

# NVLAP Assessor Training

NIST Handbook 150  
ISO/IEC 17025

# NIST Handbook 150 2006 Edition NVLAP Procedures and General Requirements

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} **ISO/IEC  
17025:2005**

General philosophy: “What the standard says. No more, no less.”

- If Handbook 150 says policy, there shall be a policy.
- If the Handbook doesn't require a policy, we do not expect the lab to have one.
- If the lab goes beyond the words and creates a requirement, they must meet it.

## Important Definitions

Shall: “is required to...”

Should: “recommended”

May: “is permitted”

Policy: statement of guiding principles

Procedure: documented, specified way to carry out an activity or a process

Arrangement: a means to meet a requirement; look for objective evidence that requirement is met; not as strict as “procedure”

Defined: documented

## Important Definitions

Shall ensure: is required to accomplish; assess by looking for evidence, not policies or procedures

Schedule: defined time line (e.g., “annually”)

Document (v): to record

Record (n): written or electronic documentation of facts or events

Sources:

ISO /IEC Directives, Part 2, 2004

ISO/IEC 17000:2004, Conformity assessment --  
Vocabulary and general principles

# 4 Management requirements for accreditation

## 4.1 Organization

**4.1.1** The laboratory or the organization of which it is part **shall** be an entity that can be held legally responsible.

**4.1.2** It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this handbook and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

**4.1.3** The management system **shall** cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

## 4.1 Organization

4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory **shall** be defined in order to identify potential conflicts of interest.



## 4.1 Organization

### 4.1.4...

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements **should** be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this handbook.

## 4.1 Organization

### 4.1.4...

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it **should** be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory **should** not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

## 4.1 Organization

### 4.1.5 The laboratory shall

- 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 (see also 5.2);

## 4.1 Organization

### 4.1.5 The laboratory shall

- 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;

## 4.1 Organization

### 4.1.5 The laboratory shall

- d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;
- e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

## 4.1 Organization

### 4.1.5 The laboratory shall

- f) specify the 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, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

## 4.1 Organization

### 4.1.5 The laboratory shall

- 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 laboratory operations;

## 4.1 Organization

### 4.1.5 The laboratory shall

- i) appoint a member of staff 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; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;



## 4.1 Organization

### 4.1.5 The laboratory shall

- j) appoint deputies for key managerial personnel (see Note);
- 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.

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

## 4.1 Organization

4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

## 4.2 Management system

- 4.2.1 The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

“to the extent necessary to assure the quality of the test and/or calibration results”

## 4.2 Management system

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

- a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;
- b) the management's statement of the laboratory's standard of service;
- c) the purpose of the management system related to quality;

## 4.2 Management system

4.2.2 ...It **shall** include at least the following:

- d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and
- e) the laboratory management's commitment to comply with this handbook and to continually improve the effectiveness of the management system.

NOTE 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 laboratory is part of a larger organization, some quality policy elements **may** be in other documents.

## 4.2 Management system

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

- Policies in QM
- Procedures in or referenced

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

## 4.2 Management system

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this handbook, shall be defined in the quality manual.

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

## 4.3 Document control

### 4.3.1 General

The laboratory **shall** establish and maintain **procedures** to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

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.



## 4.3 Document control

### 4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the management system **shall** be reviewed and approved for use by authorized personnel prior to issue. A **master list** or an equivalent **document control procedure** identifying the current revision status and distribution of documents in the management system **shall** be established and be readily available to preclude the use of invalid and/or obsolete documents.

## 4.3 Document control

### 4.3.2 Document approval and issue

#### 4.3.2.2 The procedure(s) adopted shall ensure that:

- Has to be accomplished
- Doesn't have to be specifically addressed in procedures

- a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory 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.

## 4.3 Document control

### 4.3.2 Document approval and issue

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

## 4.3 Document control

### 4.3.3 Document changes

4.3.3.1 Changes to documents **shall** be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel **shall** have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text **shall** be identified in the document or the appropriate attachments.

## 4.3 Document control

### 4.3.3 Document changes

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments **shall** be defined. Amendments **shall** be clearly marked, initialed and dated. A revised document **shall** be formally reissued as soon as practicable.

4.3.3.4 **Procedures shall** be established to describe how changes in documents maintained in computerized systems are made and controlled.

## 4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

- a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);
- b) the laboratory 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 (see 5.4.2).

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

## 4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure ...

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.

## 4.4 Review of requests, tenders and contracts

4.4.1 The laboratory **shall** establish and maintain **procedures** for the review of requests, tenders and contracts. The **policies and procedures** for these reviews leading to a contract for testing and/or calibration **shall ensure** ...

NOTE 2 The review of capability **should** establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory'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 programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.



## 4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure ...

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

## 4.5 Subcontracting of tests and calibrations

**4.5.1** When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work **shall** be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this handbook for the work in question.

**4.5.2** The laboratory **shall** advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

## 4.5 Subcontracting of tests and calibrations

**4.5.3** The laboratory is responsible 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.

**4.5.4** The laboratory **shall** maintain a **register** of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this handbook for the work in question.

## 4.6 Purchasing services and supplies

4.6.1 The laboratory **shall** 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.** **Procedures shall** exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory **shall 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. These services and supplies used **shall** comply with specified requirements. **Records** of actions taken to check compliance **shall** be maintained.

## 4.6 Purchasing services and supplies

4.6.3 **Purchasing documents** for items affecting the quality of laboratory output **shall** contain data describing the services and supplies ordered. These purchasing documents **shall** be reviewed and approved for technical content prior to release.

NOTE 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.

4.6.4 The laboratory **shall** evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and **shall** maintain **records** of these evaluations and list those approved.

## 4.7 Service to the customer

4.7.1 The laboratory **shall** be willing to 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, provided that the laboratory ensures confidentiality to other customers.

## 4.7 Service to the customer

4.7.1 The laboratory **shall** be willing...

NOTE 1 Such cooperation **may** include:

- a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory 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.

## 4.7 Service to the customer

4.7.1 The laboratory **shall** be willing...

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 laboratory **should** inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.



## 4.7 Service to the customer

4.7.2 The laboratory **shall** seek feedback, both positive and negative, from its customers. This feedback **shall** be used and analyzed to improve the management system, testing and calibration activities and customer service.

**NOTE** Examples of the types of feedback include customer satisfaction **surveys** and review of test or calibration reports with customers.

## 4.8 Complaints

The laboratory **shall** have a **policy and procedure** for the resolution of complaints received from customers or other parties. **Records shall** be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

## 4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall 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. The policy and procedures shall ensure that:

## 4.9 Control of nonconforming testing and/or calibration work

4.9.1 ...The **policy and procedures** **shall ensure** that:

- 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;

## 4.9 Control of nonconforming testing and/or calibration work

4.9.1 ...The **policy and procedures** **shall ensure** that:

- 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**.

## 4.9 Control of nonconforming testing and/or calibration work

4.9.1 ...The **policy and procedures** **shall ensure** that:

NOTE 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.

## 4.9 Control of nonconforming testing and/or calibration work

4.9.2 Where the evaluation indicates that the nonconforming work **could** recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 **shall** be promptly followed.

This means that there only has to be a **possibility** the problem could recur, or **any doubt** that the laboratory followed procedures.

## 4.10 Improvement

The laboratory **shall** continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.



## 4.11 Corrective action

### 4.11.1 General

The laboratory shall establish a policy and a procedure and shall designate 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.

## 4.11 Corrective action

### 4.11.1 General

**NOTE** A problem with the management system or with the technical operations of the laboratory 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.

## 4.11 Corrective action

### 4.11.2 Cause analysis

The procedure for corrective action **shall** start with an investigation to determine the root cause(s) of the problem.

## 4.11 Corrective action

### 4.11.2 Cause analysis

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

## 4.11 Corrective action

### 4.11.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

## 4.11 Corrective action

### 4.11.3 Selection and implementation of corrective actions

The laboratory **shall** **document** and implement any required changes resulting from corrective action investigations.

## 4.11 Corrective action

### 4.11.4 Monitoring of corrective actions

The laboratory **shall** monitor the results to ensure that the corrective actions taken have been effective.

## 4.11 Corrective action

### 4.11.5 Additional audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this handbook, the laboratory **shall ensure** that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.



## 4.11 Corrective action

**NOTE** 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

**4.12.1** Needed improvements and potential sources of nonconformities, either technical or concerning the management system, **shall** be identified. When improvement opportunities are identified or if preventive action is required, **action plans shall** be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

## 4.12 Preventive action

4.12.2 **Procedures** for preventive actions **shall** include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a proactive 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

### 4.13.1 General

4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

## 4.13 Control of records

### 4.13.1 General

4.13.1.2 All records **shall** be legible and **shall** be 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. Retention times of records shall be established.

NOTE Records may be in any media, such as hard copy or electronic media.

## 4.13 Control of records

4.13.1.3 All records shall be held secure and in confidence.

4.13.1.4 The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

## 4.13 Control of records

### 4.13.2 Technical records

4.13.2.1 The laboratory **shall** 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.

## 4.13 Control of records

### 4.13.2 Technical records

**4.13.2.1** ...The records for each test or calibration **shall** 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. The records **shall** include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.



## 4.13 Control of records

### 4.13.2 Technical records

#### 4.13.2.1 ...

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) 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.

## 4.13 Control of records

### 4.13.2 Technical records

4.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

## 4.13 Control of records

### 4.13.2 Technical records

4.13.2.3 When mistakes occur in records, each mistake **shall** be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records **shall** be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures **shall** be taken to avoid loss or change of original data.

## 4.14 Internal audits

**4.14.1** The laboratory shall 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 this handbook. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

**NOTE** The cycle for internal auditing should normally be completed in one year.

## 4.14 Internal audits

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities and operations to ensure continued compliance with the

shall **periodically**, and in accordance with a **predetermined schedule and procedure**...

- Procedure to describe how they do audits
  - ✓ Verify during document review
- Predetermined schedule
  - Doesn't have to be annual
  - ✓ Record in your report dates for audit(s) you reviewed

NOTE The cycle for internal auditing **should** normally be completed in one year.

## 4.14 Internal audits

4.14.1 The laboratory shall 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 this handbook. The internal audit process shall address all elements of the

...verify that its operations continue to comply with the requirements of the **management system and this handbook...**

- They have to verify they **continue** to comply with Handbook 150, so could use a NVLAP checklist, but...
- Handbook 150 checklist is not sufficient to cover the whole management system
- External audits (e.g. NVLAP on-sites) cannot substitute for internal audits, but can be considered in scheduling

## 4.14 Internal audits

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of

The internal audit program shall address all elements of the management system, including the testing and/or calibration activities.

- Whatever they describe in management system, they audit
- Auditing testing/calibration activities includes verifying that they **follow** methods or procedures, not just that they have the right documents
- Some LAPs have specific requirements for evaluating performance of tests

## 4.14 Internal audits

It is the responsibility of the quality manager to plan and organize audits as required by the schedule and **requested by management.**

- Management should be requesting audits when corrective action casts doubts on the laboratory's compliance with its management system or accreditation requirements. (4.11.5)

management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

**NOTE** The cycle for internal auditing should normally be completed in one year.



## 4.14 Internal audits

Such audits shall be carried out by **trained and qualified personnel** who are, wherever resources permit, **independent** of the activity to be audited.

- Lab establishes training and qualification requirements (5.2.2)
- Auditors of testing/calibration activities should be technically knowledgeable
- Independence not always possible

qualified personnel who are, wherever resources permit,  
independent of the activity to be audited.

NOTE The cycle for internal auditing should normally be completed in one year.

## 4.14 Internal audits

**4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory **shall** take timely corrective action, and **shall** **notify customers in writing** if investigations show that the laboratory results **may** have been affected.

## 4.14 Internal audits

**4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

...shall take timely corrective action...

- “Never” is not timely
- Implement procedures under 4.11, including root cause analysis

## 4.14 Internal audits

4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if

... shall notify customers in writing if investigations show that the laboratory results **may** have been affected.

- Written notification to customers may be email
  - ✓ Verify records of customer notifications
- Only has to be **possibility** results were affected, not definite proof

## 4.14 Internal audits

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them **shall** be **recorded**.

- No requirement for checklists
- Could be summary reports
- Corrective action records must meet requirements of 4.13.1
- ✓ List the records you reviewed

## 4.14 Internal audits

4.14.4 Follow-up audit activities **shall** verify and record the implementation and effectiveness of the corrective action taken.

- Follow-up “audit activities”
- Not immediately upon completion of corrective action
- Records must meet requirements of 4.13.1
- ✓ List the records you reviewed

## 4.15 Management reviews

4.15.1 In accordance with a **predetermined schedule and procedure**, the laboratory's top management **shall** periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure **their continuing suitability** and effectiveness, and to introduce necessary changes or improvements. The review **shall 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.

NOTE 1 A **typical** period for conducting a management review is once every 12 months.

NOTE 2 Results **should** feed into the laboratory 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.

## 4.15 Management reviews

**4.15.1** In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce changes or improvements. The review shall take account of:

- the suitability of policies and procedures;
- reports from managerial
- the outcome of recent internal

**...predetermined schedule and procedure...**

- 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;
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- recommendations for improvement;
- other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory 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.



## 4.15 Management reviews

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;

**...top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements**

- Covers all activities
- ✓ Record what management review records you assessed

## 4.15 Management reviews

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

The review shall take account of...

- Good practice for the lab to have all the listed items in an agenda, or records that show all items were addressed

— changes in the volume and type of the work;

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

- Some of the items may be covered and documented through other meetings.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

## 4.15 Management reviews

4.15.2 Findings from management reviews and the actions that arise from them **shall** be **recorded**. The management **shall** **ensure** that those actions are carried out within an appropriate and agreed timescale.

## 4.15 Management reviews

4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that actions are carried out within an appropriate and agreed

**Findings** from management reviews and the **actions** that arise from them shall be recorded.

- Only required to record outcomes, not inputs
- Actions must meet requirements of 4.11
- Records meet requirements of 4.13.1
- ✓ Record in assessor report any corrective or preventive action records you assessed that were related to management review

## 4.15 Management reviews

4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

- Same management that conducts review ensures actions are carried out
- Appropriateness is up to lab, but agreed timescale can be assessed
- ✓ Verify that timescales are being met

# 5 Technical requirements for accreditation

## 5.1 General

**5.1.1** Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.2);
- accommodation and environmental conditions (5.3);
- test and calibration methods and method validation (5.4);
- equipment (5.5);

## 5.1 General

**5.1.1** Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- measurement traceability (5.6 and Annex B);
- sampling (5.7);
- the handling of test and calibration items (5.8).



## 5.1 General

**5.1.2** The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory **shall** take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

## 5.2 Personnel

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

## 5.2 Personnel

### 5.2.1...

NOTE 1 In some technical areas (e.g., nondestructive testing) it **may** be required that the personnel performing certain tasks hold personnel certification. The laboratory 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.

## 5.2 Personnel

### 5.2.1...

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.

## 5.2 Personnel

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.

## 5.2 Personnel

5.2.3 The laboratory **shall** use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory **shall** **ensure** that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

## 5.2 Personnel

5.2.4 The laboratory **shall** maintain current **job descriptions** for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE 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;

## 5.2 Personnel

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

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

- the responsibilities with respect to method modification and development and validation of new methods;
- expertise and experience required;
- qualifications and training programs;
- managerial duties.



## 5.2 Personnel

5.2.5 The management shall 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. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.

## 5.2 Personnel

### 5.2.5...

This information **shall** be readily available and **shall** include the **date** on which authorization and/or competence is confirmed.

*NVLAP Note This requirement also applies to Approved Signatories (see 1.5.2).*

## 5.3 Accommodations and environmental conditions

**5.3.1** Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, **shall** be such as to facilitate correct performance of the tests and/or calibrations.

## 5.3 Accommodations and environmental conditions

### 5.3.1...

The laboratory **shall ensure** that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement.

Particular care **shall be** taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be **documented**.

## 5.3 Accommodations and environmental conditions

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

## 5.3 Accommodations and environmental conditions

5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

## 5.4 Test and calibration methods and validation

### 5.4.1 General

The laboratory **shall** use appropriate **methods** and **procedures** for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

## 5.4 Test and calibration methods and validation

### 5.4.1 General

The laboratory **shall** 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. All instructions, standards, manuals and reference data relevant to the work of the laboratory **shall** be kept up to date and **shall** be made readily available to personnel (see 4.3).



## 5.4 Test and calibration methods and validation

### 5.4.1 General

Deviation from test and calibration methods **shall** occur only if the deviation has been **documented**, technically justified, authorized, and accepted by the customer.

## 5.4 Test and calibration methods and validation

### 5.4.1 General

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It **may** be necessary to provide additional documentation for optional steps in the method or additional details.

## 5.4 Test and calibration methods and validation

### 5.4.2 Selection of methods

The laboratory **shall** 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. Methods published in international, regional or national standards **shall** preferably be used.

## 5.4 Test and calibration methods and validation

### 5.4.2 Selection of methods

The laboratory **shall ensure** that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard **shall** be supplemented with **additional details** to ensure consistent application.

## 5.4 Test and calibration methods and validation

### 5.4.2 Selection of methods

When the customer does not specify the method to be used, the laboratory **shall** select appropriate methods that have been 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.

## 5.4 Test and calibration methods and validation

### 5.4.2 Selection of methods

Laboratory-developed methods or methods adopted by the laboratory **may** also be used if they are appropriate for the intended use and if they are validated. The customer **shall** be **informed** as to the method chosen. The laboratory **shall** confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation **shall** be repeated.

## 5.4 Test and calibration methods and validation

### 5.4.2 Selection of methods

The laboratory **shall** inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

## 5.4 Test and calibration methods and validation

### 5.4.3 Laboratory-developed methods

The introduction of test and calibration methods developed by the laboratory for its own use **shall** be a **planned** activity and **shall** be assigned to qualified personnel equipped with adequate resources.

Plans **shall** be updated as development proceeds and effective communication amongst all personnel involved **shall** be ensured.



## 5.4 Test and calibration methods and validation

### 5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these **shall** be subject to agreement with the customer and **shall** include a clear **specification of the customer's requirements** and the purpose of the test and/or calibration. The method developed **shall** have been validated appropriately before use.

## 5.4 Test and calibration methods and validation

### 5.4.4 Non-standard methods

NOTE For new test and/or calibration methods, procedures **should** be developed prior to the tests and/or calibrations being performed and **should** contain at least the following information:

- a) appropriate identification;
- b) scope;
- c) description of the type of item to be tested or calibrated;
- d) parameters or quantities and ranges to be determined;
- e) apparatus and equipment, including technical performance requirements;

## 5.4 Test and calibration methods and validation

### 5.4.4 Non-standard methods

NOTE For new test and/or calibration methods, procedures **should** be developed prior to the tests and/or calibrations being performed and **should** contain at least the following information:

- f) reference standards and reference materials required;
- g) environmental conditions required and any stabilization period needed;
- h) description of the procedure, including
  - affixing of identification marks, handling, transporting, storing and preparation of items,
  - checks to be made before the work is started,

## 5.4 Test and calibration methods and validation

### 5.4.4 Non-standard methods

NOTE For new test and/or calibration methods, procedures **should** be developed prior to the tests and/or calibrations being performed and **should** contain at least the following information:

- checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
  - the method of recording the observations and results,
  - any safety measures to be observed;
- i) criteria and/or requirements for approval/rejection;
- j) data to be recorded and method of analysis and presentation;
- k) the uncertainty or the procedure for estimating uncertainty.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

5.4.5.2 The laboratory **shall** validate non-standard methods, laboratory-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. The validation **shall** be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory **shall 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 Test and calibration methods and validation

### 5.4.5 Validation of methods

#### 5.4.5.2 ...

NOTE 1 Validation **may** include procedures for sampling, handling and transportation.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

#### 5.4.5.2 ...

NOTE 2 The techniques used for the determination of the performance of a method **should** be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.



## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

#### 5.4.5.2 ...

NOTE 3 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.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, **shall** be relevant to the customers' needs.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

#### 5.4.5.3...

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review **should** be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan **should** be approved and authorized.

## 5.4 Test and calibration methods and validation

### 5.4.5 Validation of methods

#### 5.4.5.3...

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, **shall** have and **shall** apply a **procedure** to estimate the uncertainty of measurement for all calibrations and types of calibrations.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

5.4.6.2 Testing laboratories **shall** have and **shall** apply **procedures** for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory **shall** at least attempt to identify all the components of uncertainty and make a reasonable estimation, and...

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.2...

**shall ensure** that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation **shall** be based on knowledge of the performance of the method and on the measurement scope and **shall** make use of, for example, previous experience and validation data.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.2...

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- the requirements of the test method;
- the requirements of the customer;
- the existence of narrow limits on which decisions on conformity to a specification are based.



## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.2...

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation **shall** be taken into account using appropriate methods of analysis.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.3 ...

NOTE 1 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.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.3 ...

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

## 5.4 Test and calibration methods and validation

### 5.4.6 Estimation of uncertainty of measurement

#### 5.4.6.3 ...

NOTE 3 For further information, see ISO 5725 and the *Guide to the Expression of Uncertainty in Measurement*.

*NVLAP Note ANSI/NC SL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM) (see 1.4).*

## 5.4 Test and calibration methods and validation

### 5.4.7 Control of data

5.4.7.1 Calculations and data transfers **shall** be subject to appropriate checks in a **systematic** manner.

## 5.4 Test and calibration methods and validation

### 5.4.7 Control of data

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, the laboratory **shall ensure** that:

- a) computer software developed by the user is **documented** in sufficient detail and is suitably validated as being adequate for use;

## 5.4 Test and calibration methods and validation

### 5.4.7 Control of data

5.4.7.2 ...the laboratory **shall ensure** that:

- 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;



## 5.4 Test and calibration methods and validation

### 5.4.7 Control of data

5.4.7.2 ...the laboratory **shall ensure** that:

- 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.

## 5.4 Test and calibration methods and validation

### 5.4.7 Control of data

#### 5.4.7.2 ...the laboratory **shall ensure** that:

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range **may** be considered to be sufficiently validated.

However, laboratory software configuration/modifications **should** be validated as in 5.4.7.2 a).

## 5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this handbook are met.

## 5.5 Equipment

5.5.2 Equipment and its software used for testing, calibration and sampling **shall** be capable of achieving the accuracy required and **shall** comply with specifications relevant to the tests and/or calibrations concerned. Calibration **programs shall** be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) **shall** be calibrated or checked to establish that it meets the laboratory's **specification requirements** and complies with the relevant standard specifications. It **shall** be checked and/or calibrated before use (see 5.6).

## 5.5 Equipment

5.5.3 Equipment **shall** be operated by authorized personnel. Up-to-date **instructions** on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) **shall** be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result **shall**, when practicable, be uniquely identified.

## 5.5 Equipment

5.5.5 **Records** shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall 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 (see 5.5.2);
- d) the current location, where appropriate;

## 5.5 Equipment

5.5.5...The records shall include at least the following:

- 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 carried out to date;
- h) any damage, malfunction, modification or repair to the equipment.

## 5.5 Equipment

5.5.6 The laboratory **shall** 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.

NOTE Additional procedures **may** be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.



## 5.5 Equipment

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the “Control of nonconforming work” procedure (see 4.9).

## 5.5 Equipment

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration **shall** be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

## 5.5 Equipment

**5.5.9** When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory **shall ensure** that the function and calibration status of the equipment are **checked** and shown to be satisfactory before the equipment is returned to service.

## 5.5 Equipment

**5.5.10** When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks **shall** be carried out according to a defined **procedure**.

**5.5.11** Where calibrations give rise to a set of correction factors, the laboratory **shall** have **procedures** to ensure that copies (e.g., in computer software) are correctly updated.

## 5.5 Equipment

**5.5.12** Test and calibration equipment, including both hardware and software, **shall** be safeguarded from adjustments which would invalidate the test and/or calibration results.

## 5.6 Measurement traceability

### 5.6.1 General

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 **shall** be calibrated before being put into service. The laboratory **shall** have an **established program** and **procedure** for the calibration of its equipment.

## 5.6 Measurement traceability

### 5.6.1 General

NOTE Such a program **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.

*NVLAP Note See Annex B for requirements for the implementation of traceability policy in NVLAP-accredited laboratories.*

## 5.6 Measurement traceability

### 5.6.2 Specific requirements

#### 5.6.2.1 Calibration

5.6.2.1.1 For calibration laboratories, the **program** for calibration of equipment **shall** be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).



## 5.6 Measurement traceability

### 5.6.2.1.1...

A calibration laboratory establishes 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.

## 5.6 Measurement traceability

### 5.6.2.1.1...

The link to SI units **may** be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they **may** be secondary standards which are standards calibrated by another national metrology institute.

## 5.6 Measurement traceability

### 5.6.2.1.1...

When using external calibration services, traceability of measurement **shall** be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories **shall** contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 1 Calibration laboratories fulfilling the requirements of this handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

## 5.6 Measurement traceability

### 5.6.2.1.1...

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).

## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 3 Calibration laboratories 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.

## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 4 The term “identified metrological specification” means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 5 When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.



## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory **should** select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

## 5.6 Measurement traceability

### 5.6.2.1.1...

NOTE 8 The unbroken chain of calibrations or comparisons **may** be achieved in several steps carried out by different laboratories that can demonstrate traceability.

## 5.6 Measurement traceability

**5.6.2.1.2** There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration **shall** provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

## 5.6 Measurement traceability

### 5.6.2.1.2...

Participation in a suitable program of interlaboratory comparisons **is required** where possible.

## 5.6 Measurement traceability

### 5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory **shall ensure** that the equipment used can provide the uncertainty of measurement needed.

## 5.6 Measurement traceability

### 5.6.2.2 Testing

#### 5.6.2.2.1...

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements **should** be strictly followed.

## 5.6 Measurement traceability

### 5.6.2.2 Testing

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, **are required** as for calibration laboratories (see 5.6.2.1.2).

## 5.6 Measurement traceability

### 5.6.3 Reference standards and reference materials

#### 5.6.3.1 Reference standards

The laboratory **shall** have a **program and procedure** for the calibration of its reference standards. Reference standards **shall** be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory **shall** be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards **shall** be calibrated before and after any adjustment.



## 5.6 Measurement traceability

### 5.6.3.2 Reference materials

Reference materials **shall**, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials **shall** be **checked** as far as is technically and economically practicable.

## 5.6 Measurement traceability

### 5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

## 5.6 Measurement traceability

### 5.6.3.4 Transport and storage

The laboratory **shall** 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 Additional **procedures** **may** be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

## 5.7 Sampling

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

## 5.7 Sampling

### 5.7.1...

NOTE 1 Sampling is a **defined procedure** whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling **may** also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample **may** not be representative but is determined by availability.

## 5.7 Sampling

### 5.7.1...

NOTE 2 Sampling procedures **should** describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

## 5.7 Sampling

5.7.2 Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these **shall** be **recorded** in detail with the appropriate sampling data and **shall** be included in all documents containing test and/or calibration results, and **shall** be communicated to the appropriate personnel.

## 5.7 Sampling

5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.



## 5.8 Handling of test and calibration items

5.8.1 The laboratory shall 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 laboratory and the customer.

## 5.8 Handling of test and calibration items

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

## 5.8 Handling of test and calibration items

5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

## 5.8 Handling of test and calibration items

5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

## 5.8 Handling of test and calibration items

### 5.8.4 ...

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 results

5.9.1 The laboratory **shall** have quality control **procedures** for monitoring the validity of tests and calibrations undertaken. The resulting data **shall** be recorded in such a way that trends are detectable and, where practicable, statistical techniques **shall** be applied to the reviewing of the results. This monitoring **shall** be planned and reviewed and **may** include, but not be limited to, the following:

## 5.9 Assuring the quality of results

5.9.1 ...**may** include, but not be limited to, the following:

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
- b) participation in interlaboratory comparison or proficiency-testing programs;
- 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.

## 5.9 Assuring the quality of results

NOTE The selected methods **should** be appropriate for the type and volume of the work undertaken.

5.9.2 Quality control data **shall** be analyzed and, where they are found to be outside **pre-defined** criteria, planned action **shall** be taken to correct the problem and to prevent incorrect results from being reported.



## 5.10 Reporting the results

### 5.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory **shall** be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

## 5.10 Reporting the results

### 5.10.1 General

The results **shall** be reported, usually in a test report or a calibration certificate (see Note 1), and **shall** 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. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

## 5.10 Reporting the results

### 5.10.1 General

In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

## 5.10 Reporting the results

### 5.10.1 General

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 handbook are met.

## 5.10 Reporting the results

### 5.10.2 Test reports and calibration certificates

Each test report or calibration certificate **shall** include at least the following information, unless the laboratory has valid reasons for not doing so:

- a) a title (e.g., “Test Report” or “Calibration Certificate”);
- b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

## 5.10 Reporting the results

### 5.10.2 Test reports and calibration certificates

Each test report or calibration certificate **shall** include at least ...

- 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;
- d) the name and address of the customer;

## 5.10 Reporting the results

### 5.10.2 Test reports and calibration certificates

Each test report or calibration certificate **shall** include at least ...

- 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;

## 5.10 Reporting the results

### 5.10.2 Test reports and calibration certificates

Each test report or calibration certificate **shall** include at least ...

- h) reference to the sampling plan and procedures used by the laboratory 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;



## 5.10 Reporting the results

### 5.10.2 Test reports and calibration certificates

Each test report or calibration certificate **shall** include at least ...

- 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 Reporting the results

### 5.10.2 Test reports and calibration certificates

*NVLAP Note*      *NVLAP defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory (see 1.5.2).*

NOTE 1 Hard copies of test reports and calibration certificates **should** also include the page number and total number of pages.

NOTE 2 It is **recommended** that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

## 5.10 Reporting the results

### 5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports **shall**, 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;

## 5.10 Reporting the results

### 5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports **shall**, where necessary for the interpretation of the test results, include the following:

- 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;

## 5.10 Reporting the results

### 5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports **shall**, where necessary for the interpretation of the test results, include the following:

- d) where appropriate and needed, opinions and interpretations (see 5.10.5);
- e) additional information which may be required by specific methods, customers or groups of customers.

## 5.10 Reporting the results

### 5.10.3 Test reports

**5.10.3.2** In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling **shall** include the following, where necessary for the interpretation of test results:

- a) the date of sampling;
- b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

## 5.10 Reporting the results

### 5.10.3 Test reports

**5.10.3.2** In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling **shall** include the following, where necessary for the interpretation of test results:

- c) the location of sampling, including any diagrams, sketches or photographs;
- d) a reference to the sampling plan and procedures used;

## 5.10 Reporting the results

### 5.10.3 Test reports

**5.10.3.2** In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling **shall** include the following, where necessary for the interpretation of test results:

- e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
- f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.



## 5.10 Reporting the results

### 5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates **shall** 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;

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates **shall** include the following, where necessary for the interpretation of calibration 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 (see Note 2 in 5.6.2.1.1).

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

5.10.4.2 The calibration certificate **shall** relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this **shall** identify which clauses of the specification are met or not met.

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

#### 5.10.4.2 ...

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory **shall** **record** those results and maintain them for possible future reference.

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

#### 5.10.4.2 ...

When statements of compliance are made, the uncertainty of measurement **shall** be taken into account.

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, **shall** be reported.

## 5.10 Reporting the results

### 5.10.4 Calibration certificates

5.10.4.4 A calibration certificate (or calibration label) **shall not** contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement **may** be superseded by legal regulations.

## 5.10 Reporting the results

### 5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory **shall** document the basis upon which the opinions and interpretations have been made.

Opinions and interpretations **shall** be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations **should not** be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.



## 5.10 Reporting the results

### 5.10.5 Opinions and interpretations

NOTE 2 Opinions and interpretations included in a test report **may** comprise, but not be limited to, the following:

- an opinion on the statement of compliance/noncompliance of the results with requirements;
- fulfillment of contractual requirements;
- recommendations on how to use the results;
- guidance to be used for improvements.

## 5.10 Reporting the results

### 5.10.5 Opinions and interpretations

NOTE 3 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.

## 5.10 Reporting the results

### 5.10.6 Testing and calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results **shall** be clearly identified. The subcontractor **shall** report the results in writing or electronically.

When a calibration has been subcontracted, the laboratory performing the work **shall** issue the calibration certificate to the contracting laboratory.

## 5.10 Reporting the results

### 5.10.7 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this handbook **shall** be met (see also 5.4.7).

## 5.10 Reporting the results

### 5.10.8 Format of reports and certificates

The format **shall** be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention **should** be given to the layout 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 2 The headings **should** be standardized as far as possible.

## 5.10 Reporting the results

### 5.10.9 Amendments to test reports and calibration certificates

Material amendments to a test report or calibration certificate after issue **shall** be made only in the form of a further document, or data transfer, which includes the statement:

“Supplement to Test Report [or Calibration Certificate],  
serial number . . . [or as otherwise identified],”

or an equivalent form of wording.

## 5.10 Reporting the results

### 5.10.9 Amendments to test reports and calibration certificates

Such amendments **shall** meet all the requirements of this handbook.

When it is necessary to issue a complete new test report or calibration certificate, this **shall** be uniquely identified and **shall** contain a reference to the original that it replaces.