|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **4** | **General Requirements** | | | | | | |
| **4.1** | **Impartiality** |  |  |  |  |  |  |
| **4.1.1** | Has the laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality? |  |  |  |  |  |  |
| **4.1.2** | Does the laboratory management commit to impartiality? |  |  |  |  |  |  |
| **4.1.3** | Does the laboratory responsible for the impartiality of its laboratory activities and not to allow commercial, financial or other pressures to compromise impartiality? |  |  |  |  |  |  |
| **4.1.4** | Has the laboratory 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, does the laboratory able to demonstrate how it eliminates or minimizes such risk? |  |  |  |  |  |  |
| **4.2** | **Confidentiality** |  |  |  |  |  |  |
| **4.2.1** | Does the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities?  Is it informed 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) |  |  |  |  |  |  |
| **4.2.2** | When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is customer or individual concerned, unless prohibited by law, notified of the information provided? |  |  |  |  |  |  |
| **4.2.3** | Are information about the customer obtained from sources other than the customer (e.g. complainant, regulators) confidential between the customer and the laboratory? (The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source) |  |  |  |  |  |  |
| **4.2.4** | Are personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory’s behalf, keep confidential all information obtained or created during the performance of laboratory activities? |  |  |  |  |  |  |
| **5** | **Structural Requirements** |  |  |  |  |  |  |
| **5.1** | Is the laboratory legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities? |  |  |  |  |  |  |
| **5.2** | Does the laboratory shall identify management that has overall responsibility for the laboratory? |  |  |  |  |  |  |
| **5.3** | Is it defined and documented 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) |  |  |  |  |  |  |
| **5.4** | Do the laboratory activities carry out in such a way as to meet the requirements of this document, the laboratory’s customers, regulatory authorities and organizations providing recognition?  Are laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer’s facility. |  |  |  |  |  |  |
| **5.5** | Does the laboratory,   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** | Does the laboratory 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** | Does the laboratory management ensured 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**  Does the laboratory have available personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities? |  |  |  |  |  |  |
| **6.2** | **Personnel** |  |  |  |  |  |  |
| **6.2.1** | Are all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, be competent and work in accordance with the laboratory’s management system? |  |  |  |  |  |  |
| **6.2.2** | Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience? |  |  |  |  |  |  |
| **6.2.3** | Is it ensured that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations? |  |  |  |  |  |  |
| **6.2.4** | Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities? |  |  |  |  |  |  |
| **6.2.5** | Does the laboratory 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 of competence of personnel. |  |  |  |  |  |  |
| **6.2.6** | Is it authorized 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** | Are facilities and environmental conditions suitable for the laboratory activities and shall not adversely affect the validity of results? |  |  |  |  |  |  |
| **6.3.2** | Is it documented that the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities? |  |  |  |  |  |  |
| **6.3.3** | Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results? |  |  |  |  |  |  |
| **6.3.4** | Are there measures to control facilities implemented, monitored and periodically reviewed and shall include, but not be limited to:   1. access to and use of areas affecting laboratory activities; 2. prevention of contamination, interference or adverse influences on laboratory activities; 3. effective separation between areas with incompatible laboratory activities. |  |  |  |  |  |  |
| **6.3.5** | When the laboratory performs laboratory activities at sites or facilities outside its permanent control, is it ensured that the requirements related to facilities and environmental conditions of this document are met? |  |  |  |  |  |  |
| **6.4** | **Equipment** |  |  |  |  |  |  |
| **6.4.1** | Does the laboratory have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result? |  |  |  |  |  |  |
| **6.4.2** | In those cases where the laboratory uses equipment outside its permanent control, is it ensured that the requirements for equipment of this document are met? |  |  |  |  |  |  |
| **6.4.3** | Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration? |  |  |  |  |  |  |
| **6.4.4** | Are they verify that equipment conforms to specified requirements before being placed or returned into service? |  |  |  |  |  |  |
| **6.4.5** | Are equipment used for measurement capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result? |  |  |  |  |  |  |
| **6.4.6** | Does the measuring equipment calibrated when:   * the measurement accuracy or measurement uncertainty affects the validity of the reported results, * or calibration of the equipment is required to establish the metrological traceability of the reported result. * those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; * those used to make corrections to the measured value, e.g. temperature measurements |  |  |  |  |  |  |
| **6.4.7** | Are calibration programme established, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? |  |  |  |  |  |  |
| **6.4.8** | Are all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity? |  |  |  |  |  |  |
| **6.4.9** | Are equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service?  Is it isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly?  Is it examined the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure? |  |  |  |  |  |  |
| **6.4.10** | When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks carried out according to a procedure? |  |  |  |  |  |  |
| **6.4.11** | When calibration and reference material data include reference values or correction factors, is it ensured that the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements? |  |  |  |  |  |  |
| **6.4.12** | Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results? |  |  |  |  |  |  |
| **6.4.13** | Are records 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** | Does the laboratory 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** | Is it ensured that measurement results are traceable to the International System of Units (SI) through one of the following:   1. calibration provided by a competent laboratory; 2. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; 3. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. |  |  |  |  |  |  |
| **6.5.3** | When metrological traceability to the SI units is not technically possible, is it demonstrates metrological traceability to an appropriate reference, e.g.   1. certified values of certified reference materials provided by a competent producer; 2. results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison. |  |  |  |  |  |  |
| **6.6** | **Externally provided products and services** |  |  |  |  |  |  |
| **6.6.1** | Is it ensured 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** | Are there 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** | Does the laboratory 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** | Does the laboratory 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. |  |  |  |  |  |  |
| **7.1.2** | Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date? |  |  |  |  |  |  |
| **7.1.3** | When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule are clearly defined?  Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. |  |  |  |  |  |  |
| **7.1.4** | Are any differences between the request or tender and the contract resolved before laboratory activities commence?  (Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results) |  |  |  |  |  |  |
| **7.1.5** | Are customers informed of any deviation from the contract? |  |  |  |  |  |  |
| **7.1.6** | Does the contract review repeated and any amendments are communicated to all affected personnel, if a contract is amended after work has commenced? |  |  |  |  |  |  |
| **7.1.7** | Does the laboratory cooperate with customers or their representatives in clarifying the customer’s request and in monitoring the laboratory’s performance in relation to the work performed.   1. providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities; 2. preparation, packaging, and dispatch of items needed by the customer for verification purposes. |  |  |  |  |  |  |
| **7.1.8** | Does the laboratory retain records of reviews, including any significant changes?  Records shall also be retained of pertinent discussions with a customer relating to the customer’s requirements or the results of the laboratory activities. |  |  |  |  |  |  |
| **7.2** | **Selection, verification and validation of methods** |  |  |  |  |  |  |
| **7.2.1** | **Selection and verification of methods** |  |  |  |  |  |  |
| **7.2.1.1** | Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data? |  |  |  |  |  |  |
| **7.2.1.2** | All Does the laboratory keep all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, up to date and made readily available to personnel? |  |  |  |  |  |  |
| **7.2.1.3** | Does the laboratory 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 is supplemented with additional details to ensure consistent application? |  |  |  |  |  |  |
| **7.2.1.4** | When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen?  Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used. |  |  |  |  |  |  |
| **7.2.1.5** | Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance? Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. |  |  |  |  |  |  |
| **7.2.1.6** | When method development is required, is this planned activity and assigned to competent personnel equipped with adequate resources?  As method development proceeds, are periodic review carried out to confirm that the needs of the customer are still being fulfilled?  Are any modifications to the development plan approved and authorized? |  |  |  |  |  |  |
| **7.2.1.7** | Are deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer? |  |  |  |  |  |  |
| **7.2.2** | **Validation of methods** |  |  |  |  |  |  |
| **7.2.2.1** | Does the laboratory 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. |  |  |  |  |  |  |
| **7.2.2.2** | When changes are made to a validated method, are the influence of such changes determined and where they are found to affect the original validation, a new method validation is performed? |  |  |  |  |  |  |
| **7.2.2.3** | The performance characteristics of validated methods as assessed for the intended use, is it relevant to the customers’ needs and consistent with specified requirements? |  |  |  |  |  |  |
| **7.2.2.4** | Does the laboratory retain the following records of validation?   1. the validation procedure used; 2. specification of the requirements; 3. determination of the performance characteristics of the method; 4. results obtained; 5. a statement on the validity of the method, detailing its fitness for the intended use. |  |  |  |  |  |  |
| **7.3** | **Sampling** |  |  |  |  |  |  |
| **7.3.1** | Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration?  Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results?  Are sampling plan and method available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. |  |  |  |  |  |  |
| **7.3.2** | Does the sampling method describe:   1. the selection of samples or sites; 2. the sampling plan; 3. preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration. |  |  |  |  |  |  |
| **7.3.3** | Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:   1. reference to the sampling method used; 2. date and time of sampling; 3. data to identify and describe the sample (e.g. number, amount, name); 4. identification of the personnel performing sampling; 5. identification of the equipment used; 6. environmental or transport conditions; 7. diagrams or other equivalent means to identify the sampling location when appropriate; 8. deviations, additions to or exclusions from the sampling method and sampling plan. |  |  |  |  |  |  |
| **7.4** | **Handling of test or calibration items** |  |  |  |  |  |  |
| **7.4.1** | Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer?  Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration.  Are handling instructions provided with the item followed? |  |  |  |  |  |  |
| **7.4.2** | Does the laboratory have a system for the unambiguous identification of test or calibration items?  Is identification retained while the item is under the responsibility of the laboratory?  Does the system ensure that items will not be confused physically or when referred to in records or other documents? The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items. |  |  |  |  |  |  |
| **7.4.3** | Upon receipt of the test or calibration item, deviations from specified conditions are recorded?  When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding and record the results of this consultation?  When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation? |  |  |  |  |  |  |
| **7.4.4** | When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded? |  |  |  |  |  |  |
| **7.5** | **Technical records** |  |  |  |  |  |  |
| **7.5.1** | Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original?  Are technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results?  Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task? |  |  |  |  |  |  |
| **7.5.2** | Does the laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations?  Are both the original and amended data and files kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations? |  |  |  |  |  |  |
| **7.6** | **Evaluation of measurement uncertainty** |  |  |  |  |  |  |
| **7.6.1** | Does the laboratory identify the contributions to measurement uncertainty?  When evaluating measurement uncertainty, all contributions which are of significance, including those arising from sampling, have been taken into account using appropriate methods of analysis? |  |  |  |  |  |  |
| **7.6.2** | A laboratory performing calibrations, including of its own equipment, are they evaluate the measurement uncertainty for all calibrations? |  |  |  |  |  |  |
| **7.6.3** | Does the laboratory performing testing evaluate measurement uncertainty?  Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation are made based on an understanding of the theoretical principles or practical experience of the performance of the method? |  |  |  |  |  |  |
| **7.7** | Ensuring the validity of results |  |  |  |  |  |  |
| **7.7.1** | Does the laboratory have a procedure for monitoring the validity of results?  Are resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques applied to review the results?  Does this monitoring planned and reviewed and 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** | Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate?  Is this monitoring planned and reviewed and 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** | Are data from monitoring activities 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, are appropriate action taken to prevent incorrect results from being reported? |  |  |  |  |  |  |
| **7.8** | **Reporting of results** |  |  |  |  |  |  |
| **7.8.1** | General |  |  |  |  |  |  |
| **7.8.1.1** | Are results reviewed and authorized prior to release?  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. |  |  |  |  |  |  |
| **7.8.1.2** | When agreed with the customer, are results reported in a simplified way? Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available. |  |  |  |  |  |  |
| **7.8.2** | Common requirements for reports (test, calibration or sampling) |  |  |  |  |  |  |
| **7.8.2.1** | Does each report 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** | Does the laboratory responsible for all the information provided in the report, except when information is provided by the customer?  Are data provided by a customer 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, are test reports, where necessary for the interpretation of the test results, included the following:   1. information on specific test conditions, such as environmental conditions; 2. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); 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;   1. where appropriate, opinions and interpretations (see 7.8.7); 2. additional information which may be required by specific methods, authorities, customers or groups of customers. |  |  |  |  |  |  |
| **7.8.3.2** | Where the laboratory is responsible for the sampling activity, are test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? |  |  |  |  |  |  |
| **7.8.4** | **Specific requirements for calibration certificates** |  |  |  |  |  |  |
| **7.8.4.1** | In addition to the requirements listed in 7.8.2, does the calibration certificates 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);   NOTE According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.   1. the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; 2. a statement identifying how the measurements are metrologically traceable; 3. the results before and after any adjustment or repair, if available; 4. where relevant, a statement of conformity with requirements or specifications (see 7.8.6); 5. where appropriate, opinions and interpretations (see 7.8.7). |  |  |  |  |  |  |
| **7.8.4.2** | Where the laboratory is responsible for the sampling activity, does the calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? |  |  |  |  |  |  |
| **7.8.4.3** | A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. |  |  |  |  |  |  |
| **7.8.5** | **Reporting sampling–specific requirements**  Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, does reports include the following, where necessary for the interpretation of results:   1. the date of sampling; 2. unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); 3. the location of sampling, including any diagrams, sketches or photographs; 4. a reference to the sampling plan and sampling method; 5. details of any environmental conditions during sampling that affect the interpretation of the test results; 6. Information required to evaluate measurement uncertainty for subsequent testing or calibration. |  |  |  |  |  |  |
| **7.8.6** | Reporting statements of conformity |  |  |  |  |  |  |
| **7.8.6.1** | When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule? |  |  |  |  |  |  |
| **7.8.6.2** | Does the laboratory report on the statement of conformity? such that the statement clearly identifies:   1. to which results the statement of conformity applies; 2. which specifications, standards or parts thereof are met or not met; 3. the decision rule applied (unless it is inherent in the requested specification or standard). |  |  |  |  |  |  |
| **7.8.7** | **Reporting opinions and interpretations** |  |  |  |  |  |  |
| **7.8.7.1** | When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement?  Does the laboratory document the basis upon which the opinions and interpretations have been made? |  |  |  |  |  |  |
| **7.8.7.2** | The opinions and interpretations expressed in reports is it based on the results obtained from the tested or calibrated item and shall be clearly identified as such? |  |  |  |  |  |  |
| **7.8.7.3** | When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue are retained? |  |  |  |  |  |  |
| **7.8.8** | Amendments to reports |  |  |  |  |  |  |
| **7.8.8.1** | When an issued report needs to be changed, amended or re-issued, any change of information are clearly identified and, where appropriate, the reason for the change included in the report? |  |  |  |  |  |  |
| **7.8.8.2** | Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording?  Such amendments shall meet all the requirements of this document. |  |  |  |  |  |  |
| **7.8.8.3** | When it is necessary to issue a complete new report, is it uniquely identified and contain a reference to the original that it replaces? |  |  |  |  |  |  |
| **7.9** | **Complaints** |  |  |  |  |  |  |
| **7.9.1** | Does the laboratory have a documented process to receive, evaluate and make decisions on complaints? |  |  |  |  |  |  |
| **7.9.2** | Is description of the handling process for complaints available to any interested party on request?  Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it?  Does the laboratory responsible for all decisions at all levels of the handling process for complaints? |  |  |  |  |  |  |
| **7.9.3** | Does the process for handling complaints include at least the following elements and methods:   1. description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; 2. tracking and recording complaints, including actions undertaken to resolve them; 3. ensuring that any appropriate action is taken. |  |  |  |  |  |  |
| **7.9.4** | The When laboratory receiving the complaint is it responsible for gathering and verifying all necessary information to validate the complaint? |  |  |  |  |  |  |
| **7.9.5** | Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? |  |  |  |  |  |  |
| **7.9.6** | The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question? |  |  |  |  |  |  |
| **7.9.7** | Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant? |  |  |  |  |  |  |
| **7.10** | Nonconforming work |  |  |  |  |  |  |
| **7.10.1** | Does the laboratory have a procedure that 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. |  |  |  |  |  |  |
| **7.10.2** | Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)? |  |  |  |  |  |  |
| **7.10.3** | Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory’s operations with its own management system, does the laboratory implement corrective action? |  |  |  |  |  |  |
| **7.11** | **Control of data and information management** |  |  |  |  |  |  |
| **7.11.1** | Does the laboratory have access to the data and information needed to perform laboratory activities? |  |  |  |  |  |  |
| **7.11.2** | The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction?  Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation? |  |  |  |  |  |  |
| **7.11.3** | Does the laboratory information management system(s):   1. be protected from unauthorized access; 2. be safeguarded against tampering and loss; 3. be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; 4. be maintained in a manner that ensures the integrity of the data and information; 5. include recording system failures and the appropriate immediate and corrective actions. |  |  |  |  |  |  |
| **7.11.4** | When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document? |  |  |  |  |  |  |
| **7.11.5** | Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel? |  |  |  |  |  |  |
| **7.11.6** | Are calculations and data transfers checked in an appropriate and systematic manner? |  |  |  |  |  |  |
| **8** | **Management system requirements** |  |  |  |  |  |  |
| **8.1** | **Options** |  |  |  |  |  |  |
| **8.1.1** | **General**  Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results? In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B. |  |  |  |  |  |  |
| **8.1.2** | **Option A** |  |  |  |  |  |  |
|  | As a minimum, does the management system of the laboratory address the following?  - management system documentation (see 8.2)  - control of management system documentation (see 8.3)  - control of records (see 8.4)  - actions to address risks and opportunities (see 8.5)  - improvement (see 8.6)  - corrective actions (see 8.7)  - internal audits (see 8.8)  - management reviews (see 8.9) |  |  |  |  |  |  |
| **8.1.3** | **Option B**  A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9. |  |  |  |  |  |  |
| **8.2** | Management system documentation (Option A) |  |  |  |  |  |  |
| **8.2.1** | Does the laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization? |  |  |  |  |  |  |
| **8.2.2** | Are policies and objectives address the competence, impartiality and consistent operation of the laboratory? |  |  |  |  |  |  |
| **8.2.3** | Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? |  |  |  |  |  |  |
| **8.2.4** | Are all documentation, processes, systems, records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system? |  |  |  |  |  |  |
| **8.2.5** | Are all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities? |  |  |  |  |  |  |
| **8.3** | Control of management system documents (Option A) |  |  |  |  |  |  |
| **8.3.1** | Does the laboratory control the documents (internal and external) that relate to the fulfillment of this document? |  |  |  |  |  |  |
| **8.3.2** | Does the laboratory 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** | Does the laboratory establish and retain legible records to demonstrate fulfillment of the requirements in this document? |  |  |  |  |  |  |
| **8.4.2** | Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records?  Does the laboratory retain records for a period consistent with its contractual obligations?  Are access to these records consistent with the confidentiality commitments and records readily available? |  |  |  |  |  |  |
| **8.5** | Actions to address risks and opportunities (Option A) |  |  |  |  |  |  |
| **8.5.1** | Does the laboratory 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** | Does the laboratory 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** | Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results? |  |  |  |  |  |  |
| **8.6** | **Improvement (Option A)** |  |  |  |  |  |  |
| **8.6.1** | Does the laboratory identify and select opportunities for improvement and implement any necessary actions? |  |  |  |  |  |  |
| **8.6.2** | Does the laboratory seek feedback, both positive and negative, from its customers?  Are feedbacks analyzed and used to improve the management system, laboratory activities and customer service? |  |  |  |  |  |  |
| **8.7** | Corrective action (Option A) |  |  |  |  |  |  |
| **8.7.1** | When a nonconformity occurs, does the laboratory:   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. |  |  |  |  |  |  |
| **8.7.2** | Are corrective actions appropriate to the effects of the nonconformities encountered? |  |  |  |  |  |  |
| **8.7.3** | Does the laboratory retain records as evidence of:   1. the nature of the nonconformities, cause(s) and any subsequent actions taken; 2. the results of any corrective action. |  |  |  |  |  |  |
| **8.8** | Internal audits (Option A) |  |  |  |  |  |  |
| **8.8.1** | Does the laboratory 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. |  |  |  |  |  |  |
| **8.8.2** | Does the laboratory:   1. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; 2. define the audit criteria and scope for each audit; 3. ensure that the results of the audits are reported to relevant management; 4. implement appropriate correction and corrective actions without undue delay; 5. retain records as evidence of the implementation of the audit programme and the audit results. |  |  |  |  |  |  |
| **8.9** | Management reviews (Option A) |  |  |  |  |  |  |
| **8.9.1** | Does the laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document? |  |  |  |  |  |  |
| **8.9.2** | Are inputs to management review recorded and included information related to the following?  changes in internal and external issues that are relevant to the laboratory; fulfilment of objectives; suitability of policies and procedures; status of actions from previous management reviews; outcome of recent internal audits; corrective actions; assessments by external bodies; changes in the volume and type of the work or in the range of laboratory activities; customer and personnel feedback; complaints; effectiveness of any implemented improvements; adequacy of resources; results of risk identification; outcomes of the assurance of the validity of results; and other relevant factors, such as monitoring activities and training. |  |  |  |  |  |  |
| **8.9.3** | Are outputs from the management review recorded all decisions and actions related to? at least: the effectiveness of the management system and its processes; improvement of the laboratory activities related to the fulfillment of the requirements of this document; provision of required resources; any need for change. |  |  |  |  |  |  |

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| **Laboratory** |  | **Acc. No.** |
| **Type of Visit** | **Document and Record Review/Pre-Assessment/ Initial Assessment / Surveillance / Re-Assessment** | |
| **Name of the Assessor** |  | |
| **Date** |  | |