## Recommended QUESTIONNAIRE

for an expert performing evaluation of the quality management system of NMI
according to the requirements of ISO/IEC 17025 : 2005

Name of Auditor/Technical Expert: .....

Name of NMI: .....

Name of unit/laboratory: .....

| | |
|---|---|
| | Date: |

# 4. Management requirements

| 4.1 | Organization | Yes | No | Note */ |
|---|---|---|---|---|
| 1 (4.1.1) | Is the NMI an entity that can be held legally responsible? | ☐ | ☐ | |
| 2 (4.1.2) | Does the NMI meet the requirements of ISO/IEC 17025 and satisfy the needs of the customer, the regulatory authorities or organizations providing recognition when carrying out its testing and calibration activities? | ☐ | ☐ | |
| 3 (4.1.3) | Does the management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities? | ☐ | ☐ | |
| 4 (4.1.5) | Does the NMI | - | - | - |
| 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 performing tests and/or calibrations, 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 and external commercial, financial and other pressures and influences that may adversely affect the quality of their work? | ☐ | ☐ | |
| c) | • have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results? | ☐ | ☐ | |

*/ Notes may contain references to QM or other documents, indications of non-conformity, etc.

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| **d)** | • have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity? | ☐ | ☐ | |
| **e)** | • have the organization and management structure, defining its place in any parent organization, and the relationships between quality management, technical operations and support services? | ☐ | ☐ | |
| **f)** | • have the specified responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations? | ☐ | ☐ | |
| **g)** | • provide adequate supervision of testing and calibration staff, including trainees? | ☐ | ☐ | |
| **h)** | • have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of operations? | ☐ | ☐ | |
| **i)** | • have a member of staff appointed as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times and direct access to the highest level of management at which decisions are made on NMI's policy or resources? | ☐ | ☐ | |
| **j)** | • have appointed deputies for key managerial personnel? [1] | ☐ | ☐ | |
| **k)** | • ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system? | ☐ | ☐ | |
| **5 (4.1.6)** | Does top management ensure that appropriate communication processes are established within the NMI and that communication takes place regarding the effectiveness of the management system? | ☐ | ☐ | |
| Note 1: Individuals may have more than one function and it may be impractical to appoint deputies for every function. | | | | |

| **4.2** | **Management system** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.2.1)** | Is a management system appropriate to the scope of NMI's activities established, implemented and maintained? | ☐ | ☐ | |
| **2 (4.2.1)** | Does the NMI have documented policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results? | ☐ | ☐ | |
| **3 (4.2.1)** | Has the system's documentation been communicated to the appropriate personnel? | ☐ | ☐ | |
| **4 (4.2.2)** | Are the the management system policies and overall tasks related to quality, including a quality policy statement, defined in a quality manual? | ☐ | ☐ | |
| **5 (4.2.2)** | Are the overall objectives reviewed during management review? | ☐ | ☐ | |
| **6 (4.2.3)** | Does top management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? | ☐ | ☐ | |
| **7 (4.2.4)** | Has NMI's top management communicated to the personnel the importance of meeting customer requirements as well as statutory and regulatory requirements? | ☐ | ☐ | |
| **8 (4.2.5)** | Does the quality manual include or make reference to the supporting procedures including technical Procedures? | ☐ | ☐ | |
| **9 (4.2.5)** | Does the quality manual outline the structure of the documentation used in the management system? | ☐ | ☐ | |
| **10 (4.2.6)** | Are the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with ISO/IEC17025, defined in the quality manual? | ☐ | ☐ | |

**/ Notes may contain references to QM or other documents, indications of non-conformity, etc.*

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| **11 (4.2.7)** | Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented? | ☐ | ☐ | |

Note 1:
The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration NMI is part of a larger organization, some quality policy elements may be in other documents.

| **4.3** | **Document control** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **4.3.1** | **General** | - | - | - |
| **1 (4.3.1)** | Does the NMI have established and maintained 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, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals? [1, 2] | ☐ | ☐ | |
| **4.3.2** | **Document approval and issue** | - | - | - |
| **2 (4.3.2.1)** | Do authorized personnel review and approve for use, prior to issue, all documents issued to personnel in the NMI as part of the management system? | ☐ | ☐ | |
| **3 (4.3.2.1)** | Does the NMI have an established and readily available master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system to preclude the use of invalid and/or obsolete documents? | ☐ | ☐ | |
| **4 (4.3.2.2)** | Does(do) the document control procedure(s) adopted ensure that: | - | - | - |
| **a)** | • authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the NMI are performed? | ☐ | ☐ | |
| **b)** | • documents are periodically reviewed and, where necessary, revised 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 (4.3.2.3)** | Are management system documents generated by the NMI uniquely identified? | ☐ | ☐ | |
| | • the date of issue or revision identification? | ☐ | ☐ | |
| | • page numbering? | ☐ | ☐ | |
| | • the total number of pages or a mark to signify the end of the document? | ☐ | ☐ | |
| | • the issuing authority? | ☐ | ☐ | |
| **4.3.3** | **Document changes** | - | - | - |
| **6 (4.3.3.1)** | Are changes to documents reviewed and approved by the same function that performed the original review and approval unless specifically designated otherwise? | ☐ | ☐ | |
| **7 (4.3.3.1)** | Do the designated personnel have access to pertinent background information upon which to base their review and approval? | ☐ | ☐ | |
| **8 (4.3.3.2)** | Is the altered or new text identified, where practicable, in the document or the appropriate attachments? | ☐ | ☐ | |
| **9 (4.3.3.3)** | If the NMI's document control system allows for the amendment of documents by hand pending the re-issue of the documents, are the procedures and authorities for such amendments defined? | ☐ | ☐ | |
| **10 (4.3.3.3)** | Are amendments clearly marked, initialled and dated? | ☐ | ☐ | |
| **11 (4.3.3.3)** | Is a revised document formally re-issued as soon as practicable? | ☐ | ☐ | |

**/ Notes may contain references to QM or other documents, indications of non-conformity, etc.*

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| **12 (4.3.3.4)** | Does the NMI have procedures established to describe how changes in documents maintained in computerized systems are made and controlled? | ☐ | ☐ | |

Note 1:
In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

Note 2:
The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

| **4.4** | **Review of requests, tenders and contracts** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.4.1)** | Does the NMI have and maintain procedures for the review of requests, tenders and contracts? [1, 2, 3] | ☐ | ☐ | |
| **2 (4.4.1)** | Do the policies and procedures for these reviews of requests, tenders and contracts ensure that: [1, 2, 3] | - | - | - |
| **a)** | • the requirements, including the methods to be used, are adequately defined, documented and understood? | ☐ | ☐ | |
| **b)** | • the NMI has the capability and resources to meet the requirements? | ☐ | ☐ | |
| **c)** | • the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements? | ☐ | ☐ | |
| **3 (4.4.1)** | Are any differences between the request or tender and the contract resolved before any work commences? | ☐ | ☐ | |
| **4 (4.4.1)** | Is each contract acceptable both to the laboratory and the customer? | ☐ | ☐ | |
| **5 (4.4.2)** | Are records of reviews of requests, tenders and contracts, including any significant changes, maintained? [4] | ☐ | ☐ | |
| **6 (4.4.2)** | Are records of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract maintained? [4] | ☐ | ☐ | |
| **7 (4.4.3)** | Does the review cover any work that is subcontracted by the NMI? | ☐ | ☐ | |
| **8 (4.4.4)** | Is the customer informed of any deviation from the contract? | ☐ | ☐ | |
| **9 (4.4.5)** | Is the same contract review process repeated and are any amendments communicated to all affected personnel, if a contract needs to be amended after work has commenced? | ☐ | ☐ | |

Note 1:
The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

Note 2:
The review of capability should establish that the NMI possesses the necessary physical, personnel and information resources, and that the NMI's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

Note 3:
A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.

Note 4:
For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the NMI responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

| **4.5** | **Subcontracting of tests and calibrations** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.5.1)** | Does the NMI subcontract work because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity)? | ☐ | ☐ | |
| **2 (4.5.1)** | Does the NMI place this work with a competent subcontractor that complies with ISO/IEC 17025 for the work in question? | ☐ | ☐ | |
| **3 (4.5.2)** | Does the NMI advise the customer of the subcontracted work in writing and, when appropriate, gain the approval of the customer, preferably in writing? | ☐ | ☐ | |
| **4 (4.5.3)** | Does the NMI delare its responsibility to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used? | ☐ | ☐ | |
| **5 (4.5.4)** | Does the NMI maintain a register of all its subcontractors? | ☐ | ☐ | |

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|---|---|---|---|---|
| **6 (4.5.4)** | Does the NMI maintain a record of the evidence of compliance with ISO/IEC 17025 for the subcontracted work? | ☐ | ☐ | |

| **4.6** | **Purchasing services and supplies** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.6.1)** | Does the NMI have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations? | ☐ | ☐ | |
| **2 (4.6.1)** | Are there procedures for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations? | ☐ | ☐ | |
| **3 (4.6.2)** | Does the NMI ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned? | ☐ | ☐ | |
| **4 (4.6.2)** | Do the services and supplies used comply with specified requirements? | ☐ | ☐ | |
| **5 (4.6.2)** | Are records of actions taken to check compliance with the requirements maintained? | ☐ | ☐ | |
| **6 (4.6.3)** | Do purchasing documents for items affecting the quality of NMI output contain data describing the services and supplies ordered? [1] | ☐ | ☐ | |
| **7 (4.6.3)** | Are these purchasing documents reviewed and approved for technical content prior to release? | ☐ | ☐ | |
| **8 (4.6.4)** | Does the NMI evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and maintain records of these evaluations? | ☐ | ☐ | |
| **9 (4.6.4)** | Does the NMI have a list of approved suppliers? | ☐ | ☐ | |

Note 1:
The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

| **4.7** | **Service to the customer** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.7.1)** | Does the NMI cooperate with customers or their representatives in clarifying the customer's request? [1, 2] | ☐ | ☐ | |
| **2 (4.7.1)** | Does the NMI give the customer an opportunity to monitor its performance in relation to the work performed? | ☐ | ☐ | |
| **3 (4.7.1)** | Does the NMI ensure confidentiality to other customers during this monitoring? | ☐ | ☐ | |
| **4 (4.7.2)** | Does the NMI seek feedback, both positive and negative, from its customers? | ☐ | ☐ | |
| **5 (4.7.2)** | Is the feedback used and analysed to improve the management system, testing and calibration activities and customer service? | ☐ | ☐ | |

Note 1:
Such cooperation may include:

a) providing the customer or the customer's representative reasonable access to relevant areas of the NMI for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

Note 2:
Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The NMI should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

Note 3:
Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

| **4.8** | **Complaints** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.8)** | Does the NMI have a policy and procedure for the resolution of complaints received from customers or other parties? | ☐ | ☐ | |
| **2 (4.8)** | Are records of all complaints and of the investigations and corrective actions taken by the NMI maintained? | ☐ | ☐ | |

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| 4.9 | Control of noncornforming testing and/or calibration work | Yes | No | Note */ |
|---|---|---|---|---|
| 1 (4.9.1) | Does the NMI have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer? | ☐ | ☐ | |
| 2 (4.9.1) | Do the policy and procedures ensure that: [1] | - | - | - |
| a) | • the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified? | ☐ | ☐ | |
| b) | • an evaluation of the significance of the nonconforming work is made? | ☐ | ☐ | |
| c) | • correction is taken immediately, together with any decision about the acceptability of the nonconforming work? | ☐ | ☐ | |
| d) | • where necessary, the customer is notified and work is recalled? | ☐ | ☐ | |
| e) | • the responsibility for authorizing the resumption of work is defined? | ☐ | ☐ | |
| 3 (4.9.2) | Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the NMI's operations with its own policies and procedures, are corrective action procedures promptly followed? | ☐ | ☐ | |

Note 1:
Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

| 4.10 | Improvement | Yes | No | Note */ |
|---|---|---|---|---|
| 1 (4.10) | Does the NMI have documented procedures for improving the effectiveness of its management system? | ☐ | ☐ | |
| 2 (4.10) | Is the following used for improving the effectiveness of the management system: | - | - | - |
| | quality policy? | ☐ | ☐ | |
| | quality objectives? | ☐ | ☐ | |
| | audit results? | ☐ | ☐ | |
| | analysis of data? | ☐ | ☐ | |
| | corrective and preventive actions? | ☐ | ☐ | |
| | management review? | ☐ | ☐ | |

| 4.11 | Corrective action | Да | Нет | Примечание */ |
|---|---|---|---|---|
| 4.11.1 | **General** | - | - | - |
| 1 (4.11.1) | Has the NMI established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified? [1] | ☐ | ☐ | |
| 4.11.2 | **Cause analysis** | - | - | - |
| 2 (4.11.2) | Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem? [2] | ☐ | ☐ | |
| 4.11.3 | **Selection and implementation of corrective actions** | - | - | - |
| 3 (4.11.3) | Does the NMI identify potential corrective actions where they are needed? | ☐ | ☐ | |

**/ Notes may contain references to QM or other documents, indications of non-conformity, etc.*

| | | | | |
|---|---|---|---|---|
| **4 (4.11.3)** | Does the NMI select and implement the action(s) most likely to eliminate the problem and to prevent recurrence? | ☐ | ☐ | |
| **5 (4.11.3)** | Are corrective actions to a degree appropriate to the magnitude and the risk of the problem? | ☐ | ☐ | |
| **6 (4.11.3)** | Does the NMI document and implement any required changes resulting from corrective action investigations? | ☐ | ☐ | |
| **4.11.4** | **Monitoring of corrective actions** | - | - | - |
| **7 (4.11.4)** | Does the NMI continually monitor the results to ensure that the corrective actions taken have been effective? | ☐ | ☐ | |
| **4.11.5** | **Additional audits** | - | - | - |
| **8 (4.11.5)** | Does the NMI ensure that the appropriate areas of activity are audited as soon as possible where the identification of nonconformities or departures casts doubts on the NMI's compliance with its own policies and procedures, or on its compliance with ISO/IEC 17025? [3] | ☐ | ☐ | |

Note 1:
A problem with the management system or with the technical operations of the NMI may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

Note 2:
Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

Note 3:
Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

| **4.12** | **Preventive action** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.12.1)** | Does the NMI identify potential sources of nonconformities, either technical or concerning the management system? | ☐ | ☐ | |
| **2 (4.12.1)** | When improvement opportunities are identified or if preventive action is required, does the NMI develop, implement and monitor action plans to reduce the likelihood of the occurrence of such nonconformities, and does it take advantage of the opportunities for improvement? | ☐ | ☐ | |
| **3 (4.12.2)** | Do procedures for preventive actions include the initiation of such actions and the application of controls to ensure that they are effective? [1, 2] | ☐ | ☐ | |

Note 1:
Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

Note 2:
Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

| **4.13** | **Control of records** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **4.13.1** | **General** | - | - | - |
| **1 (4.13.1.1)** | Does the NMI have established and maintained procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records? [1] | ☐ | ☐ | |
| **2 (4.13.1.1)** | Do quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions? | ☐ | ☐ | |
| **3 (4.13.1.2)** | Are records legible? | ☐ | ☐ | |
| **4 (4.13.1.2)** | Are records stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss? [1] | ☐ | ☐ | |
| **5 (4.13.1.2)** | Are there retention times of records established? | ☐ | ☐ | |
| **6 (4.13.1.3)** | Are all records held secure and in confidence? | ☐ | ☐ | |
| **7 (4.13.1.4)** | Does the NMI have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records? | ☐ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **4.13.2** | **Technical records** | - | - | - |

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|---|---|---|---|---|
| **8 (4.13.2.1)** | Does the NMI retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period? [2] | ☐ | ☐ | |
| **9 (4.13.2.1)** | Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original? [3] | ☐ | ☐ | |
| **10 (4.13.2.1)** | Do the records include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results? | ☐ | ☐ | |
| **11 (4.13.2.2)** | Are observations, data and calculations recorded at the time they are made and are they identifiable to the specific task? | ☐ | ☐ | |
| **12 (4.13.2.3)** | When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and is the correct value entered alongside? | ☐ | ☐ | |
| **13 (4.13.2.3)** | Are all such alterations to records signed or initialled by the person making the correction? | ☐ | ☐ | |
| **14 (4.13.2.3)** | In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data? | ☐ | ☐ | |
| Note 1:<br>Records may be in any media, such as hard copy or electronic media. | | | | |
| Note 2:<br>In certain fields it may be impossible or impractical to retain records of all original observations. | | | | |
| Note 3:<br>Technical records are accumulations of data and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback. | | | | |

| **4.14** | **Internal audits** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.14.1)** | Does the NMI periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and ISO/IEC 17025? [1] | ☐ | ☐ | |
| **2 (4.14.1)** | Does the internal audit programme address all elements of the management system? | ☐ | ☐ | |
| **3 (4.14.1)** | Does the internal audit programme address the testing and/or calibration activities? | ☐ | ☐ | |
| **4 (4.14.1)** | Does the quality manager plan and organize audits as required by the schedule and requested by management? | ☐ | ☐ | |
| **5 (4.14.1)** | Are audits carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited? | ☐ | ☐ | |
| **6 (4.14.2)** | Does the NMI take corrective action when audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results? | ☐ | ☐ | |
| **7 (4.14.2)** | Does the NMI timely notify customers in writing if investigations show that the laboratory results may have been affected? | ☐ | ☐ | |
| **8 (4.14.3)** | Are the area of activity audited, the audit findings and corrective actions that arise from them recorded? | ☐ | ☐ | |
| **9 (4.14.4)** | Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken? | ☐ | ☐ | |
| Note 1:<br>The cycle for internal auditing should normally be completed in one year. | | | | |

| **4.15** | **Management reviews** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (4.15.1)** | In accordance with a predetermined schedule and procedure, does the NMI's top management periodically conduct a review of the NMI's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements? [1, 2, 3] | ☐ | ☐ | |

**/ Notes may contain references to QM or other documents, indications of non-conformity, etc.*

| | | | | |
|---|---|---|---|---|
| **2 (4.15.1)** | Does the review take account of: | - | - | - |
| | • the suitability of policies and procedures? | ☐ | ☐ | |
| | • reports from managerial and supervisory personnel? | ☐ | ☐ | |
| | • the outcome of recent internal audits? | ☐ | ☐ | |
| | • corrective and preventive actions? | ☐ | ☐ | |
| | • assessments by external bodies? | ☐ | ☐ | |
| | • the results of interlaboratory comparisons or proficiency tests? | ☐ | ☐ | |
| | • changes in the volume and type of the work? | ☐ | ☐ | |
| | • customer feedback? | ☐ | ☐ | |
| | • complaints? | ☐ | ☐ | |
| | • recommendations for improvement? | ☐ | ☐ | |
| | • other relevant factors, such as quality control activities, resources and staff training? | ☐ | ☐ | |
| **3 (4.15.2)** | Are findings from management reviews and the actions that arise from them recorded? | ☐ | ☐ | |
| **4 (4.15.2)** | Does the management ensure that those actions are carried out within an appropriate and agreed timescale? | ☐ | ☐ | |
| Note 1: A typical period for conducting a management review is once every 12 months. | | | | |
| Note 2: Results should feed into the NMI planning system and should include the goals, objectives and action plans for the coming year. | | | | |
| Note 3: A management review includes consideration of related subjects at regular management meetings. | | | | |

# 5. Technical requirements

| **5.2** | **Personnel** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (5.2.1)** | Does the NMI management ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates? | ☐ | ☐ | |
| **2 (5.2.1)** | Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required? [1, 2] | ☐ | ☐ | |
| **3 (5.2.2)** | Does the management of the NMI formulate the goals with respect to the education, training and skills of the NMI personnel? | ☐ | ☐ | |
| **4 (5.2.2)** | Does the NMI have a policy and procedures for identifying training needs and providing training of personnel? | ☐ | ☐ | |
| **5 (5.2.2)** | Is the training programme relevant to the present and anticipated tasks of the laboratory? | ☐ | ☐ | |
| **6 (5.2.2)** | Is the effectiveness of the training actions taken evaluated? | ☐ | ☐ | |
| **7 (5.2.3)** | Does the NMI use personnel who are employed by the NMI? | ☐ | ☐ | |
| **8 (5.2.3)** | Does the NMI use personnel who are under contract to the NMI? | ☐ | ☐ | |
| **9 (5.2.3)** | Where contracted and additional technical and key support personnel are used, does the NMI ensure that such personnel are supervised and competent and that they work in accordance with the NMI's management system? | ☐ | ☐ | |
| **10 (5.2.4)** | Does the NMI maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations? [3] | ☐ | ☐ | |
| **11 (5.2.5)** | Does the management authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment? | ☐ | ☐ | |
| **12 (5.2.5)** | Does the NMI maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel? | ☐ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| **13 (5.2.5)** | Is this information readily available and does it include the date on which authorization and/or competence is confirme? | ☐ | ☐ | |

Note 1:
In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The NMI is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.

Note 2:
The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

- relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
- knowledge of the general requirements expressed in the legislation and standards; and
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

Note 3:
Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- the responsibilities with respect to performing tests and/or calibrations;
- the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
- the responsibilities for reporting opinions and interpretations;
- the responsibilities with respect to method modification and development and validation of new methods;
- expertise and experience required;
- qualifications and training programmes;
- managerial duties.

| **5.3** | **Accommodation and environmental conditions** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (5.3.1)** | Do the facilities for testing and/or calibration in the NMI, including but not limited to energy sources, lighting and environmental conditions, facilitate correct performance of the tests and/or calibrations? | ☐ | ☐ | |
| **2 (5.3.1)** | Are the technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations documented? | ☐ | ☐ | |
| **3 (5.3.2)** | Does the NMI monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results? | ☐ | ☐ | |
| **4 (5.3.2)** | Are tests and calibrations stopped when the environmental conditions jeopardize the results of the tests and/or calibrations? | ☐ | ☐ | |
| **5 (5.3.3)** | Is there effective separation between neighbouring areas in which there are incompatible activities? | ☐ | ☐ | |
| **6 (5.3.4)** | Are access to and use of areas affecting the quality of the tests and/or calibrations controlled? | ☐ | ☐ | |

| **5.4** | **Test and calibration methods and method validation** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **5.4.1** | **General** | - | - | - |
| **1 (5.4.1)** | Does the NMI use appropriate methods and procedures for all tests and/or calibrations within its scope? | ☐ | ☐ | |
| **2 (5.4.1)** | Does the NMI have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations? | ☐ | ☐ | |
| **3 (5.4.1)** | Are all instructions, standards, manuals and reference data relevant to the work of the NMI kept up to date and readily available to personnel? | ☐ | ☐ | |
| **5.4.2** | **Selection of methods** | - | - | - |
| **4 (5.4.2)** | Does the NMI use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes? | ☐ | ☐ | |
| **5 (5.4.2)** | Are methods published in international, regional or national standards preferably used? | ☐ | ☐ | |
| **6 (5.4.2)** | Does the NMI ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so? | ☐ | ☐ | |
| **7 (5.4.2)** | Is it possible, when necessary, to supplement the standard with additional details to ensure consistent application? | ☐ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| **5.4.3** | **NMI-developed methods** | - | - | - |
| **8 (5.4.3)** | Is the introduction of test and calibration methods developed by the NMI for its own use a planned activity and is it assigned to qualified personnel equipped with adequate resources? | ☐ | ☐ | |
| **9 (5.4.3)** | Are plans updated as development proceeds and is effective communication amongst all personnel involved ensured? | ☐ | ☐ | |
| **5.4.4** | **Non-standard methods** | - | - | - |
| **10 (5.4.4)** | Is the method developed validated appropriately before use? | ☐ | ☐ | |
| **5.4.5** | **Validation of methods** | - | - | - |
| **11 (5.4.5.1)** | Is it confirmed during validation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled? | ☐ | ☐ | |
| **12 (5.4.5.2)** | Does the NMI validate non-standard methods, NMI-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use? | ☐ | ☐ | |
| **13 (5.4.5.2)** | Is the validation as extensive as is necessary to meet the needs of the given application or field of application? [1, 2] | ☐ | ☐ | |
| **14 (5.4.5.2)** | Does the NMI record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use? | ☐ | ☐ | |
| **5.4.6** | **Estimation of uncertainty of measurement** | - | - | - |
| **15 (5.4.6.1)** | Does the NMI have and apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations? | ☐ | ☐ | |
| **16 (5.4.6.3)** | Are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis, when estimating the uncertainty of measurement? [3, 4, 5] | ☐ | ☐ | |
| **5.4.7** | **Control of data** | - | - | - |
| **17 (5.4.7.1)** | Are calculations and data transfers subject to appropriate checks in a systematic manner? | ☐ | ☐ | |
| **18 (5.4.7.2)** | When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the NMI ensure that: | - | - | - |
| **a)** | • computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use? [6] | ☐ | ☐ | |
| **b)** | • procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing? | ☐ | ☐ | |
| **c)** | • computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data? | ☐ | ☐ | |

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| |
|---|
| Note 1:<br>The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:<br>- calibration using reference standards or reference materials;<br>- comparison of results achieved with other methods;<br>- interlaboratory comparisons;<br>- systematic assessment of the factors influencing the result;<br>- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience. |
| Note 2:<br>When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out. |
| Note 3:<br>Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator. |
| Note 4:<br>The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty. |
| Note 5:<br>For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement. |
| Note 6:<br>Commercial off-the-shelf software (e.g. wordprocessing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, NMI software configuration/modifications should be validated as in 5.4.7.2 a). |

| 5.5 | Equipment | Yes | No | Note */ |
|---|---|---|---|---|
| 1 (5.5.1) | Is the NMI furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations? | ☐ | ☐ | |
| 2 (5.5.1) | Does the NMI ensure that the requirements of ISO/IEC 17025 are met in those cases where it needs to use equipment outside its permanent control? | ☐ | ☐ | |
| 3 (5.5.2) | Are equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required and do they comply with specifications relevant to the tests and/or calibrations concerned? | ☐ | ☐ | |
| 4 (5.5.2) | Are calibration programmes established for key quantities or values of the instruments where these properties have a significant effect on the results? | ☐ | ☐ | |
| 5 (5.5.2) | Is equipment (including that used for sampling) calibrated or checked, before being placed into service, to establish that it meets the NMI's specification requirements and complies with the relevant standard specifications? | ☐ | ☐ | |
| 6 (5.5.2) | Is equipment checked and/or calibrated before use? | ☐ | ☐ | |
| 7 (5.5.3) | Is equipment operated by authorized personnel? | ☐ | ☐ | |
| 8 (5.5.3) | Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate personnel? | ☐ | ☐ | |
| 9 (5.5.4) | Is each item of equipment with its software used for testing and calibration and significant to the result uniquely identified, when practicable? | ☐ | ☐ | |
| 10 (5.5.5) | Are records of each item of equipment and its software significant to the tests and/or calibrations performed maintained? | ☐ | ☐ | |
| 11 (5.5.5) | Do the records include at least the following: | - | - | - |
| a) | • the identity of the item of equipment and its software? | ☐ | ☐ | |
| b) | • the manufacturer's name, type identification, and serial number or other unique identification? | ☐ | ☐ | |
| c) | • checks that equipment complies with the specification? | ☐ | ☐ | |
| d) | • the current location, where appropriate? | ☐ | ☐ | |
| e) | • the manufacturer's instructions, if available, or reference to their location? | ☐ | ☐ | |
| f) | • dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration? | ☐ | ☐ | |
| g) | • the maintenance plan, where appropriate, and maintenance | ☐ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| | carried out to date? | | | |
| h) | • any damage, malfunction, modification or repair to the equipment? | ☐ | ☐ | |
| 12 (5.5.6) | Does the NMI have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration? [1] | ☐ | ☐ | |
| 13 (5.5.7) | Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service? | ☐ | ☐ | |
| 14 (5.5.7) | Is thisequipment isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly? | ☐ | ☐ | |
| 15 (5.5.7) | Does the NMI examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and institute the "Control of nonconforming work" procedure? | ☐ | ☐ | |
| 16 (5.5.8) | Is all equipment under the control of the NMI and requiring calibration labelled, coded or otherwise identified, whenever practicable, to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due? | ☐ | ☐ | |
| 17 (5.5.9) | When, for whatever reason, equipment goes outside the direct control of the NMI, does the NMI ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service? | ☐ | ☐ | |
| 18 (5.5.10) | Are intermediate checks carried out according to a defined procedure, when they are needed to maintain confidence in the calibration status of the equipment? | ☐ | ☐ | |
| 19 (5.5.11) | Does the NMI have procedures to ensure that copies (e.g. in computer software) are correctly updated, where calibrations give rise to a set of correction factors? | ☐ | ☐ | |
| 20 (5.5.12) | Are test and calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test and/or calibration results? | ☐ | ☐ | |
| Note 1: Additional procedures may be necessary when measuring equipment is used outside the permanent NMI for tests, calibrations or sampling. | | | | |

| 5.6 | Measurement traceability | Yes | No | Note */ |
|---|---|---|---|---|
| 5.6.1 | **General** | - | - | - |
| 1 (5.6.1) | Is all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling calibrated before being put into service? | ☐ | ☐ | |
| 2 (5.6.1) | Does the NMI have an established programme and procedure for the calibration of its equipment? [1] | ☐ | ☐ | |
| 5.6.2 | **Specific requirements** | - | - | - |
| 5.6.2.1 | **Calibration** | - | - | - |
| 3 (5.6.2.1.1) | Is there a programme for calibration of NMI equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)? Does the NMI establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement? [2] | ☐ | ☐ | |
| 4 (5.6.2.1.1) | Is the link to SI units achieved by reference to national measurement standards which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or by reference to secondary standards which are standards calibrated by another national metrology institute? [3, 4, 5, 6, 7] | ☐ | ☐ | |
| 5 (5.6.2.1.2) | Does theNMI participate in a suitable programme of interlaboratory comparisons? | ☐ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| **5.6.2.2** | **Testing** | - | - | - |
| **5.6.3** | **Reference standards and reference materials** | - | - | - |
| **5.6.3.1** | **Reference standards** | - | - | - |
| **6 (5.6.3.1)** | Does the NMI have a programme and procedure for the calibration of its reference standards? | ☐ | ☐ | |
| **5.6.3.2** | **Reference materials** | - | - | - |
| **7 (5.6.3.2)** | Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials? | ☐ | ☐ | |
| **8 (5.6.3.2)** | Are internal reference materials checked as far as is technically and economically practicable? | ☐ | ☐ | |
| **5.6.3.3** | **Intermediate checks** | - | - | - |
| **9 (5.6.3.3)** | Are checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials carried out according to defined procedures and schedules? | ☐ | ☐ | |
| **5.6.3.4** | **Transport and storage** | - | - | - |
| **10 (5.6.3.4)** | Does the NMI have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity? | ☐ | ☐ | |

Note 1:
Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

Note 2:
Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights
and Measures (CIPM).

Note 3:
Calibration NMIs that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

Note 4:
When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Note 5:
Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the NMI is located.

Note 6:
If a NMI wishes or needs to obtain traceability from a national metrology institute other than in its own country, this NMI should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

Note 7:
The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different NMIs that can demonstrate traceability.

| **5.8** | **Handling of test and calibration items** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (5.8.1)** | Does the NMI have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the NMI and the customer? | ☐ | ☐ | |
| **2 (5.8.2)** | Does the NMI have a system for identifying test and/or calibration items? | ☐ | ☐ | |
| **3 (5.8.2)** | Is the identification retained throughout the life of the item in the NMI? | ☐ | ☐ | |
| **4 (5.8.2)** | Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents? | ☐ | ☐ | |
| **5 (5.8.2)** | Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the NMI? | ☐ | ☐ | |
| **6 (5.8.3)** | Are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded upon receipt of the test or calibration item? | ☐ | ☐ | |
| **7 (5.8.4)** | Does the NMI have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration | ☐ | ☐ | |

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| | | | | |
|---|---|---|---|---|
| | item during storage, handling and preparation? [1, 2, 3] | | | |
| **8 (5.8.4)** | Are handling instructions provided with the item strictly followed? | ☐ | ☐ | |
| **9 (5.8.4)** | Are specified environmental conditions maintained, monitored and recorded when items have to be stored or conditioned under these conditions? | ☐ | ☐ | |
| **10 (5.8.4)** | Does the NMI have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned, where a test or calibration item or a portion of an item is to be held secure? | ☐ | ☐ | |
| Note 1: Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes. | | | | |
| Note 2: A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples. | | | | |
| Note 3: Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later. | | | | |

| **5.9** | **Assuring the quality of test and calibration results** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **1 (5.9.1)** | Does the NMI have quality control procedures for monitoring the validity of tests and calibrations undertaken? | ☐ | ☐ | |
| **2 (5.9.1)** | Is resulting data recorded in such a way that trends are detectable? | ☐ | ☐ | |
| **3 (5.9.1)** | Are statistical techniques applied to the reviewing of the results, where practicable? | ☐ | ☐ | |
| **4 (5.9.1)** | Is this monitoring planned and reviewed? | ☐ | ☐ | |
| **5 (5.9.1)** | Does this monitoring include, for example the following: [1] | - | - | - |
| **a)** | • regular use of certified reference materials and/or internal quality control using secondary reference materials? | ☐ | ☐ | |
| **b)** | • participation in interlaboratory comparison or proficiency-testing programmes? | ☐ | ☐ | |
| **c)** | • replicate tests or calibrations using the same or different methods? | ☐ | ☐ | |
| **d)** | • retesting or recalibration of retained items? | ☐ | ☐ | |
| **e)** | • correlation of results for different characteristics of an item? | ☐ | ☐ | |
| **6 (5.9.2)** | Are quality control data analysed? | ☐ | ☐ | |
| **7 (5.9.2)** | Are planned actions taken to correct the problem and to prevent incorrect results from being reported? | ☐ | ☐ | |
| Note 1: The selected methods should be appropriate for the type and volume of the work undertaken. | | | | |

| **5.10** | **Reporting the results** | **Yes** | **No** | **Note */** |
|---|---|---|---|---|
| **5.10.1** | **General** | - | - | - |
| **1 (5.10.1)** | Are the results of each test, calibration, or series of tests or calibrations carried out by the NMI reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods, usually in a test report or a calibration certificate, that include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used? [1, 2] | ☐ | ☐ | |
| **2 (5.10.1)** | Does the NMI report the results in a simplified way in the case of tests or calibrations performed for internal customers? | ☐ | ☐ | |
| **3 (5.10.1)** | Is any information listed which is to be included in the report or certificate in accordance with ISO/IEC 17025 and which is not reported to the customer readily available in the NMI which carried out the tests and/or calibrations? | ☐ | ☐ | |
| **5.10.2** | **Test reports and calibration certificates** | - | - | - |
| **4 (5.10.2)** | Does each test report or calibration certificate include at least the following information, unless the NMI has valid reasons | - | - | - |

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| | | | | |
|---|---|---|---|---|
| | for not doing so: [3, 4] | | | |
| **a)** | • a title (e.g. "Test Report" or "Calibration Certificate")? | ☐ | ☐ | |
| **b)** | • the name and address of the NMI, and the location where the tests and/or calibrations were carried out, if different from the address of the NMI? | ☐ | ☐ | |
| **c)** | • unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate? [3] | ☐ | ☐ | |
| **d)** | • the name and address of the customer? | ☐ | ☐ | |
| **e)** | • identification of the method used? | ☐ | ☐ | |
| **f)** | • a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated? | ☐ | ☐ | |
| **g)** | • the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration? | ☐ | ☐ | |
| **h)** | • reference to the sampling plan and procedures used by the NMI or other bodies where these are relevant to the validity or application of the results? | ☐ | ☐ | |
| **i)** | • the test or calibration results with, where appropriate, the units of measurement? | ☐ | ☐ | |
| **j)** | • the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate? | ☐ | ☐ | |
| **k)** | • where relevant, a statement to the effect that the results relate only to the items tested or calibrated? | ☐ | ☐ | |
| **5.10.3** | **Test reports** | - | - | - |
| **5 (5.10.3.1)** | Do test reports, where necessary for the interpretation of the test results, include the following: | - | - | - |
| **a)** | • deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions? | ☐ | ☐ | |
| **b)** | • where relevant, a statement of compliance/non-compliance with requirements and/or specifications? | ☐ | ☐ | |
| **c)** | • where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit? | ☐ | ☐ | |
| **d)** | • where appropriate and needed, opinions and interpretations? | ☐ | ☐ | |
| **e)** | • additional information which may be required by specific methods, customers or groups of customers? | ☐ | ☐ | |

| | | | | |
|---|---|---|---|---|
| **5.10.4** | **Calibration certificates** | - | - | - |
| **6 (5.10.4.1)** | Do calibration certificates include the following, where necessary for the interpretation of calibration results: | - | - | - |
| **a)** | • the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results? | ☐ | ☐ | |
| **b)** | • the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof? | ☐ | ☐ | |
| **c)** | • evidence that the measurements are traceable? | ☐ | ☐ | |
| **5.10.6** | **Testingand calibration results obtained from subcontractors** | - | - | - |
| **7 (5.10.6)** | Are these results clearly identified, when the test report contains results of tests performed by subcontractors? | ☐ | ☐ | |

**/ Notes may contain references to QM or other documents, indications of non-conformity, etc.*

| | | | | |
|---|---|---|---|---|
| **8 (5.10.6)** | Does the subcontractor report the results in writing or electronically? | ☐ | ☐ | |
| **9 (5.10.6)** | When a calibration has been subcontracted, does the NMI performing the work issue the calibration certificate to the contracting NMI? | ☐ | ☐ | |
| **5.10.7** | **Electronic transmission of results** | - | - | - |
| **10 (5.10.7)** | Are the requirements of ISO/IEC 17025 met (items 5.10, 5.4.7), in the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means? | ☐ | ☐ | |
| **5.10.8** | **Format of reports and certificates** | - | - | - |
| **11 (5.10.8)** | Is the format of reports and certificates designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse? [4, 5] | ☐ | ☐ | |
| **5.10.9** | **Amendments to test reports and calibration certificates** | - | - | - |
| **12 (5.10.9)** | Are material amendments to a test report or calibration certificate after issue made only in the form of a further document or data transfer? | ☐ | ☐ | |
| **13 (5.10.9)** | Does this form include the statement:<br>"Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]",<br>or an equivalent form of wording? | ☐ | ☐ | |
| **14 (5.10.9)** | Do such amendments meet all the requirements of ISO/IEC 17025 (item 5.10)? | ☐ | ☐ | |
| **15 (5.10.9)** | Are a complete new test report and calibration certificate uniquely identified and do they contain a reference to the original that they replace, when it is necessary to issue these? | ☐ | ☐ | |

Note 1:
Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

Note 2:
The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

Note 3:
Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

Note 7:
In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.

Note 4:
Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

Note 5:
The headings should be standardized as far as possible.

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*/ Notes may contain references to QM or other documents, indications of non-conformity, etc.