NIST HANDBOOK 150 REQUIREMENTS ANALYSIS: 1994 EDITION AND 2001 EDITION

This requirements analysis identifies the differences between the 1994 and 2001 editions of NIST Handbook 150: *NVLAP Procedures and General Requirements.* The object of the analysis is to identify which requirements in the new edition were not sufficiently addressed in the old edition. NVLAP-accredited laboratories will need this information in order to update their documented quality systems.

This document has retained the format of the General Operations Checklist (2001) for easy reference and comparison. Items marked with ✦ were not sufficiently addressed in the 1994 edition of NIST Handbook 150. For items that were addressed in the 1994 edition, the text boxes contain bolded references to the relevant clauses of section 285.33 of the 1994 edition. The annotation "PG-1" refers to NVLAP Policy Guide PG-1-1998: *Use of Accredited Calibration Laboratories by NVLAP-Accredited Testing and Calibration Laboratories to Achieve Traceability of Measurement.*

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.

(b)(1)(i)

Legal name of laboratory ownership:

___ **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 client, the regulatory authorities or organizations providing recognition.

(b)(1)(ii) - needs of client not addressed in old standard

___ **4.1.3** The laboratory 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.

(b)(1)(ii)

___ **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.

(b)(2)(iii) - need to identify potential conflicts not addressed in old standard

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.

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 judgement. The third-party testing or calibration laboratory should not engage in any

activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall:

___ a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality 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);

(b)(2)(i)

___ 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;

(b)(2)(ii)

___ c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

(b)(2)(ix)

___ d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

(b)(2)(xi)

___ 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;

(c)(2)(ii), (iii)

___ 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;

(b)(2)(iv)

___ 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;

(b)(2)(v)

___ 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;

(b)(2)(vi)

Name of person:
Area of responsibility:
Repeat as necessary:

___ 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 quality system 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;

(b)(2)(vii)

Name of person:

___ j) appoint deputies for key managerial personnel (see note).

(b)(2)(viii)

Name(s):

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

4.2 Quality system

4.2.1

___ a) The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities.

(c)(1)(i)

___ b) 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.

(c)(1)(ii)

___ c) The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

(c)(1)(iii), (v)

___ **4.2.2** The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

(c)(1)(iv), (c)(2)(1)

___ a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients;

(c)(2)(i)

___✦ b) the management's statement of the laboratory's standard of service;

___ c) the objectives of the quality system;

(c)(2)(i)

___ 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

(c)(2)(v)

___ e) the laboratory management's commitment to compliance with this handbook.

(c)(2)(i)

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 clients' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3

___ a) The quality manual shall include or make reference to the supporting procedures including technical procedures.

(c)(2)(vii), (x), (xi), (xiii), (xv), (xvii), (xviii), (xix)

___✦ b) It shall outline the structure of the documentation used in the quality system.

___ **4.2.4** 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.

(c)(2)(v)

4.3 Document control

4.3.1 General

___ The laboratory shall establish and maintain procedures to control all documents that form part of its quality 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.

(c)(2)(iv)

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 4.12.

4.3.2 Document approval and issue

4.3.2.1

___✦ a) All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue.

___✦ b) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

___✦ 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.

4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include:

___✦ a) the date of issue and/or revision identification,

___✦ b) page numbering,

___✦ c) the total number of pages or a mark to signify the end of the document, and

___✦ d) the issuing authority(ies).

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.

4.3.3.3

___✦ a) If the laboratory's documentation 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.

___✦ b) 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:

(c)(2)(ix)

___✦ 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)(2)(ix)

___✦ c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2).

___✦ d) 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 client.

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 clients, reviews of requests, tenders and contracts can be performed in a simplified way.

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.

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

___✦ **4.4.2** Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

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

___✦ **4.4.3** The review shall also cover any work that is subcontracted by the laboratory.

___✦ **4.4.4** The client shall be informed of any deviation from the contract.

___✦ **4.4.5** If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

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.

(l)(i), (l)(3)(ii)

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

(l)(2), (l)(3)(iv)

___✦ **4.5.3** The laboratory is responsible to the client for the subcontractor's work, except in the case where the client 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.

(l)(2)

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.

(m)(1), (2), (h)(8)

4.6.2

___ a) 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.

(m)(2)

___ b) Records of actions taken to check compliance shall be maintained.

(m)(3)

___ **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.

(m)(2)

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 quality system standard under which they were made.

4.6.4

___ a) The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and

(m)(3)

___ b) shall maintain records of these evaluations and list those approved.

(m)(3)

4.7 Service to the client

___✦ The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

NOTE 1 Such cooperation may include:

a) Providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client;

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

NOTE 2 Such cooperation may include: Clients value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g., client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

4.8 Complaints

___ **4.8.1** The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties.

(n)(1)

___ **4.8.2** Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).

(n)(1)

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 client. The policy and procedures shall ensure that:

(c)(2)(xv)

___✦ 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;

(k)(6)

___✦ c) Corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work;

___ d) where necessary, the client is notified and work is recalled;

(k)(6)

___✦ e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality 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.

___✦ **4.9.2** 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 4.10 shall be promptly followed.

4.10 Corrective action

4.10.1 General

___ The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

(c)(2)(xv)

NOTE A problem with the quality 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 clients or staff observations.

4.10.2 Cause analysis

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

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

4.10.3 Selection and implementation of corrective actions

___✦ a) 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.

___✦ b) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

___✦ c) The laboratory shall document and implement any required changes resulting from corrective action investigations

4.10.4 Monitoring of corrective actions

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

4.10.5 Additional audits

___ Where the identification of nonconformances 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 4.13 as soon as possible.

(n)(2)

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.

4.11 Preventive action

4.11.1

___✦ a) Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified.

___✦ b) If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

___✦ **4.11.2** 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.

4.12 Control of records

4.12.1 General

___ **4.12.1.1** 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.

(j)(1)

4.12.1.2

___ a) 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.

(j)(2)

___ b) Retention times of records shall be established.

(j)(2)

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

___ **4.12.1.3** All records shall be held secure and in confidence.

(j)(2)

___ **4.12.1.4** The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

(h)(7)(v)

4.12.2 Technical records

4.12.2.1

___ a) 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.

(j)(1)

___ b) 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.

(j)(1)

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

(j)(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, clients' notes, papers and feedback.

___✦ **4.12.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.12.2.3

___✦ a) 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.

___ b) In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

(h)(7)(iii)

4.13 Internal audits

4.13.1

___ a) 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 quality system and this handbook. The internal audit program shall address all elements of the quality 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.

(c)(3)

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

(c)(3)

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

___ **4.13.2** 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 clients in writing if investigations show that the laboratory results may have been affected.

(c)(3)

___ **4.13.3** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

(c)(5)

___ **4.13.4** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

(c)(5)

4.14 Management reviews

___ **4.14.1** In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality 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:

(c)(4)

___✦ a) the suitability of policies and procedures;

___✦ b) reports from managerial and supervisory personnel;

___✦ c) the outcome of recent internal audits;

___✦ d) corrective and preventive actions;

___✦ e) assessments by external bodies;

___✦ f) the results of interlaboratory comparisons or proficiency tests;

___✦ g) changes in the volume and type of the work;

___✦ h) client feedback;

___✦ i) complaints;

___✦ j) 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.

4.14.2

___ a) Findings from management reviews and the actions that arise from them shall be recorded.

(c)(5)

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

(c)(5)

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

___✦ **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

___ a) 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.

(d)(1)

___ b) 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.

(d)(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 client.

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.

___ **5.2.2** 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.

(d)(2)

5.2.3

___✦ a) The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

___✦ b) 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 quality system.

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

(c)(2)(v)

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

5.2.5

___✦ a) 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.

___ b) 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.

(d)(3)

___✦ c) 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 1.5.4).

5.3 Accommodation and environmental conditions

5.3.1

___ a) 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.

(e)(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.

(e)(2)

___✦ b) The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2

___ a) 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.

(e)(3)

___ b) Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

(e)(2)

___ **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.

(e)(4)

___ **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.

(e)(5)

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

(e)(6)

5.4 Test and calibration methods and method validation

5.4.1 General

___ a) 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.

(h)(2)

___ b) 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.

(h)(1)

___ c) 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).

(h)(1)

___ d) Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

(h)(4)

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.

5.4.2 Selection of methods

___ a) The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.

(h)(3)

___✦ b) When necessary, the standard shall be supplemented with additional details to ensure consistent application.

___ c) When the client 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. 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.

(h)(4)

___✦ d) The client shall be informed as to the method chosen.

___✦ e) 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.

___✦ f) The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

___✦ a) 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.

(h)(4)

___✦ b) Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

(h)(4)

5.4.4 Non-standard methods

___ a) When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration.

___ b) The method developed shall have been validated appropriately before use.

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;

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,
- 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.

5.4.5 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.

5.4.5.2

___ a) 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.

(h)(4) - implied

___✦ b) 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.

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

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.

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.

___✦ **5.4.5.3** 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 clients' needs.

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 client are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

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.

5.4.6 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.

(h)(2)

___✦ **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 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.

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 client;
- the existence of narrow limits on which decisions on conformance to a specification are based.

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).

___ **5.4.6.3** 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.

(h)(2)

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.

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.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

NVLAP Note: ANSI/NCSL 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).

5.4.7 Control of data

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

(h)(6)

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;

(h)(7)(ii)

___ 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;

(h)(7)(iii)

___ 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.

(h)(7)(iv)

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 5.4.7.2a).

5.5 Equipment

5.5.1

___ a) 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).

(f)(1)(i)

___ b) 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.

(f)(1)(ii)

5.5.2

___ a) 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.

(g)(2)

___ b) Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

(g)(1)

___ c) 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).

(g)(1)

___ **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.

(h)(1)

___ **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.

(f)(3)

___ **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:

(f)(4)

___ a) the identity of the item of equipment and its software;

(f)(4)(i)

___ b) the manufacturer's name, type identification, and serial number or other unique identification;

(f)(4)(ii)

___ c) checks that equipment complies with the specification (see 5.5.2);

(f)(4)(vii)

___ d) the current location, where appropriate;

(f)(4)(iv)

___ e) the manufacturer's instructions, if available, or reference to their location;

(f)(4)(vi)

___ f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

(f)(4)(vii)

___ g) the maintenance plan, where appropriate, and maintenance carried out to date;

(f)(4)(viii)

___ h) any damage, malfunction, modification or repair to the equipment.

(f)(4)(ix)

___ **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.

(c)(2)(xiii)

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

5.5.7

___ a) 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.

(f)(2)

___ b) 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).

(f)(2)

___ **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.

(f)(3)

___ **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.

(f)(1)(ii)

___✦ **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.

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

(i)(5)

5.6 Measurement traceability

5.6.1 General

___ a) 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.

(g)(1)

___ b) The laboratory shall have an established program and procedure for the calibration of its equipment.

(g)(1)

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.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1

___ a) 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*).

(g)(2)

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. 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.

___ b) 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.

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___ c) 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).

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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.

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

NOTE 3 Calibration 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.

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.

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.

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.

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

___ **5.6.2.1.2** 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

(g)(3)

___ a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

(g)(3) note ii

___ b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

(g)(3) note iv

___ c) Participation in a suitable program of interlaboratory comparisons is required where possible.

(g)(2) second note

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.

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.

___✦ **5.6.2.2.2** 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).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

___ a) The laboratory shall have a program and procedure for the calibration of its reference standards.

(g)(5)

___ b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.

(g)(5)

___ c) 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.

(g)(4)

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.

(g)(7)

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.

(g)(6)

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

___ a) 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.

(h)(5)

___✦ b) 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.

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.

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.

___✦ **5.7.2** Where the client 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.

___✦ **5.7.3** 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 client.

(i)(4)

5.8.2

___ a) The laboratory shall have a system for identifying test and/or calibration items.

(i)(1)

___✦ b) The identification shall be retained throughout the life of the item in the laboratory.

___ c) 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.

(i)(1)

___✦ d) The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3

___ a) 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.

(i)(2)

___ b) 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 client for further instructions before proceeding and shall record the discussion.

(i)(2)

5.8.4

___ a) 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.

(i)(3)

___ b) Handling instructions provided with the item shall be followed.

(i)(3)

___ c) When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

(i)(3)

___ d) 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.

(i)(3)

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the quality of test and calibration results

___ a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

(c)(6)

___ b) 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.

(c)(6) implied

___ c) This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

(c)(6) implied

___ 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;

(c)(6)(iii)

___ 2) participation in interlaboratory comparison or proficiency-testing programs;

(c)(6)(ii)

___ 3) replicate tests or calibrations using the same or different methods;

(c)(6)(iv)

___ 4) retesting or recalibration of retained items;

(c)(6)(v)

___ 5) correlation of results for different characteristics of an item.

(c)(6)(vi)

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

5.10 Reporting the results

5.10.1 General

___ a) 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.

(k)(1)

___ b) 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 client 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.

(k)(1)

___ c) In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, 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 client shall be readily available in the laboratory which carried out the tests and/or calibrations.

(k)(1) note

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.

5.10.2 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");

(k)(2)(i)

___ 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;

(k)(2)(ii)

___ 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;

(k)(2)(iii)

___ d) the name and address of the client;

(k)(2)(iv)

___ e) identification of the method used;

(k)(2)(vii)

___ f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

(k)(2)(v), (vi)

___ 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;

(k)(2)(vii)

___ 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;

(k)(2)(ix)

___ i) the test or calibration results with, where appropriate, the units of measurement;

(k)(2)(xi)

___ j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

k)(2)(xiii)

___ k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

(k)(2)(xiv)

NVLAP Note: NVLAP defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory (see 1.5.4).

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.

5.10.3 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;

(k)(2)(x)

___✦ b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

___ c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;

(k)(2)(xii)

___✦ d) where appropriate and needed, opinions and interpretations (see 5.10.5);

___✦ e) additional information which may be required by specific methods, clients or groups of clients.

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);

___✦ c) the location of sampling, including any diagrams, sketches or photographs;

___✦ d) a reference to the sampling plan and procedures used;

___✦ 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.

5.10.4 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;

(k)(2)(x)

___ b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

(k)(2)(xii)

___ c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).

(k)(2)(xix)

5.10.4.2

___ a) The calibration certificate shall relate only to quantities and the results of functional tests.

(k)(2)(xiv)

___✦ b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

___✦ c) 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.

___✦ d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

___✦ **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.

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

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.

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.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

___ a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.
(k)(3)

___✦ b) The subcontractor shall report the results in writing or electronically.

___✦ c) When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

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).
(k)(7)

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.
(k)(4)

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.

5.10.9 Amendments to test reports and calibration certificates

___ a) 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.

(k)(5)

___ b) Such amendments shall meet all the requirements of this handbook.

(k)(5)

___ c) 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.

(k)(5)

Annex A (normative)

Referencing NVLAP Accreditation

The following conditions, which pertain to the use of the term *NVLAP* and the NVLAP logo, shall be met by a laboratory in order to become and remain accredited. Failure to comply with these conditions may result in suspension or revocation of a laboratory's accreditation.

___ a) The laboratory shall have a policy and procedure for controlling the use of the term *NVLAP* and the NVLAP logo.

(c)(2)(xx)

___✦ b) The term and logo shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.

___✦ c) When the term *NVLAP* is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code.

___✦ d) Reference to the NVLAP Lab Code by an applicant laboratory that has not yet achieved accreditation shall include a statement accurately reflecting the laboratory's status.

___✦ e) When the NVLAP logo is used to reference a laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code in an approved caption. The caption shall appear below and in close proximity to the logo. The following captions have been approved by NVLAP:

- "For the scope of accreditation under NVLAP Lab Code 000000-0" (fig. 1)
- "NVLAP Lab Code 000000-0" (fig. 2).

f) The form of the NVLAP logo must conform to the following guidelines:

___✦ 1) The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.

___✦ 2) The aspect ratio (height to width) shall be 1 to 2.25 (fig. 3).

___✦ 3) The logo and caption shall be of a size that allows the caption to be easily read. The size of the caption shall not exceed the size of the logo itself.

___✦ 4) The logo shall appear in black, blue, or other color approved by NVLAP, and may be filled or unfilled. In the case of a filled logo, the same color shall be used for the outline and the fill.

___ g) The name of at least one Approved Signatory shall appear on a test or calibration report that displays the NVLAP logo or references NVLAP accreditation. A computer-generated report may have the Approved Signatory's name printed along with the test or calibration results, as long as there is evidence that there is a system in place to ensure that the report cannot be generated without the

review and consent of the Approved Signatory. There may be legal or contractual requirements for original signatures to appear on the report.

(k)(2)(xvii)

___✦ h) When the term and logo are used on test or calibration reports, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

___ A test or calibration report that contains both data covered by the accreditation and data not covered by the accreditation shall clearly identify the data that are not covered by the accreditation.

(k)(8)

___ The report must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the NVLAP accreditation."

(k)(8)(i), (ii)

___✦ i) When the term and logo are used on test or calibration reports that also include work done by subcontracted laboratories, such use shall be limited to reports in which some or all of the data are from tests or calibrations performed by the laboratory under its scope of accreditation.

___ A test or calibration report that contains both data covered by the accreditation and data provided by a subcontractor shall clearly identify the data that were provided by the subcontracted laboratory.

(l)(3)(iii)

___ The report must prominently display the following statement at the beginning of the report: "This report contains data that were produced under subcontract by Laboratory X." If the subcontracted laboratory is accredited by NVLAP, then its Lab Code should also be stated.

(l)(3)(v)

___ If the subcontracted laboratory is accredited by a body other than NVLAP, then the name of the accreditation body and the laboratory's number or other unique identifier should also be stated. If the subcontracted laboratory is not accredited, then this must be stated.

(l)(3)(v)

___ j) Each test and calibration report bearing the term or logo shall include a statement that the report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government.

(k)(2)(xvi)

___✦ k) When used in a contract or proposal, the term and logo shall be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.

FOR THE SCOPE OF ACCREDITATION UNDER NVLAP LAB CODE 000000-0

Figure 1. NVLAP Logo and caption 1.

NVLAP LAB CODE 000000-0

Figure 2. NVLAP Logo and caption 2.

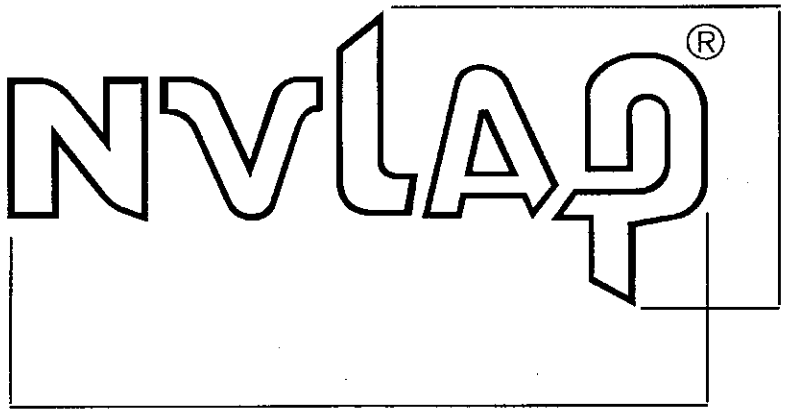

Figure 3. Aspect ratio of the NVLAP logo (width to height).

Annex B (normative)

Implementation of Traceability Policy in Accredited Laboratories

It is a fundamental requirement that the results of all accredited calibrations and the results of all calibrations required to support accredited tests shall be traceable to national and international standards of measurement. NIST Handbook 150 (and ISO/IEC 17025) details the specific requirements for traceability to be met by testing and calibration laboratories. This annex provides guidance as to how these requirements may be met and how traceability of measurement can be assured by an accredited laboratory.

B.1 General

___ a) Laboratories shall be able to demonstrate proper use of traceable standards and test and measurement equipment by competent laboratory personnel in a suitable environment in performing the tests for which accreditation is desired or held. This demonstration will include the determination of the appropriate measurement uncertainty.

PG-1-1998 & (g)(2)

___ b) Calibration certificates received by NVLAP-accredited testing and calibration laboratories with new or recalibrated equipment shall meet the requirements of ISO/IEC 17025. The certificates must include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

PG-1

Note to assessor: The NVLAP assessor(s) must, for each measurement parameter, indicate which method the laboratory has employed to achieve traceability. Select from B.2.1, B.2.2, B.2.3, B.2.4, or B.2.5 below. If B.2.4 or B.2.5 are selected, supporting documentation is also required as indicated.

B.2 Demonstration of traceability

___ **B.2.1** NVLAP-accredited laboratories may submit appropriate physical standards and test and measurement equipment directly to NIST or, when appropriate, to another national metrology institute. Accredited laboratories may obtain certified reference materials from NIST (called Standard Reference Materials under copyright) or from another national metrology institute. Use of a national metrology institute other than NIST shall be documented and will be assessed by NVLAP.

PG-1(1)

___ **B.2.2** Testing laboratories that perform calibrations only for themselves do not need to be accredited as calibration laboratories. Calibration laboratories that perform specific calibrations only for themselves to support their accredited services do not need to be accredited for those calibrations. For the purpose of assuring traceability, an accredited laboratory may calibrate its own equipment if the appropriate requirements of NIST Handbook 150 have been met.

PG-1(2)

___ **B.2.3** NVLAP-accredited laboratories that do not demonstrate traceability as described in B.2.1 or B.2.2, shall use accredited calibration laboratory services wherever available. Accredited calibration laboratories are those accredited by NVLAP or by any accrediting body with which NVLAP has a mutual recognition arrangement. A listing of NVLAP-accredited calibration laboratories and of accreditation bodies with which NVLAP currently has agreements is available from NVLAP.

PG-1(3)

___ **B.2.4** If a NVLAP-accredited laboratory submits physical standards or test and measurement equipment to a calibration service provider that is not accredited by NVLAP or by an accrediting body with which NVLAP has a mutual recognition arrangement, the laboratory shall:

PG-1(4)

___✦ a) document that an appropriate accredited calibration service provider is not available;

___ b) audit the claim of traceability of the provider of the calibration service and document the following areas related to the calibration and claim of traceability of its standards and test and measurement equipment:

PG-1(4)(A & D)

___ 1) information regarding assessment of the quality system used by the calibration service provider;

PG-1(4)(D)(i)

___ 2) the calibration procedure(s) used by the calibration service provider;

PG-1(4)(D)(ii)

___ 3) the physical standards or other test and measurement equipment used by the calibration service provider (including evidence of traceability to standards maintained by NIST or an appropriate national metrology institute and copies of relevant calibration certificates);

PG-1(4)(D)(iii)

___✦ 4) information regarding the calibration intervals of relevant standards or other test and measurement equipment;

___ 5) the environmental conditions of the laboratory;

PG-1(4)(D)(iv)

___ 6) the method(s) by which uncertainties are determined (e.g., Guide to the Expression of Uncertainty in Measurement (GUM); and

PG-1(4)(D)(v)

___ 7) the relative uncertainties achieved at all steps of the process;

PG-1(4)(D)(vi)

___ c) pursue the traceability chain until traceability to appropriate stated references is completely validated, when a calibration service provider submits physical standards and/or test and measurement equipment used in the calibration to another laboratory(s) not accredited by NVLAP;

PG-1(4)(C)

___ d) enter the audit documentation, including all findings of nonconformance and resolutions of those findings, into the laboratory's quality management record-keeping system.

PG-1(4)(C)

NOTE An on-site visit to the provider of the calibration service is encouraged, but is not required as long as the information listed above is obtained and otherwise verified. Self-declaration of compliance to ISO/IEC 17025 or other relevant standards by a calibration service provider is not acceptable evidence of verification of traceability. Citation of a NIST Test Number by the calibration service provider likewise is not acceptable evidence of verification of traceability.

___ **B.2.5** If traceable calibration is not available or appropriate, laboratories may demonstrate comparison to a widely used standard that is clearly specified and mutually agreeable to all parties concerned, particularly in measurements where NIST does not maintain a U.S. national standard. For example, NIST does not maintain a standard for all hardness testing scales. There are several widely used commercial standards available for hardness. However, these standards may not all give equivalent measurement results; therefore, it is important to specify which standard is used and to obtain agreement among all parties involved that the choice made is acceptable.

PG-1(5)