National Institute of Standards and Technology

NVLAP

National Voluntary Laboratory Accreditation Program

NVLAP PROCEDURES

U.S. CODE OF FEDERAL REGULATIONS
TITLE 15 - Commerce and Foreign Trade
SUBTITLE A - Office of the Secretary of Commerce
CHAPTER II - National Institute of Standards and Technology
PART 7 - National Voluntary Laboratory Accreditation Program Procedures

NISTIR 4493

NOVEMBER 1990

U.S. Department of Commerce
National Institute of Standards and Technology
Gaithersburg, Maryland 20899

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Jeffrey Horlick
Hazel M. Richmond

National Voluntary Laboratory
Accreditation Program

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U.S. DEPARTMENT OF COMMERCE
Robert A. Mosbacher, Secretary

National Institute of Standards and Technology
Dr. John W. Lyons, Director

INTRODUCTION

The NVLAP Procedures are Part 7 of Title 15 of the U.S. Code of Federal Regulations (CFR) and were first published in the Federal Register on February 25, 1976. The Procedures became effective on that date. The Federal Register notice stated: "The purpose of this part (...of the CFR...) is to establish procedures under which a National Voluntary Laboratory Accreditation Program will function."

A revision of the Procedures was published in the Federal Register on November 8, 1984 to become effective on December 10, 1984. The Register notice cites four major reasons for revising the NVLAP Procedures:

> "First, the steps involved in establishing a laboratory accreditation program (LAP) and operating NVLAP needed to be streamlined to increase efficiency and to reduce costs. Budget constraints made this streamlining imperative. Second, large portions of Parts 7a, 7b, and 7c were repetitious. Consolidating the comparable sections of each part into one section reduces the total amount of text and makes the NVLAP Procedures easier to read and follow. Third, the accreditation criteria need to be updated in light of the recent developments by national and international bodies, particularly as reflected in the International Organization for Standardization (ISO) document ISO Guide 25 (revised), "General Requirements for the Technical Competence of Testing Laboratories," and ASTM E548, "Criteria for the Evaluation of Testing and Inspection Agencies." Fourth, since interaction with national laboratory accreditation systems of other countries is becoming increasingly important in fostering international trade, reciprocal recognition of accredited laboratories requires similar criteria and procedures."

The Omnibus Trade and Competitiveness Act of 1988 (Public Law No. 100-418) renamed the National Bureau of Standards as the National Institute of Standards and Technology. A subsequent reorganization of NIST transferred certain responsibilities of the Office of Product Standards Policy (OPSP) to the National Voluntary Laboratory Accreditation Program (NVLAP). On September 12, 1990, authority was granted to amend the NVLAP Procedures to reflect the name change and the transfer of responsibilities.

15 CFR Part 7

Published: February 25, 1976
Revised: December 10, 1984
Amended: September 12, 1990

CODE OF FEDERAL REGULATIONS
TITLE 15 - COMMERCE AND FOREIGN TRADE
SUBTITLE A - OFFICE OF THE SECRETARY OF COMMERCE
CHAPTER II - NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
PART 7 - NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM PROCEDURES
(15 CFR Part 7)

Effective: December 1984, Amended: September 1990

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SUBPART A - GENERAL INFORMATION

Sec. 7.1 Purpose

The purpose of Part 7 is to set out procedures under which the National Voluntary Laboratory Accreditation Program (NVLAP) will function.

Sec. 7.2 Description and goal of NVLAP

(a) NVLAP is a system for accrediting testing laboratories found competent to perform specific tests or types of tests. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (Section 7.32) and to conform to the criteria (Section 7.33) as tailored and interpreted for the test methods, types of test methods, products, services, or standards for which the laboratory seeks accreditation.

(b) NVLAP is a voluntary system which:

(1) Provides national recognition for competent laboratories;
(2) Provides laboratory management with a quality assurance check of the performance of their laboratories;
(3) Identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems; and
(4) Provides laboratories with guidance from technical experts to aid them in reaching a higher level of performance resulting in the generation of improved engineering and product information.

(c) NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. The specific test methods, types of test methods, products, services, or standards to be included in a LAP must be requested. The Director of the National Institute of Standards and Technology (NIST) does not unilaterally propose or decide the scope of a LAP. Communication with other laboratory accreditation systems is fostered to encourage development of common criteria and approaches to accreditation and to promote the domestic, foreign, and international acceptance of test data produced by the accredited laboratories.

(d) NVLAP is carried out to be compatible with and recognized by domestic, foreign, and international systems for laboratory accreditation so as to enhance the universal acceptance of test data produced by NVLAP-accredited laboratories.

Sec. 7.3 Layout of procedures

Subpart A describes considerations which relate in general to all aspects of NVLAP. Subpart B describes how new LAPs are requested, developed and announced, and how LAPs are terminated. Subpart C describes procedures for accrediting laboratories. Subpart D sets out the conditions and criteria for NVLAP accreditation.

Sec. 7.4 Definitions

Accreditation criteria means a set of requirements used by an accrediting body which a laboratory must meet to be accredited.

Advisory Committee means the National Laboratory Accreditation Advisory Committee.

Director of NIST means the Director of the National Institute of Standards and Technology or designee.

Laboratory accreditation is a formal recognition that a testing laboratory is competent to carry out specific tests or types of tests.

Laboratory assessment means the on-site examination of a testing laboratory to evaluate its compliance with specified criteria.

LAP means a laboratory accreditation program established and administered under NVLAP.

NIST means the National Institute of Standards and Technology.

NVLAP means the National Voluntary Laboratory Accreditation Program.

Person means associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies--as well as divisions thereof--and individuals.

Product means a type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing means methods of checking laboratory testing performanc by means of interlaboratory tests.

Testing laboratory is a laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products.

Traceability of the accuracy of measuring instruments is a documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

Sec. 7.5 Establishment and functions of a National Laboratory Accreditation Advisory Committee

(a) The Director of NIST shall establish a National Laboratory Accreditation Advisory Committee (Advisory Committee) and appoint its chairperson and members following the filing of a charter setting forth the purpose and nature of the committee.

(b) The composition of the Advisory Committee will be approximately as follows:
   (1) One-third from federal, state and local governments;
   (2) One-third from testing laboratories (independent, corporate, and academic); and
   (3) One-third from users of testing laboratories, academia, consultants, and consumers.

(c) The Advisory Committee will be governed by the Federal Advisory Committee Act (5 U.S.C. App. 2). Persons selected to serve on the Advisory Committee may be paid travel expenses and per diem.

(d) The Advisory Committee shall function solely in an advisory capacity with functions to include the following:
   (1) Assessing the future and continuing role of NVLAP and laboratory accreditation in terms of the changing requirements of industry and commerce;
   (2) Advising on the technical requirements of testing laboratories and those served by the laboratories;
   (3) Advising on the necessity and implementation of proposed amendments to the criteria referenced in Section 7.33;
   (4) Evaluating the interaction of other laboratory accreditation systems with NVLAP; and
   (5) Reviewing and giving recommendations on the development of international accreditation activities and assessing the impact of such activities on NVLAP.

(e) The Advisory Committee shall meet periodically as called upon or may be consulted through periodic mailings.

Sec. 7.6 User information

(a) NVLAP shall prepare and publish at least once each year a directory of accredited laboratories.

(b) NVLAP shall periodically prepare supplements to the directory of accredited laboratories covering new accreditation actions taken, including initial accreditations, renewals, suspensions, terminations, and revocations.

Sec. 7.7 Information collection requirements

The information collection requirements contained in these procedures have been approved by the Office of Management and Budget under the Paperwork Reduction Act and have been assigned OMB control number 0693-0003.

SUBPART B - ESTABLISHING A LAP

Sec. 7.11 Requesting a LAP

(a) Any person may request the Director of NIST to establish a LAP.

(b) Each request must be in writing and must include:
- (1) The scope of the LAP in terms of products or testing services proposed for inclusion;
- (2) Specific identification of the applicable standards and test methods including appropriate designations, and the organizations or standards writing bodies having responsibility for them;
- (3) A statement of need for the LAP including:
  - (i) Technical and economic reasons why the LAP would benefit the public interest;
  - (ii) Evidence of a national need to accredit testing laboratories for the specific scope beyond that served by an existing laboratory accreditation program in the public or private sector;
  - (iii) An estimate of the number of laboratories that may seek accreditation; and
  - (iv) An estimate of the number and nature of the users of such laboratories; and
- (4) A statement of the extent to which the requestor is willing to support necessary developmental aspects of the LAP with funding and personnel.

(c) NVLAP may request clarification of the information required by paragraph (b) of this section.

(d) Before determining the need for a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request if the request complies with Section 7.11(b). The notice will:
- (1) Describe the scope of the requested LAP;
- (2) Indicate how to obtain a copy of the request; and
- (3) State that anyone may submit comments on the need for a LAP to NVLAP within 60 days of the date of the notice.

Sec. 7.12 LAP development decision

(a) The Director of NIST shall establish all LAPs on the basis of need. Government agencies and private sector organizations may establish the need by using Sections 7.13 and 7.14.

(b) After receipt of the request, the Director of NIST shall analyze it to determine if a need exists for the requested LAP. In making this determination, the Director of NIST shall consider the following:
- (1) The needs and scope of the LAP initially requested;
- (2) The needs and scope of the user population;
- (3) The nature and content of other relevant public and private sector laboratory accreditation programs;
- (4) Compatibility with the criteria referenced in Section 7.33;
- (5) The importance of the requested LAP to commerce, consumer well-being, or the public health and safety;

(6) The economic and technical feasibility of accrediting testing laboratories for the test methods, types of test methods, products, services, or standards requested; and
(7) Recommendations from written comments for altering the scope of the requested LAP by adding or deleting test methods, types of test methods, products, services, or standards.

(c) If the Director of NIST decides that a need has been demonstrated, and if resources are available to develop a LAP, NVLAP shall notify interested persons of the decision to proceed with development of a LAP.

(d) If the Director of NIST concludes that there is a need for a LAP but there are no resources for development, NVLAP shall notify the requestor and other interested persons of the decision not to proceed until resources become available.

(e) If the Director of NIST decides that a need for a LAP has not been demonstrated, NVLAP shall notify the requestor and other interested persons of the decision and the reasons not to proceed with development of a LAP.

Sec. 7.13 Request from a government agency

(a) Any federal, state or local agency responsible for regulatory or public service programs established under statute or code, which has determined a need to accredit testing laboratories within the context of its programs, may request the Director of NIST to establish a LAP.

(b) Each request must be in writing and must include the information required in Section 7.11(b) and:
(1) A description of the procedures followed or a citation of the specific authority used to determine the need for a LAP; and
(2) For state and local government agencies, a statement of why the LAP should be of national scope.

(c) NVLAP may request clarification of the information required by paragraph (b) of this section.

(d) Before deciding to proceed with development of a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting government agency within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision to proceed or not to proceed with development of a LAP.

Sec. 7.14 Request from a private sector organization

(a) Any private sector organization which has determined a need to accredit testing laboratories for specific products or testing services, may request the Director of NIST to establish a LAP if it uses procedures meeting the following conditions:

(1) Public notice of meetings and other activities including requests for LAPs is provided in a timely fashion and is distributed to reach the attention of interested persons;

(2) Meetings are open and participation in activities is available to interested persons;

(3) Decisions reached by the private sector organization in the development of a request for a LAP represent substantial agreement of the interested persons;

(4) Prompt consideration is given to the expressed views and concerns of interested persons;

(5) Adequate and impartial mechanisms for handling substantive and procedural complaints and appeals are in place; and

(6) Appropriate records of all meetings are maintained and the official procedures used by the private sector organization to make a formal request for a LAP are made available upon request to any interested person.

(b) Each request must be in writing and must include the information required in Section 7.11(b) and a description of the way in which the organization has met the conditions specified in paragraph (a) of this section.

(c) NVLAP may request clarification of the information required by paragraph (b) of this section.

(d) Before deciding to proceed with development of a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting private sector organization within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision to proceed or not to proceed with development of a LAP.

Sec. 7.15 Development of technical requirements

(a) Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in Section 7.33 to the test methods, types of test methods, products, services, or standards covered by the LAP.

(b) NVLAP shall develop the technical requirements based on expert advice. This advice may be obtained through one or more informal public workshops or other suitable means.

(c) NVLAP shall make every reasonable effort to ensure that the affected testing community within the scope of the LAP is informed of any planned workshop. Summary minutes of each workshop will be prepared. A copy of the minutes will be made available for inspection and copying at the NIST Records Inspection Facility.

Sec. 7.16 Coordination with federal agencies

As a means of assuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by established LAPs, NVLAP shall communicate and consult with appropriate officials within those agencies.

Sec. 7.17 Announcing the establishment of a LAP

(a) When NVLAP has completed the development of the technical requirements of the LAP and established a schedule of fees for accreditation, NVLAP shall publish a notice in the FEDERAL REGISTER announcing the establishment of the LAP.

(b) The notice will:
   (1) Identify the scope of the LAP; and
   (2) Advise how to apply for accreditation.

(c) NVLAP shall establish fees in amounts that will enable the LAP to be self-sufficient. NVLAP shall revise the fees when necessary to maintain self-sufficiency.

Sec. 7.18 Adding to an established LAP

Written requests will be considered from any person wishing to add specific standards, test methods, or types of test methods to an established or developing LAP. NVLAP may choose to make them available for accreditation under a LAP when:

(a) The additional standards, test methods, or types of test methods requested are directly relevant to the LAP;

(b) It is feasible and practical to accredit testing laboratories for the additional standards, test methods, or types of test methods; and

(c) It is likely that laboratories will seek accreditation for the additional standards, test methods, or types of test methods.

Sec. 7.19 Termination of a LAP

(a) The Director of NIST may terminate a LAP when the Director of NIST determines that a need no longer exists to accredit testing laboratories for the products or testing services covered under the scope of the LAP. In the event that the Director of NIST proposes to terminate a LAP, a notice will be published in the FEDERAL REGISTER setting forth the basis for that determination.

(b) The notice published under paragraph (a) of this section will provide a 60-day period for submitting written comments on the proposal to terminate the LAP. All written comments will be made available for public inspection and copying at the NIST Records Inspection Facility.

(c) After the comment period, the Director of NIST shall determine if public support exists for the continuation of the LAP. If public comments support the continuation of the LAP, the Director of NIST shall publish a FEDERAL REGISTER notice announcing the continuation of the LAP. If public support does not exist for continuation, the LAP will be terminated effective 90 days after the date of the published notice of intent to terminate the LAP.

(d) If the LAP is terminated, NVLAP shall no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted will remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP.

SUBPART C - ACCREDITING A LABORATORY

Sec. 7.21 Applying for accreditation

(a) Any laboratory may request an application for accreditation in any established LAPs in accordance with instructions provided in notices announcing the formal establishment of LAPs.

(b) Upon receipt of a laboratory's application, NVLAP shall:
   (1) Acknowledge receipt of the application;
   (2) Request further information, if necessary;
   (3) Confirm payment of fees before proceeding with the accreditation process; and
   (4) Specify the next step(s) in the accreditation process.

(c) In accepting an application from a foreign-based laboratory, NVLAP shall take into consideration the policy of the host government regarding the acceptance of test data from laboratories accredited by NVLAP or other foreign accreditation systems.

Sec. 7.22 Assessing and evaluating a laboratory

(a) Information used to evaluate a laboratory's compliance with the conditions for accreditation set out in Section 7.32, the criteria for accreditation set out in Section 7.33, and the technical requirements established for each LAP will include:
   (1) On-site assessment reports;
   (2) Laboratory responses to identified deficiencies; and
   (3) Laboratory performance on proficiency tests.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories by contract or other means in such a way as to minimize potential conflicts of interest.

(c) NVLAP shall inform each applicant laboratory of any action(s) that the laboratory must take to complete the requirements for assessment and evaluation.

Sec. 7.23 Granting and renewing accreditation

(a) NVLAP, after reviewing an evaluation report, shall grant or renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, no later than 30 days following the date of submittal of the report. If accreditation action is not taken within this time limit, NVLAP shall notify the laboratory stating the reasons for the delay.

(b) If accreditation is granted or renewed, NVLAP shall:
   (1) Provide a certificate of accreditation to the laboratory;
   (2) Identify the scope and terms of the laboratory's accreditation;

(3) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and
(4) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

(d) If an accredited laboratory fails to complete the assessment and evaluation process for renewal before its accreditation expires, NVLAP shall notify the laboratory stating that its accreditation has expired and reiterating the action(s) the laboratory must take to renew its accreditation.

Sec. 7.24 **Denying, suspending, and revoking accreditation**

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to request a hearing under the provisions of 5 U.S.C. 556. If the laboratory requests a hearing, the proposed denial or revocation will be stayed pending the outcome of the hearing held under provisions of 5 U.S.C. 556. 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 that 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of his/her intent to revoke its accreditation. If accreditation is suspended, NVLAP shall notify 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. Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test report during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:
(1) Completes the assessment and evaluation process; and
(2) Meets the conditions and criteria for accreditation that are set out in Subpart D.

Sec. 7.25 Voluntary termination of accreditation

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. NVLAP shall terminate the laboratory's accreditation and shall notify the laboratory stating that its accreditation has been terminated in response to its request.

SUBPART D - CONDITIONS AND CRITERIA FOR ACCREDITATION

Sec. 7.31 Application of accreditation conditions and criteria

(a) To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in Section 7.32 and the criteria set out in Section 7.33 as tailored for specific LAPs.

(b) The conditions leading to accreditation include acceptance of the responsibilities of an accredited laboratory and requirements for information disclosure.

(c) The criteria are tailored and interpreted for the test methods, types of test methods, products, services or standards of the relevant LAP. These tailored criteria are the technical requirements for accreditation developed through the procedures of Section 7.15.

(d) In applying the conditions, criteria, and technical requirements for accreditation, NVLAP shall not:

(1) Prohibit accreditation solely on the basis of a laboratory's affiliation or nonaffiliation with manufacturing, distributing, or vending organizations, or because the laboratory is a foreign firm; or

(2) Develop, modify, or promulgate test methods, standards, or comparable administrative rules.

Sec. 7.32 Conditions for accreditation

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) Be assessed and evaluated initially and on a periodic basis;

(2) Demonstrate, on request, that it is able to perform the tests representative of those for which it is seeking accreditation;

(3) Pay all relevant fees;

(4) Participate in proficiency testing as required.

(5) Be capable of performing the tests for which it is accredited according to the latest version of the test method within one year after its publication or within another time limit specified by NVLAP;

(6) Limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted;

(7) Limit all its test work or services for clients to those areas where competence and capacity are available;

(8) Limit advertising of its accredited status to letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications, and use the NVLAP logo under guidance provided by NVLAP;

(9) Inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NIST;

(10) Maintain records of all actions taken in response to testing complaints for a minimum of one year;

(11) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected;
(12) Report to NVLAP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and
(13) Return to NVLAP the certificate of accreditation for possible revision or other action should it:
  (i) Be requested to do so by NVLAP;
  (ii) Voluntarily terminate its accredited status; or
  (iii) Become unable to conform to any of these conditions the applicable criteria of Section 7.33 and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:
(1) Legal name and full address;
(2) Ownership of the laboratory;
(3) Organization chart defining relationships that are relevant to performing testing covered in the accreditation request;
(4) General description of the laboratory, including its facilities and scope of operation;
(5) Name and telephone number of the authorized representative of the laboratory;
(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of test reports that reference NVLAP accreditation; and
(7) Other information as may be needed for the specific LAP(s) in which accreditation is sought.

Sec. 7.33 Criteria for accreditation

(a) Quality System
(1) The laboratory shall operate under an internal quality assurance program appropriate to the type, range, and volume of work performed. The quality assurance program must be designed to ensure the required degree of accuracy and precision of the laboratory's work and should include key elements of document control, sample control, data validation, and corrective action. The quality assurance program must be documented in a quality manual or equivalent (e.g., operations notebook) which is available for use by laboratory staff. A person(s) must be identified as having responsibility for maintaining the quality manual.

(2) The quality manual must include as appropriate:
  (i) The laboratory's quality assurance policies including procedures for corrective action for detected test discrepancies;
  (ii) Quality assurance responsibilities for each function of the laboratory;
  (iii) Specific quality assurance practices and procedures for each test, type of test, or other specifically delineated function performed;

(iv) Specific procedures for retesting, control charts, reference materials, and inter-laboratory tests; and

(v) Procedures for dealing with testing complaints.

(3) The laboratory shall periodically review its quality assurance system by or on behalf of management to ensure it's continued effectiveness. These reviews must be recorded with details of any corrective action taken.

(b) Staff

(1) The laboratory shall:

(i) Be staffed by individuals having the necessary education, training, technical knowledge, and experience for their assigned functions; and

(ii) Have a job description for each professional, scientific, supervisory and technical position, including the necessary education, training, technical knowledge, and experience.

(2) The laboratory shall document the test procedures each staff member has been assigned to perform.

(3) The laboratory shall have a description of its training program for ensuring that new or untrained staff are able to perform tests properly and uniformly to the requisite degree of precision and accuracy.

(4) The laboratory shall be organized:

(i) So that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work; and

(ii) In such a way that staff members are aware of both the extent and the limitation of their area of responsibility.

(5) The laboratory shall have a technical manager (or similar title) who has overall responsibility for the technical operations of the laboratory.

(6) The laboratory shall have one or more signatories approved by NVLAP to sign test reports that reference NVLAP accreditation. Approved signatories shall:

(i) Be competent to make a critical evaluation of test results; and

(ii) Occupy positions within the laboratory's organization which makes them responsible for the adequacy of test results.

(c) Facilities and Equipment

(1) The laboratory shall be furnished with all items of equipment and facilities for the correct performance of the tests and measurements for which accreditation is granted and shall have adequate space, lighting, and environmental control, and monitoring to ensure compliance with prescribed testing conditions.

(2) All equipment must be properly maintained to ensure protection from corrosion and other causes of deterioration. Instructions for a proper maintenance procedure for those items of equipment which require periodic maintenance must be available. Any item of equipment or component thereof which has been subjected to overloading or mishandling, gives suspect results, or has been shown by calibration or otherwise to be defective, must be taken out of service and clearly labelled until it has been repaired. When placed back in service, this equipment must be shown by test or calibration to be performing its function satisfactorily.

(3) Records of each major item of equipment must be maintained. Each record must include:
   (i) The name of the item of equipment;
   (ii) The manufacturer's name and type, identification and serial number;
   (iii) Date received and date placed in service;
   (iv) Current location, where appropriate;
   (v) Details of maintenance; and
   (vi) Date of last calibration, next calibration due date, and calibration report references.

(d) Calibration

The laboratory shall:

(1) Calibrate new testing equipment before putting it into service;
(2) Recalibrate, at regular intervals, in-service testing equipment with the calibration status readily available to the operator;
(3) Perform checks of in-service testing equipment between the regular calibration intervals, where relevant;
(4) Maintain adequate records of all calibrations and recalibrations; and
(5) Provide traceability of all calibrations and reference standards of measurement where these standards exist. Where traceability of measurements to primary (national or international) standards is not applicable, the laboratory shall provide satisfactory evidence of the accuracy or reliability of test results (e.g., by participation in a suitable program of interlaboratory comparison).

(e) Test Methods and Procedures

The laboratory shall:

(1) Conform in all respects with the test methods and procedures required by the specifications against which the test item is to be tested, except that whenever a departure becomes necessary for technical reasons the departure must be acceptable to the client and recorded in the test report;
(2) Have data to prove that any departures from standard methods and/or procedures due to apparatus design or for other reasons do not detract from the expected or required precision of the measurement;
(3) Maintain a test plan for implementing testing standards and procedures including adequate instructions on the use and operation of all relevant equipment, on the handling and preparation of test items (where applicable), and on standard testing techniques where the absence of such instructions could compromise the test. All instructions, testing standards, specifications, manuals, and reference data relevant to the work of the laboratory must be kept up-to-date and made readily available to the staff;
(4) Maintain measures for the detection and resolution of in-process testing discrepancies for manual and automatic test equipment and electronic data processing equipment, where applicable;
(5) Maintain a system for identifying samples or items to be tested, which remains in force from the date of receipt of the item to the date of its disposal, either through documents or through marking to ensure that there is no confusion regarding the identity of the samples or test items and the results of the measurements made; and

(6) Maintain rules for the receipt, retention, and disposal of test items, including procedures for storage and handling precautions to prevent damage to test items which could invalidate the test results. Any relevant instructions provided with the tested item must be observed.

(f) Records

The laboratory shall:

(1) Maintain a record system which contains sufficient information to permit verification of any issued report;

(2) Retain all original observations, calculations and derived data, for one year unless a longer period is specified; and

(3) Hold records secure and in confidence, as required.

(g) Test Reports

(1) The laboratory shall issue test reports of its work which accurately, clearly, and unambiguously present the specified test results and all required information. Each test report must include the following information as applicable:

(i) Name and address of the laboratory;

(ii) Identification of the test report by serial number, date, or other appropriate means;

(iii) Name and address of client;

(iv) Description and identification of the test specimen, sample, or lot of material represented;

(v) Identification of the test specification, method, or procedure used;

(vi) Description of sampling procedure, if appropriate;

(vii) Any deviations, additions to, or exclusions from the test specifications;

(viii) Measurements, examinations, and derived results supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified;

(ix) A statement of measurement uncertainty, where relevant;

(x) Identification of the organization and the person accepting technical responsibility for the test report and date of issue;

(xi) A statement that the report must not be reproduced except in full with the approval of the laboratory; and

(xii) A statement to the effect that the test report relates only to the items tested.

(2) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g. "Supplement to test report serial number ....," which meets the relevant requirements of Section 7.33(g)(1).

(3) The laboratory shall retain a copy of each test report issued for one year unless a longer period is specified by NVLAP.

(4) The laboratory shall ensure that all test reports endorsed with the NVLAP logo are signed by an approved signatory.

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Jeffrey Horlick, Hazel M. Richmond

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1. ABSTRACT (A 200-WORD OR LESS FACTUAL SUMMARY OF MOST SIGNIFICANT INFORMATION. IF DOCUMENT INCLUDES A SIGNIFICANT BIBLIOGRAPHY OR LITERATURE SURVEY, MENTION IT HERE.)

The NVLAP Procedures are a part of the U.S. Code of Federal Regulations and set forth the conditions under which the National Voluntary Laboratory Accreditation Program (NVLAP) will function.

The Procedures contain general information about NVLAP, requirements for establishing a program in a specific field of testing, the process for accrediting a laboratory, and conditions and criteria for accreditation.

NVLAP is a system for accrediting testing laboratories found competent to perform specific tests and types of tests. Competence is defined as the ability of a laboratory to meet conditions and conform to criteria specified in the Procedures as tailored and interpreted for the test methods, types of test methods, products, services, or standards for which the laboratory seeks accreditation.

2. KEY WORDS (6 TO 12 ENTRIES; ALPHABETICAL ORDER; CAPITALIZE ONLY PROPER NAMES; AND SEPARATE KEY WORDS BY SEMICOLONS)

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