  This includes facilities and equipment for PT test item manufacturing, handling, calibration, testing, storage and dispatch, for data processing, for communications, and for retrieval of materials and records. |  |  |  |  | |
| 4.3.2 | Does the PTP ensure that the environmental conditions do not compromise the PT scheme or the required quality of operations?  Particular care shall be taken when operations are undertaken at sites away from the PTP’s permanent facilities or are undertaken by subcontractors.  Are the technical requirements for accommodation and environmental conditions that can affect the PT documented? |  |  |  |  | |
| 4.3.3 | Is the access to and use of areas affecting the quality of the PT scheme controlled?  Does the PTP determine the extent of the control based on its particular circumstances? |  |  |  |  | |
| 4.3.4 | Does the PTP identify environmental conditions that can significantly influence the quality of the PT test items and any testing and calibration carried out (including conditions that are required by relevant specifications and measurement procedures)?  Does the PTP control and monitor these conditions, and record all relevant monitoring activities?  Are relevant PT activities stopped when the environmental conditions jeopardize the quality or the operations of the PT scheme? |  |  |  |  | |
| 4.3.5 | Is there effective separation between the neighbouring areas in which are incompatible activities?  Are actions taken to prevent cross-contamination? |  |  |  |  | |
| 4.3.6 | Does PTP ensure that performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of the PT test items are appropriately validated and maintained? |  |  |  |  | |
| PTP 001 2.3.1 | Does the PTP have documented procedures for handling, maintaining stability and storage of proficiency test items?  Is the facility suitably equipped for handling the PT items?  Are all units of PT items uniquely identifiable at all times? |  |  |  |  | |
| PTP 001 2.3.2 | When microbiological tests are undertaken for the PT items, does the layout of the testing facility   * generally provide for sample receipt, washing up and sterilisation, media preparation and general testing areas? * designed to minimise potential contamination of samples and to ensure protection of testing staff? * allow PTP involved in handling pathogenic organisms to take special environmental precautions? |  |  |  |  | |
| PTP 001 2.3.3 | Does the PTP implement a system to ensure that the equipment used for manufacturing, handling, calibration and testing of proficiency test items are all properly calibrated, verified and maintained? |  |  |  |  | |
| **4.4** | **Design of PT schemes** |  |  |  |  | |
| 4.4.1 | Planning |  |  |  |  | |
| 4.4.1.1 | Does the PTP identify and plan those processed which directly affect the quality of the PT scheme and ensure that they are carried out in accordance with prescribed procedures? |  |  |  |  | |
| 4.4.1.2 | PTP shall not subcontract the planning of the PT scheme.  Note: The PTP can ultilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4) |  |  |  |  | |
| 4.4.1.3 | Does the PTP document a plan before commencement of the PT scheme that addresses the objectives, purpose and basic design of the PT scheme?  Including the following information and, where appropriate, reasons for its selection or exclusion? |  |  |  |  | |
| a) | Name and address of the PTP? |  |  |  |  | |
| b) | Name, address and affiliation of the coordinator and other personnel involved in the design and operation of the PT scheme? |  |  |  |  | |
| c) | Activities to be subcontracted and the names and addresses of subcontractors involved in the PT scheme? |  |  |  |  | |
| d) | Criteria to be met for participation? |  |  |  |  | |
| e) | Number and type of expected participants in the PT scheme? |  |  |  |  | |
| f) | Selection of the measurand(s), or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in specific PT round? |  |  |  |  | |
| g) | A description of the range of values or characteristics, or both to be expected for the PT test items? |  |  |  |  | |
| h) | Potential major sources of errors involved in the area of PT offered? |  |  |  |  | |
| i) | Requirements for the production, quality control, storage and distribution of the PT test items? |  |  |  |  | |
| j) | Reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected? |  |  |  |  | |
| k) | A description of the information which is to be supplied to participants and the time schedule for the various phases of the PT scheme? |  |  |  |  | |
| l) | For continuous PT schemes, the frequency or dates upon which PT 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? |  |  |  |  | |
| m) | Any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements? |  |  |  |  | |
| n) | Procedures for the test or measurement methods to be used for the homogeneity and stability testing of the PT test items and, where applicable, to determine their biological variability? |  |  |  |  | |
| o) | Preparation of any standardized reporting formats to be used by the participants? |  |  |  |  | |
| p) | A detailed description of the statistical analysis to be used? |  |  |  |  | |
| q) | The origin, metrological traceability and measurement uncertainty of any assigned values? |  |  |  |  | |
| r) | Criteria for the evaluation of performance of participants? |  |  |  |  | |
| s) | A description of the data, interim reports or information to be returned to participants? |  |  |  |  | |
| t) | A description of the extent to which participant results, and the conclusions that will be based on the outcome of the PT scheme, are to be made public? |  |  |  |  | |
| u) | Actions to be taken in the case of lost or damaged PT test items? |  |  |  |  | |
| 4.4.1.4 | Does the PTP 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). |  |  |  |  | |
| 4.4.1.5 | Is technical expertise used, as appropriate, to determine matters such as the following? |  |  |  |  | |
| a) | Planning requirements as listed in 4.4.1.3? |  |  |  |  | |
| b) | Identification and resolution of any difficulties expected in the preparation and maintenance of homogenous PT test items, or in the provision of a stable assigned value for a PT test item? |  |  |  |  | |
| c) | Preparation of detailed instructions for the participants? |  |  |  |  | |
| d) | Comments on any technical difficulties or other remarks raised by the participants in previous PT rounds? |  |  |  |  | |
| e) | Provision of advice in evaluating the performance of participants? |  |  |  |  | |
| f) | Comments on the results and performance of participants as whole and, where appropriate, groups of participants or individual participants? |  |  |  |  | |
| g) | Provision of advice for participants (within limits of confidentiality), either individually or within the report? |  |  |  |  | |
| h) | Responding to feedback from participants? |  |  |  |  | |
| i) | Planning or participating in technical meetings with participants? |  |  |  |  | |
| 4.4.2 | Preparation of PT Test Items |  |  |  |  | |
| 4.4.2.1 | Does the PTP establish and implement procedures to ensure that PT test items are prepared in accordance with the plan described in 4.4.1?  Note: It is advisable that due consideration to the preparation of sufficient numbers of PT test items, in order to allow for the need to replace any such test items lost or damaged during distribution, or intended to be provided for use after the results for the PT scheme have been evaluated. Such uses can include training aids for participants or use as a reference material. |  |  |  |  | |
| 4.4.2.2 | Does the PTP establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all PT test items?  Do the procedures ensure that materials used to manufacture PT test items are obtained in accordance with relevant regulatory and ethical requirements? |  |  |  |  | |
| 4.4.2.3 | Do PT test items match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing and calibration? |  |  |  |  | |
| 4.4.2.4 | In PT schemes that require participants to prepare or manipulate, or both prepare and manipulate, the PT test items and submit it to the PTP, does the PTP issue instructions for preparation, packaging and transport of the PT test item? |  |  |  |  | |
| 4.4.3 | Homogeneity and Stability |  |  |  |  | |
| 4.4.3.1 | Are criteria for suitable homogeneity and stability established and be based on the effect that in-homogeneity and instability have on the evaluation of the participants’ performance?  Note1: The requirements in this subclause are intended to ensure that every participant receives comparable PT test items, and that these test items remain stable throughout the PT. careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.  Note2: In some cases, it is not feasible for the test items to be subjected to homogeneity and stability testing. Such cases would include, for example, limited material is available to prepare the testing items.  Note3: In some cases, materials that are not sufficiently homogenious or stable are the best available; in such cases, they can still be useful as test items, provided that the uncertainties of the assigned values or the evaluation of results takes due account of this (see B3.1.3 & ISO 13528:2005, Annex B).  Note4: Considerations for homogeneity and stability are further discussed in ISO 17034, ISO Guide 35 and ISO 13528. |  |  |  |  | |
| 4.4.3.2 | Are the procedures for the assessment of homogeneity and stability documented and conducted, where applicable, in accordance with appropriate statistical designs?  Where possible, does the PTP use a statistically random selection of a representative number of test items from the whole batch of test material in order to assess the homogeneity of the material?  Note: In some cases, the use of a random stratified or systematic selection of test items from the whole batch is more appropriate. |  |  |  |  | |
| 4.4.3.3 | Is the assessment of homogeneity normally performed after the 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?  Note1: Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.  Note2: On some occasions, homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons. |  |  |  |  | |
| 4.4.3.4 | Are test items demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the PT, 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 test item, and/or taken into account in the evaluation criteria? |  |  |  |  | |
| 4.4.3.5 | Are the test items from previous rounds retained for future use? Are the property values to be determined in the PT scheme confirmed by the PTP prior to distribution? |  |  |  |  | |
| 4.4.3.6 | In the circumstances where homogeneity and stability testing is not feasible, does the PTP demonstrate that the procedures used to collect, produce, package and distribute the test items are sufficient for the purpose of the PT? |  |  |  |  | |
| 4.4.4 | Statistical Design |  |  |  |  | |
| 4.4.4.1 | Are statistical designs developed to meet the objectives of the scheme, based in 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)  Note1: Statistical design covers the process of planning, collection, analysis and reporting of the PT scheme data. Statistical designs are often based on stated objectives for the PT scheme, such as detection of certain types of errors with specified power or determination of assigned values with specified measurement uncertainty.  Note2: 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 test items.  Note3: In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used. |  |  |  |  | |
| 4.4.4.2 | Does the PTP document the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results, and provide a description of the reasons for their selection and assumptions upon which they are based?  Is the PTP able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out with prescribed procedures? |  |  |  |  | |
| 4.4.4.3 | In designing a statistical analysis, does the PTP give careful consideration to the following? |  |  |  |  | |
| a) | The accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measurand or characteristic in the PT? |  |  |  |  | |
| b) | The minimum number of participants in the PT 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, does the PTP document, and provides to participants, details of the alternative approaches used to assess participant performance? |  |  |  |  | |
| c) | The relevance of significant figures to the reported results, including the number of decimal places? |  |  |  |  | |
| d) | The number of test items to be tested or measurement and the number of repeat tests, calibrations or measurement s to be conducted on each test item or each determination? |  |  |  |  | |
| e) | The procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria? |  |  |  |  | |
| f) | Procedures to be used to identify or handle outliers, or both? |  |  |  |  | |
| g) | Where relevant, the procedures for the evaluation of values excluded from statistical analysis? |  |  |  |  | |
| h) | Where appropriate, the objectives to be met for the design and the frequency of PT rounds? |  |  |  |  | |
| 4.4.5 | Assigned Values |  |  |  |  | |
| 4.4.5.1 | Does the PTP document the procedure for determining the assigned values for the measurerands or characteristics in a particular PT scheme?  Does the procedure take into account the metrological traceability and measurement uncertainty required to demonstrate that the PT scheme is fit for its purpose?  Note: Metrological traceability is not always possible or appropriate. |  |  |  |  | |
| 4.4.5.2 | Do PT schemes in the area of calibration have assigned values with metrological traceability, including measurement uncertainty? |  |  |  |  | |
| 4.4.5.3 | For PT schemes in areas other than calibration, is the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value determined by taking into account specified requirements of participants or other interested parties, or by the design of the PT scheme?  Note: The required metrological traceability chain can differ depending in the type of test item, the measurerand or characteristic, and the availability of traceable calibrations and reference materials. |  |  |  |  | |
| 4.4.5.4 | When a consensus value is used as the assigned value (see Annex B), does the PTP document the reason for that selection and is the estimated uncertainty of the assigned value as described in the plan for the PT scheme? |  |  |  |  | |
| 4.4.5.5 | Does the PTP have a policy regarding the disclosure of the assigned values?  Does the policy ensure that participants cannot gain advantage from early disclosure? |  |  |  |  | |
| **4.5** | **Choice of Method or Procedure** |  |  |  |  | |
| 4.5.1 | Are participants normally be expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with routine procedures?  Does the PTP instruct the participants to use a specified method in accordance with the design of the PT scheme? |  |  |  |  | |
| 4.5.2 | Where participants are permitted to use a method of their choice, does the PTP: |  |  |  |  | |
| a) | Have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods? |  |  |  |  | |
| b) | Be 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? |  |  |  |  | |
| **4.6** | **Operation of PT Schemes** |  |  |  |  | |
| 4.6.1 | Instructions for Participants |  |  |  |  | |
| 4.6.1.1 | Does the PTP give participants sufficient prior notice before sending test items, providing the date on which the test items are likely to arrive or to be dispatched, unless the design of the PT scheme makes it inappropriate to do so? |  |  |  |  | |
| 4.6.1.2 | Does the PTP give detailed documented instructions to all participants?  Do instructions to participants include: |  |  |  |  | |
| a) | The necessity to treat test items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the PT scheme which required departure from this principle)? |  |  |  |  | |
| b) | Details of factors which could influence the testing or calibration of the test items, e.g. the nature of the test items, conditions of storage, whether the PT scheme is limited to selected test methods, the timing of the testing or measurement? |  |  |  |  | |
| c) | Detailed procedure for preparing or conditioning, or both preparing and conditioning, of the test item before conducting the tests or calibrations? |  |  |  |  | |
| d) | Any appropriate instructions on handling the test items, including any safety requirements? |  |  |  |  | |
| e) | 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 measurement? |  |  |  |  | |
| f) | 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, does this include the coverage factor and, whenever practicable, the coverage probability?  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”). |  |  |  |  | |
| g) | The latest date for the provider to receive the PT or measurement results for analysis? |  |  |  |  | |
| h) | Information on the contact details of the PTP for enquiries? |  |  |  |  | |
| i) | Instructions on return of the test items, where applicable? |  |  |  |  | |
| 4.6.2 | Proficiency Test Items Handling & Storage |  |  |  |  | |
| 4.6.2.1 | Does the PTP ensure that test items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants? |  |  |  |  | |
| 4.6.2.2 | Does the PT provide secure storage areas or stock rooms, or both, which prevent damage or deterioration of any test item between preparation and distribution?  Are appropriate procedures for authorizing dispatch to, and receipt from, such areas defined? |  |  |  |  | |
| 4.6.2.3 | When appropriate, is the condition of stored or stocked test items, chemicals and materials assessed at specified intervals during their storage life in order to detect possible deterioration? |  |  |  |  | |
| 4.6.2.4 | Where potentially hazardous test items, chemicals and materials are used, are facilities available to ensure their safe handling, decontamination and disposal? |  |  |  |  | |
| 4.6.3 | Packaging, Labeling and Distribution of Proficiency Test Items |  |  |  |  | |
| 4.6.3.1 | Does the PTP control packaging and labeling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements?  Note: The improper distribution of 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 vapors or engine gases which can be encountered during transport. |  |  |  |  | |
| 4.6.3.2 | Does the PTP specify relevant environmental conditions for the transport of test items?  Where relevant, does the PTP monitor the pertinent environmental conditions of the test item during transport and assess the impact of the environmental influences on the test item? |  |  |  |  | |
| 4.6.3.3 | In PT Schemes where participants are required to transport the test items to other participants, are instructions documented for this transport supplied? |  |  |  |  | |
| 4.6.3.4 | Does the PTP ensure that labels are securely attached to the packaging of individual test items and are designed to remain legible and intact throughout the PT testing round? |  |  |  |  | |
| 4.6.3.5 | Does the PTP follow a procedure to enable the confirmation of delivery of test items?  Note: This could be achieved in accordance with 4.6.1.1 by asking the participants to inform the PTP if test items have not been received in line with the schedule of dates provided. |  |  |  |  | |
| **4.7** | **Data Analysis and Evaluation of PT Scheme Results** |  |  |  |  | |
| 4.7.1 | Data Analysis and Records |  |  |  |  | |
| 4.7.1.1 | Are all data processing equipment and software validated in accordance with procedures before being brought into use?  Is there any computer system maintenance which includes a back-up process and system recovery plan?  Are the results from such maintenance and operational checks recorded? |  |  |  |  | |
| 4.7.1.2 | 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? |  |  |  |  | |
| 4.7.1.3 | Does data analysis generate summary statistics and performance statistics, and associated information consistent with the statistical design of the PT scheme? |  |  |  |  | |
| 4.7.1.4 | Is the influence of outliers on summary statistics minimized by the use of robust statistical methods or appropriate tests to detect statistical outliers? |  |  |  |  | |
| 4.7.1.5 | Does the PTP document criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation (e.g. miscalculations, transpositions and other gross errors)? |  |  |  |  | |
| 4.7.1.6 | Does the PTP have documented criteria and procedures to identify and manage 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)? |  |  |  |  | |
| 4.7.2 | Evaluation of Performance |  |  |  |  | |
| 4.7.2.7 | Does the PTP use valid methods of evaluation which meet the purpose of the PT scheme?  Are these methods documented and include a description of the basis for the evaluation?  The evaluation of performance shall not be subcontracted (see 5.5.2). |  |  |  |  | |
| 4.7.2.2 | Where appropriate for the purpose of the PT scheme, does the PTP provide expert commentary on the performance of participants with regard to the following? |  |  |  |  | |
| a) | Overall performance against prior expectations, taking measurement uncertainties into account? |  |  |  |  | |
| b) | Variation within and between participants, and comparisons with any previous PT rounds, similar PT schemes, or published precision data? |  |  |  |  | |
| c) | Variation between methods or procedures? |  |  |  |  | |
| d) | Possible sources of error (with reference to outlier) and suggestions for improving performance? |  |  |  |  | |
| e) | Advice and educational feedback to participants as part of the continual improvement procedures of participants? |  |  |  |  | |
| f) | Situations where unusual factors make evaluation of results and commentary on performance impossible? |  |  |  |  | |
| g) | Any other suggestions, recommendations or general comments? |  |  |  |  | |
| h) | Conclusions? |  |  |  |  | |
|  | Note: It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular PT scheme. These can include updated summarized of performance for individual participants over successive PT rounds of a continuous PT scheme. Such summaries can be further analysed and trends highlighted, if required. |  |  |  |  | |
| PTP 001 2.7.1 | Does the PTP conduct the evaluation of participant performance itself?  If data analysis is subcontracted, are the confidentiality of participants’ identities maintained and not disclosed to the subcontractors?  Do the subcontractors return all original results provided by participants, processed data and analysed results to the PTP for further evaluation of participants’ performance? |  |  |  |  | |
| **4.8** | **Reports** |  |  |  |  | |
| 4.8.1 | Are PT reports clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants??  The authorization of the final report shall not be subcontracted (see 5.5.2)  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. |  |  |  |  | |
| 4.8.2 | Do reports include the following, unless it is not applicable or the PTP has valid reasons for not doing so? |  |  |  |  | |
| a) | The name and contact details for the PTP? |  |  |  |  | |
| b) | The name and contact details of the coordinator? |  |  |  |  | |
| c) | The name(s), function (s), and signature(s) or equivalent identification of per(s) authorizing the report? |  |  |  |  | |
| d) | An indication of which activities are subcontracted by the PTP? |  |  |  |  | |
| e) | The date of issue and status (e.g. preliminary, interim, or final) of the report? |  |  |  |  | |
| f) | Page numbers and a clear indication of the end of the report? |  |  |  |  | |
| g) | A statement of the extent to which results are confidential? |  |  |  |  | |
| h) | The report number and clear indication of the PT scheme? |  |  |  |  | |
| i) | A clear description of the PT test items used, including necessary details of the PT item’s preparation and homogeneity and stability assessment? |  |  |  |  | |
| j) | The participants’ results? |  |  |  |  | |
| k) | Statistical data and summaries, including assigned values and range of acceptable results and graphical displays? |  |  |  |  | |
| l) | Procedures used to establish any assigned value? |  |  |  |  | |
| n) | Details of the metrological traceability and measurement uncertainty of any assigned value? |  |  |  |  | |
| m) | Procedures used to establish the standard deviation of proficiency assessment, or other criteria for evaluation? |  |  |  |  | |
| o) | 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)? |  |  |  |  | |
| p) | Comments on participants’ performance by the PTP and technical advisers? |  |  |  |  | |
| q) | Information about the design and implementation of the PT scheme? |  |  |  |  | |
| r) | Procedures used to statistically analyse the data? |  |  |  |  | |
| s) | Advice on the interpretation of the statistical analysis? |  |  |  |  | |
| t) | Comments or recommendations, based on the outcomes of the PT round? |  |  |  |  | |
|  | Note: For continuous PT 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 the PT scheme protocols or in periodic summary reports that are available to participants. |  |  |  |  | |
| 4.8.3 | Are reports made available to the participants within planned timescales?  In sequential PT schemes, e.g. turn-around time may be very long, and in schemes involving perishable materials, preliminary or anticipated results may be provide before final results are disclosed.  Note: This allows for early investigation of possible error |  |  |  |  | |
| 4.8.4 | Does the PTP have a policy for the use of reports by individuals and organisations? |  |  |  |  | |
| 4.8.5 | When it is necessary to issue a new or amended report for a PT scheme, does it include the following? |  |  |  |  | |
| a) | A unique identification? |  |  |  |  | |
| b) | A reference to the original report that it replaces or amends? |  |  |  |  | |
| c) | A statement concerning the reason for the amendment or re-issue? |  |  |  |  | |
| PTP 001 2.8.1 | Does the accredited PTP carry out the preparation, approval and issue of interim report for each round and the annual summary report of a continuous PT scheme or the final report of a one-off scheme included in the scope of accreditation? |  |  |  |  | |
| PTP 001 2.8.2 | Where technical comments other than on the performance of participants are made and included in endorsed PT report, is a clear and explicit disclaimer given in the report that they are not covered under the scope of accreditation? |  |  |  |  | |
| **4.9** | **Communication with Participants** |  |  |  |  | |
| 4.9.1 | Does the PTP make detailed information available about the PT scheme?  Does it include? |  |  |  |  | |
| a) | Relevant details of the scope of the PT scheme? |  |  |  |  | |
| b) | Any fees for participation? |  |  |  |  | |
| c) | Documented eligibility criteria for participation? |  |  |  |  | |
| d) | Confidentiality arrangements? |  |  |  |  | |
| e) | Details of how to apply? |  |  |  |  | |
| 4.9.2 | Are participants advised promptly by the PTP of any changes in the PT scheme design or operation? |  |  |  |  | |
| 4.9.3 | Are there any documented procedures for enabling participants to appeal against the evaluation of their performance in a PT scheme?  Is the availability of this process communicated to the PT scheme participants? |  |  |  |  | |
| 4.9.4 | Are relevant records of communication with participants maintained and retained, as appropriate? |  |  |  |  | |
| 4.9.5 | If the PTP issues statements of participation or performance, do they contain sufficient information to not be misleading? |  |  |  |  | |
| PTP 001 2.9.1 | Does the PTP have documented procedures for handling participants that are found to be involved in falsification and collusion of results? |  |  |  |  | |
| **4.10** | **Confidentiality** |  |  |  |  | |
| 4.10.1 | Is the identity of participants in a PT scheme kept confidential and know only to persons involved in the operation of the PT scheme, unless the participant waives confidentiality? |  |  |  |  | |
| 4.10.2 | Is all the information supplied by the PTP treated as confidential?  Note: Participants can elect to waive confidentiality within the PT 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 PT results can be provided to the relevant authority by the participants themselves. |  |  |  |  | |
| 4.10.3 | When an interested party requires the PT results to be directly provided by the PTP, are the participants aware of the arrangement in advance of participation? |  |  |  |  | |
| 4.10.4 | In exceptional circumstances, when a regulatory authority requires PT results to be directly provided to the authority by the PTP, are the affected participants notified of this action in writing? |  |  |  |  | |
| PTP 001 2.10.1 | Does the PTP inform subcontractors and external coordinators that they are not allowed to retain any form of information and processed data? |  |  |  |  | |
| **5** | **Management Requirements** |  |  |  |  | |
| **5.1** | **Organization** |  |  |  |  | |
| 5.1.1 | Is the PTP, or the organization of which it is part, an entity that is legally identifiable and accountable? |  |  |  |  | |
| 5.1.2 | Do the PTP’s responsibilities include carrying out its PT operations in such a way as to meet the requirements of ISO/IEC 17043 and to satisfy the needs of the participants, regulatory authorities and organisations providing recognition? |  |  |  |  | |
| 5.1.3 | Does the management system cover work carried out in the PTP’s permanent facilities, at sites away from its permanent facilities, and in associated temporary facilities? |  |  |  |  | |
| 5.1.4 | If the PTP is part of an organisation performing other activities, then does the PTP identify the responsibilities of key personnel in the organization that have an involvement in or could influence on the PT activities, 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 PTP are conducted with impartiality? |  |  |  |  | |
| 5.1.5 | Does the PTP: |  |  |  |  | |
| a) | 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 PT schemes, and to initiate actions to prevent or minimize such departures? |  |  |  |  | |
| b) | 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? |  |  |  |  | |
| c) | 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? |  |  |  |  | |
| d) | Have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgment or operational integrity? |  |  |  |  | |
| e) | Define the organization and management structure, its place in any parent organization, and the relationships between quality management, technical operations and support services? |  |  |  |  | |
| f) | Specify the responsibility, authority, interrelationships and required competence of all personnel who manage, perform or verify work affecting the quality of the operation of PT schemes? |  |  |  |  | |
| g) | 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? |  |  |  |  | |
| h) | Provide adequate supervision of technical staff, including trainees, by person familiar with procedures for each activity? |  |  |  |  | |
| i) | Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of the PT 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? |  |  |  |  | |
| j) | Appoint a member of staff as quality manager (names as appropriate) who, irrespective of other duties and responsibilities, with defined responsibility and authority for ensuring that the management system is implemented and followed at all times.  Does the quality manager have direct access to the highest level of management at which decisions are taken on the PTP’s policies or resources? |  |  |  |  | |
| k) | Appoint deputies for key managerial personnel? |  |  |  |  | |
|  | Note: Where PTPs 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. |  |  |  |  | |
| 5.1.6 | Does the top management ensure that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the management system? |  |  |  |  | |
| PTP 001 3.1.1 | Does the applicant or accredited PTP carry out its work in accordance with the relevant laws and regulations of Singapore or of the country where the PTP is located? |  |  |  |  | |
| PTP 001 3.1.2 | Is the applicant or accredited PTP a legal entity?  Does it take responsibility for all activities involved in the operation of the proficiency testing scheme included in its scope of accreditation? |  |  |  |  | |
| PTP 001 3.1.3 | Is the PTP scheme listed separately under its scope of accreditation?  Note: A PTP scheme could be designed for any field of testing for any purpose for participants to satisfy the SAC proficiency testing requirements, for instance, a scheme for chemical testing of construction materials, and another scheme for steel testing, etc. |  |  |  |  | |
| PTP 001 3.1.4 | Does the PTP establish suitable firewall to ensure that all information on the performance of participants is not disclosed to anyone including staff members who may have a conflict of interest?  Does the PTP provide evidence that its PT schemes are conducted with impartiality?  Note: Where a PTP is part of a larger organisation, the organisational arrangements should be such that departments having conflicting interests, such as operation, commercial marketing or financial should not adversely influence the provider’s compliance with the requirements of this document. In this regard, the PTP should particularly take note of ISO/IEC 17043 clause 5.1.4 if it also provides testing or calibration services to external customers. |  |  |  |  | |
| PTP 001 3.1.5 | Where the PTP’s laboratory is also a participant of the concerned proficiency testing scheme, does the PTP   * have documented procedures and mechanisms established to prevent collusion and falsification of results? * ensure the personnel involved in the operation of the PT scheme different from the personnel participating in the scheme? |  |  |  |  | |
| **5.2** | **Management System** |  |  |  |  | |
| 5.2.1 | Does the PTP establish, implement and maintain a management system appropriate to its scope of activities, including the type, range and volume of PT that it provides? |  |  |  |  | |
| 5.2.2 | Does the PTP define and document its policies, programmes, procedures and instructions to the extent necessary to assure the quality of all aspects of PT.  Is the system’s documentation communicated to, understood by, available to, and implemented by the appropriate personnel?  Note: These aspects include, but are not limited to, PT 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), valuation of participant performance, distribution of PT test items, storage and transport procedures, statistical treatment of test results, and reporting. |  |  |  |  | |
| 5.2.3 | Does the PTP’s management system policies related to quality, including a quality policy statement, defined in a quality manual (named as appropriate). Are the overall objectives established and reviewed during management review?  Is the quality policy statement issued under the authority of top management?  Does it include at least the following? |  |  |  |  | |
| a) | The management’s commitment to the quality of its PT services to participants and other customers? |  |  |  |  | |
| b) | The management’s statement of the standard of service? |  |  |  |  | |
| c) | The purpose of the management systems related to quality? |  |  |  |  | |
| d) | A requirement that all personnel concerned with the PT activities familarise themselves with the quality documentation and implement the policies and procedures in their work? |  |  |  |  | |
| e) | The management’s commitment to comply with ISO/IEC 17043 and to continually improve the effectiveness of the management system? |  |  |  |  | |
| 5.2.4 | Does the top management provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness? |  |  |  |  | |
| 5.2.5 | Does the top management communicate to the organisation the importance of meeting the customers’ requirements, as well as statutory and regulatory requirements? |  |  |  |  | |
| **5.3** | **Document Control** |  |  |  |  | |
| 5.3.1 | General |  |  |  |  | |
|  | Does the PTP establish and maintain procedures to control all documents that form part of its management system (internally generated, or from external sources, such as regulations, standards, other normative documents, PT scheme protocols, test or calibration methods, or both test and calibration methods, as well as drawings, software specifications, instructions and manuals? |  |  |  |  | |
| 5.3.2 | Document Approval and Issue |  |  |  |  | |
| 5.2.3.1 | Are 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 for identifying the current revision status and distribution of documents in the management system established and be readily available, in order to prevent the use of invalid or obsolete documents, or both? |  |  |  |  | |
| 5.3.2.2 | Are procedures adopted to ensure that: |  |  |  |  | |
| a) | Authorized editions of appropriate documents are available at all locations where activities essential to the effective operation of PT schemes are performed? |  |  |  |  | |
| b) | Documents are periodically reviewed and updated, as necessary, to ensure continuing suitability and compliance with applicable requirements? |  |  |  |  | |
| c) | Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use? |  |  |  |  | |
| d) | Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked? |  |  |  |  | |
| 5.3.2.3 | Are management system documents generated by the PTP 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? |  |  |  |  | |
| 5.3.3 | Document Changes |  |  |  |  | |
| 5.3.3.1 | Are changes to the documents reviewed and approved by the same function that performed the original review and approval, unless specifically designated as otherwise?  Do the designated personnel have access to pertinent background information upon which to base their review and approval? |  |  |  |  | |
| 5.3.3.2 | Where practicable, is the altered text or new text identified in the document or the appropriate attachments? |  |  |  |  | |
| 5.3.3.3 | If the PTP’s document control system allows for amendment of document by hand, pending re-issue of the documents, are the procedures and authorities for such amendments defined?  Are the amendments clearly marked, initialed and dated?  Is a revised document issued as soon as practicable? |  |  |  |  | |
| 5.3.3.4 | Are procedures established to describe how changes in documents are maintained in computerized systems are made and controlled? |  |  |  |  | |
| **5.4** | **Review of Requests, Tenders and Contracts** |  |  |  |  | |
| 5.4.1 | Does the PTP establish and maintain policies and procedures for the review of requests, tenders and contracts?  Does the review ensure that: |  |  |  |  | |
| a) | The requirements, including those for test and calibration methods, measuring equipment and PT test items to be used, are adequately defined, documented and understood? |  |  |  |  | |
| b) | The PTP has the capability and resources to meet the requirements? |  |  |  |  | |
| c) | The PT scheme is technically appropriate? |  |  |  |  | |
|  | Note1: This review is particularly important when a customer requests a PT scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.  Note2: This review can be simplified when the PT scheme is fully described in a catalogue or other notice, and the participant is enrolling for a routine shipment. |  |  |  |  | |
| 5.4.2 | Are the records of such reviews, including any changes, maintained?  Are records maintained for 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? |  |  |  |  | |
| 5.4.3 | Does the review cover all aspects of the request, including any work that is subcontracted by the PTP? |  |  |  |  | |
| 5.4.4 | Are the participants and other customers, as appropriate, informed of any deviation in the contract or agreed PT scheme design? |  |  |  |  | |
| 5.4.5 | If a request or contract is amended after the PT scheme is underway, is the same review process repeated and any amendments communicated to all affected personnel? |  |  |  |  | |
| **5.5** | **Subcontracting Services** |  |  |  |  | |
| 5.5.1 | When a PTP subcontracts work, does the PTP demonstrate that the subcontractors’ experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of IES/IEC 17043 and other appropriate standards. |  |  |  |  | |
| 5.5.2 | The PTP shall not subcontract the planning of the PT scheme (see 4.4.1.2), the evaluation of performance (see 4.7.2.1) or the authorisation of the final report (see 4.8.1).  Note: This does not preclude the PTP utilizing advice or assistance from any advisors, experts or steering group. |  |  |  |  | |
| 5.5.3 | Does the PTP inform participants, in advance and in writing, of services that are, or may be, subcontracted?  Note: This notification can, for example, take the form of a statement in the PT scheme documentation, such as the following: “Various aspects of the PT scheme can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the PTP is responsible for this work”. |  |  |  |  | |
| 5.5.4 | Is the PTP responsible for to the participants and other customers for the subcontractor’s work, except in the case where a regulatory authority specifies which subcontractor to be used? |  |  |  |  | |
| 5.5.5 | Does the PTP maintain a register of all subcontractors used in the operation of PT schemes, including the scope of subcontracting and a record of the competence assessment against relevant parts of ISO/IEC 17043 and other appropriate standards for the work in question? |  |  |  |  | |
| PTP 001 3.5.1 | If a PTP subcontracts any of its activities for the production, testing, measurement, sampling, storage, and distribution of the PT items (i.e. PT materials/samples or measurement artefacts), or for data processing and distribution of the PT records, are the work and responsibilities of each subcontractor clearly defined and documented? |  |  |  |  | |
| PTP 001 3.5.2 | Does the applicant or accredited PTP ensure that the subcontractor responsible for the testing/measuring activities, or other activities which have an impact on the quality of its PT schemes, operates under a suitable quality system, carries out the subcontracted activities according to well-defined documented procedures and meets the accreditation requirements in this technical note? |  |  |  |  | |
| PTP 001 3.5.3 | Does the PTP have a written agreement with its subcontractors which requires its subcontractors not to represent themselves to anybody that they are accredited with respect to the subcontracted activities?  Does the accredited PTP ensure that its subcontractors follow the relevant accreditation requirements and regulations?  Note: It should be emphasised that accreditation is granted to the PTP, not to its subcontractors. SAC officers may impose suspension of the accreditation when the PTP fails to ensure that its subcontractors follow any of the SAC accreditation regulation or requirement relevant to the situation concerned. |  |  |  |  | |
| **5.6** | **Purchasing Services and Supplies** |  |  |  |  | |
| 5.6.1 | Does the PTP have a policy and procedure(s) for the selection of services and supplies that it uses and that affect the quality of its PT schemes?  Do procedures exist for the purchase, reception and storage of reagents, PT test items, reference materials and other consumable materials relevant for the PT schemes? |  |  |  |  | |
| 5.6.2 | Does the PTP ensure that purchased supplies, equipment and consumable materials that affect the quality of the PT schemes are not used until they have been inspected or otherwise verified as complying specifications or requirements?  Are records taken to check compliance maintained? |  |  |  |  | |
| 5.6.3 | Do purchasing documents for items affecting the quality of PT schemes contain data describing the services and supplies ordered?  Are these purchasing documents reviewed and approved for technical content prior to release? |  |  |  |  | |
| 5.6.4 | Does the PTP evaluate suppliers of critical supplies and services which affect the quality of PT schemes?  Does the PTP maintain records of these evaluations, and list of those suppliers that are approved?  Note: It is understood that some PTPs can be required to implement their purchasing procedures in accordance with policies defined by their parent company or a host organization. |  |  |  |  | |
| PTP 001 3.6.1 | Are there documented criteria on the selection of supplies and records of evaluation of the selected supplies?  Are records kept for the different brands/ batch/ lot of those items which bear a critical influence of the test or examination results?  Do the records from each supplier include results of the acceptance tests on each new batch/lot?  Are separate records kept for each manufacturer supplying major items of equipment?  Do the records from each manufacturer include results of the acceptance tests and the subsequent maintenance history of the equipment?  Are there documented procedures for delivery/courier of proficiency test items?  Are these procedures communicated to the delivery/courier service providers?  Are there documented criteria and evaluation of the delivery/courier service providers? |  |  |  |  | |
| PTP 001 3.6.2 | Does the PTP comply with the requirements in 3.6.1, where applicable, to purchasing of external services? |  |  |  |  | |
| **5.7** | **Service to the Customer** |  |  |  |  | |
| 5.7.1 | Is the PTP willing to cooperate with participants and other customers in clarifying customer’s requests and in monitoring the PTP’s performance in relation to the work performed, provided that the PTP assures confidentiality to its participants? |  |  |  |  | |
| 5.7.2 | Does the PTP seek feedback, both positive and negative, from its customers?  Are feedback used and analysed to improve the management system, PT schemes, and customer service?  Note: Examples of the types of feedback include customer satisfaction surveys and review of PT reports with customers. |  |  |  |  | |
| PTP 001 3.7.1 | If applicable, are the feedbacks from all clients, including internal clients sought? |  |  |  |  | |
| **5.8** | **Complaints and Appeals** |  |  |  |  | |
|  | Does the PTP have a policy and procedure(s) for the resolution of complaints, appeals, investigations and corrective actions taken by the PTP? |  |  |  |  | |
| PTP 001 3.8.1 | Does the PTP notify SAC immediately, when a complaint involving a SAC accredited PT scheme is not satisfactorily resolved within 90 days from the date of its receipt? |  |  |  |  | |
| **5.9** | **Control of Nonconforming Work** |  |  |  |  | |
| 5.9.1 | Does the PTP have a policy and procedure(s) implemented when any aspect of its activities does not conform to its own procedures or the agreed requirements of its customers?  Does the policy and procedure(s) ensure that: |  |  |  |  | |
| a) | The responsibilities and authorities for the management of non-conforming work are designated and actions (including halting work of ongoing programmes and withholding reports, as necessary) are defined and taken when non-conforming work is identified? |  |  |  |  | |
| b) | An evaluation of the significance of the non-conforming work is made? |  |  |  |  | |
| c) | A decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work? |  |  |  |  | |
| d) | PT scheme participants and other customers, as appropriate, are informed and the non-conforming PT test items or reports already sent to participants are recalled or disregarded? |  |  |  |  | |
| e) | The responsibility for authorization of the resumption of work is defined?  Note: Identification of non-conforming 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, qualit6y control, preparations of PT test items, homogeneity and stability tests, data analysis, instructions to participants, and materials handling and storage. |  |  |  |  | |
| 5.9.2 | Where the evaluation indicates that non-conforming work could occur or that there is doubt about the compliance of the PTP or subcontractor with their own policies and procedures are corrective actions promptly followed? |  |  |  |  | |
| **5.10** | **Improvement** |  |  |  |  | |
| PTP 001 3.10.1 | Are the PT facilities able to show evidences of how continuous improvement is sought in the work place? |  |  |  |  | |
|  | Does the PTP continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review? |  |  |  |  | |
| **5.11** | **Corrective Actions** |  |  |  |  | |
| 5.11.1 | General |  |  |  |  | |
|  | Does the PTP establish a policy and procedure(s) and have designated appropriate personnel for implementing corrective actions when non-conforming work or departures from the policies and procedures in the management system or technical operations have been identified?  Note: See 5.8.1, Note. |  |  |  |  | |
| 5.11.2 | Cause Analysis |  |  |  |  | |
|  | 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 the potential causes of the problem is required. Potential causes could include customer requirements, PT test items and their specifications, methods and procedures, staff skills and training, consumable supplies, preparations of the PT test items, homogeneity and stability tests, statistical design, instructions to participants, and materials handling and storage. |  |  |  |  | |
| 5.11.3 | Selection and Implementation of Corrective Actions |  |  |  |  | |
| 5.11.3.1 | Where corrective action is needed, does the PTP identify potential corrective actions?  Does it select and implement the action(s) most likely to eliminate the problem and to prevent? |  |  |  |  | |
| 5.11.3.2 | Are corrective actions appropriate to the magnitude and risk of the problem? |  |  |  |  | |
| 5.11.3.3 | Does the PTP document and implement any required changes resulting from corrective action investigations? |  |  |  |  | |
| 5.11.5 | Additional Audits |  |  |  |  | |
|  | Where the identification of nonconforming activities or departure from authorized procedures cast doubts on the compliance of the PTP with its own policies and procedures or on its compliance with ISO/IEC 17043, does the PTP ensure that the appropriate areas of activity are 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 PT scheme is identified. |  |  |  |  | |
| 5.12 | Preventive Actions |  |  |  |  | |
| 5.12.1 | Are areas of improvements and potential sources of non-conforming work, either technical or concerning the management system, identified?  When improvement opportunities are identified, or if preventive action is required, are actions plans developed, implemented and monitored, to reduce the likelihood of such non-conforming work and to take advantage of the opportunities for improvement? |  |  |  |  | |
| 5.12.2 | Does the preventive action procedure include the initiation of such actions and application of controls to ensure that they are effective? |  |  |  |  | |
| **5.13** | **Control of Records** |  |  |  |  | |
| 5.13.1 | General |  |  |  |  | |
| 5.13.1.1 | Does the PTP establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of records?  Do quality records include reports from internal audits and management reviews, as well as records of corrective and preventive actions?  Note: Records can be in form of any type of media, such as hard copy or electronic storage media. |  |  |  |  | |
| 5.13.1.3 | Are all records kept secure and confidential and in accordance with relevant regulatory requirements? |  |  |  |  | |
| 5.13.1.4 | Does the PTP follow procedures to protect and back-up records stored electronically and to prevent unauthorized access or amendment of these records? |  |  |  |  | |
| 5.13.2 | Technical Records |  |  |  |  | |
| 5.13.2.1 | Does the PTP retain records of all technical data relating to each PT round for a defined period, including, but not necessarily limited to: |  |  |  |  | |
| a) | Results of homogeneity and stability testing? |  |  |  |  | |
| b) | Instructions to participants? |  |  |  |  | |
| c) | Participants’ original responses? |  |  |  |  | |
| d) | Collated data for statistical analysis? |  |  |  |  | |
| e) | Information required for reports (see 4.8)? |  |  |  |  | |
| f) | Final reports (summary or individual, or both)? |  |  |  |  | |
|  | Note1: It is advisable to retain sufficient information to establish an audit trail for the processing of results from PT rounds.  Note2: Technical records are accumulations of data and information which result from carrying out all PT activities. They can include forms, contracts, work sheets, work books, check sheets, work notes, sub-contractor reports and participant feedback. |  |  |  |  | |
| 5.13.2.2 | Are data entry, checking and calculation recorded at the time they are made and shall be identifiable to the specific task and to the personnel responsible? |  |  |  |  | |
| 5.13.2.3 | When mistakes occur in records and alterations are made, are actions taken to: |  |  |  |  | |
| a) | Identify the change and date of alteration? |  |  |  |  | |
| b) | Avoid loss of original data? |  |  |  |  | |
| c) | Identify the person making the alteration? |  |  |  |  | |
| **5.14** | **Internal Audit** |  |  |  |  | |
| 5.14.1 | Does the PTP 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 ISO/IEC 17043?  Does the internal audit programme address all elements of the management system, including technical procedures and PT test item preparation, storage and distribution, as well as reporting activities for the operation of a PT scheme?  It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.  Are internal audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited? |  |  |  |  | |
| 5.14.2 | When audit findings cast doubt upon the effectiveness of the operations, including the suitability and correctness of the PT test items, procedures, statistical evaluations and data presentation, does the PTP take timely corrective action and notify its customers or participants, or both, in the PT schemes whose activities may have been affected? |  |  |  |  | |
| 5.14.3 | Is the area of audited activity, the audit findings and any corrective actions that arise from them recorded? |  |  |  |  | |
| 5.14.4 | Do follow-up audit activities verify and record the implementation and effectiveness of any corrective actions taken? |  |  |  |  | |
| PTP 001 3.14.1 | Does the internal audit schedule cover all the elements of the management system over a twelve-month period?  Does the audit determine if: |  |  |  |  | |
| a) | Procedures described in the management system are being followed? |  |  |  |  | |
| b) | Objectives (as defined in the management system) are being achieved? |  |  |  |  | |
| c) | Designated duties are being carried out satisfactorily? |  |  |  |  | |
| d) | There are opportunities for improvements? |  |  |  |  | |
| PTP 001 3.14.3 | Are the corrective actions submitted to address the findings of internal audit verified and accepted by the relevant internal auditor? |  |  |  |  | |
| PTP 001 3.14.4 | Does the facility send its internal audit report to SAC three months prior to the on-site assessment? |  |  |  |  | |
| **5.15** | **Management Reviews** |  |  |  |  | |
| 5.15.1 | In accordance with a pre-determined schedule and procedure, does the PTP’s top management periodically conduct a review of the PTP’s management system and PT activities, in order to ensure their continued suitability and effectiveness and to introduce any necessary changes or improvements?  Does the review take into account of: |  |  |  |  | |
| a) | The suitability of policies and procedures? |  |  |  |  | |
| b) | Reports from management and supervisory personnel? |  |  |  |  | |
| c) | The outcome of recent internal audits? |  |  |  |  | |
| d) | Corrective and preventive actions? |  |  |  |  | |
| e) | Assessment by external bodies? |  |  |  |  | |
| f) | Changes in the volume and type of work? |  |  |  |  | |
| g) | Customer, advisory group or participant feedback? |  |  |  |  | |
| h) | Complaints and appeals? |  |  |  |  | |
| i) | Recommendations for improvement? |  |  |  |  | |
| j) | Other relevant factors, such as resources and staff training? |  |  |  |  | |
|  | Note1: A typical period for conducting a management review is once every 12 months.  Note2: Results can feed into the PTP’s planning system and can include the objectives and actions plans.  Note3: A management review includes consideration of related subjects at regular management meetings.  Note4: Where the PTP is part of a larger organization, it can be appropriate to hold a separate review meeting to cover PT testing activities. |  |  |  |  | |
| 5.15.2 | Are findings from management reviews, and actions that arise from them, recorded?  Does the management ensure that those actions are discharged within an appropriate and agreed timescale? |  |  |  |  | |
| PTP 001 3.15.1 | Does the facility’s management review the effectiveness of the management system once every twelve months? |  |  |  |  | |
|  | **SAC 01 requirements** | | | | | |
| **A.**  3.1(a)  3.1 (b)  (i)  (ii)  (iii)  (iv)  (v)  (vi)  (vii)  (viii)  3.1(c)  3.1(d)  3.1(e)  3.1(f)  3.1(g)  3.1(h)  3.1 (i)  3.1 (j) | **Obligations of the accredited organisations**  Offer to all customers a standard of service consistent with the SAC terms and conditions and maintain impartiality and integrity in all operations;  Immediately notify SAC on:  any change in its legal, commercial, ownership or organizational status;  Any changes in organisation, top management and key personnel who could affect the performance or competence of the facility;  Plans to conduct any accredited activities outside the Republic of Singapore;  Change of resources and premises, where the accredited facility has the responsibility to inform SAC at least 3 months in advance;  Any lawsuit or criminal investigation of the accredited organisation or its staff;  Any changes to the scope of accreditation;  Any significant changes in main policies;  Any other matters that may affect the ability of the accredited organisation to fulfil requirements for accreditation;  Adhere to the rules for the use of the SAC Accreditation Marks and reference to accreditation status  Not to use the accreditation status in such a manner as to bring SAC into disrepute and not make any statement related to the accreditation which SAC may consider misleading or unauthorized.  Provide reasonable facilities, such as accommodation, cooperation, and access to documentation, inspection methods, test / calibration standards, personnel, inspection site, calibration and testing areas for the assessors and SAC staff to discharge their duties during assessments and resolution of complaints. This include reserving a right to visit any certified organizations of SAC accredited certification bodies as a means of verification that audits are properly conducted;  Make prompt payment to SAC of all necessary fees levied by SAC;  Upon the withdrawal of accreditation forthwith discontinue its use of reference to accreditation and withdraw all advertising materials which contains any reference to accreditation;  Make a clear and unequivocal statement in all contacts with its customers that a certificate of accreditation in no way implies that the product or service is approved by SAC; and  Not represent or hold itself out as being the agent or partner of SAC or make any representations on behalf of SAC.  Ensure the standard of service and integrity of reports are maintained during relocation. Endorsed reports can continue to be issued prior to SAC verification of continual compliance at the new location. Should subsequent findings from SAC during the reassessment show the  accreditation requirements are compromised, this may warrant for recall of reports issued. |  |  |  | SAC 01  Not applicable to PTP scheme | |
| B. | Follow up on last year findings | | | | |
| C. | Other Observation and Comments | | | | |
| D. | Additional Notes | | | | |