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2006 EDITION

National Voluntary
Laboratory Accreditation Program

PROCEDURES AND GENERAL REQUIREMENTS

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NVLAP AND THE NVLAP LOGO

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Foreword

The NIST Handbook 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series is comprised of the following publications:

- NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;

- NIST Handbook 150-xx program-specific handbooks, which supplement NIST Handbook 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP laboratory accreditation programs (LAPs).

The 2006 edition of NIST Handbook 150 supersedes and replaces the 2001 edition. Overall, the changes are minimal and there are no significant changes to the technical requirements. The 2006 edition incorporates changes resulting from the release of the newest editions of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, and ISO/IEC 17011, *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies.*

In addition to editorial improvements, the following main changes have been made to this handbook with respect to the previous edition:

- revision of Clauses 1, 2, and 3 to incorporate previously issued NVLAP Policy Guides, updated definitions and references, and requirements found in ISO/IEC 17011:2004;

- revision of Clauses 4 and 5 to incorporate Clauses 4 and 5 of ISO/IEC 17025:2005 in their entirety and to include notes specific to NVLAP as needed;

- addition of two new annexes, Annex C and Annex D.

Annexes A through D form a normative part of this handbook, meaning that they are integral parts of the handbook and contain provisions to which it is necessary to conform in order to claim compliance with the handbook requirements.

This handbook is available on the NVLAP web site (http://www.nist.gov/nvlap) and on request from NVLAP.

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

Introduction

As set forth in Part 285 of Title 15 of the U.S. Code of Federal Regulations, the National Voluntary Laboratory Accreditation Program (NVLAP) accredits testing and calibration laboratories that are found competent to perform specific tests or calibrations, or types of tests or calibrations. NIST Handbook 150 presents the basic procedures under which NVLAP operates, and the general accreditation requirements for testing and calibration laboratories. Clauses 4 and 5 and the annexes of the handbook contain the general requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate an appropriate management system, are technically competent, and are able to generate technically valid results.

NVLAP operates an accreditation system that is compliant with ISO/IEC 17011, which requires that the competence of applicant laboratories be assessed by the accreditation body against all of the requirements of ISO/IEC 17025. The managerial and technical requirements of ISO/IEC 17025 are contained in their entirety in Clauses 4 and 5 of this handbook. Clause 4 specifies the requirements for sound management. Clause 5 specifies the requirements for technical competence for the type of tests and/or calibrations the laboratory undertakes.

Growth in the use of management systems generally has increased the need to ensure that laboratories that form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001, as well as with ISO/IEC 17025. Care was taken by the ISO Committee on Conformity Assessment (CASCO) to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system. Testing and calibration laboratories that comply with the requirements of this handbook will, therefore, also operate in accordance with ISO 9001, as stated in the introduction of 17025:2005.

The acceptance of testing and calibration results among economies worldwide should be facilitated if laboratories comply with this handbook and obtain NVLAP accreditation. NVLAP has entered into mutual recognition arrangements (MRAs) with equivalent accreditation bodies that comply with ISO/IEC 17011 and applicable MRA documents. The use of this handbook will promote cooperation between laboratories and other bodies, and assist in the exchange of information and experience and in the harmonization of standards and procedures.

1 General information

1.1 Purpose and scope

1.1.1 NIST Handbook 150 sets forth the procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both testing and calibration laboratories.

1.1.2 NIST Handbook 150, the NIST Handbook 150-xx program-specific handbook, and the program-specific on-site assessment checklist, if applicable, constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation in a specific Laboratory Accreditation Program (LAP).

1.1.3 This handbook is for use by laboratories in developing the management and technical systems that govern their operations. Laboratory customers, regulatory authorities, and accreditation bodies may also use it as a basis upon which to judge the competence of laboratories.

1.1.4 If a testing or calibration laboratory fulfills the requirements of this handbook, it meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in this handbook (Clause 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2000, *Quality management systems—Requirements,* and are aligned with its pertinent requirements. (See Annex A, A.2.)

1.1.5 Compliance with regulatory and safety requirements for the operation of laboratories is not addressed by this handbook. Such requirements may be addressed in the NIST Handbook 150-xx series of program-specific handbooks.

1.2 Organization of handbook

1.2.1 Clause 1 of this handbook describes considerations that relate in general to all aspects of NVLAP. Clause 2 describes how LAPs are requested, developed, announced, and terminated. Clause 3 provides information about the accreditation process, including arrangements for granting, maintaining, extending, reducing, suspending, and withdrawing accreditation. Clauses 4 and 5 contain the requirements for NVLAP accreditation as found in Clauses 4 and 5 of ISO/IEC 17025:2005. Annexes A through D present requirements for referencing NVLAP accreditation and achieving traceability, conditions for NVLAP accreditation, and information and requirements for laboratories located outside of the United States.

1.2.2 Notes are included in this handbook to provide clarification of the text, examples, and guidance; they do not contain requirements.

1.2.3 The term *NVLAP Note* is used in Clause 5 to indicate a NVLAP reference to or clarification of a particular technical requirement in order to distinguish it from the notes contained in ISO/IEC 17025.

1.3 Description of NVLAP

1.3.1 The National Voluntary Laboratory Accreditation Program (NVLAP) is a U.S. Government entity administered by the National Institute of Standards and Technology (NIST), an agency of the U.S. Department of Commerce. NVLAP accredits testing and calibration laboratories found competent to perform specific tests or calibrations, or types of tests or calibrations.

1.3.2 NVLAP is a voluntary system that provides a mechanism for the recognition of testing and calibration laboratories based on internationally accepted standards. It identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems, and promotes the acceptance of test and calibration results among economies and accreditors to support trade facilitation activities worldwide.

1.3.3 NVLAP laboratory accreditation programs (LAPs) are established on the basis of requests and demonstrated need. The specific tests or calibrations, types of tests or calibrations, or standards to be included in a LAP are determined by an open process during the development of the LAP (see Clause 2). NVLAP does not unilaterally propose or decide the scope of a LAP.

1.3.4 NVLAP administers its policies and procedures in a nondiscriminatory manner. Access to NVLAP accreditation is not conditional on the size of a laboratory or on its membership in any association or group, nor is it conditional upon the number of laboratories already accredited. NVLAP's accreditation services are available to public and private testing and calibration laboratories, including commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state, and local government laboratories.

1.3.5 NVLAP accreditation is based on evaluation of a laboratory's management and technical qualifications and competence for conducting specific test methods, measurements, and services in specified fields of testing or calibration. Accreditation is granted only after thorough evaluation of an applicant has demonstrated that all NVLAP requirements have been fulfilled, and is acknowledged by the issuance of a Certificate of Accreditation and a Scope of Accreditation, which details the specific test methods, measurements and services for which a laboratory has been accredited.

1.3.6 NVLAP operates a management system that is compliant with ISO/IEC 17011:2004.

1.3.7 NVLAP accreditation does not relieve a laboratory from complying with applicable federal, state, and local laws and regulations.

1.4 References

The following documents are referenced in the text or notes of this handbook.

— ANSI/NCSL Z540-2-1997 (R2002), *U.S. Guide to the Expression of Uncertainty in Measurement*

— BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, *Guide to the Expression of Uncertainty in Measurement* (GUM), 1993

— BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, *International Vocabulary of Basic and General Terms in Metrology* (VIM), 1993

— ILAC-G21:2002, *Cross Frontier Accreditation—Principles for Avoiding Duplication*

— ISO 9000:2000, *Quality management systems—Fundamentals and vocabulary*

— ISO 9001:2000, *Quality management systems—Requirements*

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

— ISO/IEC 17011:2004, *Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies*

— ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

— ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

— ISO/IEC Guide 2:2004, *Standardization and related activities—General vocabulary*

— ISO/IEC Guide 43-1:1997, *Proficiency testing by interlaboratory comparisons—Part 1: Development and operation of proficiency testing schemes*

— ISO/IEC Guide 43-2:1997, *Proficiency testing by interlaboratory comparisons—Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*

— ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*

— ISO-ILAC-IAF Joint Communiqué on the Management Systems Requirements of ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, 18 June 2005, available at <http://ts.nist.gov/ts/htdocs/210/214/docs/17025JointCommunique.pdf>

— NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 edition

1.5 Terms and definitions

For the purposes of this handbook, the relevant terms and definitions given in ISO/IEC 17000 and VIM apply.

NOTE General definitions related to quality are given in ISO 9000, whereas ISO/IEC 17000 gives definitions specifically related to certification and laboratory accreditation. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and VIM are used.

1.5.1
accreditation
Formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of tests or calibrations.

1.5.2
Approved Signatory
An individual who is designated by a laboratory and deemed competent by NVLAP to sign accredited laboratory test or calibration reports. An Approved Signatory is responsible for the technical content of the report and is the contact person for questions or problems with the report. Approved Signatories have responsibility, authority and technical capability within the organization for the results produced.

1.5.3
assessment, on-site
Systematic, independent, documented process for determining laboratory competence and for obtaining records, statements of fact or other relevant information by NVLAP assessors at the laboratory facilities and other places where test or calibration services are provided with the objective of determining the extent to which NVLAP requirements are fulfilled.

NOTE FROM ISO/IEC 17000:2004: Whilst "audit" applies to management systems, "assessment" applies to conformity assessment bodies as well as more generally.

1.5.4
Authorized Representative
Individual who is authorized by laboratory top management to commit the laboratory to fulfill the NVLAP conditions for accreditation (see Annex C). The Authorized Representative reports to NVLAP changes that may affect the laboratory's capability, scope of accreditation, or compliance with accreditation requirements.

1.5.5
best measurement capability
Smallest uncertainty of measurement a laboratory can achieve within its scope of accreditation, when performing more-or-less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve or reproduce a unit of that quantity or one or more of its values, or when performing more-or-less routine calibrations of nearly ideal measurement instruments designed for the measurement of that quantity.

1.5.6
Certificate of Accreditation
Document issued by NVLAP to a laboratory that has been granted NVLAP accreditation. A Certificate of Accreditation is always issued with a Scope of Accreditation. (See also **Scope of Accreditation**.)

1.5.7
customer
Any person or organization that engages the services of a testing or calibration laboratory.

1.5.8
competence
Ability of a laboratory to conduct tests and perform calibrations in accordance with the specified standards and to produce accurate, proper, fit for purpose, technically valid data and test and calibration results.

1.5.9
interlaboratory comparisons
Organization, performance and evaluation of tests or calibrations on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (See also **proficiency testing (laboratory)**.)

NOTE In some circumstances, one of the laboratories involved in the intercomparison may be the laboratory which provided the assigned value for the test item.

[ISO/IEC Guide 43-1:1997, 3.7 expanded]

1.5.10
laboratory
Organization that performs tests and/or calibrations. When a laboratory is part of an organization that carries out activities additional to testing and calibration, the term *laboratory* refers only to those parts of that organization that are involved in the testing and calibration process. A laboratory's activities may be carried out at a permanent, temporary, or remote location.

NVLAP further defines laboratory as being a physical entity—that is, a testing or calibration facility that is separate and apart physically from any other laboratory whether or not sharing common ownership, management, or quality systems with any other laboratory(s).

1.5.11
LAP
Laboratory Accreditation Program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

1.5.12
management system
System to establish policy and objectives and to achieve those objectives.

NOTE A management system of an organization may include different management systems, such as a **quality management system**, a financial management system, or an environmental management system.

[ISO 9000:2000, 2.2.2]

1.5.13
measurement assurance
Process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well-characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts.

1.5.14
measuring and test equipment (M & TE)
All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

NOTE In the context of this handbook, the term *measuring and test equipment* is taken to encompass *measurement instruments* and *measurement standards*. Moreover, a *reference material* is considered to be a type of *measurement standard.*

1.5.15
nonconformity
Nonfulfillment of NVLAP requirements for accreditation; previously referred to as a *deficiency*.

1.5.16
NVLAP Lab Code
Unique numeric identifier assigned by NVLAP to each laboratory. It is used for identification, record-keeping, and data base management. (See also Annex A.)

1.5.17
NVLAP logo
The graphic version of the NVLAP acronym. Use of the NVLAP logo alone is reserved for NVLAP. Accredited laboratories are permitted to use the NVLAP logo only as part of the NVLAP symbol. (See also **NVLAP symbol** and Annex A.)

1.5.18
NVLAP symbol
The NVLAP logo combined with the NVLAP Lab Code and an acceptable caption. The NVLAP symbol is the graphical representation that an accredited laboratory is permitted to use in referencing its accredited status. (See also **NVLAP logo** and Annex A.)

1.5.19
objective evidence
Data supporting the existence or verity of something.

NOTE Objective evidence may be obtained through observation, measurement, test, or other means.

[ISO 9000:2000, 3.8.1]

1.5.20
precision
Repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

1.5.21
proficiency testing (laboratory)
Determination of laboratory testing performance by means of interlaboratory comparisons. (See also **interlaboratory comparisons**.)

NOTE For the purposes of this handbook, the term *laboratory proficiency testing* is taken in its widest sense and includes, for example:

a) Qualitative schemes—for example, where laboratories are required to identify a component of a test item.

b) Data transformation exercises—for example, where laboratories are furnished with sets of data and are required to manipulate the data to provide further information.

c) Single item testing—where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.

d) One-off exercises—where laboratories are provided with a test item on a single occasion.

e) Continuous schemes—where laboratories are provided with test items at regular intervals on a continuing basis.

f) Sampling—for example, where individuals or organizations are required to take samples for subsequent analysis.

[ISO/IEC Guide 43-1:1997, 3.6]

1.5.22
quality management system
System to establish a quality policy and quality objectives and to achieve those objectives.

[ISO 9000:2000, 2.2.3]

1.5.23
quality manual
Document specifying the quality management system of an organization.

[ISO 9000:2000, 2.7.4]

1.5.24
requirement
Provision that conveys criteria to be fulfilled.

[ISO/IEC Guide 2:2004, 7.5]

NOTE NVLAP requirements are mandatory and must be fulfilled to achieve and maintain accreditation. NVLAP requirements are contained in NIST Handbook 150, NIST Handbook 150-xx series, checklists, application forms, NVLAP Policy Guides, and NVLAP Laboratory Bulletins.

1.5.25
revocation
Removal of the accredited status of a laboratory if the laboratory is found to have violated the conditions for accreditation.

1.5.26
Scope of Accreditation
Document issued by NVLAP to a laboratory that has been granted NVLAP accreditation. The Scope of Accreditation lists the test methods or services, or calibration services, for which the laboratory is accredited. (See also **Certificate of Accreditation**.)

1.5.27
sub-facility
Laboratory operating under the technical direction and quality system of an accredited main facility.

NOTE NVLAP previously differentiated between *main facilities* and *sub-facilities*. With certain exceptions, this classification is no longer used by NVLAP.

1.5.28
suspension
Temporary removal by NVLAP of the accredited status of a laboratory for all or part of its scope of accreditation when it is determined (by the laboratory or by NVLAP) that the laboratory does not meet the conditions for accreditation.

1.5.29
test method
Defined technical procedure to determine one or more specified characteristics of a material or product.

1.5.30
traceability
Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

NOTE 1 The concept is often expressed by the adjective *traceable*.

NOTE 2 The unbroken chain of comparisons is called a *traceability chain.*

[VIM:1993, 6.10]

1.5.31
uncertainty of measurement
Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

NOTE 1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

NOTE 2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

NOTE 3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

[VIM:1993, 3.9]

1.5.32
uncertainty, Type A (evaluation of)
Method of evaluation of uncertainty by the statistical analysis of series of observations.

[GUM:1993, 2.3.2]

1.5.33
uncertainty, Type B (evaluation of)
Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

[GUM:1993, 2.3.3]

1.6 NVLAP information

NVLAP makes the following information publicly available through its web site, <www.nist.gov/nvlap>:

a) a description of the NVLAP program and the fields of accreditation offered by NVLAP;

b) information about the accreditation process and the requirements for accreditation (i.e., NIST Handbook 150, the NIST Handbook 150 series of program-specific handbooks, on-site assessment checklists, and laboratory bulletins);

c) the NVLAP fee policy and schedule;

d) a directory of NVLAP-accredited laboratories, which includes the name and address, accreditation effective and expiration dates, and scope of accreditation of each accredited laboratory;

e) information about mutual recognition arrangements to which NVLAP is a signatory;

f) various publications and forms for the use and benefit of accredited laboratories, NVLAP assessors and technical experts, and other interested parties.

NOTE This information is also available in paper format upon request.

1.7 Confidentiality

1.7.1 To the extent permitted by applicable laws, NVLAP will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.

1.7.2 In addition, NVLAP and the laboratory seeking accreditation acknowledge and agree that the accreditation assessments and proficiency testing work done by NVLAP is done in accordance with the authority granted to NIST by Title 15 United States Code Section 3710a. NVLAP and the laboratory further agree that to the extent permitted by law, NIST will protect information obtained during application, on-site assessment, proficiency testing, evaluation, and accreditation from disclosure pursuant to Title 15 USC 3710a(c)(7)(A) and (7)(B) for a period of five years after it is obtained.

1.7.3 For the first five years that laboratory information is held by NVLAP, the provisions of 1.7.1 and 1.7.2 will be in force. Information in NVLAP's possession for more than five years will continue to be held in confidence under the provisions of 1.7.1.

1.8 Referencing NVLAP accreditation (see also Annex A)

1.8.1 The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (see 1.5.18) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing or calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol.

1.8.2 NVLAP's policy is to control the use of the term and symbol and to ensure that accredited laboratories express their accredited status in a manner that is clear and accurate, and not misleading. This policy applies to test and calibration reports, letterheads, contracts, business cards, brochures, advertising, web sites, and any other use not specified herein.

1.8.3 NVLAP-accredited laboratories are authorized to use the term *NVLAP* and the NVLAP symbol to reference their accredited status, subject to the conditions presented in Annex A. Failure to comply with the conditions may result in suspension or revocation of a laboratory's accreditation.

1.8.4 Use of the term or logo by other persons and organizations shall be authorized in writing by NVLAP on a case-by-case basis.

1.8.5 Photographic and electronic copies of the logo are available from NVLAP upon request.

1.8.6 Use of the term and symbol by a laboratory whose status is suspended, revoked, or voluntarily terminated is specified in 3.10, 3.11, and 3.12.

1.9 Mutual recognition

1.9.1 NVLAP maintains signatory member status in several Mutual Recognition Arrangements (MRAs), including the International Laboratory Accreditation Cooperation (ILAC) MRA and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA. The ILAC MRA signatories represent more than 50 laboratory accreditation bodies in more than 40 countries around the world. APLAC is an Asia Pacific Economic Cooperation (APEC) Specialist Regional Body and a regional accreditation cooperation within ILAC. Through MRAs, NVLAP actively promotes the worldwide acceptance of test reports and calibration certificates from NVLAP-accredited laboratories.

1.9.2 As a signatory to the ILAC and APLAC MRAs, NVLAP meets the requirements of ISO/IEC 17011, ILAC/IAF A2, and other specific MRA requirements. In accordance with these MRAs, NVLAP-accredited laboratories meet the requirements of ISO/IEC 17025.

The MRAs serve to demonstrate the equivalence of the operation of signatory member accreditation bodies. As a consequence, the competence (within the accredited scopes) of laboratories accredited by these bodies is demonstrated and recognized by all signatory accreditation bodies. The international market place can then be more confident in accepting calibration certificates and test reports issued by accredited laboratories. Links to the texts of the MRAs are given on the NVLAP web site.

1.9.3 NVLAP may establish and develop special programs in response to requests from government agencies where it has been determined that the subject of accreditation is inherently a government function, especially where matters of national security are concerned. Some of these programs may not be covered by or subject to the requirements of any MRA. NVLAP will clearly identify such programs.

1.10 Accreditation of laboratories located outside of the United States

NVLAP has established policies and requirements for accreditation of laboratories located outside of the United States (see Annex D). These policies include the NVLAP commitment to abide by its mutual recognition arrangement obligations concerning cross-frontier accreditation activities.

1.11 Complaints

NVLAP employs a formal system to address complaints, which includes procedures for determining the validity of complaints, taking appropriate and effective actions, responding to complainants, and record-keeping. A complaint regarding the activities of NVLAP or of a NVLAP-accredited laboratory may be lodged by any person or organization. Information about the complaint should be put in writing and mailed, faxed, or e-mailed to NVLAP, along with supporting documentation, if available. A complaint concerning a NVLAP-accredited laboratory should first be addressed by the laboratory against which the complaint is lodged.

2 LAP establishment, development and implementation

2.1 Bases for establishment

2.1.1 General

NVLAP establishes LAPs in response to legislative or administrative actions or to requests from government agencies and private sector entities.

2.1.2 LAPs established through legislative or administrative actions

Upon receipt of a mandate for a LAP based on legislative or administrative action, NVLAP publishes a *Federal Register* notice stating the purpose and general scope of the LAP and identifying government agencies having oversight. The notice will also provide information to any interested party wishing to receive routine information on the development of the LAP.

2.1.3 LAPs established by request

2.1.3.1 A request to establish a LAP must be made in writing to the Chief of NVLAP. Each request must include:

a) the scope of the LAP in terms of products, testing services, or calibration services proposed for inclusion;

b) specific identification of the applicable standards and test methods, including appropriate designations, and the organizations or standards-writing bodies having responsibility for them;

c) a statement of the perceived need for the LAP;

d) an estimate of the anticipated demand for the program, including the number of laboratories that are likely to seek accreditation and an estimate of the number and nature of the users of such laboratories;

e) a statement of the extent to which the requestor will support necessary developmental aspects of the LAP with funding and personnel.

2.1.3.2 If the requestor is a federal, state, or local government agency, then the request should also include a description of the procedures followed or a citation of the specific authority used to identify a need for the LAP. For state and local government agencies, the request should also include a statement explaining why the LAP should be of national scope.

2.1.3.3 If the requestor is a private sector entity, then the request should also include a description of the process by which the request was developed (e.g., public meetings representing a balance of interests or input from interested parties).

2.1.3.4 NVLAP may request clarification of the information submitted in the request.

2.1.3.5 The Chief of NVLAP analyzes the request and any supporting information received, and after consultation with interested parties through public workshops and other means to ensure open participation, determines if there is need for the requested LAP.

2.1.3.6 The Chief of NVLAP may decide to either:

a) develop the LAP, if a need has been demonstrated and resources are available for the LAP's development;

b) defer development of the LAP until resources become available, if a need has been demonstrated and there are no resources for development; or

c) not develop the LAP, if a need has not been demonstrated.

2.1.3.7 The Chief of NVLAP shall inform the requestor and other interested parties of the LAP decision.

2.2 Development of technical requirements

2.2.1 Technical requirements for accreditation are specific for each LAP. They tailor the general requirements contained in Clauses 4 and 5 to the tests or calibrations, types of tests or calibrations, or standards covered by the LAP.

2.2.2 NVLAP develops the technical requirements based on relevant and impartial expert advice, ensuring that all interested parties have the opportunity for effective involvement. This advice may be obtained directly through public workshops or other suitable means.

2.2.3 When NVLAP organizes workshops or other means of collecting input, it provides the opportunity for all interested parties to attend and/or respond. One means typically used is announcing

such activities in the *Federal Register*. A summary of each workshop is prepared and made available upon request.

2.2.4 When any part of the development of technical requirements is sponsored or undertaken by another organization, NVLAP ensures that the same conditions for balanced representation and participation are fulfilled.

2.2.5 NVLAP communicates and consults with appropriate officials from those federal agencies that may have an interest in and may be affected by established LAPs, facilitating their effective and meaningful cooperation, input, and participation.

2.3 Announcing the establishment of a LAP

When NVLAP has completed the development of the technical requirements, it publishes a notice in the *Federal Register* announcing the establishment of the LAP. The notice identifies the scope of the LAP and advises laboratories how to apply for accreditation.

2.4 Adding to or modifying a LAP

2.4.1 A LAP may be added to, modified, or realigned based on either a written request or a need identified by NVLAP. Any person wishing to add or delete specific tests or calibrations, types of tests or calibrations, or standards may submit a request to NVLAP.

2.4.2 NVLAP may choose to make additions or modifications available for accreditation in a LAP when:

a) the additional tests or calibrations, types of tests or calibrations, or standards requested are directly relevant to the LAP;

b) it is feasible and practical to accredit testing or calibration laboratories for the additional tests or calibrations, types of tests or calibrations, or standards;

c) it is likely that laboratories will seek accreditation for the additional tests or calibrations, types of tests or calibrations, or standards.

2.4.3 The process for modifying a LAP depends on the nature of the modification. Significant changes to a LAP may be subject to a process similar to that described in 2.2. Minor changes (e.g., addition of methods for technologies already included in a LAP) may be handled in a less formal manner.

2.5 Termination of a LAP

2.5.1 The Chief of NVLAP may terminate a LAP when he/she determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP.

If the Chief of NVLAP determines that input from interested parties is necessary prior to making the determination to terminate a LAP, a *Federal Register* notice is published soliciting comments on the proposed termination.

In the event that the Chief of NVLAP decides to terminate a LAP, a notice will be published in the *Federal Register* setting forth the basis for that determination.

2.5.2 When a LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP. Technical expertise will be maintained by NVLAP while any accreditation remains effective.

3 Accreditation process

3.1 Application for initial accreditation (see 3.7 for renewal of accreditation)

3.1.1 General

A laboratory may apply for accreditation in any of the established LAPs. In order to initiate the accreditation process, the applicant laboratory shall submit a completed application along with a quality manual and relevant associated documentation, agree to conditions for accreditation, and pay all required fees.

3.1.2 Required information

3.1.2.1 An applicant laboratory shall complete an application for accreditation that includes, but is not limited to, the following information:

a) the legal name and full address of the laboratory;

b) the ownership of the laboratory;

c) the Authorized Representative's name and contact information;

d) the names, titles and contact information for laboratory staff nominated to serve as Approved Signatories of test or calibration reports that reference NVLAP accreditation;

e) an organizational chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;

f) a general description of the laboratory, including its facilities and scope of operation;

g) the requested scope of accreditation.

3.1.2.2 In addition to the application for accreditation, the laboratory shall provide its quality manual and related management system documentation to NVLAP for review (see 3.2.2).

3.1.3 Conditions for accreditation

By signing the application, the laboratory's Authorized Representative commits the laboratory to fulfill the conditions for accreditation listed in Annex C of this handbook. The Authorized Representative

should review all documents provided with the application package and become familiar with NVLAP requirements before signing the application.

3.1.4 Fees for accreditation

NVLAP operates on a cost-reimbursable basis from fees paid by participating laboratories. The NVLAP web site includes a description of the fee structure, fee refund policy, and current fee schedule. The fee schedule is reviewed annually and is revised as necessary. It is normally published following the beginning of the federal government fiscal year (October 1).

3.1.5 Review of application

Upon receipt of a laboratory's application for accreditation, NVLAP assigns a NVLAP Lab Code to the applicant laboratory; acknowledges receipt of the application in writing; reviews the information supplied by the laboratory for adequacy; requests further information, if necessary; confirms payment of fees; and specifies the next step(s) in the accreditation process.

3.2 Activities prior to on-site assessment

3.2.1 Assignment of assessor(s)

3.2.1.1 NVLAP selects assessors on the basis of their professional and academic achievements, experience in the field of testing or calibration, management experience, training, technical knowledge, and communications skills.

3.2.1.2 NVLAP assigns qualified assessors to evaluate all information collected from an applicant laboratory and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

3.2.1.3 Assessors are assigned to conduct an on-site assessment of a particular laboratory on the basis of how well their experience matches the type of testing or calibration to be assessed, as well as the absence of conflicts of interest. NVLAP provides the laboratory with a short biographical sketch of each assessor. A lead assessor will be assigned for team assessments. A laboratory may request an alternate assessor if a conflict of interest or prior business relationship exists.

3.2.2 Document review

3.2.2.1 The NVLAP assessor(s) assigned to an assessment reviews the laboratory's quality manual and related management system documentation submitted with the application to ensure they cover all aspects of the management system related to quality and, if followed, satisfy the requirements in this handbook. A NVLAP assessor may ask for additional management system documents and/or records in order to facilitate the review.

3.2.2.2 The NVLAP assessor may identify nonconformities in the documentation. Nonconformities are discussed with the Authorized Representative and the laboratory is given the opportunity to address them prior to the on-site assessment. Based on the document review, NVLAP may require that the laboratory address the nonconformities before the on-site assessment is scheduled. In such cases, the assessor will provide a list of the nonconformities to the laboratory in writing. Where the management system documentation requires significant revision, NVLAP may require that the laboratory improve its documentation and submit it for further review prior to proceeding with the accreditation process.

3.2.3 Scheduling of on-site assessment

3.2.3.1 The laboratory is contacted by the assessor to schedule a mutually acceptable date for the on-site assessment. An assessment normally takes one to five days depending on the proposed scope of accreditation. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory.

3.2.3.2 If a laboratory requires that its established assessment date be changed, it shall contact the assessor(s) and NVLAP. The laboratory is responsible for any costs associated with the date change.

3.2.3.3 Following initial accreditation, an on-site assessment will be conducted during the first renewal year, and every two years thereafter. Delay of assessments beyond these frequencies may affect a laboratory's accreditation status.

3.3 On-site assessment

3.3.1 Conduct of on-site assessment

3.3.1.1 An on-site assessment is conducted at all laboratory locations where tests or calibrations are performed. When tests or calibrations are performed at locations other than laboratory premises, NVLAP will determine the process for assessing these activities. The process may include observing tests or calibrations performed at these locations.

3.3.1.2 Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others. Checklists are normative documents that include and expand upon the requirements outlined in NIST Handbook 150 and the NIST Handbook 150-xx series.

3.3.1.3 At the beginning of the assessment, an opening meeting is conducted with management and laboratory personnel to explain the purpose of the on-site assessment and to discuss the schedule for the assessment activities.

3.3.1.4 During the assessment, the assessor examines the management system, reviews quality and technical records, examines equipment and facilities, interviews staff, observes demonstrations of testing or calibrations, and examines tests or calibration reports.

3.3.1.5 In order to conduct an appropriate assessment of competence, the assessor requires access to laboratory records for all staff members who routinely perform, or affect the quality of the testing or calibration for which accreditation is sought. This includes resumes, job descriptions of key personnel, training, and competency evaluations. The assessor need not be given information that violates individual privacy, such as salary, medical information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or in separate folders that contain only the information that the NVLAP assessor needs to review.

3.3.1.6 At the conclusion of the assessment, the assessor conducts a closing meeting to discuss observations and any nonconformities with the Authorized Representative and other responsible laboratory staff.

3.3.2 On-site assessment report

3.3.2.1 At the closing meeting, the assessor submits a written report on the compliance of the laboratory with the accreditation requirements. The report shall include as a minimum:

a) date(s) of assessment;

b) the names of the assessor(s) responsible for the report;

c) the names and addresses of all the laboratory sites assessed;

d) the assessed scope of accreditation or reference thereto;

e) comments and/or nonconformities cited by the assessor(s) on the compliance of the laboratory with the accreditation requirements;

f) a copy of completed checklists.

3.3.2.2 The Authorized Representative signs the report to acknowledge that the assessor has discussed its content and agrees to respond to NVLAP regarding resolution of nonconformities within 30 days (see 3.3.3).

3.3.2.3 The assessor forwards the original report to NVLAP and leaves a copy with the laboratory.

3.3.2.4 NVLAP is responsible for the content of the on-site assessment report, including the stating of nonconformities.

3.3.3 Nonconformity notification and resolution

3.3.3.1 A laboratory is informed of nonconformities during the on-site assessment, and nonconformities are documented in the on-site assessment report [see 3.3.2.1 e)].

3.3.3.2 A laboratory shall respond in writing to NVLAP within 30 days of the date of the on-site assessment report, addressing all documented nonconformities. The response shall be signed by the Authorized Representative and shall include documentation that the specified nonconformities have either been corrected or will be corrected as described in a plan of corrective actions. A corrective action plan must include a list of actions, target completion dates, and names of persons responsible for discharging those actions.

3.3.3.3 All nonconformities shall be satisfactorily resolved before initial accreditation may be granted. Should resolution take longer than 30 days, the laboratory may submit a corrective action plan in its initial response, and provide evidence of resolution when the planned actions have been completed. At that time, NVLAP will continue with the accreditation process.

3.3.3.4 Once accreditation has been granted, nonconformities affecting the outcome of tests or calibrations shall be addressed and corrected within the 30-day limit. Evidence shall be supplied which clearly demonstrates that actions taken fully resolve the nonconformities, thereby removing any concern as to the quality of results of the tests or calibrations conducted by the laboratory. Should resolution take longer than 30 days, the laboratory's accreditation may be subject to adverse action. In those cases where nonconformities do not directly affect the results of tests or calibrations, such as those related to record-keeping, NVLAP, at its discretion, may accept a plan of corrective action as satisfactory resolution.

When this occurs, laboratories are expected to submit sufficient objective evidence (see 1.5.19) to demonstrate that the nonconformities have been resolved according to the plan.

3.3.3.5 When responding to nonconformities, a laboratory shall reference each nonconformity by the item number shown on the on-site assessment checklist.

3.3.3.6 The laboratory may ask for clarification of a nonconformity from either the assessor during the closing meeting or the appropriate NVLAP Program Manager at any time. A laboratory may also challenge the validity of a nonconformity by writing to the appropriate NVLAP Program Manager.

3.3.3.7 If substantial nonconformities are cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All nonconformities and resolutions will be subject to thorough review and evaluation prior to an accreditation decision (see 3.5).

3.4 Proficiency testing

3.4.1 General

3.4.1.1 Proficiency testing, along with document review and on-site assessment, is an integral part of the NVLAP accreditation process. The performance of tests or calibrations and reporting of results from proficiency testing assists NVLAP in determining a laboratory's competence and the effectiveness of its management system. Information obtained from proficiency testing helps to identify technical problems in a laboratory.

3.4.1.2 NVLAP proficiency testing is consistent with the provisions contained in ISO/IEC Guide 43: 1997 (Parts 1 and 2), where applicable. Proficiency testing may be organized by NVLAP itself or by a NVLAP-approved provider of services.

3.4.1.3 When appropriate activities are available, NVLAP requires that each laboratory:

a) participate in one proficiency testing activity prior to gaining initial accreditation, and

b) participate in one proficiency testing activity related to each major sub-area of each LAP in which it is accredited at least every four years.

3.4.1.4 Information about proficiency testing programs, service providers, and frequency of participation is given in the program-specific handbooks and in applications for accreditation.

3.4.2 Types of proficiency testing

3.4.2.1 Proficiency testing requirements are associated with most fields of accreditation. Proficiency testing techniques vary depending on the nature of the test item, the method in use, and the number of laboratories participating.

3.4.2.2 Proficiency testing using interlaboratory comparisons may utilize randomly selected specimens from a batch of uniform material, selected specimens with known properties and results, artifacts with similar properties that have not been characterized, and one-of-a-kind artifacts.

3.4.2.3 Proficiency testing for calibration laboratories may involve comparison of the results of measurements made by the laboratory on selected instruments or artifacts with calibration results obtained independently by NVLAP.

3.4.3 Analysis and reporting

Proficiency testing data are analyzed by NVLAP and each participant's own results are reported only to them. Summary results are available upon request to other interested parties (e.g., professional societies and standards-writing bodies). The identity and performance of individual laboratories are kept confidential.

3.4.4 Proficiency testing nonconformities

3.4.4.1 Unsatisfactory participation in any NVLAP proficiency testing program is a technical nonconformity that must be resolved in order to obtain initial accreditation or maintain accreditation.

3.4.4.2 Proficiency testing nonconformities are defined as, but not limited to, one or more of the following:

a) failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

b) failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials;

c) failure to produce acceptable test or calibration results when using Standard Reference Materials or special artifacts whose properties are well-characterized and known to NVLAP.

3.4.4.3 NVLAP will notify the laboratory of proficiency testing nonconformities and actions to be taken to resolve the nonconformities. Denial or suspension of accreditation will result from failure to resolve nonconformities.

3.5 Accreditation decision

3.5.1 The Chief of NVLAP is responsible for all NVLAP accreditation actions, including granting, renewing, suspending, and revoking any NVLAP accreditation.

3.5.2 The accreditation decision is based on NVLAP review of information gathered during the accreditation process and a determination of whether or not all requirements for accreditation have been fulfilled.

3.5.3 The evaluation process considers the laboratory's record as a whole, including:

a) information provided on the application;

b) results of management system documentation review;

c) on-site assessment reports;

d) actions taken by the laboratory to correct nonconformities;

e) results of proficiency testing, if required.

3.5.4 Based on this evaluation, NVLAP determines whether or not a laboratory should be accredited. If the evaluation reveals nonconformities beyond those identified in the assessment process, NVLAP will inform the laboratory in writing of the nonconformities, and the laboratory shall respond as specified in 3.3.3. All nonconformities must be resolved to NVLAP's satisfaction before accreditation can be granted.

3.6 Granting accreditation

3.6.1 Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four accreditation renewal dates (January 1, April 1, July 1, or October 1) is assigned to the laboratory and is usually retained as long as the laboratory remains in the program. The renewal period is one year; accreditation expires and is renewable on the assigned date.

3.6.2 Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.

3.6.3 When accreditation is granted, NVLAP provides to the laboratory a Certificate of Accreditation and a Scope of Accreditation, which includes:

a) the name and address of the laboratory that has been accredited;

b) the scope of the accreditation, including:

— the tests or calibrations, or types of tests or calibrations, for which accreditation has been granted,

— for calibrations, the type of measurement performed, the measurement range, and best measurement uncertainty,

— for tests, the materials or products tested, the methods used, and the tests performed, and

— for specific tests and calibrations for which accreditation has been granted, the methods used defined by written standards or reference documents that have been accepted by the accreditation body;

c) the laboratory's Authorized Representative;

d) the effective and the expiration dates of the accreditation;

e) the NVLAP Lab Code.

3.7 Renewal of accreditation

3.7.1 Each accredited laboratory receives a renewal application package before the expiration date of its accreditation to allow sufficient time to complete the renewal process.

3.7.2 Fees for renewal are charged according to services required as listed on the NVLAP fee schedule.

3.7.3 Both the application and fees must be received by NVLAP prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

3.7.4 On-site assessments of currently accredited laboratories are performed in accordance with the procedures in 3.2 and 3.3. If nonconformities are found during the assessment of an accredited laboratory, the laboratory must submit a satisfactory response concerning resolution of nonconformities within 30 days of notification or face possible suspension or revocation of accreditation.

3.7.5 Undue delay in the resolution of nonconformities may necessitate another on-site assessment at additional cost to the laboratory.

3.8 Monitoring visits

3.8.1 In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

3.8.2 The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review nonconformity resolutions; verify reported changes in the laboratory's personnel, facilities, or operations; or administer proficiency testing, when appropriate.

3.9 Changes to scope of accreditation

A laboratory may request in writing changes to its scope of accreditation. If the laboratory requests additions to its scope, it must meet all NVLAP requirements for the additional tests or calibrations, types of tests or calibrations, or standards. The need for an additional on-site assessment and/or proficiency testing will be determined by NVLAP on a case-by-case basis.

A laboratory may also request deletions from it scope of accreditation. The deletions may be temporary (see 3.10) or permanent.

3.10 Suspension of accreditation

3.10.1 If it is determined that an accredited laboratory does not comply with the conditions for accreditation, NVLAP may suspend the laboratory's accreditation. That determination may be made by NVLAP (e.g., based on evidence obtained during the assessment process) or by the laboratory (e.g., by notifying NVLAP of a major change in accordance with Annex C, item f). Suspension can be for all or part of a laboratory's accreditation. Depending on the nature of the issues involved, NVLAP may also propose to revoke accreditation (see 3.11).

3.10.2 If a laboratory's accreditation is suspended, NVLAP notifies the laboratory of that action, stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated. A reassessment of the laboratory may also be required for reinstatement. Conditions of suspension include prohibiting the laboratory from using the NVLAP

symbol on its test or calibration reports, correspondence, and advertising during the suspension period in the area(s) affected by the suspension.

3.10.3 NVLAP will not require a suspended laboratory to return its Certificate and Scope of Accreditation, but the laboratory shall refrain from using the NVLAP symbol in the area(s) affected until such time as the problem(s) leading to the suspension has been resolved. When accreditation is reinstated, NVLAP will authorize the laboratory to resume testing or calibration activities in the previously suspended area(s) as an accredited laboratory.

3.11 Denial and revocation of accreditation

3.11.1 If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP informs the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision. Revocation can be for all or part of a laboratory's scope of accreditation.

3.11.2 The laboratory has 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST (see 3.13). If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the 30-day period.

3.11.3 If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation (see 3.12).

3.11.4 A laboratory whose accreditation has been revoked shall cease use of the NVLAP symbol on any of its reports, correspondence, or advertising related to the area(s) affected by the revocation. If the revocation is total, NVLAP will instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP symbol from all test or calibration reports, correspondence, and advertising. If the revocation affects only some, but not all of the items listed on a laboratory's Scope of Accreditation, NVLAP will issue a revised Scope that excludes the revoked area(s) in order that the laboratory might continue operations in accredited areas.

3.11.5 A laboratory whose accreditation has been denied or revoked, may reapply (see 3.1) and be accredited if the laboratory:

a) completes the assessment and evaluation process;

b) meets the NVLAP conditions for accreditation.

3.12 Voluntary termination of accreditation

3.12.1 A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so.

3.12.2 Upon receipt of a request for termination, NVLAP will terminate the laboratory's accreditation, notify the laboratory that its accreditation has been terminated, and instruct the laboratory to return its Certificate and Scope of Accreditation and to remove the NVLAP symbol from all test and calibration reports, correspondence, and advertising.

3.12.3 A laboratory whose accreditation has been voluntarily terminated may reapply (see 3.1) and be accredited if the laboratory:

a) completes the assessment and evaluation process;

b) meets the NVLAP conditions for accreditation.

3.13 Appeals

3.13.1 A laboratory has the right to appeal any adverse decision made by NVLAP. Such decisions include refusal to accept an application; refusal to proceed with an assessment; corrective action requests; changes in scope of accreditation; decision to deny, suspend, or revoke accreditation; and any other action that impedes the attainment of accreditation.

3.13.2 Appeals are handled by the next higher level in the organization. Appeals of decisions made by NVLAP Program Managers (e.g., acceptance of an application, corrective action requests) are handled by the Chief of NVLAP. Appeals of decisions made by the NVLAP Chief (e.g., final accreditation, revocation of accreditation) are handled by the Director of NIST. In some cases, an advisory panel of experts may be called to address appeals of a technical nature.

3.13.3 The party assigned to investigate the appeal decides on the validity of the appeal and, if appropriate, renders a decision. NVLAP advises the appellant of the outcome of these deliberations and any recourse for further appeal.

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.

4.1.4 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.

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 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.

4.1.5 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);

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;

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;

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;

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;

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;

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.

4.1.6 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.

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;

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.

4.2.3 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.

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.

4.2.6 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.

4.3.2 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.

4.3.2.2 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 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).

4.3.3 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 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.

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

NOTE 2 The review of capability should establish that the 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 customer 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 customer relating to the customer'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 customer, provided that the customer's requirements

remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

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

4.4.4 The customer 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.

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.

4.5.3 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.

4.6.3 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.

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.

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.

4.7.2 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:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

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

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

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.

4.9.2 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.

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.

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.

4.11.2 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 customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

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.

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

4.11.4 Monitoring of corrective actions

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

4.11.5 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.

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 of 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.

4.12.2 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.

4.13.1.2 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.

4.13.1.3 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.

4.13.2 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. 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.

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.

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

4.13.2.3 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.

4.14.2 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.

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

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

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.

4.15.2 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.

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 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.

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.

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. The effectiveness of the training actions taken shall be evaluated.

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.

5.2.4 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;

— 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 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. 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 Accommodation 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.

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.

5.3.2 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.

5.3.3 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 method 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.

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

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

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. 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.

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. 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.

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

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.

5.4.4 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.

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 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.

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 customers' 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 customer 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.

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 customer;

— the existence of narrow limits on which decisions on conformity 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.

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.*

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) (see 1.4).

5.4.7 Control of data

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

5.4.7.2 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;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

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.

5.5.2 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).

5.5.3 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.

5.5.5 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;

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.

5.5.6 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.

5.5.7 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).

5.5.8 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.

5.5.9 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.

5.5.10 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.

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.

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 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*).

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. 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).

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:

— 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.

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

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

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.

5.6.3.2 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.

5.6.3.3 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.

5.6.3.4 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.

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 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.

5.7.3 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.

5.8.2 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.

5.8.3 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.

5.8.4 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.

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

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:

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.

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.

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.

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.

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”);

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;

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;

e) identification of the method used;

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

g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;

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

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.

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.

5.10.3 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;

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

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

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

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;

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).

5.10.4.2 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.

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.

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 customer. 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 customer. Such dialogue should be written down.

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.

5.10.7 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).

5.10.8 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.

5.10.9 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.

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.

Annex A
(normative)

Referencing NVLAP accreditation

A.1 Conditions for referencing the NVLAP term, logo, and symbol

The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (NVLAP logo with approved caption) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing or calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol.

In order to become and remain accredited, laboratories shall comply with the following conditions pertaining to the use of the term *NVLAP*, the NVLAP logo, and NVLAP symbol. Failure to comply with these conditions may result in suspension or revocation of a laboratory's accreditation.

a) An applicant laboratory that has not yet achieved accreditation may make reference to its applicant status. If the NVLAP Lab Code is used, it shall be accompanied by a statement accurately reflecting the laboratory's status. An applicant laboratory shall not use the NVLAP term, logo or symbol in a manner that implies accreditation.

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

c) The term and/or symbol shall not be used in a manner that brings NVLAP into disrepute or misrepresents a laboratory's scope of accreditation or accredited status.

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

e) When the NVLAP symbol is used to reference a laboratory's accredited status, it shall be comprised of the NVLAP logo and 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) When the NVLAP symbol is used, the form of the NVLAP logo must conform to the following guidelines:

   — The logo shall stand by itself and shall not be combined with any other logo, symbol, or graphic.

   — The aspect ratio (width to height) shall be 2.25 to 1 (Fig. 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.

— 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 symbol 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.

h) When the term and/or symbol 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. 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."

i) When the term and/or symbol 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. 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. 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.

j) Each test or calibration report bearing the term and/or symbol 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) When used in a contract or proposal, the term and/or symbol shall be accompanied by a description of the laboratory's scope of accreditation and current accreditation status.

l) Laboratories shall not use the terms *certified* or *registered* when referencing their NVLAP accreditation or conformance to ISO/IEC 17025 requirements. The correct term is *accredited*.

A.2 Joint ISO-ILAC-IAF Communiqué

On June 18, 2005, a Joint ISO-ILAC-IAF Communiqué on the Management Systems Requirements of ISO/IEC 17025:2005 was issued. The text of this communiqué reads as follows:

"A laboratory's fulfillment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2000 *Quality Management Systems–Requirements* and are aligned with its pertinent requirements."

Laboratories may find this language useful when discussing the issue of ISO 9001 certification versus ISO/IEC 17025 accreditation with its customers. A copy of the Communiqué may be found on the NVLAP web site.

A.3 Approved symbols

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.

Height = 1

Width = 2.25 (does not include registration mark)

Aspect ratio of 2.25:1

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

Annex B
(normative)

Implementation of traceability policy in accredited laboratories

B.1 Policy overview

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 the SI (the International System of Units) through standards maintained by the National Institute of Standards and Technology (NIST) or other internationally recognized national metrology institutes (NMIs). 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.

Internationally recognized NMIs are those that are signatory to the Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA) titled "Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes" and that have the necessary calibration services listed in Appendix C of the MRA, Calibration and Measurement Capabilities (CMC). For more details on the CIPM MRA and the CMC database, please see <http://www.bipm.org/en/convention/mra/> or visit the NVLAP web site.

B.2 General

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.

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.

B.3 Demonstration of traceability

B.3.1 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.

B.3.2 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.

B.3.3 NVLAP-accredited laboratories that do not demonstrate traceability as described in B.3.1 or B.3.2, 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.

B.3.4 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:

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:

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

    2) the calibration procedure(s) used by the calibration service provider,

    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),

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

    5) the environmental conditions of the laboratory,

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

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

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;

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

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.3.5 If traceable calibration services are 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.

Annex C
(normative)

Conditions for accreditation

To become accredited and maintain accreditation, a laboratory shall agree in writing to comply with the NVLAP conditions for accreditation. The laboratory's Authorized Representative (see 1.5.4) shall sign the NVLAP General Application Form to attest that the information in the application is correct and to commit the laboratory to fulfill the following conditions:

a) comply at all times with the NVLAP requirements for accreditation as set forth in NIST Handbook 150 and relevant technical documents;

b) fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

c) participate in proficiency testing as required;

d) follow NVLAP conditions for referencing accreditation status (see Annex A);

e) resolve all nonconformities;

f) report to NVLAP within 30 days any major changes that affect the laboratory's:

— legal, commercial, organizational, or ownership status,

— organization and management; e.g., key managerial staff,

— policies or procedures, where appropriate,

— location,

— personnel, equipment, facilities, working environment or other resources, where significant,

— Authorized Representative or Approved Signatories, or

— other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements of this handbook and relevant technical documents.

Annex D

(normative)

Accreditation of laboratories located outside of the United States

D.1 Additional requirements for laboratories located outside of the United States

D.1.1 If laboratory documents are not in English, or laboratory personnel do not speak English, it is the responsibility of the laboratory to provide an interpreter(s), subject to NVLAP approval, to assist the NVLAP assessors during the on-site assessment. The interpreter(s) will assist the assessors with conversing directly with laboratory management and technical staff and with reviewing laboratory documentation. Documents such as quality manuals, procedures, standards, and test reports sent to NVLAP prior to on-site assessments or reviewed during assessments may be required to be provided in English to verify compliance with NVLAP requirements.

D.1.2 If the fees listed on the NVLAP fee schedule do not cover the cost of an on-site assessment, the laboratory will be responsible for all additional costs; e.g., travel by NVLAP assessors, shipment of proficiency testing materials to the laboratory, and additional administrative expenses. To ensure that the initial or renewal application is processed without delay, payment (in U.S. currency) of the appropriate fees should accompany the application. When all the additional costs associated with the application have been identified, an invoice for any additional fee amount owed will be sent to the laboratory.

D.1.3 Pursuant to U.S. Department of Commerce export regulations and/or U.S. Department of State International Traffic in Arms Regulations, certain technologies, equipment, data and software may not be exported from the United States to certain foreign destinations without first obtaining an export license or official approval. If a laboratory uses or possesses regulated technologies, NVLAP requires that the laboratory possess, and show upon request, the appropriate license or official U.S. Government approval. For export and license information for the Department of Commerce regulations, see the Bureau of Industry and Security web site, <http://www.bis.doc.gov/PoliciesAndRegulations/index.htm>. For export and license information regarding the State Department International Traffic in Arms Regulations, see the Directorate of Defense Trade Controls web site, <http://www.pmdtc.org>.

D.2 Cross-frontier policy

D.2.1 To meet its obligations as a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (Arrangement), NVLAP has a cross-frontier accreditation policy in harmony with ILAC-G21:2002, *Cross Frontier Accreditation—Principles for Avoiding Duplication*. When a laboratory located outside of the United States applies for NVLAP accreditation, it is NVLAP policy to communicate with and cooperate with, whenever possible, ILAC Arrangement signatory laboratory accreditation bodies in the economy of the applicant laboratory.

The purpose of the cross-frontier policy is to ensure that test reports and calibration certificates issued by accredited laboratories will be accepted worldwide and to increase confidence among laboratory accreditation bodies worldwide while reducing the burden on laboratories caused by duplicate accreditations.

D.2.2 NVLAP will discuss this policy with applicant laboratories before NVLAP contacts any laboratory accreditation bodies in the laboratory's own economy.