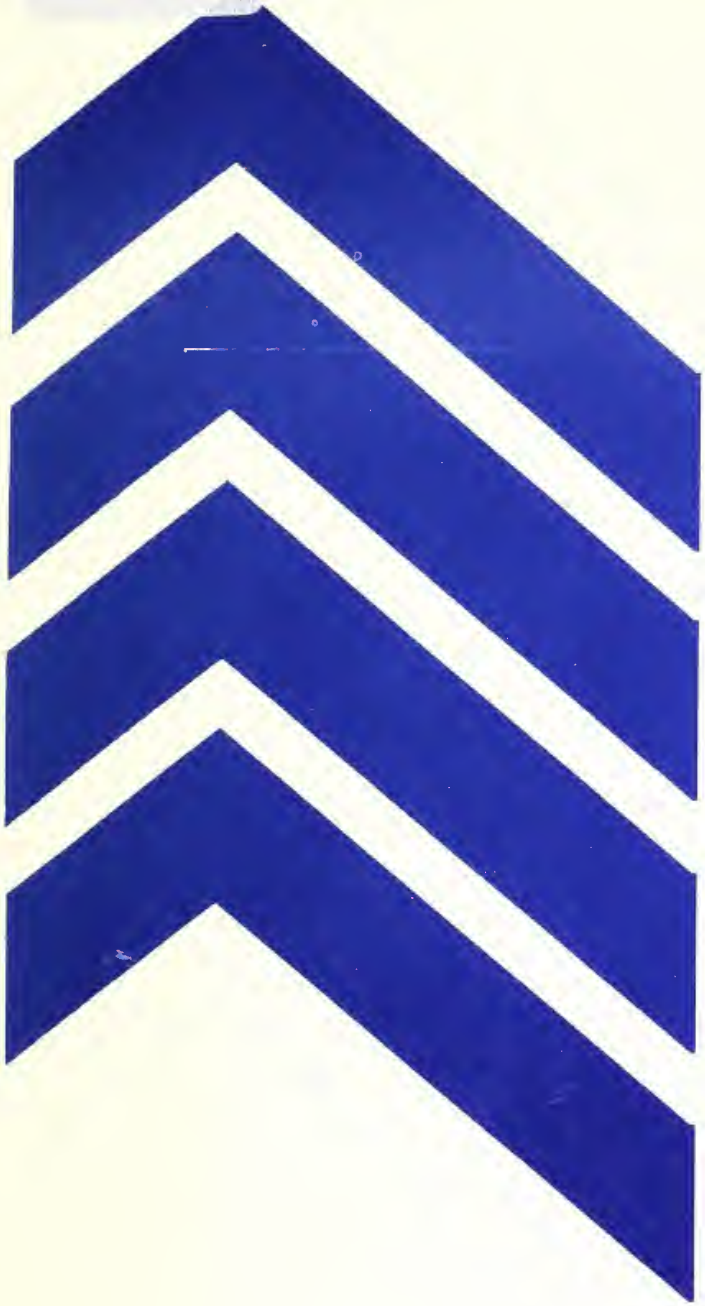
NVLAP®

National
Voluntary
Laboratory
Accreditation
Program



Procedures and General Requirements

NIST HANDBOOK 150

U.S. Department of Commerce
Technology Administration
National Institute of Standards
and Technology

The National Institute of Standards and Technology was established in 1988 by Congress to "assist industry in the development of technology . . . needed to improve product quality, to modernize manufacturing processes, to ensure product reliability . . . and to facilitate rapid commercialization . . . of products based on new scientific discoveries."

NIST, originally founded as the National Bureau of Standards in 1901, works to strengthen U.S. industry's competitiveness; advance science and engineering; and improve public health, safety, and the environment. One of the agency's basic functions is to develop, maintain, and retain custody of the national standards of measurement, and provide the means and methods for comparing standards used in science, engineering, manufacturing, commerce, industry, and education with the standards adopted or recognized by the Federal Government.

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- Systems and Software Technology
- Computer Security
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- Advanced Systems

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- Applied and Computational Mathematics[2]
- Statistical Engineering[2]
- Scientific Computing Environments[2]
- Computer Services[2]
- Computer Systems and Communications[2]
- Information Systems

[1] At Boulder, CO 80303.
[2] Some elements at Boulder, CO 80303.

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National Voluntary Laboratory Accreditation Program

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James L. Cigler and Vanda R. White, Editors

March 1994

U.S. Department of Commerce
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Technology Administration
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NVLAP AND THE NVLAP LOGO

PREFACE

NIST Handbook 150 is intended for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under the National Voluntary Laboratory Accreditation Program (NVLAP). It presents the basic procedures and general accreditation requirements of NVLAP for use in accrediting calibration and testing laboratories.

This handbook contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), "National Voluntary Laboratory Accreditation Program Procedures and General Requirements," plus all general procedures, criteria, and policies formerly contained in the individual NVLAP technical handbooks and separately published NVLAP policies. This organization of the material was adopted so that users of the handbook can readily access all general accreditation requirements for a given subject in one place. Subpart D, Sections 285.33(a) through (n), is essentially identical to the language of ISO Guide 25, "General requirements for the competence of calibration and testing laboratories."

A small black triangle appears in the left-hand margin of selected lines of text throughout this handbook; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP). In Sections 285.33(a) through (n), the marked text additions result from NVLAP interpretation of ISO Guide 25 via ANSI/NCSL Z540-1-1994 (draft). Section 285.33(o), based in large part on the requirements of MIL-STD-45662A, was added in its entirety as contained in ANSI/NCSL Z540-1-1994 (draft) for assessment of quality systems for the control of Measuring and Test Equipment (M & TE).

A brief review of the evolution of the current CFR Part 285 follows:

> The NVLAP Procedures and General Requirements were first published in the *Federal Register* on February 25, 1976, and 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."
>
> The Procedures were revised on December 10, 1984 and again on September 12, 1990, and a notice of proposed revisions was published in the *Federal Register* on July 27, 1993.
>
> ***December 10, 1984 Revision.*** A revision of the Procedures was published in the *Federal Register* on November 8, 1984 to become effective on December 10, 1984. The *Federal Register* notice cited 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."

September 12, 1990 Revision. The Omnibus Trade and Competitiveness Act of 1988 (Public Law No. 100-418) renamed the National Bureau of Standards (NBS) as the National Institute of Standards and Technology (NIST). A subsequent reorganization of NIST transferred certain responsibilities of the Office of Standards Services (OSS) 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.

March 1994 Revision. This revision was made for the following reasons:

1. To expand the procedures to include accreditation of calibration laboratories following establishment of the Calibration LAP (*Federal Register* notice Monday, May 18, 1992).

2. To update the Procedures to ensure compatibility with generally accepted conformity assurance and conformity assessment concepts.

3. To incorporate international changes, especially to be consonant with relevant International Organization for Standardization (ISO) documents (e.g., ISO Guides 25, 38, 43, and 58, and the ISO 9000 series of standards). NVLAP accreditation actions conform to ISO Guide 58, and laboratories accredited by NVLAP fulfill the ISO 25 guidelines.

4. To facilitate and promote acceptance of calibration and test results between countries to avoid barriers to trade. Provisions in this regard will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, harmonize standards and procedures, and establish the basis for bilateral and multilateral agreements.

Any questions or comments on this handbook should be submitted to the National Institute of Standards and Technology/NVLAP, Building 411, Room A162, Gaithersburg, MD 20899; phone (301) 975-4016; FAX (301) 926-2884.

ACKNOWLEDGMENTS

The preparation of this document has been a joint effort, with the input of representatives from other government agencies, laboratories, and the private sector. Acknowledgment of their efforts is in order; however, the listing of all of the individual names is impossible. The submissions by individuals and companies of letters offering suggestions for improvement to this document were also very welcome, as were the contributions of those who attended the public workshops.

Special recognition is made of the considerable contributions of David F. Alderman, Jeffrey Horlick, Lawrence S. Galowin, and S. Wayne Stiefel of the NVLAP staff in the revisions to the NVLAP Code of Federal Regulations and the augmenting material of this publication; their knowledge and judgment were essential for the comprehensive scope achieved. Major contributions were made by Jon M. Crickenberger and C. Douglas Faison, who coordinated the addition of material specific to the Calibration Laboratory Accreditation Program (LAP).

Several NIST measurement divisions, members of the National Conference of Standards Laboratories (NCSL) Total Quality Management (TQM) Committee and its chairman, Gary Davidson, are recognized for their tireless efforts. Special thanks are given to Joe D. Simmons, Chief of the NIST Calibration Program, and Norman B. Belecki, Group Leader in the NIST Electricity Division, for their contributions to broadening the NVLAP procedures to embrace the special features required for a comprehensive Calibration LAP.

Sincere appreciation for prepublication support is extended to Sherrie L. Abrecht, Leslie T. King, Maria A. Lancaster, Channing L. Monti, Margaret G. Musick, and Lisa Warfield of the NVLAP administrative staff.

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SUBPART A - GENERAL INFORMATION

Sec. 285.1 Purpose

The purpose of Part 285 of the Code of Federal Regulations is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both calibration laboratories and testing laboratories in response to:

(a) mandates by the Federal Government through legislative or administrative action;

(b) requests from a government agency (Section 285.13); and

(c) requests from a private sector organization (Section 285.14).

Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

Sec. 285.2 Organization 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. 285.3 Description and goal of NVLAP

(a) NVLAP is a system for accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (Section 285.32) and to conform to the criteria (Section 285.33) in NVLAP publications for specific calibration and test methods.

(b) NVLAP is a process which:

(1) provides the technical and administrative mechanisms for national and international recognition for competent laboratories based on a comprehensive procedure for promoting confidence in calibration and testing laboratories that show that they operate in accordance with NVLAP's requirements;

NOTE: NVLAP operates under a Quality Management System to ensure that the NVLAP program meets the requirements of the U.S. Code of Federal Regulations (as augmented), and the various international standards for laboratory accreditation and quality management (see Section 285.4, *References*).

(2) provides laboratory management with documentation for use in the development and implementation of their quality systems;

(3) identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

(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; and

(5) promotes the acceptance of calibration and test results between countries, and facilitates cooperation between laboratories and other bodies to assist in the exchange of information and experience, facilitating removal of non-tariff barriers to trade and promoting the harmonization of standards and procedures.

(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 calibration and test methods, types of calibration and test methods, products, services, or standards to be included in a LAP are determined by an open process during the establishment of the LAP (see Section 285.11).

The U.S. Department of Commerce, National Institute of Standards and Technology, formerly the National Bureau of Standards (NBS), administers NVLAP.

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 programs are established:

(1) for public and private calibration and testing laboratories, including commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state, and local government laboratories;

(2) to meet legal requirements, regulations or codes, and contract specifications, or to be recognized as demonstrably competent to meet the needs of its clients; and

(3) as the basis for guidance to facilitate agreements on mutual recognition of accreditation of laboratories between NVLAP and other accreditation organizations.

(e) NVLAP accreditation is:

(1) based on evaluation of a laboratory's technical qualifications and competence for conducting specific test methods, measurements and services in specified fields of calibration or testing;

(2) granted only after thorough evaluation of the applicant has demonstrated that all NVLAP criteria have been met;

(3) acknowledged by the issuance of two documents to attest to that compliance: (1) a Certificate of Accreditation, and (2) a Scope of Accreditation which details the specific test methods, measurements and services for which a laboratory has been accredited;

(4) administered in a nondiscriminatory manner;

(5) not conditional on the size of the laboratory or on its membership in any association or group; and

(6) based on assessing the competence of the laboratory against all of the NVLAP requirements.

Sec. 285.4 References

NVLAP is designed to be compatible with domestic and foreign laboratory accreditation programs to ensure the universal acceptance of test data produced by NVLAP-accredited laboratories. In this regard, these procedures are compatible with:

(a) the most recent official publications of ISO Guides 2, 25, 30, 38, 43, 45, 49, 58, and Standards 8402, 9001, 9002, 9003, and 9004;

(b) *International vocabulary of basic and general terms in metrology (VIM)*, and *Guide to the expression of uncertainty in measurement*, issued by International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP), and International Organization of Legal Metrology (OIML);

(c) the most recent official publications of ISO Guidelines 10011-1 and 10011-2;

(d) MIL-STD 45662A; Calibration System Requirement; 1988;

(e) NIST Technical Note 1297; *Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results*; 1993; and

(f) NCSL Recommended Practice #7; *Laboratory Design*; July 25, 1993.

Sec. 285.5 Definitions

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out

specific tests or calibrations or types of tests or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Approved Signatory (of an accredited laboratory): An individual who is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports.

NOTE: The Approved Signatory is responsible for the technical content of the report and is the person to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report. Approved Signatories shall be persons with responsibility, authority and technical capability within the organization for the results produced. The laboratory must maintain a list of Approved Signatories and make that list available for review during on-site assessments and to NVLAP upon request.

Assessment (of a laboratory): The on-site examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Authorized Representative (of an accredited laboratory): An individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements. (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory.)

NOTE: The laboratory must designate an Authorized Representative who has authority to sign the NVLAP application and commit the laboratory to fulfill the NVLAP requirements. Only the Authorized Representative can authorize a change in the scope or nature of the laboratory's application. This person is listed in NVLAP directories and will receive all correspondence and inquiries from NVLAP.

Calibration: A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES:

(a) The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system, or the assignment of values to marks on arbitrary scales.

(b) A calibration may also determine other metrological properties.

(c) The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.

(d) The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve.

Calibration certificate or report: Document that presents calibration results and other information relevant to a calibration.

Calibration method: A defined technical procedure for performing a calibration.

Certificate of Accreditation: A document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. The Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied with a Scope of Accreditation.

Client: Any person or organization that engages the services of a testing or calibration laboratory.

Competence: The ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods.

Deficiency: The non-fulfillment of NVLAP conditions and/or criteria for accreditation.

Director of NIST: The Director of the National Institute of Standards and Technology or designate.

Error: The difference between the true and measured value of a quantity.

Interlaboratory comparisons: Organization, performance and evaluation of calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Influence quantity: A quantity which is not the subject of the measurement but which influences the value of the measurand or the indication of the measuring instrument. Examples: ambient temperature; frequency of a measured alternating voltage.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

NOTE: 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).

NVLAP previously differentiated between "main facilities" and "sub-facilities." This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a "sub-facility" may request to be "grandfathered" in its accreditation renewal under the former classification as a "sub-facility," including the unique conditions associated with that classification.)

Any variation from this policy, other than the "grandfathering" exception, must be evaluated on its own merits. NVLAP reserves the right to decide whether or not to recognize variations.

Laboratory accreditation body: Body that conducts and administers a laboratory accreditation system and grants accreditation.

Laboratory accreditation system: System that has its own rules of procedure and management for carrying out laboratory accreditation.

LAP: A laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

Limits of permissible error (of a measuring instrument): The extreme values of an error permitted by specifications, regulations, etc., for a given measuring instrument.

NOTE: This term is frequently referred to as "tolerance" in the United States.

Measurand: A quantity subjected to measurement.

NOTE: As appropriate, this may be the "measured quantity" or the "quantity to be measured."

Measurement: The set of operations having the object of determining the value of a measurand.

Measurement assurance: A 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.

Measuring and test equipment: 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 "measuring instruments" and "measurement standards." Moreover, a "reference

material" is considered to be a type of "measurement standard."

Measuring instrument: A device intended to make a measurement, alone or in conjunction with supplementary equipment.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

NVLAP Lab Code: A unique alphanumeric identifier assigned by NVLAP to each applicant laboratory; e.g., 1000 or 1000-00. It is used by NVLAP for identification, recordkeeping, and data base management. A laboratory uses its Lab Code in all correspondence with NVLAP. The Lab Code is cross-referenced with the laboratory's name, laboratory accreditation program (LAP), and geographic location in the NVLAP annual directory.

Person: 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.

Precision: The repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

Product: 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: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

NOTE: The quality audit typically applies, but is not limited, to a quality system or elements thereof, to processes, to products, or to services. Such audits are often called "quality system audit," "process quality audit," "product quality audit," or "service quality audit."

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality system review: A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and new objectives resulting from changing circumstances.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials. A "certified reference material" means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

Resolution: The smallest discrete or discernible change in a value that can be measured.

Revocation: Revocation is the removal of the accredited status of a laboratory when it is found to have violated the terms of its accreditation.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Stability: The ability of a measuring instrument to maintain constant its metrological characteristics.

NOTE: It is usual to consider stability with respect to time. Where stability with respect to another quantity is considered, this should be stated explicitly.

Standard, international (measurement): A standard recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned.

Standard, measurement: A material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

Standard, mutual consent: An artifact or process that is used as a de facto standard by mutual consent of the supplier and customer when no recognized U.S. national or international standard is available.

Standard, national (measurement): A standard, recognized by a national decision, to serve in a country as the basis for assigning values to standards of the quantity concerned.

Standard, primary: A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Standard, reference: (See definition of *Reference standard*.)

Standard, secondary: A standard whose value is assigned by comparison with a primary standard of the same quantity.

Standard, transport (or transfer): A standard used as an intermediary to compare standards.

Standard, working: A standard usually calibrated against a reference standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials.

Statistical Process Control (SPC): A systematic process for monitoring the validity of a calibration or the value of a laboratory standard using statistical tools as a basis for decision.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Suspension: Suspension is a temporary removal of the accredited status of a laboratory when it is found to be out of compliance with the terms of its accreditation.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

Testing laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products or materials.

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.

Traceability of the accuracy of measuring instruments: 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.

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.

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

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

Verification: Confirmation by examination and provision of evidence that specified requirements have been met.

NOTES:

(a) In connection with the management of measuring equipment and/or processes, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the limits of permissible error defined in a standard, regulation or specification peculiar to the management of the measuring equipment and/or processes.

(b) The result of verification leads to a decision either to restore to service, or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases documentation of the verification performed is kept on the measuring instrument's individual record.

(c) The verification process is frequently referred to as "calibration" in the United States.

Sec. 285.6 NVLAP documentation

NVLAP publications are available for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under the NVLAP program. Accredited laboratories will be sent revised publications routinely. Publications include:

(a) the Procedures and General Requirements, (15 CFR Part 285);

(1) United States Code of Federal Regulations (CFR)

The primary document describing the legal basis for NVLAP, including procedures for establishing accreditation activities and the criteria and general requirements for accreditation of laboratories, is contained in the U.S. Code of Federal Regulations, Title 15 - Commerce and Foreign Trade, Subtitle B - Regulations Relating to Commerce and Foreign Trade, Chapter II - National Institute of Standards and Technology, Part 285 - "National Voluntary Laboratory Accreditation Program Procedures and General Requirements." CFR Part 285 is available as a reprint of the U.S. Code, and is incorporated in official NIST publications.

(2) NIST Handbook 150

NIST Handbook 150 contains the U.S. Code [(1) above] plus additional material specifying NVLAP interpretation of the U.S. Code related to calibration and testing laboratory programs.

(b) handbooks containing the administrative and operational procedures and technical requirements for specific LAPs;

A series of handbooks in the 150 series (i.e.; 150-1 ..... n) provides technical guidance, criteria and requirements for calibration and testing laboratories. A separate handbook is published for each Laboratory Accreditation Program (LAP) or unique field of testing (e.g., anyone interested in the general and specific procedures and requirements for the Energy Efficient Lighting Products LAP needs NIST Handbook 150 plus NIST Handbook 150-1, *Energy Efficient Lighting Products, Lamps and Luminaires*). Amplifying technical information related to specific fields of calibration is also published as part of the series (e.g., *Calibration Laboratories Technical Guide*).

(c) a directory of accredited laboratories, published annually and updated periodically;

The annual directory contains the name and address, Authorized Representative, phone number, scope of accreditation, and the accreditation renewal date for

each accredited laboratory. The directory is distributed nationally and internationally to participating laboratories, manufacturers, suppliers, retailers, professional and trade associations, standards groups, and government agencies.

(d) Policy Guides that provide changes to the Procedures and General Requirements and Handbooks between formal revisions of those publications.

Sec. 285.7 Confidentiality

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

Sec. 285.8 Referencing NVLAP accreditation

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

(a) Follow NVLAP guidance when advertising its accredited status (including the use of the NVLAP logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

(1) The term "NVLAP" and the NVLAP logo (NVLAP®) are federally registered trademarks of the National Institute of Standards and Technology and the federal government, which retain exclusive rights to their use.

(2) NIST reserves the right to control the quality of the use of the term "NVLAP" and of the logo itself.

(3) Use of the NVLAP logo on letterhead, brochures, and calibration or test reports, should be accompanied by the following: "Accredited by the National Voluntary Laboratory Accreditation Program for the specific scope of accreditation under Lab Code XXXX."

(4) Permission for advertising NVLAP accreditation and use of the logo is conditional on and limited to those cases of calibration or test reports that describe calibration or testing within the scope of NVLAP accreditation.

(5) The name of at least one Approved Signatory must appear on all calibration or test reports endorsed with the NVLAP logo or referencing NVLAP accreditation.

Laboratory calibration or test reports carrying the NVLAP logo need not be signed individually by the Approved Signatory, except when required by legislation, or a client, or for other legal reasons. Computer-generated forms may have the signatory's name printed along with the calibration or test results, as long as there is evidence that there is a system in place to ensure that the calibration or test reports can not be generated without consent/review of the Approved Signatory.

(6) Photographic and electronic copies of the logo are available from NVLAP upon request.

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

Sec. 285.9 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. 285.11 Requesting a LAP

(a) A request to establish a LAP must be made to the Director of NIST;

(b) Each request must include:

(1) the scope of the LAP in terms of products, calibration services, 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 the perceived 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 calibration or 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 are likely to 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 submitted according to paragraph (b) of this section.

(d) Before determining whether a LAP should be established, the Director of NIST shall publish a *Federal Register* notice of the receipt of a LAP request if the request complies with Section 285.11(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.

(e) Following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director shall publish a *Federal Register* notice:

(1) stating the purpose of the LAP including the national or international need;

(2) describing the general scope of the LAP;

(3) identifying government agencies having oversight; and

(4) providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP.

(f) Consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements.

Sec. 285.12 LAP development decision

(a) The Director of NIST shall establish all LAPs on the basis of need.

(1) A mandate to develop a LAP by NVLAP will be interpreted as a de facto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.

(2) Government agencies may document the need by using Section 285.13, and private sector organizations by using Section 285.14.

(b) After receipt of the request, the Director of NIST shall analyze it to determine if there is need 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;

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(3) the nature and content of other relevant public and private sector laboratory accreditation programs;

(4) compatibility with the criteria referenced in Section 285.33;

(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 laboratories for the calibration or test methods, types of calibration or 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 that 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. 285.13 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 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 285.11(b) and:

(1) a description of the procedures followed or a citation of the specific authority used to identify a need for a LAP; and

(2) for state and local government agencies, a statement explaining why the LAP should be of national scope.

(c) NVLAP may request clarification of the information required by Section 285.11(b).

(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. 285.14 Request from a private sector organization

(a) Any private sector organization which has determined a need to accredit laboratories for specific products, calibrations, 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 285.11(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 Section 285.11(b).

(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 whether or not to proceed with development of a LAP.

Sec. 285.15 Development of technical requirements

(a) Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in Section 285.33 to the calibration or test methods, types of calibration or 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 calibration or 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. 285.16 Coordination with federal agencies

As a means of ensuring 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. 285.17 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 it to recover its full costs, and shall, from time to time as necessary, revise the fees for this purpose.

Sec. 285.18 Adding to or modifying an established LAP

(a) Established or developing LAPs may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, calibration or test methods, or types of calibration or test methods or a need identified by NIST.

(b) NVLAP may choose to make the additions or modifications available for accreditation under a LAP when:

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

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

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

(c) A laboratory requesting the addition of calibration parameters, test methods or services to its Scope of Accreditation must meet all NVLAP criteria for the additional calibration parameters, test methods or services; e.g., technical requirements, proficiency testing, payment of fees, etc. The need for an additional on-site assessment and/or proficiency testing will be determined on a case-by-case basis.

Sec. 285.19 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 laboratories for the 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 shall 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. In the absence of public support 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 will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP.

SUBPART C - ACCREDITING A LABORATORY

Sec. 285.21 Applying for accreditation

(a) A laboratory may complete and remit an application for accreditation in any of the established LAPs.

(1) A NVLAP application package is sent to a laboratory on request. It includes the ***General Application***, ***Program-Specific Application***, ***NVLAP Fee Schedule***, the ***Program Handbook***, and all documents needed for understanding of the NVLAP program and requirements. This could include relevant Technical Guides in the fields of calibration for which a laboratory has requested accreditation.

(2) The ***General Application*** must be completed and signed by the Authorized Representative of the laboratory. Before completing and signing the application, the Authorized Representative should review all documents and become familiar with NVLAP requirements.

(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) Accreditation of laboratories outside of the United States may require:

(1) translation of laboratory documentation into English;

NOTE: In cases where laboratory documents are not in English, or laboratory personnel do not speak English, it is the responsibility of the laboratory to provide a translator to assist the NVLAP assessor(s) during the on-site assessments. The translator will assist the assessor(s) in conversing directly with laboratory management and technical staff and in reviewing laboratory documentation. Documents such as quality assurance manuals, protocols, standards, and test reports sent to NVLAP prior to on-site assessments or reviewed during assessments need not be translated into English solely for NVLAP purposes.

(2) payment of additional traveling expenses for on-site assessments and proficiency testing;

NOTE: Some of the fees listed on the NVLAP Fee Schedule may be insufficient to cover the costs incurred by an applicant laboratory located outside the U.S. In such cases, the laboratory will be responsible for all additional costs incurred. Additional fees will be charged, if necessary, for travel by NVLAP assessor(s) outside of the U.S., for shipment of proficiency testing materials to the laboratories and for any additional administrative expenses. To ensure that the initial or renewal application is processed without delay, payment (in U.S. currency) of the appropriate listed 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.

(3) export licenses.

NOTE: For certain scientific and technical equipment to be exported from the United States, a license issued by the U.S. Department of Commerce may be required. If a laboratory uses such equipment, NVLAP requires that the laboratory possess, and show upon request, an export license. For export license information, contact the U.S. Department of Commerce, Export Administration, Exporter Assistance, P.O. Box 273, Washington, DC 20230, telephone (202) 482-4811, FAX (202) 482-3617.

(d) NVLAP Fees

NVLAP receives no appropriated public funds. NVLAP operates on a cost-reimbursable basis from fees paid by participating laboratories that apply for accreditation in specific NVLAP fields of testing or calibration. For fee calculation purposes, a field is considered to be any area of accreditation that is a separate line item on the NVLAP Fee Schedule (for example, GOSIP is a separate field of testing even though it is part of the Computer/Electronics program).

The fee structure incorporates five major fee categories:

(1) The *Initial Application Fee* covers costs associated with processing an applicant for the first time. It is paid only one time per laboratory and is due with the initial application for accreditation.

(2) The *Administrative/Technical Support Fee* covers costs associated with NVLAP and other NIST staff conducting the program in all areas for which accreditation is offered and for providing these services to participating laboratories.

This fee is due annually regardless of the accreditation status of a laboratory. Laboratories which have been enrolled in a program for more than 1 year and are not yet accredited will be invoiced annually for the Administrative/Technical Support Fee, based on the date the laboratory's initial application was accepted by NVLAP.

(3) The *On-Site Assessment Fee* covers costs incurred for on-site assessment visits. On-site assessments are conducted prior to initial accreditation and every 2 years thereafter; therefore, this fee is due only for a renewal year in which an assessment is scheduled.

NOTE: The optional use of a preassessment visit will be considered if it is decided that such a visit would result in a better definition of the scope of accreditation which has been requested by the laboratory. In such cases the preassessment costs will be charged to the laboratory in addition to the actual On-Site Assessment Fee.

A laboratory will be charged for an additional assessment visit if required as the result of deficiencies in meeting NVLAP technical criteria. The fee for this additional assessment visit is the same as the On-Site Assessment Fee on the NVLAP Fee Schedule.

A laboratory will not be charged separately for a monitoring visit, which may be initiated by NVLAP at any time during the accreditation period for cause or on a random selection basis.

(4) The *Proficiency Testing Fee* covers costs relating to the provision of proficiency test samples and artifacts, the collection and analysis of laboratory results, and reports to NVLAP staff.

The Proficiency Testing Fee, which is paid with a laboratory's initial or renewal application, covers the rounds of proficiency testing scheduled for a given year. If a laboratory has participated in the scheduled rounds of testing, but has not yet attained accreditation, it will be invoiced prior to each subsequent round of proficiency testing until it submits its first renewal application. If proficiency testing is performed every other year, the fee is due only in the year that testing is scheduled to be performed.

(5) The *Test Method Fee* covers incremental costs associated with technical support related to the number and complexity of test methods selected by a laboratory within a given program. This fee is charged per test method; therefore, the total Test Method Fee depends on the total number of test methods selected and varies from application to application within a program.

(e) Fee Refund Policy

This refund policy applies to laboratories that withdraw from the NVLAP program. It covers each of the five major fee categories as follows:

(1) The *Initial Application Fee* is nonrefundable.

(2) The amount of the *Administrative/Technical Support Fee* and the *Test Method Fee* to be refunded depends upon the length of time that has elapsed between the laboratory's renewal date and the date NVLAP was notified of the decision to withdraw.

*Time of withdrawal (# of months after renewal date)**	*Refund amount*
Less than 3 months	3/4
3 months to less than 6 months	1/2
6 months to less than 9 months	1/4
9 months or greater	No refund

* If a laboratory is seeking initial accreditation (i.e., has never been accredited for a specific program), the time of withdrawal will be counted as the number of months after the date the initial application was received.

(3) The *On-Site Assessment Fee* is refundable only if no on-site related costs have been incurred. Otherwise, costs incurred will be deducted from the On-Site Assessment Fee.

(4) The portion of the *Proficiency Testing Fee* for any proficiency testing planned but not sent to the laboratory, or for any proficiency testing that was not initiated, will be refunded. No refund will be given for artifacts sent but returned unmeasured by the laboratory.

Sec. 285.22 Assessing and evaluating a laboratory

(a) Information used to evaluate a laboratory's compliance with the conditions for accreditation set out in Section 285.32, the criteria for accreditation set out in Section 285.33, and the technical

requirements established for each LAP will include (not necessarily in this order):

(1) application and other material submitted by the laboratory (Section 285.32(b));

(2) on-site assessment reports;

(3) laboratory performance on proficiency tests;

(4) laboratory responses to identified deficiencies; and

(5) technical evaluation.

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

The laboratory will be contacted to schedule a mutually acceptable date for the on-site assessment *after payment* of the required fees and will be notified of any additional information which must be supplied, and of any applicable proficiency testing requirements which must be completed, for the technical evaluation.

(1) Technical Experts

NVLAP uses Technical Experts (TEs) as assessors and evaluators. They may be engineers or scientists currently active in the field, consultants, college professors or retired persons. They are selected on the basis of their professional and academic achievements, experience in the field of testing or calibration, management experience, and tact in dealing with people. Their services are generally contracted as required; they are normally not NVLAP staff members.

Assessors are TEs selected to conduct an on-site assessment of a particular laboratory on the basis of how well their individual experience matches the type of testing or calibration to be assessed, as well as absence of conflict of interest. The laboratory has the right to appeal the assignment of an assessor and may request an alternate.

Evaluators are TEs selected to review the record of the laboratory as a whole, including the application, assessment report, deficiencies, corrections to deficiencies, and proficiency test results. Based on the totality of the record, the evaluators recommend whether or not a laboratory should be accredited. The evaluators are matched to the type of testing or calibration being evaluated. Like assessors, evaluators are selected to avoid conflict of interest.

(2) On-Site Assessment

Before initial accreditation and every 2 years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria. NVLAP assigns an asscssor or a team of assessors and provides the laboratory with a short biographical sketch of the assessor(s). A lead assessor will be assigned if needed. The laboratory may request an alternate assessor if a conflict of interest or prior business relationship exists.

Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others. However, assessors have some latitude to make judgments about a laboratory's compliance with the NVLAP criteria.

An assessment normally takes 1 to 5 days depending on the scope of the laboratory's application. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory. During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of calibrations or testing, and examines calibration or test reports.

The assessor reviews laboratory records including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the calibration or testing for which accreditation is sought. The assessor need not be given information which 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 separate, official folders that contain only the information that the NVLAP assessor needs to review.

At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any deficiencies with the Authorized Representative and other responsible laboratory staff. A written assessment report, signed by the Authorized Representative to acknowledge receipt of the report, will be left with the laboratory, and a copy forwarded to NVLAP.

The final report submitted to the laboratory shall include as a minimum:

(i) date(s) of assessment;

(ii) the names of the person(s) responsible for the report;

(iii) the names and addresses of all the laboratory sites assessed;

(iv) the assessed scope of accreditation or reference thereto; and

(v) comments and/or deficiencies cited by the assessor(s) on the compliance of the laboratory with the accreditation requirements.

(3) Deficiency Notification and Resolution

A deficiency is the failure of a laboratory to meet a NVLAP criterion. Deficiencies may be determined during on-site assessments, monitoring visits, proficiency testing, NVLAP staff review, and technical evaluation. Laboratories are informed of deficiencies during the on-site assessment and through other correspondence.

When a laboratory is notified of deficiencies, it must respond in writing to NVLAP within 30 days of the notification. The response must provide documentation, signed by the Authorized Representative, that the specified deficiencies have either been corrected or include a plan of action to make corrections. The plan must include a list of actions, dates of completion, and responsible persons.

A currently accredited laboratory must submit a satisfactory response concerning resolution of deficiencies within 30 days of notification or face possible suspension or revocation of accreditation.

Calibration of test equipment, materials, computer software, or measuring system implementations (which have a critical effect on the function accredited) that are identified as deficient (fail to meet the NVLAP criteria) should not be used for further NVLAP-accredited calibration or testing until corrective action has been completed and documented. Evidence of correction must be sent to NVLAP.

If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and corrective actions will be verified during subsequent assessments and technical evaluations.

(4) Proficiency testing

Proficiency testing is an integral part of the NVLAP accreditation process. The performance of calibrations or tests and reporting of results using proficiency testing provides NVLAP with a way to determine the overall effectiveness of the laboratory. Information obtained from proficiency testing helps to identify problems in a laboratory. When problems are found, NVLAP works with the laboratory staff to solve them.

Each field of calibration or testing has proficiency testing requirements. 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. Proficiency testing may use *intralaboratory* techniques such as comparisons of computer software implementations to reference implementations, use of standard reference materials, and use of fundamental physical laws. Proficiency testing for calibration laboratories may involve the comparison of calibration results obtained independently by the laboratory and NIST/NVLAP on a selected instrument or artifact.

Proficiency testing data are analyzed by NVLAP and reports of the results are made known to the participants. 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.

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

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

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

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

(iii) failure to submit laboratory control data as required;

(iv) performance as a statistically outlying laboratory in two successive rounds of proficiency testing or showing a general pattern of outlying results over three or more rounds; and

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

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

(5) Technical Evaluation

A review panel is formed to determine if all technical requirements have been fulfilled. Each panel is composed of one or more NVLAP Technical Experts (evaluators) who are matched to the type of calibration or testing being evaluated and are selected to avoid conflict of interest. The evaluation is based on a review of the record of the laboratory as a whole, including:

(i) information provided on the application;

(ii) results of quality system documentation review;

(iii) on-site assessment reports;

(iv) actions taken by the laboratory to correct deficiencies;

(v) results of proficiency testing; and

(vi) information from any monitoring visits of the laboratory.

Based on this evaluation, the panel recommends whether or not a laboratory should be accredited. If the technical evaluation reveals additional deficiencies, written notification of the deficiencies will be made to the laboratory. The laboratory must respond as specified in the previous section, *Deficiency Notification and Resolution*.

All deficiencies must be resolved before accreditation can be granted.

(6) Monitoring Visits

In addition to regularly scheduled assessments, monitoring visits may be conducted by assessors or by NIST staff 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.

The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review deficiency resolutions, verify reported changes in the laboratory's personnel, facilities, or operations, or assist in resolving problems related to proficiency testing and other laboratory operations.

(c) NVLAP shall inform each applicant laboratory of any additional action(s) that the laboratory must take to qualify for accreditation.

Sec. 285.23 Granting and renewing accreditation

Accreditation is granted for a specified period, usually one year. Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four renewal dates is assigned (January 1, April 1, July 1, or October 1) and is usually retained as long as the laboratory remains in the program.

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.

(a) NVLAP will take action to (1) grant initial accreditation, or (2) renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements.

(b) If accreditation is granted or renewed, NVLAP shall:

(1) provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;

(2) 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

(3) 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.

Each accredited laboratory will be sent a renewal application package before the expiration date of its accreditation to allow sufficient time to complete the renewal process. Fees for renewal are charged according to services required as listed on the NVLAP Fee Schedule.

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

Sec. 285.24 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 appeal the decision to the Director of NIST. 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.

(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 NVLAP's intent to revoke 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.

If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the 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 Sections 285.32 and 285.33.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports 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.

If accreditation is revoked, the laboratory must return its Certificate of Accreditation and cease use of the NVLAP logo on any of its reports, correspondence, or advertising.

Sec. 285.25 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 will terminate the laboratory's accreditation and notify the laboratory that its accreditation has been terminated in response to its request.

Sec. 285.26 Change in status of laboratory

Accreditation of a laboratory is based on specific conditions and criteria, including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation (see Section 285.32(a)(11)).

SUBPART D - CONDITIONS AND CRITERIA FOR ACCREDITATION

Sec. 285.31 Application of accreditation conditions and criteria

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in Section 285.32, the criteria set out in Section 285.33, and the guidance provided in the Handbooks for specific LAPs.

Sec. 285.32 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 calibrations or tests representative of those for which it is seeking accreditation;

(3) pay all fees;

(4) participate in proficiency testing as required;

(5) be capable of performing the calibrations or tests for which it is accredited according to the latest version of the calibration or 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 calibrations, tests or services for which accreditation is granted;

(7) resolve all deficiencies;

(8) limit all its work or services for clients to those areas where competence and capacity are available;

(9) maintain records of all actions taken in response to complaints for a minimum of one year;

(10) maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render calibration or test reports objectively and without bias is not adversely affected;

(11) 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

NOTE: In addition, a laboratory shall report to NVLAP within 30 days any major changes involving the following: deletion of a calibration parameter, test method or testing service for which it is accredited; or inability to perform calibrations, test methods or services for which it is accredited.

(12) return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for 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 285.33, and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information to NVLAP or its designated contractor:

(1) legal name and full address;

(2) ownership of the laboratory;

(3) organization chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;

(4) general description of the laboratory, including its facilities and scope of operation;

(5) name, address, and telephone and FAX number of the Authorized Representative of the laboratory;

(6) names or titles and qualifications of laboratory staff nominated to serve as approved signatories of calibration or test reports that reference NVLAP accreditation;

(7) the laboratory quality manual; and

(8) other information as may be needed for the specific LAP(s) in which accreditation is sought.

Sec. 285.33 Criteria for accreditation

(a) Scope

(1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria, may be specified by NVLAP, depending upon the specific character of the task of the laboratory.

(3) This section is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

(4) A General Operations Checklist is used to verify compliance with the criteria of this section.

(b) Organization and management

(1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet these requirements.

(2) The laboratory shall:

(i) have managerial staff with the authority and resources needed to discharge their duties;

(ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) nominate deputies in case of absence of the technical or quality manager;

(ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

NOTE: It is recognized that this is not always 'a requirement for a laboratory. Where confidentiality and protection of proprietary rights are required by the customer, the laboratory policies and procedures shall be documented in the quality manual.

(x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs;

(xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) Quality system, audit and review

(1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of these procedures. The quality manual and related quality documentation shall also contain:

(i) a quality policy statement, including objectives and commitments, by top management;

(ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) the relations between management, technical operations, support services and the quality system;

(iv) procedures for control and maintenance of documentation;

(v) job descriptions of key staff and reference to the job descriptions of other staff;

(vi) identification of the laboratory's approved signatories;

(vii) the laboratory's procedures for achieving traceability of measurements;

(viii) the laboratory's scope of calibrations and/or tests;

(ix) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(x) reference to the calibration, verification and/or test procedures used;

(xi) procedures for handling calibration and test items;

(xii) reference to the major equipment and reference measurement standards used;

(xiii) reference to procedures for calibration, verification and maintenance of equipment;

(xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) procedures to be followed for feedback and corrective action whenever discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) procedures for dealing with complaints;

(xviii) procedures for protecting confidentiality and proprietary rights;

(xix) procedures for audit and review;

(xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

(xxi) a statement of the laboratory's policy for establishing and changing calibration intervals for equipment it controls; and

(xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. When the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

(4) The quality system adopted to satisfy the requirements of this section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

(i) internal quality control plans using whenever possible statistical techniques;

NOTE: Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

(ii) participation in proficiency testing or other interlaboratory comparisons;

(iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

(iv) replicate testings using the same or different methods;

(v) retesting of retained items;

(vi) correlation of results for different characteristics of an item.

(d) Personnel

(1) The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) Accommodation and environment

(1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

NOTE: Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

NOTE: It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE: It is the laboratory's responsibility to comply with relevant health, safety and environmental requirements. This aspect, however, is outside the scope of this handbook.

(f) Equipment and reference materials

(1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) the name of the item of equipment;

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

(iii) date received and date placed in service;

NOTE: For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

(iv) current location, where appropriate;

(v) condition when received (e.g., new, used, reconditioned);

(vi) copy of the manufacturer's instructions, where available;

(vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) details of maintenance carried out to date and planned for the future;

(ix) history of any damage, malfunction, modification or repair; and

(x) measured value observed for each parameter found to be out of tolerance during ealibration/verification.

(g) Measurement traceability and calibration

(1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever available, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

NOTE: Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) Calibration and test methods

(1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

NOTES:

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, this shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) the requirements of these procedures are complied with;

(ii) computer software is documented and adequate for use;

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

(iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) Handling of calibration and test items

(1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

NOTE: Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) Records

(1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

EXCEPTION: The retention of all original observations, calculations, and derived data in the calibration record system is not a mandatory requirement for calibration laboratories, although it is encouraged as good laboratory practice.

(2) All records (including those listed in 285.33(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

NOTE: The period of retention shall be specified in the quality manual.

(k) Certificates and reports

(1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

NOTE: It is recognized that the results of each calibration do not always result in the production of a calibration certificate or report. Whenever a certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

(i) a title, e.g., "Calibration Certificate", "Test Report" or "Test Certificate";

(ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

(iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

(iv) name and address of client, where appropriate;

(v) description and unambiguous identification of the item calibrated or tested;

(vi) characterization and condition of the calibration or test item;

(vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

EXCEPTION: Although it is encouraged as good laboratory practice, the requirement for inclusion of the date received is not mandatory for calibration laboratories.

(viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

(ix) reference to sampling procedure, where relevant;

(x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

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

(xii) a statement of the estimated uncertainty of the calibration or test result (where relevant);

(xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

(xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

(xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

(xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

(xvii) the signature of an Approved Signatory for all test and calibration reports endorsed with the NVLAP logo;

(xviii) special limitations of use; and

(xix) traceability statement.

(3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified.

(4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

(5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number... [or as otherwise identified]," or equivalent form of wording. Such amendments shall meet all the relevant requirements of 285.33(j).

(6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

NOTE: Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

(7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of these procedures are met and that confidentiality is preserved.

(8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

(i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

(ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the

accreditation, the client must be so advised.

(l) Subcontracting of calibration or testing

(1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the calibration or testing to another party.

(2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

(3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

(i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

(ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s), and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

(iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

(iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

(v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

if NVLAP-accredited,

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed."

if not NVLAP-accredited,

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) Outside support services and supplies

(1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and

consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) Complaints

(1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 285.33(c)(3).

NOTE: This is interpreted to mean that complaints in those areas of activity and responsibility involved must be promptly resolved.

(o) Measuring and test equipment (M & TE)

NOTE: This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

(i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

(ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with 285.33(b) through (n) of this handbook.

(iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning due to mishandling, misuse, or unusual results.

(iv) All operations performed by the supplier in compliance with this handbook shall be subject to customer verification at unscheduled intervals.

(v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with the requirements of this handbook.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

(i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of 285.33(o) of this handbook and any deviations shall be submitted with supporting documentation to the customer for approval.

(ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of 285.33(f)(1), 285.33(g)(1), and 285.33(h)(2) of this handbook.

(iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

(iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

(v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of 285.33(h)(1) and 285.33(h)(2) of this handbook.

(vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

(vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this handbook.

(viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n) of this handbook.

(ix) Records: The requirements of this handbook shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

(x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

(xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to 285.33(l) of this handbook to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

(xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

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This handbook contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), "National Voluntary Laboratory Accreditation Program Procedures and General Requirements," plus all general procedures, criteria, and policies formerly contained in the individual NVLAP technical handbooks and separately published NVLAP policies. This organization of the material was adopted so that users of the handbook can readily access all general accreditation requirements for a given subject in one place. Subpart D, Sections 285.33(a) through (n), is essentially identical to the language of ISO Guide 25, "General requirements for the competence of calibration and testing laboratories," with additions as a result of NVLAP interpretation of ISO Guide 25 via ANSI/NCSL Z540-1-1994 (draft). Section 285.33(o) was added in its entirety as contained in ANSI/NCSL Z540-1-1994 (draft) for assessment of quality systems for the control of Measuring and Test Equipment (M & TE), and is based in large part on the requirements of MIL-STD-45662A.

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