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| Instructions on filling this document  The lab personnel should fill it completely and send it to PNAC while submitting the application form and quality system and give cross references to its clauses in the quality manual/ procedures/ forms etc. Please note that only giving reference to a particular procedure may not be sufficient in most of the cases.  PNAC’s Assessors Verification & remarks column will be filled in by the concerned officer in PNAC. | | | |
| Name of the Lab: | | | Name of PNAC’s assessor |
| Address: | | |
| ISO/IEC 17025 Clause Ref. | Requirement | Lab’s Reference to its QSD | PNAC’s Assessor verification & remarks |
| 4.1 | Impartiality |  |  |
| 4.1.1 | Laboratory activities shall be undertaken impartiality and structured and managed so as to safeguard impartiality |  |  |
| 4.1.2 | The laboratory management shall be committed to impartiality |  |  |
| 4.1.3 | The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality. |  |  |
| 4.1.4 | The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. |  |  |
| 4.1.5 | If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. |  |  |
| 4.2 | Confidentiality |  |  |
| 4.2.1 | The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. |  |  |
| 5 | Structural requirements |  |  |
| 5.1 | The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities. |  |  |
| 5.2 | The laboratory shall identify management that has overall responsibility for the laboratory. |  |  |
| 5.3 | The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. |  |  |
| 5.5 | The laboratory shall:   1. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; 2. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; 3. document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results. |  |  |
| 5.6 | The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:   1. implementation, maintenance and improvement of the management system; 2. identification of deviations from the management system or from the procedures for performing laboratory activities; 3. initiation of actions to prevent or minimize such deviations; 4. reporting to laboratory management on the performance of the management system and any need for improvement; 5. ensuring the effectiveness of laboratory activities. |  |  |
| 5.7 | Laboratory management shall ensure that:   1. communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; 2. the integrity of the management system is maintained when changes to the management system are planned and implemented. |  |  |
| 6 | Resource requirements |  |  |
| 6.1 | General |  |  |
|  | The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities. |  |  |
| 6.2 | Personnel |  |  |
| 6.2.1 | All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system. |  |  |
| 6.2.2 | The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. |  |  |
| 6.2.3 | The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. |  |  |
| 6.2.5 | The laboratory shall have procedure(s) and retain records for:   1. determining the competence requirements; 2. selection of personnel; 3. training of personnel; 4. supervision of personnel; 5. authorization of personnel; 6. monitoring competence of personnel. |  |  |
| 6.2.6 | The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:   1. development, modification, verification and validation of methods; 2. analysis of results, including statements of conformity or opinions and interpretations; 3. report, review and authorization of results. |  |  |
| 6.3 | Facilities and environmental conditions |  |  |
| 6.3.1 | The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. |  |  |
| 6.3.2 | The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. |  |  |
| 6.4 | Equipment |  |  |
| 6.4.1 | The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. |  |  |
| 6.4.3 | The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration. |  |  |
| 6.4.6 | Measuring equipment shall be calibrated when:   * the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or * calibration of the equipment is required to establish the metrological traceability of the reported results. |  |  |
| 6.4.7 | The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. |  |  |
| 6.4.11 | When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. |  |  |
| 6.4.12 | The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results. |  |  |
| 6.4.13 | Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:   1. the identity of equipment, including software and firmware version; 2. the manufacturer's name, type identification, and serial number or other unique identification; 3. evidence of verification that equipment conforms with specified requirements; 4. the current location; 5. calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval; 6. documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity; 7. the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; 8. details of any damage, malfunction, modification to, or repair of, the equipment. |  |  |
| 6.5 | Metrological traceability |  |  |
| 6.5.1 | The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. |  |  |
| 6.5.2 | The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:   1. calibration provided by a competent laboratory; or 2. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or 3. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. |  |  |
| 6.6 | Externally provided products and services |  |  |
| 6.6.1 | The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:   1. are intended for incorporation into the laboratory’s own activities; 2. are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; 3. are used to support the operation of the laboratory. |  |  |
| 6.6.2 | The laboratory shall have a procedure and retain records for:   1. defining, reviewing and approving the laboratory’s requirements for externally provided products and services; 2. defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; 3. ensuring that externally provided products and services conform to the laboratory’s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer; 4. taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers. |  |  |
| 6.6.3 | The laboratory shall communicate its requirements to external providers for:   1. the products and services to be provided; 2. the acceptance criteria; 3. competence, including any required qualification of personnel; 4. activities that the laboratory, or its customer, intends to perform at the external provider's premises. |  |  |
| 7 | Process requirements |  |  |
| 7.1 | Review of requests, tenders and contracts |  |  |
| 7.1.1 | The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:   1. the requirements are adequately defined, documented and understood; 2. the laboratory has the capability and resources to meet the requirements; 3. where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval; 4. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. |  |  |
| 7.2 | Selection, verification and validation of methods |  |  |
| 7.2.1 | Selection and verification of methods |  |  |
| 7.2.1.1 | The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. |  |  |
| 7.2.1.2 | All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel. |  |  |
| 7.2.1.3 | The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. |  |  |
| 7.2.1.6 | When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized. |  |  |
| 7.2.2 | Validation of methods |  |  |
| 7.2.2.1 | The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.   1. calibration or evaluation of bias and precision using reference standards or reference materials; 2. systematic assessment of the factors influencing the result; 3. testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; 4. comparison of results achieved with other validated methods; 5. Interlaboratory comparisons; 6. evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method. |  |  |
| 7.3 | Sampling |  |  |
| 7.3.1 | The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. |  |  |
| 7.4 | Handling of test or calibration items |  |  |
| 7.4.1 | The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed. |  |  |
| 7.5 | Technical records |  |  |
| 7.5.1 | The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task. |  |  |
| 7.6 | Evaluation of measurement uncertainty |  |  |
| 7.6.1 | Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis. |  |  |
| 7.7 | Ensuring the validity of results |  |  |
| 7.7.1 | The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:   1. use of reference materials or quality control materials; 2. use of alternative instrumentation that has been calibrated to provide traceable results; 3. functional check(s) of measuring and testing equipment; 4. use of check or working standards with control charts, where applicable; 5. intermediate checks on measuring equipment; 6. replicate tests or calibrations using the same or different methods; 7. retesting or recalibration of retained items; 8. correlation of results for different characteristics of an item; 9. review of reported results; 10. intralaboratory comparisons; 11. testing of blind sample(s). |  |  |
| 7.7.2 | The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:   1. participation in proficiency testing; 2. participation in interlaboratory comparisons other than proficiency testing. |  |  |
| 7.7.3 | Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported. |  |  |
| 7.8 | Reporting of results |  |  |
| 7.8.1 | General |  |  |
| 7.8.1.1 | The results shall be reviewed and authorized prior to release. |  |  |
| 7.8.1.2 | The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records. |  |  |
| 7.8.2 | Common requirements for reports (test, calibration or sampling) |  |  |
| 7.8.2.1 | Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:   1. a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”); 2. the name and address of the laboratory; 3. the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities; 4. unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; 5. the name and contact information of the customer; 6. identification of the method used; 7. a description, unambiguous identification, and, when necessary, the condition of the item; 8. the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; 9. the date(s) of performance of the laboratory activity; 10. the date of issue of the report; 11. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; 12. a statement to the effect that the results relate only to the items tested, calibrated or sampled; 13. the results with, where appropriate, the units of measurement; 14. additions to, deviations, or exclusions from the method; 15. identification of the person(s) authorizing the report; 16. clear identification when results are from external providers. |  |  |
| 7.8.2.2 | The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received. |  |  |
| 7.8.3 | Specific requirements for test reports |  |  |
| 7.8.3.1 | In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:   1. information on specific test conditions, such as environmental conditions; 2. where relevant, a statement of conformity with requirements or specifications; 3. where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:    * it is relevant to the validity or application of the test results;    * a customer's instruction so requires, or    * the measurement uncertainty affects conformity to a specification limit; 4. where appropriate, opinions and interpretations; 5. additional information that may be required by specific methods, authorities, customers or groups of customers. |  |  |
| 7.8.4 | Specific requirements for calibration certificates |  |  |
| 7.8.4.1 | In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:   1. the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); 2. the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; 3. a statement identifying how the measurements are metrologically traceable; 4. the results before and after any adjustment or repair, if available; 5. where relevant, a statement of conformity with requirements or specifications; 6. where appropriate, opinions and interpretations. |  |  |
| 7.8.5 | Reporting sampling – specific requirements |  |  |
| 7.8.6 | Reporting statements of conformity |  |  |
| 7.8.7 | Reporting opinions and interpretations |  |  |
| 7.8.8 | Amendments to reports |  |  |
| 7.9 | Complaints |  |  |
| 7.10 | Nonconforming work |  |  |
| 7.10.1 | The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:   1. the responsibilities and authorities for the management of nonconforming work are defined; 2. actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; 3. an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; 4. a decision is taken on the acceptability of the nonconforming work; 5. where necessary, the customer is notified and work is recalled; 6. the responsibility for authorizing the resumption of work is defined. |  |  |
| 7.11 | Control of data and information management |  |  |
| 8 | Management system requirements |  |  |
| 8.1 | Options |  |  |
| 8.2 | Management system documentation (Option A) |  |  |
| 8.2.1 | Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. |  |  |
| 8.2.2 | The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory. |  |  |
| 8.3 | Control of management system documents (Option A) |  |  |
| 8.3.1 | The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. |  |  |
| 8.3.2 | The laboratory shall ensure that:   1. documents are approved for adequacy prior to issue by authorized personnel; 2. documents are periodically reviewed, and updated as necessary; 3. changes and the current revision status of documents are identified; 4. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; 5. documents are uniquely identified; 6. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose. |  |  |
| 8.4 | Control of records (Option A) |  |  |
| 8.4.1 | The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document. |  |  |
| 8.4.2 | The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available. |  |  |
| 8.5 | Actions to address risks and opportunities (Option A) |  |  |
| 8.5.1 | The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:   1. give assurance that the management system achieves its intended results; 2. enhance opportunities to achieve the purpose and objectives of the laboratory; 3. prevent, or reduce, undesired impacts and potential failures in the laboratory activities; 4. achieve improvement. |  |  |
| 8.5.2 | The laboratory shall plan:   1. actions to address these risks and opportunities; 2. how to:  * integrate and implement these actions into its management system; * evaluate the effectiveness of these actions. |  |  |
| 8.5.3 | Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results. |  |  |
| 8.6 | Improvement (Option A) |  |  |
| 8.6.1 | The laboratory shall identify and select opportunities for improvement and implement any necessary actions. |  |  |
| 8.6.2 | The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service. |  |  |
| 8.7 | Corrective actions (Option A) |  |  |
| 8.7.1 | When a nonconformity occurs, the laboratory shall:   1. react to the nonconformity and, as applicable:  * take action to control and correct it; * address the consequences;  1. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:  * reviewing and analysing the nonconformity; * determining the causes of the nonconformity; * determining if similar nonconformities exist, or could potentially occur;  1. implement any action needed; 2. review the effectiveness of any corrective action taken; 3. update risks and opportunities determined during planning, if necessary; 4. make changes to the management system, if necessary. |  |  |
| 8.8 | Internal audits (Option A) |  |  |
| 8.8.1 | The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:   1. conforms to:  * the laboratory’s own requirements for its management system, including the laboratory activities; * the requirements of this document;  1. is effectively implemented and maintained. |  |  |
| 8.9 | Management reviews (Option A) |  |  |
| 8.9.1 | The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. |  |  |

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To be filled in during pre-assessment (onsite visit) by PNAC Assessor

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| Brief history of the lab and its legal status | |
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| Status of implementation of the standard w.r.t records | |
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| Is the laboratory having sufficient and trained human resources to carry out its testing? | |
|  | |
| Has the lab carried out testing for customer? If not, how does it ensure competence of its personnel? | |
|  | |
| Which methods are being used for testing? Are they the updated international method? | |
|  | |
| How is traceability to international standards maintained? | |
|  | |
| Which type of internal and external quality controls are in practice? Where is the lab participating for PT/ILC and for which tests? | |
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| Recommendation on its preparation for full assessment? | |
|  | |
| Are there any major gaps that need to be addressed before initial assessment? | |
|  | |
| Suggestion on no of man days/ type of team and scope to be assessed | |
|  | |
| PNAC’s Assessor name & signature | Lab’s representative |
| Date | Date |