STATE WEIGHTS AND MEASURES LABORATORIES

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State Weights and Measures Laboratories

Program Handbook

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Preface

NIST manages the State Laboratory Program that began with the New State Standards Program established by Congress in 1965 as part of its continuing support to the States. This program of the NIST Office of Weights and Measures (OWM) is designed to provide guidance, technical support, and assistance to State legal metrology laboratories to ensure accurate and traceable measurements from NIST to the local jurisdictions. The program operates through continued partnership with the State laboratories to manage numerous measurement-related activities.

Significant changes have been made to the accreditation program and to this Program Handbook since the previous edition was published in 1985. The accreditation program has incorporated national and international standards; though the OWM accreditation program is operated independently from the National Voluntary Laboratory Accreditation Program (NVLAP), the general and technical criteria used in both programs are identical. The following list shows key changes in this edition of the Handbook:

- Information associated with the National Type Evaluation Program (NTEP) is no longer covered in this program handbook.

- Parts 3 and 4 are policy and procedure information specific to OWM operations and accreditation process; Figure 1 is a flow chart showing the accreditation process.

- Parts 5 and 6 incorporate ANSI/NCSL Z540-1-1994 (parts I and II) with NVLAP additions and OWM NOTES. These sections are included as Subpart D in NIST Handbook 150, NVLAP Procedures and General Requirements. OWM NOTES added to parts 5 and 6 are additional policy or requirements that apply generally to all legal metrology laboratories without regard to accreditation level.

- Part 7 is taken from the NVLAP Calibration Laboratories Draft Technical Guide, but has been edited for publication. OWM and the National Conference on Weights and Measures (NCWM) ISO 9000 Task Force prepared the mass and volume sections, and reviewed them at a special NVLAP workshop in December 1992 (mass criteria only), at a NVLAP workshop in November 1993, and at all six regional metrology meetings in 1993, 1994, and at the 1994 NCWM meeting. Laboratories performing temperature measurements were given the opportunity to review the temperature section. Diane Lee (NIST) prepared the moisture section; it was reviewed at the Southeastern Measurement Assurance Program (SEMAP) regional metrology meeting in 1993.

Note regarding SI units:
Appropriate SI units of measure have been used throughout this document where possible. Since commercial applications in the United States use units other than SI or other accepted metric units, this document may reference other common units in current use.

Acknowledgments and History

This Program Handbook, first published by Henry V. Oppermann and John K. Taylor in 1985, documented and formalized the program whereby NIST recognized the capabilities of State legal metrology laboratories. Prior to that time, the NIST Office of Weights and Measures issued "Certificates of Participation" to States participating in the program. In 1985, OWM started certifying laboratories against the criteria in Handbook 143, Program Handbook. The 1985 criteria were based on International Standards Organization (ISO/IEC) Guide 25 (1982), General Requirements for the Competence of Calibration and Testing Laboratories.

The Office of Weights and Measures began the process of updating this Program Handbook in 1991. Due to the many activities related to ISO 9000 in the United States and questions regarding how those activities would impact the State laboratories, ISO standards were circulated to the State laboratories in 1991.

The National Conference of Standards Laboratories (NCSL), Total Quality Management (TQM) Committee also started working on the development and adoption of a single U.S. national standard for calibration laboratories in 1991. The NCSL TQM Committee included representatives from NIST, Department of Defense, Department of Energy, Nuclear Regulatory Commission, Federal Aviation Administration, and numerous industries.

In 1992, the National Conference on Weights and Measures (NCWM) established an ISO 9000 Task Force. After review of the 1985 version of the Handbook and ISO/IEC Guide 25 to determine the conformance status of State laboratories, the group recommended the use of one standard in the United States (consistent with the NCSL position) for the accreditation of calibration laboratories to:

1) reduce the number of redundant laboratory audits;
2) improve measurement compatibility and acceptance of measurement results between laboratories in the United States and internationally; and
3) comply with the ISO-series standards for quality.

The NCSL TQM Committee became an official ANSI standards writing body (Committee Z 540) and published the new U.S. standard as Z540-1-1994 (July 1994). ANSI/NCSL Z540-1-1994 incorporates ISO Guide 25 and Mil-Std-45662A. Since NCSL published this new standard in 1994:

1) the Department of Defense has rescinded Mil-Std-45662A in favor of the Z540-1-1994 standard;
2) the NIST National Voluntary Laboratory Accreditation Program (NVLAP) has adopted and referenced ANSI/NCSL Z540-1-1994;
3) the American Association for Laboratory Accreditation (A2LA), a private accrediting body, has also adopted the standard; and
4) the NIST Office of Weights and Measures, has incorporated the standard into Parts 5 and 6 of this document. Additional requirements consistent with NVLAP requirements and with the needs of the legal metrology system are included.

Table of Contents

1. Program Summary

State legal metrology laboratories are custodians at the State level of measurement standards that serve as the basis for assuring equity in the marketplace and as reference standards for calibration services for indigenous industry. As part of its program to encourage a high degree of technical and professional competence in such activities, the National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM) has developed performance standards and formalized procedures for voluntary accreditation of State legal metrology laboratories. Certificates of accreditation are issued upon evaluation of the laboratory's ability to make reliable metrological measurements (principally mass, volume, length, and temperature).

Accreditation of State Legal Metrology Laboratories

This Handbook describes the procedures followed in accrediting State (and a few other jurisdictional) legal metrology laboratories for competence. An accredited laboratory must satisfy general and technical requirements for each measurement area in which accreditation is desired (see Appendix B). This program is managed by the Office of Weights and Measures of the National Institute of Standards and Technology.

The general requirements in sections 5 and 6 incorporate ISO Guide 25, ISO Guide 38 and ISO Guide 10012-1 (as stated in the U.S. Standard ANSI/NCSL Z540-1-1994, and as adopted by the NVLAP Calibration Laboratories Accreditation Program) and address internationally accepted quality practices and good management practices for calibration and testing laboratories. In addition to ISO Guide 25 and NVLAP requirements, sections 5 and 6 contain additional general requirements as "notes" that are specific for State legal metrology laboratories. (See Section 8. References.)

The technical criteria amplify general criteria (ISO Guide 25, ANSI/NCSL Z540-1-1994) for each specific measurement parameter as needed. Technical requirements of the NIST/OWM accreditation program are identical to the NVLAP guidelines as published in the draft of NIST/NVLAP Handbook 150-2, Calibration Laboratories Technical Guide. The technical requirements include demonstration that: 1) suitable test equipment, calibration standards, defined test procedures, and the general facilities necessary for good metrological services are available; and 2) that staff have a comprehensive understanding of calibration, measurement, and test requirements and are capable of applying them.

Under this voluntary accreditation program, laboratories appraise their compliance with the requirements, using appropriate checklists which are reviewed and evaluated by NIST/OWM.

Following acceptable review and evaluation, which includes an on-site assessment and proficiency testing, NIST/OWM issues a certificate of accreditation indicating recognized competence areas with defined parameters and scope of accreditation. Accreditation may be granted for a period up to 2 years, but on an annual basis each accredited laboratory must review its status, complete an internal audit, including management and quality system review, and submit the evaluation along with a statement

that no adverse changes have taken place in order for the accreditation to remain in effect.

Types of assistance available from the National Institute of Standards and Technology are listed in Appendix A.

General

Each State legal metrology laboratory is encouraged to study this Handbook carefully and to apply for accreditation in all areas in which it provides measurement services. NIST/OWM reserves the right to deny or withdraw accreditation. In such cases, NIST/OWM will notify the State in writing of deficiencies, and provide guidelines for corrective action. In the case of withdrawal, NIST will attempt to reach agreement with the State on the timing of the corrective action in order to keep the accreditation in force conditionally.

2. Glossary

The following section contains the definitions of a number of terms in the sense in which they are used throughout this Handbook. Where applicable, definitions are taken from: 1) NIST Handbook 150, NVLAP Procedures and General Requirements, 1994, wherever possible; 2) The International Vocabulary of Basic and General Terms in Metrology (VIM: 1994); or 3) NIST Handbook 143, Program Handbook, 1985 edition. Many of the NIST Handbook 150 definitions are taken from the VIM:1994.

Accreditation - a formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of tests or calibrations. (HB 150)

Accreditation Criteria - a set of requirements used by an accrediting body which a laboratory must meet in order to be accredited. (HB 150)

Accreditation Process - the process of demonstrating whether a calibration laboratory is capable of fulfilling specified accreditation requirements.

Approved Signatory (of an accredited laboratory) - an individual who is recognized by OWM as competent to sign accredited laboratory calibration or test reports. (HB 150, modified)

NOTE: The Approved Signatory is responsible for the technical content of the report and is the person to be contacted by OWM, 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 OWM upon request.

Authorized Representative (of an accredited laboratory) - an individual who is authorized by the laboratory or the parent organization to sign the OWM Request for Accreditation form and commit the laboratory to fulfill the OWM requirements. (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory. Only the Authorized Representative can authorize a change in the scope or nature of the laboratory's Request for Accreditation.) (HB 150, modified)

Calibration - a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand. (HB 150)

Also: comparison of a measurement standard or instrument with another standard or instrument to detect, correlate, report, or eliminate by adjustment any inaccuracy of the compared.

Corrective Action - an action taken to eliminate the causes of an existing deficiency or other undesirable situation in order to prevent recurrence.

Deficiency - the nonfulfillment of NIST/OWM conditions and/or criteria for accreditation. (HB 150, modified)

Good Laboratory Practices (GLP) - an acceptable way to perform some basic

operation or activity in a laboratory, that is known, or believed to influence, the quality of its outputs. GLPs ordinarily are essentially independent of the measurement techniques used. (HB 143, 1985)

Good Measurement Practices (GMP) - an acceptable way to perform some operation associated with a specific measurement technique, and which is known or believed to influence the quality of the measurement. (HB 143, 1985)

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. (HB 150)

Internal Assessment - the process of self-appraisal of a calibration or testing laboratory using specified general and technical criteria and checklists to evaluate compliance to accreditation requirements; may be used as a quality management review as well.

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. (HB 150)

Length Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of length standards. (HB 143, 1985)

Mass Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of mass standards or test weights; generally divided into small mass ($\leq$ 10 kg) and large mass ($>$ 10 kg) areas. (HB 143, 1985)

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. (HB 150)

NVLAP - the NIST National Voluntary Laboratory Accreditation Program.

On-Site Assessment - a formal examination or official inspection of a calibration or testing laboratory to evaluate its compliance with specific laboratory accreditation criteria.

OWM - The NIST Office of Weights and Measures (Weights and Measures Program).

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. (HB 150)

Preventive Action - an action taken to eliminate the cause of a potential deficiency or other undesirable situation in order to prevent occurrence.

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. (HB 150)

Quality Control - the operational techniques and activities that are used to fulfil requirements for quality.

Quality Manual - A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation. (HB 150)

RMAP - Regional Measurement Assurance Program. A regional approach to ensuring measurement assurance through periodic gathering to conduct training, interlaboratory comparisons, and continuous improvement activities. OWM jointly operates six regional MAPs in cooperation with the State laboratories.

Scope of Accreditation - A document issued by OWM which lists the test methods or services, or calibration services for which the laboratory is accredited. The scope for each measurement area includes the range and the best uncertainty reported at each level. (HB 150, modified)

Standard, Check (or control) - a standard that is used as part of a process measurement assurance program to provide a "check" on the process and standards to ensure that the standards, measurement results, and measurement processes are within acceptable statistical limits.

Standard, Intrinsic - Intrinsic standards are based on well-characterized laws of physics, fundamental constants, or invariant properties of materials, and they make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. (NCSL, Traceability Resolution Meeting. 1/25/96)

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. (HB 150)

Standard, Reference - A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (HB 150)

Standard, Secondary - a standard whose value is assigned by comparison with a primary standard of the same quantity. (HB 150)

Standard, Working - a standard that is usually calibrated against a reference standard, and is used routinely to calibrate or check material measures, measuring instruments, or reference materials. (HB 150)

Standard Operating Procedure (SOP) -a procedure adopted for repetitive use when performing a specific measurement or sampling operation. It may be a standard

method or one developed by the user. (HB 143, 1985)

State Laboratory Program - A program of the NIST Office of Weights and Measures designated to provide guidance, technical support, and assistance to State legal metrology laboratories to ensure accurate and traceable measurements from NIST to the local jurisdictions.

Temperature Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of temperature standards.

Tolerance Testing - a measurement operation performed to determine whether the actual value of a standard, artifact, or instrument is within a permitted tolerance of its nominal value. An error and uncertainty value must first be determined before one can assess the tolerance status. (HB 143, 1985)

Traceability - the 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. (VIM:1994)

A measurement quality assurance system and periodic verification are required to ensure that the accuracy of the measurement is within the stated limits of uncertainty.

Uncertainty - parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. (HB 150)

Volume Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of volume standards; generally divided into small volume ($\leq$ 20 L) and large volume ($>$ 20 L) areas. (HB 143, 1985)

3. General Information and Operational Requirements

3.1 Purpose

The NIST Enabling Act (31 Stat. 1449, 15 USC 271, Chapter 6 Weights and Measures) as modified by "authorities and functions pursuant to the Omnibus Trade and Competitiveness Act of 1988," provides the legislative authority to accredit State legal metrology laboratories. Authorization includes "the provision of means and methods for making measurements consistent with those of the national standards." Compliance with the accreditation criteria contained in this Handbook is the most effective means for ensuring accurate measurements consistent with national standards.

3.2 Description, Quality Policy, and Objectives

In 1965, Congress funded NIST to establish the State Standards Program to provide new standards of mass, volume, and length to the States, the District of Columbia, Puerto Rico, and the Virgin Islands to update their weights and measures laboratories and increase their measurement capabilities. The program also provided the laboratory equipment necessary for the States to use the standards in their measurement services.

As part of the States' responsibilities in the distribution of standards and equipment, each jurisdiction was required to provide an acceptable laboratory facility meeting specifications established under the State Standards Program and maintain acceptable staffing. The laboratory metrologist was required to complete training at NIST in the use of the standards and equipment.

State Laboratory Program Quality Policy:

It is the policy of the State Laboratory Program to help all State laboratories achieve and maintain accreditation and to enable accredited State legal metrology laboratories to provide their customers accurate and traceable measurement services in an environment of continuous quality improvement.

As part of its continuing support to the States, NIST manages the State Laboratory Program. This is a program of the NIST Office of Weights and Measures designated to provide guidance, technical support, and assistance to State legal metrology laboratories to ensure accurate and traceable measurements from NIST to the local jurisdictions. The program operates through continued partnership with the State laboratories to manage numerous activities within the program.

OWM objectives are to:

1. Support the basic level of measurement services required for legal metrology enforcement/oversight activities;

2. Provide technical support for the accuracy and traceability of State legal metrology laboratories to the national standards through development, training, publication of, and use of standard procedures, protocols, and measurement assurance programs;

3. Provide and maintain the accreditation program for State legal metrology laboratories as evidence of continuing measurement traceability to include auditing the use and care of the

physical standards of mass, length, and volume; and

4. Assist the States to upgrade and expand the measurement services of State legal metrology laboratories to satisfy the changing needs of their clients.

3.3 Scope of Accreditation

3.3.1 Voluntary and noncontractual

The accreditation of State legal metrology laboratories is a voluntary, nonregulated program of support to the States. While accreditation is not federally mandated, accreditation provides a cost-effective means for providing evidence of measurement accuracy and traceability. (See sections 3.9.8 and 3.9.9.)

3.3.2 Legal compliance requirements

While there are currently no federal requirements for accreditation, some States have weights and measures laws that require continued accreditation by NIST as evidence for maintaining traceability for primary standards used in the enforcement of weights and measures laws.

3.3.3 Limitations

The OWM accreditation program is limited in scope. It is provided for government legal metrology laboratories only. The NIST National Voluntary Laboratory Accreditation Program (NVLAP) offers accreditation services to all laboratories and is not limited in the scope of whom they will accredit.

3.3.4 Liability

NIST accreditation does not certify individual measurements made by a State, but formally recognizes that the State laboratory has the capability to perform reliable measurements and that the metrologist has been trained in the proper procedures to provide these measurements. The accreditation also indicates that the metrologist has submitted the data requested by NIST for accreditation. Each laboratory is responsible for verifying its measurement traceability. NIST assumes no liability for the accuracy and traceability of individual measurement results provided by an accredited laboratory.

3.4 Technical Support and Assistance

OWM offers consultative and technical support to the State legal metrology laboratories regardless of their accreditation status through informal and formal means. Informal assistance may be in the form of telephone, facsimile, e-mail, or written requests and assistance. Formal support and assistance are available through the training program and the Regional Measurement Assurance Program (RMAP) of the State Laboratory Program. See Appendix A for types of technical assistance available.

3.5 Confidentiality

To the extent permitted by applicable laws, OWM will seek to ensure confidentiality of all information obtained relating to the application, on-site assessment, evaluation, and accreditation of laboratories. *Exception: see section 3.9.9.*

Results of proficiency tests are generally discussed openly at annual RMAP meetings in the spirit of continuous improvement and

teamwork. Proficiency testing may be held confidential if any participating State laboratory requests confidentiality of the results in writing to OWM prior to the beginning of each interlaboratory comparison.

3.6 Development of Requirements

3.6.1 Use of national and international standards wherever available

When national or international standards are available in the area of accreditation requirements for calibration laboratories, OWM will adopt such standards after suitable review. Adoption rather than independent development of standards is required by federal law wherever feasible and appropriate.

3.6.2 Laboratory review, solicitation of comment by those affected

The technical requirements associated with the current version of Handbook 143 were developed in conjunction with an ISO 9000 Task Force of the National Conference on Weights and Measures. The technical requirements for mass and volume have been incorporated into the draft of NIST Handbook 150-2, Calibration Laboratories Technical Guide. Draft laboratory publications are reviewed by affected laboratories prior to publication.

3.7 Documentation

General and technical requirements of accreditation for State laboratories are maintained and published by the NIST Office of Weights and Measures. Additional documents and records to support the program are maintained by the NIST Office of Weights and Measures.

In addition to this publication, which includes the general and technical requirements for State laboratory accreditation, other publications are available:

- **NIST Special Publication (SP) 791, State Weights and Measures Laboratories: State Standards Program Description and Directory**

This document contains a general program description and laboratory directory and is updated annually.

- **NIST Handbook 145 Handbook for the Quality Assurance of Metrological Measurements**

This handbook contains laboratory procedures that are used in NIST/OWM Training Program and are recommended for use in State laboratories. Adequate data must be provided by the laboratory to justify deviation from documented procedures. This handbook includes Good Laboratory Practices, Good Measurement Practices, and Standard Operating Procedures.

- **NIST IR 5672, Advanced Mass Measurements and Measurement Assurance Program for State Calibration Laboratories**

This publication documents guidelines for facilities, equipment, standards, and training recommended for precision mass calibration and measurement control programs. It is consistent with the technical criteria for mass calibration.

- **NIST IR 5802, Quality Manual Template**

This publication is a quality manual template developed as a model for State weights and Measures laboratories. It conforms to ISO/IEC Guide 25, ANSI/NCSL Z540-1-1994, and NVLAP documentation requirements.

3.8 Records

Records related to accreditation or accuracy and traceability of measurements and standards for each State are maintained in the NIST Office of Weights and Measures. Procedures regarding record retention are maintained in the Office of Weights and Measures. These documents include but are not limited to the following:

a. Traceability records for primary standards
b. Measurement Control Data (control charts and surveillance tests) - latest year
c. Training
d. Quality Manuals (latest version)
e. Proficiency Testing (round robin reports of the RMAPs)
f. Internal Audits (including management review)
g. On-site Assessment Reports

Letters verifying accreditation status, traceability, and accompanying records may be provided to a State, or on its behalf to customers, when formally requested in writing on official letterhead. Facsimile requests are not acceptable.

3.9 Rights, Duties, Responsibilities of the Accredited Laboratory

3.9.1 Display of accreditation certificates

The laboratory is encouraged to post its Certificate of Accreditation in the laboratory and may copy it for customer/client use as evidence of accreditation. The copy of the accreditation certificate must include the Scope of Accreditation (if not incorporated into the certificate.)

3.9.2 Use of accreditation status on calibration reports

The laboratory may reference its accreditation status on reports only if the laboratory is accredited in that particular measurement parameter and scope at the level specified on the calibration report. The laboratory must make no statements regarding accreditation for measurement parameters or levels of uncertainty which are not covered by the accreditation.

3.9.3 Reference to accreditation status

A laboratory may reference its accreditation status in promotional literature provided that it is consistent with NIST legal policy (15 CFR Ch. 11, 200.113) on the use of the NIST name (and NVLAP name and logo if applicable). This policy has been circulated to all State laboratories, is available in the Office of Weights and Measures as well as most local libraries. A general condition on the use of the NIST name is that it may not be used for endorsement purposes, but may be used to make factual statements regarding accreditation or traceability. Use of the NIST name or NVLAP name or logo should be accompanied by the following: "Accredited

by the Office of Weights and Measures (and the National Voluntary Laboratory Accreditation Program if appropriate) for the specific scope of accreditation under Lab Code XXXX."

3.9.4 Notification of change

The laboratory must advise the NIST OWM of any changes that affect the quality of measurement services provided by the laboratory. This includes, but is not limited to: changes in staff, damage to or loss of environmental controls in its facility, damage or change of laboratory equipment used to provide measurement services, and damage, replacement, or recalibration of primary standards used to provide measurement services (including improvements as well as adverse changes). Any change that may adversely affect the quality of measurement results is particularly important and must be reported.

3.9.5 Provide timely submissions

OWM solicits information from all laboratories each year as a reminder of the accreditation requirements. The laboratory must submit a report between October 1 and November 15 of each year. This submission must include those items specifically requested, but is not limited to the items listed in the accreditation process. Requests for technical assistance may be made at the same time. Routine failure of a laboratory to provide requested material in a timely manner will result in limited accreditation periods.

3.9.6 Reciprocity with other OWM-accredited laboratories

Accredited State laboratories may have reciprocity with other accredited State laboratories as a part of the voluntary registration program for service agents. Reciprocal acceptance of calibration reports should be limited to laboratories that have maintained accreditation. Calibration reports from laboratories that have failed to maintain accreditation should be refused.

3.9.7 Subcontracting

Little or no subcontracting is conducted by State legal metrology laboratories. In the event that a laboratory determines that it is in its best interest to subcontract calibrations, it should only subcontract to other accredited laboratories.

3.9.8 Failure to maintain accreditation

Any laboratory that fails to maintain accreditation will be encouraged to correct deficiencies and be given an opportunity to submit evidence of corrective action for whatever deficiency exists. A laboratory that has lost accreditation status may subsequently comply with the accreditation criteria. Laboratories are encouraged to work closely with the NIST Office of Weights and Measures to reestablish accreditation as soon as possible. OWM will assist each laboratory as much as possible based on need and resources available.

3.9.9 Notification of accreditation status

The NIST Office of Weights and Measures reserves the right to notify state and federal agencies as well as any indigenous industry of a State regarding accreditation status. This is generally accomplished through the periodic publication of a laboratory directory.

3.9.10 Response to deficiencies and corrective action requests

A laboratory will have a specified amount of time to respond to deficiencies addressed through annual review, internal management review, NIST OWM review, or through an on-site assessment conducted by NIST staff or its designated technical experts (TEs). At the end of the specified time period, the laboratory may be given a "conditional accreditation" detailed later in this publication. In the event that the laboratory fails to respond, or fails to respond adequately, it will not be accredited in the particular area under question until such time as it responds or corrects deficiencies. The laboratory has the right to appeal OWM decisions as described later in this publication.

4. Accreditation Process

A flowchart depicting the accreditation process is shown in figure 1. Details of this process are provided in this section. An overview of the accreditation process includes:

- an annual solicitation by OWM;
- technical review of submitted material (see list in Table 1);
- review of on-site assessment results;
- review of proficiency testing results; and
- issuance of an accreditation certificate along with a scope of accreditation.

4.1 Request for Accreditation and Fees

Each State legal metrology laboratory, plus Puerto Rico, the District of Columbia, the Virgin Islands, Los Angeles County, and the Grain Inspection and Packers and Stockyards Administration (GIPSA) Master Scale may automatically renew their accreditation; however, a Request for Accreditation must be submitted each year that details the requested Scope of Accreditation. An annual evaluation is conducted by OWM.

Responsibility for measurement accuracy and traceability as used in commerce is cooperatively shared by a number of federal and state agencies. An excellent working partnership exists between the State legal metrology laboratories and NIST, OWM. The laboratories provide payment-in-kind through voluntary efforts for many of the activities needed to maintain the accreditation process in partnership with OWM. As a result of this partnership and shared responsibilities, no fees are charged to these laboratories for support of the accreditation process.

4.2 Annual Solicitation

Accreditation material is annually solicited by NIST via a detailed memorandum between August 1 and September 15.

4.2.1 Annual submission period

Laboratories are to submit the Request for Accreditation, along with specifically requested items each year between October 1 and November 15. If a laboratory fails to submit material in a timely manner, there is a risk that the accreditation certificate will not be renewed by the expiration date of the previous certificate. Certificates expire December 31 each year (or every 2 years) and are renewed January 1. Material must be submitted each year for the certificate to remain in effect. Material submitted late will be processed as expeditiously as possible once it has been received by the NIST OWM.

4.2.2 Information to be submitted

The information to be submitted annually varies depending on the particular circumstances of each laboratory's accreditation and will be detailed in the solicitation memorandum. Requested information is always related to specific accreditation criteria.

Generally, a Request for Accreditation, a complete checklist and all associated forms and charts must be submitted each time the laboratory's accreditation is due to expire. A list of items is detailed in Table 1. If accreditation has lapsed, it is treated as a renewal.

4.3 On-site Assessments (Monitoring and Requested)

Since all laboratories were initially established with the technical support and guidance of the NIST OWM in the late 1960's or early 1970's and have been visited by OWM staff, all on-site assessments initiated by OWM are considered monitoring assessments. Essential monitoring assessments are conducted periodically, generally in conjunction with training or regional meetings. Additional on-site assessments may be requested by the laboratory and will be conducted as practically feasible.

The primary objectives of on-site assessments are to: 1) ensure that the laboratories maintain laboratory quality by complying with documented accreditation criteria and 2) assist the laboratories to improve their overall operations, facilities, equipment, standards, or staff. On-site assessments may be conducted by NIST staff or by contracted TEs.

Technical Experts will use checklists and all formal assessment reports will follow the same general format to ensure consistency from one laboratory assessment to another. Assessments generally take between 1 and 3 days and are conducted to minimize disruption of normal laboratory operations. Since most State laboratories operate with minimal staff, as much advance notice as possible of the assessment date is given for scheduling purposes.

All OWM records concerning a given laboratory are available to OWM staff, NVLAP staff, or an assigned TE for evaluation of accreditation only. These include quality manuals, training records, RMAP attendance records, results of internal audits, results of round robin or other proficiency tests, control charts, NIST calibration reports, reports of tests, and any previous correspondence with the laboratory. During the actual on-site assessment, the assessor verifies information contained in the files through meetings with management and laboratory staff, by examination of facility, equipment, standards, test reports, quality documents, and procedures, and by observation of procedures. The assessor need not be given any information which violates individual privacy such as salary, medical information, or performance reviews outside the scope of the accreditation program.

4.3.1 NIST staff

On-site assessments of the laboratories may or may not be conducted by NIST OWM staff. However, NIST staff will prepare all final laboratory assessment reports and communicate assessment results to the management and staff of each laboratory.

4.3.2 Technical Experts

TEs (may also be called regional assessors) are metrologists with technical expertise plus appropriate auditing training and skills and discretion who have been selected to conduct on-site assessments for the State Laboratory Program. Criteria for selection are based on professional and academic achievement and are maintained in the NIST Office of Weights and Measures.

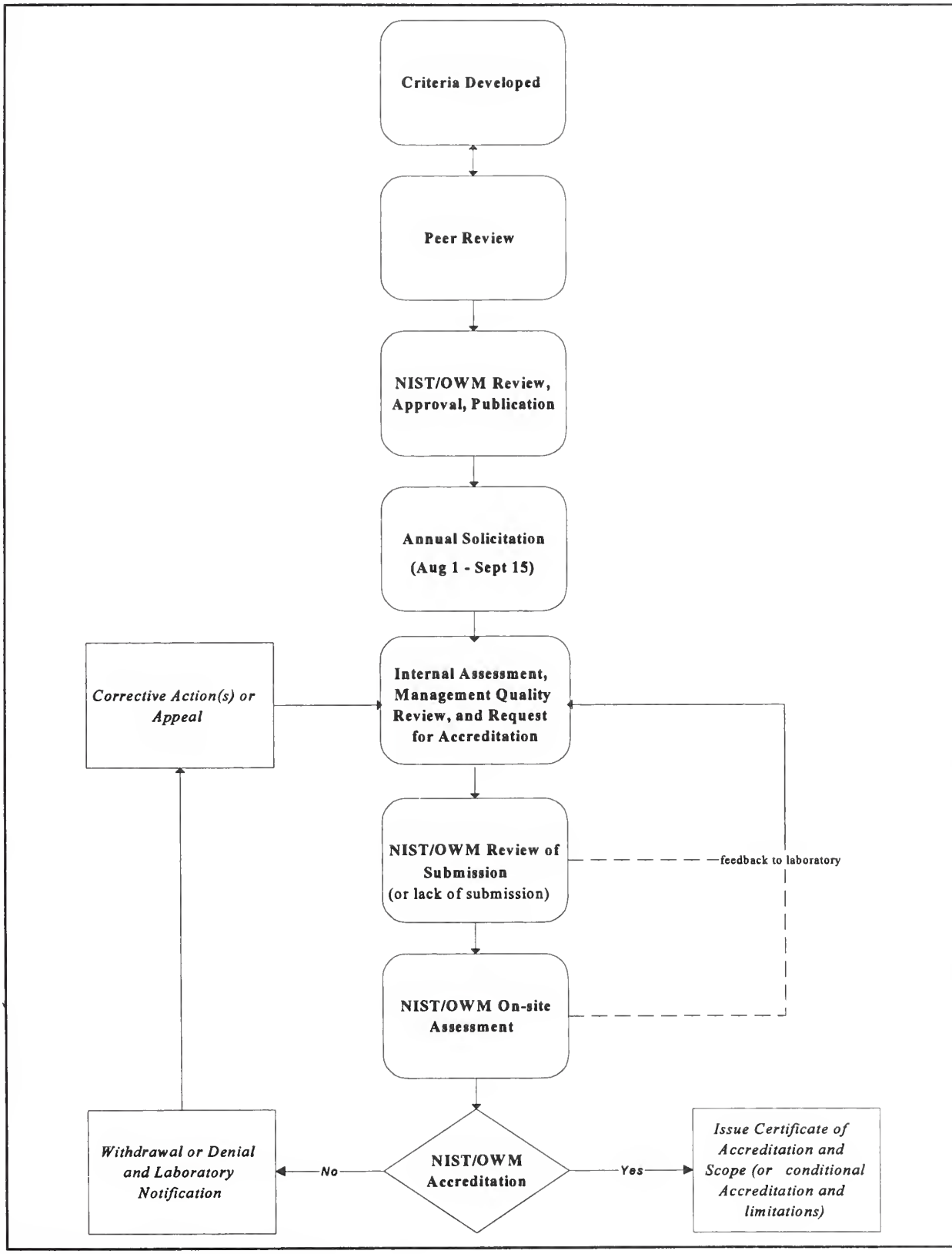

Figure 1. Accreditation process

OWM strives to ensure fairness and impartiality in its assessments. TEs are required to sign a form regarding laboratory confidentiality. Concerns regarding any TEs should be brought to OWM's attention in writing. Records are maintained for the assessments each TE has conducted. NIST may provide additional training in auditing techniques for regional assessors. TEs may draft assessment reports; however, these reports will be reviewed and finalized by OWM staff.

4.3.3 Assessment report and invitation to respond

Either a draft assessment report or the assessor's notes may be left with laboratory staff or management at the close of a formal assessment. A formal assessment report may be issued to the laboratory detailing deficiencies and the expected preventive or corrective action. The laboratory is given an opportunity to respond or appeal stated deficiencies. An assessor may or may not be fully aware of specific laboratory conditions and clarification may be appropriate, thus the laboratory response may include additional clarification. The laboratory is expected to comply with deficiencies as soon as possible and to implement preventive action as a normal course of operations. The laboratory must submit a corrective action plan to OWM within 30 days of receiving a final report. This does not mean that deficiencies must be corrected within that time period; it only means that a plan for corrective action must be completed and submitted. OWM will respond to the laboratory regarding the acceptability of the laboratory response.

4.3.4 Contents of assessment report

The assessment report will contain, as a minimum, the following information:

a. name and address of the laboratory;
b. date of the assessment;
c. criteria used to conduct the assessment;
d. parameters and scope of accreditation for the assessment;
e. name(s) of the assessors and affiliations;
f. name(s) of laboratory management and staff contacted during assessment;
g. list of additional records reviewed in addition to the on-site assessment (such as the quality manual, training records, control charts, or round robin results maintained by OWM);
h. references to the Program Handbook when deficiencies are identified;
i. recommendations and preventive action for laboratory improvement and discussion related to cited observations; and
j. deficiencies and corrective action required to meet accreditation criteria and discussion related to cited observations.

4.4 Proficiency Testing

Interlaboratory comparisons (round robins) are conducted as a part of each regional measurement assurance program and constitute one of the primary methods used for assessment of competence. The other primary method is the assignment of Laboratory Auditing Program (LAP) problems upon the completion of each training seminar. However, on-site assessments may include demonstration of procedures, retest of a

calibration item, or test of artifacts submitted directly to the laboratory.

Acceptable results of proficiency tests are essential for accreditation to be granted; further investigation will be conducted to resolve any deficiencies. Proficiency testing results will be analyzed against accepted and/or standardized data analysis methods. As with on-site assessments and accreditation decisions, the laboratory may contact OWM regarding proficiency testing results if they believe an analysis was incorrect or if insufficient information was available for a complete evaluation.

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

a. failure to meet specified proficiency testing performance requirements or objectives prescribed at the outset of the round robin;
b. failure to participate in a regularly scheduled round of proficiency testing for which the laboratory has received instructions and/or materials;
c. failure to submit laboratory control data as required specific to each round robin;
d. 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
e. failure to produce acceptable calibration or test results when using special artifacts whose properties are well-characterized and known to NIST OWM.

4.5 NIST Technical Evaluation

Technical evaluation is conducted prior to awarding an accreditation certificate and includes a full review of all available technical information regarding the laboratory. This may include annual accreditation submissions, control charts, quality manuals, assigned training problems, on-site assessment reports, results of proficiency tests, training records, attendance and participation at RMAPs, plus any other relevant information affecting the quality of the laboratory's measurement results.

4.5.1 Review of submissions

Submissions will be reviewed and feedback provided to laboratories with the same level of significance as an on-site assessment. Preventive action will be recommended and corrective action will be required for noted deficiencies.

4.5.1.1 New, renewal, or expansion

Any laboratory that is to receive a new certificate for January 1 must submit laboratory material between October 1 and November 15. Material will be reviewed by OWM between November 15 and December 31.

4.5.1.2 Maintenance

If a laboratory has multi-year accreditation, OWM will review material between November 15 and March 1 of the following year. In the event that material is not submitted during the appropriate time frame, OWM will review the material as time is available, giving preference to laboratories without current accreditation.

4.6 Accreditation Periods and Policy

Selection of accreditation periods is based on OWM judgment of the degree to which a laboratory meets accreditation criteria and whether the laboratory routinely submits data in a timely manner. While minor deficiencies may not affect a laboratory's ability to establish accreditation, they will result in a shorter accreditation period to encourage the necessary oversight to achieve corrective action.

Each laboratory will be given every opportunity to provide input to OWM for evaluation and to provide feedback to OWM assessments and evaluations. Any laboratory has the right to appeal accreditation decisions in writing to the NIST, Office of Weights and Measures.

Complaints regarding the operation of the accreditation program, on-site assessments, document review by NIST or any NIST-assigned technical expert should be forwarded to the NIST OWM in writing.

4.6.1 Full renewal - 2 year

For those laboratories fully meeting accreditation criteria, a 2-year accreditation certificate will be issued; however, additional data must continue to be submitted annually for review as requested. Laboratories receiving a 2-year certificate generally meet NVLAP accreditation criteria although a NVLAP assessment would determine the full extent of compliance. Any laboratory not accredited by OWM for a 2-year period should not apply for NVLAP accreditation.

4.6.2 One-year renewal

For laboratories where OWM management and oversight are required, or when minor deficiencies exist, a 1-year accreditation certificate may be issued based on the judgement of OWM staff that acceptable measurements will continue to be provided to laboratory customers.

NOTE: Until the new criteria in this handbook are fully met (including documentation), a laboratory will not be issued a 2-year certificate of accreditation.

4.6.3 Conditional renewal

A 1-year *conditional* certificate of accreditation may be granted when numerous deficiencies exist in the facilities, equipment, standards, staff, or overall laboratory operations, *and* the laboratory is working to meet accreditation criteria. *Conditional* accreditation will only be issued to meet legal weights and measures requirements and limitations will be stated in writing. *Conditional* accreditation will be marked on the certificate.

4.6.4 Maintenance

If accreditation for a laboratory has not expired, an annual review of submitted data and any laboratory on-site assessments may be conducted; however, no new certificate will be issued since the current certificate is valid.

4.6.5 Suspension, withdrawal, denial

In the event that circumstances change significantly during an accreditation cycle, it is the responsibility of the laboratory to notify OWM. Any situation that critically affects the laboratory's ability to provide accurate and

traceable measurements may be cause for temporary suspension of accreditation until criteria are met.

A laboratory may choose to withdraw from specific levels of accreditation based on circumstances in the laboratory, but may be reinstated any time it fully meets accreditation criteria.

The result of an on-site assessment or of document review may include denial of accreditation. Clear evidence of deficiencies will be provided to the laboratory in writing along with the required minimum corrective action. Denial of accreditation may be modified based on the laboratory response or resolution of an appeal.

Table 1. Accreditation submission requirements

Reference	Item Description	Annual	Change or Renewal	Updated
Appendix B	Request for Accreditation, Parameters and Scope, Approved Signatories, Authorized Representative	x	change	
Appendix C	Part 1, Internal Assessment and Management Review	x	change	
Appendix C	Part 2, Internal Assessment Checklist		as requested, change	
Appendix D	Summary of Services and Uncertainties Charts		renewal	x
	Laboratory Quality Manual			x
	Measurement control - control charts, surveillance tests	To be submitted if requested in annual solicitation memorandum or if technical support is needed; will be reviewed during on-site assessments		
	NIST calibration reports for standards			x
	Laboratory Auditing Program (LAP) problems assigned in Training Program			x (as completed)

5. General Technical Requirements for Calibration Laboratories

This section sets out the general NIST/OWM general technical requirements with which a legal metrology calibration laboratory must comply in order to be accredited to carry out specific calibrations. The requirements of sub-sections 5.1 through 5.13 are comparable to the requirements of ISO/IEC Guide 25 as they apply to calibration laboratories and as written in the ANSI/NCSL Z540-1-1994 U.S. national standard.

NOTE: Additional sections have been added in the form of "OWM NOTES" to identify how each section will be interpreted for State legal metrology laboratories.

5.1 Organization and Management

5.1.1 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 the requirements of this Handbook.

5.1.2 The laboratory shall:

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

b) 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;

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

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

e) 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. Management practices shall be such as to ensure adequate supervision;

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

g) 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;

OWM NOTE: It is recognized that multifunctions may exist in small laboratories whereby it is difficult or impossible to maintain a distinction between a "technical manager" and a "quality manager." In these cases, OWM technical evaluation and assessment will serve as an independent review as needed or required.

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

i) have documented policy and procedures to ensure the protection of customers' 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.

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

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

OWM NOTE: Organizational responsibilities must be defined and identified on an organization chart or similar device. The chart must depict the relation of the laboratory to its parent organization and to other units that report to the same parent. Position descriptions shall be available for each staff member and each shall know his/her responsibilities within the organization.

5.2 Quality System, Audit and Review

5.2.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration 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.

5.2.2 The quality manual and related documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Handbook. The quality manual and related documentation shall also contain:

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

b) the organization and management structure of the laboratory, its place in any parent organization and related organizational charts;

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

d) procedures for control and maintenance of documentation;

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

f) identification of the laboratory's approved signatories;

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

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

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

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

k) procedures for handling calibration and verification items;

l) reference to the major equipment and reference measurement standards used;

m) reference to procedures for calibration, verification and maintenance of equipment used;

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

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

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

q) procedures for dealing with complaints;

r) procedures for protecting confidentiality and proprietary rights;

s) procedures for audit and review;

t) a statement of the laboratory's policy for establishing and changing calibration intervals for equipment it controls;

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

v) a description of the laboratory's policy regarding the use of the NIST certificate of accreditation (OWM or NVLAP) and NVLAP logo, if appropriate.

OWM NOTE: The list of items in this section is not a complete list of all items that must be included in a quality manual. The NIST Office of Weights and Measures provides NIST IR 5802, Quality Manual Template for the State laboratories to use as a baseline which complies with these requirements and must be sufficiently modified to match specific program details. All modifications must be evaluated against these criteria. All updates must be submitted for review.

5.2.3 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. Where the audit findings cast doubt on the correctness or validity of the laboratory's

calibration 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).

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

OWM NOTE: Appendix C contains an "Internal Assessment and Management Review" form that is to be used for this activity and is to be submitted annually or as circumstances change in the laboratory.

5.2.5 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 time frame.

5.2.6 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:

a) internal quality control using whenever possible statistical techniques;

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

b) participation in proficiency testing and other interlaboratory comparisons;

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

d) replicate measurements using the same or different methods;

e) retesting of retained items;

f) correlation of results for different characteristics of an item.

OWM NOTE: The laboratory shall maintain a list of control charts or surveillance activities maintained by the laboratory. Measurement control requirements must be in place for each measurement service provided by the laboratory. The quality manual template contains forms that may be used by the laboratory to list control charts, surveillance activities, and proficiency tests. This documentation must be available during on-site assessments and submitted to the NIST Office of Weights and Measures as requested.

5.3 Personnel

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

5.3.2 The calibration laboratory shall ensure that the training of its personnel is kept up-to-date consistent with employee assignments and development.

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

OWM NOTE: The NIST Office of Weights and Measures provides training to State legal metrology laboratories. State metrologists are required to complete the appropriate level of training as indicated in Table 2 (p. 36), for the laboratory to be accredited at designated levels. Information regarding the training program is maintained in the Office of Weights and Measures.

5.4 Accommodation and Environment

OWM NOTE: Section 7 of this Handbook contains specific technical requirements for various measurement parameters that will be used for additional guidance in laboratory assessments.

5.4.1 Laboratory accommodation, calibration areas, energy sources, lighting, temperature, humidity, 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 guidelines found in the NCSL Recommended Practice #7, *Laboratory Design,* July 25, 1993.

5.4.2 The environment in which these activities are undertaken shall be specified and not invalidate the results or adversely affect the required uncertainty 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.

5.4.3 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, line voltage, temperature, and sound and vibration levels, as appropriate to the calibrations concerned.

5.4.4 There shall be effective separation between neighboring areas when the activities therein are incompatible.

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

5.4.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.

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

5.5 Equipment and Reference Materials

5.5.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations. In those cases

where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Handbook are met.

5.5.2 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.

5.5.3 Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

5.5.4 Records shall be maintained of each item of equipment and all reference materials significant to the calibrations performed. The records shall include:

a) the name of the item of equipment;

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

c) date received and date placed in service;

d) current location, where appropriate;

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

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

g) dates and results of calibrations and/or verifications and date or criteria when the calibration and/or verification expires;

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

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

j) measured value observed for each parameter found to be out of tolerance during calibration/verification.

OWM NOTE: The quality manual template contains a chart to list of equipment and its current performance evaluation. This information will be requested during on-site assessments, and the chart may be requested annually for review with measurement control documents.

5.6 Measurement Traceability and Calibration

5.6.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations 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 to 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.

5.6.2 The overall program of calibration and/or verification of equipment shall be designed and operated so as to ensure that,

wherever applicable, measurements made by the laboratory are traceable to national, international, or intrinsic standards of measurement where available. Calibration certificates and/or reports shall, wherever applicable, state the traceability to national, international, or intrinsic 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.

Where applicable, the methodology of the ISO Guide to the Expression of Uncertainty in Measurement: 1993, shall be used as the basis for expression of uncertainty of the 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.

5.6.3 Where traceability to national, international or intrinsic standards of measurement is not available, traceability requirements may be satisfied by:

a) participation in a suitable program of interlaboratory comparisons or proficiency testing;

b) internationally accepted standards in the field concerned;

c) suitable reference materials;

d) ratio or reciprocity-type measurements; or

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

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

5.6.5 Reference standards of measurement shall be calibrated by a competent body that can provide traceability to a national, international, or intrinsic standard of measurement. There shall be a program of calibration and verification for reference standards.

OWM NOTE: A competent body will generally be interpreted as NIST or a NIST-accredited laboratory.

5.6.6 Where relevant, reference standards and measuring and testing equipment shall be subject to in-service checks between calibrations and verifications.

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

OWM NOTE: Copies of calibration reports for primary standards used in the laboratory are maintained in the NIST Office of Weights and Measures. The laboratory must submit updated calibration reports as available. If reports are not from NIST, they should be from another accredited laboratory.

5.7 Calibration Methods

5.7.1 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, where the absence of such instructions could jeopardize the calibrations. 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.

5.7.2 The laboratory shall use appropriate methods and procedures for all calibrations/verifications and related activities within its responsibility (including, but not limited to, sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration data).

a) 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.

b) 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 or analyses are not used, then the uncertainty of calibration or verification shall not exceed 25 percent of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

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

5.7.4 Where it is necessary to employ methods that have not been established as standard, these 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.

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

5.7.6 Calculations and data transfers shall be subject to appropriate checks.

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

a) the requirements of this Handbook are complied with;

b) computer software is documented and adequate for use;

c) 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;

d) 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 data;

e) 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.

5.7.8 Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory that can affect the results of calibrations.

OWM NOTE: The NIST Office of Weights and Measures maintains NIST Handbook 145, Handbook for the Quality Assurance of Metrological Measurements. States must reference this handbook and use it for all applicable measurement procedures unless data or other evidence is available to support acceptable results using another procedure. Other procedures must be submitted to OWM for review and approval by the NIST Office of Weights and Measures. Use of uniform procedures is critical for maintaining the integrity of the legal measurement system.

5.8 Handling of Calibration Items

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

5.8.2 Upon receipt of the calibration item, any abnormalities or departures from standard condition as prescribed in the relevant calibration method shall be recorded. Where there is any doubt as to the item's suitability for calibration, where the item does not conform to the description provided, or where the calibration 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.

5.8.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration item, during storage, handling, preparation, and calibration; 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 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 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.

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

5.8.4 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.

5.9 Records

5.9.1 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 shall contain sufficient information to permit repetition of the calibration. 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.

5.9.2 All records (including those listed in 5.5.4 pertaining to calibration equipment), certificates and reports shall be safely stored, held secure and in confidence to the client for the period specified in the quality manual (to the extent allowable by law).

5.10 Certificates and Reports

5.10.1 When a certificate or report is issued, the results of the calibration, or series of calibrations carried out by the laboratory shall be accurate, clear, unambiguous and objective, in accordance with any instructions in the calibration methods. The results should normally be reported in a calibration report or certificate and shall include all the information necessary for the interpretation of the calibration results and all information required by the method used.

5.10.2 Each certificate or report shall include at least the following information:

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

b) name and address of laboratory, and location where the calibration was carried out if different from the address of the laboratory;

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

d) name and address of client, where appropriate;

e) description and unambiguous identification of the item calibrated;

f) characterization and condition of the calibration item;

g) date(s) of performance of calibration, where appropriate;

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

i) reference to sampling procedure, where relevant;

j) any deviation from, additions to or exclusions from the calibration method, and any other information relevant to a specific calibration, such as environmental conditions;

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

l) a statement of the estimated uncertainty of the calibration result (where relevant);

m) 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;

n) where relevant, a statement to the effect that the results relate only to the items calibrated;

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

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

q) the signature of an Approved Signatory for all calibration reports endorsed with the NIST accreditation status or NVLAP logo, if appropriate;

r) special limitations of use; and

s) traceability statement.

5.10.3 Where the certificate or report contains results of calibrations performed by subcontractors, these results shall be clearly identified.

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

5.10.5 Material amendments to a calibration report or calibration certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Report [or Calibration Certificate], serial number... [or as otherwise identified]," or equivalent form of wording. Such amendments shall meet all the relevant requirements of subsection 5.9 of this Handbook.

5.10.6 The laboratory shall notify customers promptly, in writing, of:

a) any event such as the identification of defective calibration equipment that casts doubt on the validity of results given in any calibration report or certificate, or amendment to a report or certificate. Such notification shall quantify the magnitude of error created in the calibration results.

b) 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.

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

5.11 Subcontracting of Calibration

5.11.1 Where a laboratory subcontracts any part of the calibration, this work shall be placed with an accredited laboratory complying with the requirements of this Handbook. 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 competence criteria as the laboratory with respect to the work being subcontracted. The laboratory shall advise the client, in writing, of its intention to subcontract any portion of the calibration to another party.

5.11.2 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.

5.11.3 The laboratory shall maintain subcontracting policy and procedures and shall clearly identify in the report to the client the subcontractor and exactly which data were obtained by the laboratory and which data were obtained by the subcontractor.

5.12 Outside Support Services and Supplies

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

5.12.2 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 concerned.

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

5.13 Complaints

5.13.1 The laboratory shall have documented policies 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.

5.13.2 Where a complaint, or any other circumstance, raises a concern regarding the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Handbook or otherwise concerning the quality of the laboratory's calibrations, the laboratory shall ensure that complaints in those areas of activity and responsibility involved are promptly investigated and resolved.

6. Quality Assurance Requirements for Measuring and Test Equipment

NOTE: This section applies to the control of measuring and test equipment used to assure that supplies and services comply with prescribed customer requirements. It is based in large part of 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 standard.

6.1 General Requirements

6.1.1 The supplier shall establish and document a system to control the calibration of measuring and test equipment (M&TE) as necessary to assure the conformance of supplies and services to customer specifications.

6.1.2 M&TE used to determine compliances to customer specifications shall be calibrated or verified in accordance with Section 5 of this Handbook.

6.1.3 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 because of mishandling, misuse, or unusual results.

6.1.4 All operations performed by the supplier in compliance with this Handbook shall be subject to customer verification at unscheduled intervals.

6.1.5 The supplier shall carry out or arrange to be 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.

6.1.6 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.

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

6.2 Detailed Requirements

6.2.1 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 section 6 of this handbook and any deviations shall be submitted with supporting documentation to the customer for approval.

6.2.2 Adequacy of measurement standards

Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of sections 5.5.1, 5.6.1, and 5.7.2 of this handbook.

6.2.3 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 necessary, correcting compensations shall be applied to measurement results.

6.2.4 Intervals of calibration and verification

M&TE shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that the 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.

6.2.5 Calibration Procedures

Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of 5.7.1 and 5.7.2 of this handbook.

6.2.6 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.

6.2.7 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.

6.2.8 Calibration sources

M&TE requiring calibration shall be calibrated or verified by laboratories which have been accredited.

6.2.9 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.).

6.2.10 Calibration Status

M&TE shall be labeled to indicate calibration status. A calibration 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 calibration 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 broken tamper-resistant seals.

6.2.11 Control of subcontractor calibration

The supplier is responsible for assuring that a subcontractor's calibration laboratory conforms to the requirements in Section 5 of this Handbook to the degree necessary to assure compliance with customer requirements. Accreditation of a laboratory according to these requirements by a third-party activity acceptable to the customer may serve as the basis for compliance with this requirement.

6.2.12 Storage And Handling

M&TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration of the equipment.

Table 2. Training requirements

Accreditation Level	Training Required	For Whom	How Often
Minimum (for legal metrological activities)	• Basic Laboratory Metrology Seminar (2 weeks) • Basic LAP problems - acceptable completion • Attendance at Regional Measurement Assurance Program meeting annually	Usually all staff At least one staff member	Once Once Annually
Calibration	• All of the above, plus: • Intermediate Laboratory Metrology Seminar (1 week) • Intermediate LAP problems - acceptable completion	Usually all staff; at least one	Every 3-4 years unless attending RMAP annually
Advanced mass calibration	• All of the above, plus: • Advanced Mass Measurements Seminar • Advanced LAP problems completed	At least one if working at this level	At least once; for updates as needed
Thermometry	• Attendance at a NIST Precision Thermometry Seminar	At least one as needed	At least once; for updates as needed

NOTE: The Quality Manual Template (NIST IR 5802) contains a form that can be used to document training and dates.

7. Specific Technical Guidelines

The following information is primarily from the NVLAP Calibration Laboratories Technical Guide.

> "This section provides examples and guidelines, not requirements, to technical experts and interested calibration laboratories, on good laboratory practices and recommended standards. Therefore, the guide language reflects this philosophy through the use of "shoulds" instead of "shalls" (along with other less prescriptive language) when describing criteria. Absolute requirements are not presented here since they depend on the measurement uncertainty for which an applicant laboratory wishes to be accredited. This is a business decision for each laboratory and beyond the scope of this voluntary program. Simply stated, to be accredited an applicant laboratory must have a quality system and be able to prove (and document) that it does what it says it does (i.e., correctly calibrate to a stated uncertainty).
>
> This guide is dynamic in that new parameters may be added and existing criteria updated and improved."

Accreditation Parameter Summary

Each laboratory must specify the range and uncertainty level for each parameter for which it requests accreditation. Uncertainties must be defined at each level. For example, a chart must be available that will state each nominal mass, each nominal volume, and so on, with the associated uncertainty.

Table 3. Accreditation parameter summary

Parameter	Range/Application	Expanded Uncertainty
Mass	laboratory to detail nominal ranges and uncertainties: e.g., 30 kg to 1 mg; Echelon II	
Echelon I	ASTM Class 1, 1.1, OIML Class E1, E2	0.25 mg at 1 kg, and 1 to 5 mg/kg
Echelon II	ASTM Class 2, 3, OIML Class F1, F2	1 mg/kg to 20 mg/kg
Echelon III	ASTM Class 4, 5, 6, OIML Class M1, M2, M3 NIST Class F, legal/regulatory enforcement	20 mg/kg to 1 000 mg/kg
Length	laboratory to specify range: e.g., 10 cm to 20 meter tapes	
Tapes, bench method	up to 25 meters (100 ft)	0.0 001 m to 0.000 14 m
Tapes, tape method	up to 25 meters (100 ft)	0.000 15 m to 0.000 25 m
Rules, direct comparison	up to 0.5 cm (18 in)	< 0.000 05 m
Volume	laboratory to specify ranges: e.g., 2 µLiter micropipettes to 2000 mL glass flasks	
Gravimetric	syringes, micropipettes, glass standards, and metal provers	0.000 10 mL/L
Volume transfer	glass standards and metal provers	< 0.001 mL/L
Temperature	laboratory to specify type and ranges: e.g., -10 °C to 200 °C; Echelon II	
Echelon I	SPRT's	≤ ± 0.005 °C
Echelon II	Thermistors, thermocouples	> ± 0.005 °C to ≤ ± 0.05 °C
Echelon III	Liquid-in-glass thermometers	> ± 0.05 °C to ≤ ± 0.20 °C
Echelon IV	Liquid-in-glass, dial type, pyrometers	> ± 0.20 °C to ≤ ± 1.0 °C
Echelon V	Infra-red sensors, thermographs	> ± 1.0 °C to ≤ ± 5.0 °C
Tuning Forks	as used for law enforcement	0.05 mph, estimate based on interlaboratory tests
Hydrometers	sugar, syrup, petroleum	estimate
Time	stopwatches used for law enforcement	significantly less than tolerances; estimated at 2 s for a 24 hr test
Grain Moisture	programs for testing grain and commodity moisture	
Oven Methods	laboratory to specify methods and products	0.2% moisture content
Chemical Methods		0.2% moisture content

7.1 Technical Criteria for Dimensional Laboratories (NVLAP Calibration Laboratories Technical Guide)

7.1.1 Scope

The purpose of this section is to specify the specific technical criteria needed to meaningfully assess the competence of a calibration laboratory that performs dimensional calibrations. The artifact calibrations currently included in the accreditation program are:

a. steel tapes; and
b. rigid rules.

NOTE: Much of this section applies dimensional measurements that are more complex than the calibration of tapes and rules; however, it is the responsibility of the laboratory to determine which sections are applicable.

7.1.2 References

[1] ANSI/ASME B 89.6.2, Temperature and Humidity Environment for Dimensional Measurements.

7.1.3 Statistical Process Control

7.1.3.1 All sources of variability for the calibration should be monitored by subsystem calibration (e.g., thermometer, force gage calibration) and the use of check standards to ensure that the calibrations are carried out under controlled conditions. The laboratory should maintain and document some form of statistical process control (SPC) commensurate with the uncertainty levels of the calibration. The SPC control parameters should be based on measurements of check standards (or closure parameters resulting from self-calibration or ratio methods) and the repeatability of multiple measurements. The frequency and number of process control checks should be appropriate for the number of calibrations as well as the level of uncertainty and reliability claimed for the calibration.

7.1.3.2 The laboratory should have control artifacts which adequately span the range of materials and sizes normally calibrated by the laboratory. Every measured value of each control should be recorded and compared to its historical value to determine that the process is in control. The comparison may be made via a plotted control chart with appropriate control limits or by numerical comparison using the t-distribution. The expected control values should be updated at least yearly using the most current 1 or more years of data.

7.1.4 Accommodation and Environment

7.1.4.1 The temperature in the calibration area should nominally be 20 °C (degrees Celsius) with a maximum variation and rate of change depending on the materials and the uncertainty level needed for the calibration. Measurements at temperatures other than 20 °C may be made if the proper thermal expansion corrections are applied and the component of uncertainty reflecting the uncertainty in

thermal expansion coefficients of the artifacts is calculated and added to the total uncertainty of the calibration. For comparison measurements the uncertainty component should reflect the uncertainty in the thermal expansion of both the master and unknown artifacts.

7.1.4.2 For length calibrations of the type in legal metrology laboratories, the immediate environment should be ± 2 °C of 20 °C, and should be measured with an accuracy of 0.5 °C. The temperature variation should be less than ± 1 °C over 24 hours and ± 0.5 °C during any 1-hour period. Other environmental conditions may be acceptable as long as the effects are included in the uncertainty determination.

7.1.4.3 The measured length should be corrected to a reference temperature of 20 °C using the known linear thermal expansion coefficient of the material.

7.1.4.4 The temperature stability of the environment should be sufficient for the gage and measurement system to be in thermal equilibrium. Measurements may be made in slowly changing environments if a suitable measurement model, which includes the effects of the drift, is used. Theoretical and experimental verification of the model should be available.

7.1.4.5 For typical gages made of well characterized materials (steel, carbide or ceramic), 0.000 001 per °C should be used as the thermal expansion coefficient uncertainty unless there is documentation of a lower value.

7.1.4.6 The relative humidity in the calibration room should not exceed 50 percent.

7.1.4.7 Excessive vibration should be avoided in the calibration room. If an obvious source of vibration exists, precautions should be taken to prevent adverse effects on the laboratory's measurements.

7.1.4.8 The laboratory should have a documented policy regarding responses to problems with the environment.

7.1.5 Equipment and Reference Materials

7.1.5.1 The laboratory should have the equipment needed to make auxiliary measurements on artifacts. (e.g., flatness of gage blocks, roundness of ring gages)

7.1.5.2 The laboratory should have temperature measuring capabilities suitable to the calibration procedure. Calibrations involving direct comparisons of artifacts of similar size and materials will, in general, have modest requirements. Absolute calibrations or comparisons between artifacts of different sizes and/or materials will require more accurate temperature measurement.

7.1.5.3 A laboratory that certifies artifacts to tolerance grades should demonstrate a measurement uncertainty which does not exceed 25 percent of the tolerance. Exceptions to this ratio should be

accepted for measurement systems which are documented to be the state-of-the-art and approved by the customer.

7.1.5.4 A laboratory that makes mechanical comparisons of masters and test pieces of dissimilar materials should have force measuring equipment to determine the force on the probe or probes. A correction for differential probe penetration should be applied as long as the probe has maintained its rounded shape. On old comparators the probe radius may be altered to the point where a correction would induce error.

7.1.5.5 A laboratory that makes absolute measurements using displacement measuring sensors, such as interferometers or linear scales, should have environmental monitoring equipment appropriate to the sensor.

7.1.5.6 A laboratory that makes absolute measurements using a contact device should have force measuring equipment to determine the force on the probe or probes. A correction for probe penetration should be applied if appropriate.

7.1.5.7 A laboratory that makes interferometric measurements should have: (1) equipment for making high-accuracy temperature measurements, and (2) equipment for determining the index of refraction of air.

7.1.6 Calibration Methods

7.1.6.1 When calibrations are made by comparison to master gages of the different nominal sizes the temperature control of the gages and the measurement environment should be increased.

7.1.6.2 The laboratory should have a manual outlining the procedures to be followed for each type of calibration. For calibration of graded sets, the procedure should name the grades which are calibrated by the procedure.

7.1.6.3 The procedures used for related services, such as checks of roundness, relapping, repair, or replacement of damaged or out-of-tolerance gages should be clearly stated.

7.1.6.4 Procedures related to the calibration of rigid rules and tapes used by legal metrology laboratories are as follows from NIST Handbook 145:

Tape to tape method for tapes. (SOP 11);
Bench method for tapes. (SOP 12);
Rigid rule calibration. (SOP 10); and
Pi tape calibration (SOP 23).

7.1.7 Handling of Calibration Items

7.1.7.1 Artifacts should be cleaned and stored in a manner to prevent accidental contact with material which could damage the gaging surfaces.

7.1.7.2 Care should be taken to prevent steel artifacts from rusting. Steel artifacts should be coated with a rust inhibiting grease whenever there is a potential for exposure to an environment over 50 percent relative humidity. If artifacts cannot be greased other materials (e.g., rust inhibiting paper) or methods should be used to inhibit rust.

7.1.7.3 After cleaning, artifacts should be allowed to come to adequate thermal equilibrium in the calibration environment before measurement. Artifacts should be placed on a soaking plate or in position on the measuring machine long enough to ensure that they are at the proper temperature. The soaking time will depend on the size and the thermal properties of the artifacts and plate. Specific guidelines for soaking times should be stated in the measurement procedure. The heating effects from optical radiation, body heat, and system location should be minimized.

7.1.7.4 In general, to prevent thermal changes and corrosion of the gaging surfaces, artifacts should not be handled with bare hands. Gloves or tongs should be used whenever possible.

7.1.8 Certificates and Reports

7.1.8.1 All content of certificates or reports of calibration should conform to the guidelines of NCSL Recommended Practice RP-11.

7.1.8.2 All certificates or reports of calibration should contain an uncertainty statement which is scientifically determined from measurement data and which agrees with the laboratory's stated definition.

7.1.8.3 The uncertainty should be derived from a model of the measurement system which includes (as applicable) the uncertainties caused by:

a. Master artifact calibration;
b. Long term reproducibility of measurement system;
c. Thermal expansion correction for gages and measurement scales;
    1. Thermometer calibration
    2. Thermal expansion coefficient
    3. Thermal gradients (internal, gage-gage, gage-scale)
d. Interferometry;
    1. Measurement uncertainty of refractometer
    2. Index of refraction formula
    3. Environmental measurements (air temperature, air pressure, humidity, etc.)
    4. Calibration of light source frequency

5. Phase correction for reflected light
6. Obliquity and slit corrections

e. Instrument geometry;
   1. Abbe offset and instrument geometry errors
   2. Scale and gage alignment (cosine errors)
   3. Gage support geometry (anvil flatness, block flatness)

f. Probe penetration correction;

g. Rotary axis errors (radial and axial displacements, tilt);

h. Analysis algorithms (data fitting, filtering); and

i. Other factors as appropriate.

7.1.8.4 The method used to affix the calibration items should be described in detail. In general, differences in fixture configurations between calibration and use will introduce errors in the calibration.

7.2 Technical Criteria for Mass Laboratories (NVLAP Calibration Laboratories Technical Guide, with OWM modifications)

7.2.1 Scope

The purpose of this section is to specify the specific technical criteria needed to meaningfully assess the competence of a calibration laboratory that performs mass calibrations.

7.2.1.1 A laboratory should declare its measurement capability in terms of uncertainties for each mass value. For many laboratories these uncertainties correspond to three arbitrary echelons of measurements which roughly correspond to weight classifications at nominal mass value ranges of measurements. For laboratories seeking accreditation at an uncertainty range that corresponds to a specific echelon, the scope of accreditation should follow the echelons as defined in Table 4 with a declared range of nominal mass values and their associated uncertainties. Recommended ranges of mass values are provided in Table 5. A summary of sections 7.2.3, 7.2.5.1, 7.2.5.6, and 7.2.6.1 are provided in Table 8.

7.2.1.2 The echelon stated by the laboratory is associated with the standards, procedures, measurement control, facilities, equipment, staff capability, and the overall level of performance according to Table 4, and is specifically defined by the expanded uncertainty. Echelons are evaluated by all of these factors in addition to the laboratory's reported uncertainties.

Table 4. Mass calibration echelons

Echelon	Typical Test & Verification Levels	Expanded Uncertainty of the Measurements
I, (Extra Fine Accuracy)	OIML, Classes E1, E2 ASTM, Classes 1, 1.1	The expanded uncertainty should be less than tolerances in this range.
II, (Fine Accuracy)	OIML, Classes F1, F2 ASTM, Classes 2, 3	The expanded uncertainty is usually less than 1/3 to 1/4 of stated tolerances .
III, (Medium Accuracy)	OIML, Classes M1, M2, M3 ASTM, Classes 4, 5, 6 NIST, Class F	The expanded uncertainty is usually less than 1/9 or 1/10 of the tolerances in this range; however, uncertainty exceptions up to 1/3 of the tolerances may be made for legal metrology applications.

Table 5. Recommended "Scope of Accreditation" for mass calibration

Echelon	Scope of Accreditation Nominal Value Range ± Uncertainty	
I	≥ 30 kg (define limit)	
	30 kg to 1 mg	
	1 kg to 1 mg	
	100 g to 1 mg	
II	≥ 30 kg (define limit)	for special applications:
	30 kg to 1 mg	≥ 1000 lb (define limit)
	1 kg to 1 mg	≥ 50 lb (define limit)
	100 g to 1 mg	50 lb to 0.001 lb
III	≥ 30 kg (define limit)	normal applications:
	30 kg to 1 g	≥ 1000 lb (define limit)
	1 kg to 1 g	≥ 50 lb (define limit)
	100 g to 1 g	50 lb to 0.001 lb

7.2.1.3 The reported uncertainty of mass standards calibrated by a mass calibration laboratory will vary depending on available balances and the nominal value of the mass standard being tested. Thus, a laboratory may perform calibrations at Echelon I in some ranges, for example at 1 kg, and may perform calibrations at Echelon II, e.g., 20 kg, in other ranges. The laboratory performs calibrations in a specified range as requested; however, all laboratories may not be capable of meeting the requirements of all echelons. Differing equipment, skills, knowledge, measurement control, and demonstrated competence are required for each of the echelons. Demonstrated competence in one echelon is insufficient to guarantee adequate performance in the others.

7.2.2 References

[1] ANSI/ASTM E 617, Standard Specification for Laboratory Weights and Precision Mass Standards, Aug 15, 1991.

[2] OIML International Recommendation 111, Weights of Classes E_1, E_2, F_1, F_2, M_1, M_2, M_3, 1994.

[3] NIST Handbook 105-1, Specifications and tolerances for Reference Standards and field Standard Weights and Measures, Specifications and Tolerances for Field Standard Weights, (NIST Class F), 1990.

[4] NBS Technical Note 844, Designs for the Calibration of Small Groups of Standards in the Presence of Drift, Cameron, J. M., Hailes, G. E., 1974.

[5] NBS Technical Note 952, Designs for the Calibration of Standards of Mass, Cameron, J. M., Croarkin, M. C., Raybold, R. C., 1977.

[6] NIST IR 5672, Advanced Mass Calibrations and Measurement Assurance Program Requirements for State Calibration Laboratories, Fraley, K. L., Harris, G. L., 1995.

7.2.3 Statistical Process Control

7.2.3.1 Appropriate measurement control programs should be in place and available for review for each echelon and nominal mass range for which calibration data is provided. Note Table 8 for appropriate measurement control programs for each echelon. Appropriate data includes balance standard deviations that represent process variation and well-characterized check standard values.

7.2.3.2 Measurement control techniques should exhibit results consistent with the procedures used to perform calibrations and should be integral to the measurement to accurately reflect the measurement process. For those situations where statistical information is not inherent to the process, i.e., simple measurements without built-in redundancy checks, additional measurements should be made to provide experimental characterization of the measurement sufficient for an adequate estimation of the process uncertainty. Those data should be available for review.

7.2.4 Accommodation and Environment

7.2.4.1 To be deemed capable of making adequate measurements, calibration laboratories should provide an environment with adequate environmental controls appropriate for the level of measurements to be made, according to echelons defined herein. The environmental conditions are summarized in Table 6.

Table 6. Environmental facility guidelines for mass laboratories

Echelon	Temperature	Relative Humidity
I	20 °C to 23 °C, a set point ± 1 °C, maximum change 0.5 °C/h	30% to 55%
II	20 °C to 23 °C, a set point ± 2 °C, maximum change 1.0 °C/h	30% to 55%
III	18 °C to 25 °C, maximum change 1.0 °C/h	30% to 60%

7.2.4.2 Cleanliness guidelines are usually met without clean-room type air handling systems by maintaining clean-room type practices. Excessive air exchange rates negatively affect balance performance. The laboratory should maintain limited access to the calibration area and minimize contamination (provide a clean surface) for locations where calibration items are being tested. Activities such as smoking, eating, or drinking and items such as paper products, printers, and files contribute to the difficulty of maintaining adequate cleanliness and are not recommended. A positive pressure, laminar-type air flow is usually needed to maintain cleanliness recommendations and to minimize air currents.

7.2.4.3 Vibration should not diminish the performance of precision analytical balances and mass comparators. Proximity to heavy machinery, railways, heavily traveled highways, or similar sources of known vibration is not recommended. Steps are often taken to attenuate vibration to an acceptable level of stability with methods such as massive piers (solid marble or concrete tables), isolated foundations, or elimination of the source. Balances and mass comparators used for Echelons I and II generally require massive piers, independent piers, and/or an isolated foundation; pneumatic or hydraulic tables are inappropriate.

7.2.4.4 Undesirable effects due to static electricity should be controlled, if needed, with methods such as humidity, anti-static deionizing radiation devices, the grounding of balances or operators, or with the use of special conductive flooring and selection of proper clothing for staff.

7.2.5 Equipment and Reference Materials

7.2.5.1 Minimum reference standards should be available at each echelon and range, for which the laboratory is accredited, as recommended in Table 8. Sufficient historical data and uncertainty analysis should be available to support the standards used.

7.2.5.2 The accuracy of auxiliary instruments for Echelons I and II, (e.g., scale, analytical balance, mass comparator) is less important than the precision of the instrument due to algorithms used in mass calibration. However if such equipment is repaired, it should be reevaluated to ascertain its current level of precision prior to use, and the uncertainty estimate should reflect the post repair performance.

7.2.5.3 The precision of the scale, analytical balance, or mass comparator, as determined through appropriate process control charts, should be suitable for the echelon at which it is used. For an application where external standards are used for comparison, appropriate control charts should be maintained to evaluate the process standard deviation. Note Table 8 summary for further evaluation.

7.2.5.4 Means should be provided to measure barometric air pressure, air temperature, and relative humidity of the laboratory environment as indicated in Table 7; documentation of the accuracy and traceability is required. These instruments should be used in close proximity to the balance being used. For Echelon I, temperature may be measured inside the weighing chamber when there is a difference between the air temperature in the balance chamber and the surrounding area. For Echelon III, where buoyancy corrections are generally negligible, recording environmental data is useful in the

support of general environmental requirements of the previous section but the accuracy generally does not affect measurement results.

Table 7. Environmental equipment accuracy

Parameter	Barometric Pressure	Temperature	Relative Humidity
Echelon I	± 65 Pa (0.5 mm Hg)	± 0.1 °C	± 5%
Echelon II	± 135 Pa (1.0 mm Hg)	± 0.5 °C	± 10%
Echelon III	The laboratory maintains documented accuracy.		

7.2.5.5 For Echelon I, the laboratory should state the presence of a possible systematic error in the combined uncertainty associated with the use of an assumed density in the primary or reference standards (additional Type B component) or the laboratory should have appropriate means to measure the density of mass standards. If the magnetic susceptibility of the mass standards is evaluated, it should be indicated on calibration reports. The methods used to determine density or magnetic susceptibility should be documented.

7.2.5.6 Each mass standard used as a reference standard by the laboratory should be calibrated by NIST or by an accredited laboratory with capability adequate to sustain the accuracy required and maintain traceability to BIPM. The laboratory should provide evidence, such as periodic surveillance, that the standard is, in principle, acceptable for providing calibration services at each echelon. Note Table 8 for traceability guidelines.

7.2.5.7 Balances used as a direct comparison to the mass unit, should be given a verification test or calibration prior to use. For an application requiring balance accuracy, the laboratory should choose appropriate and correct calibration algorithms. Balances used as dividers and multipliers of the mass unit should be capable of the appropriate accuracy and linearity requirements of the accuracy class for which they are used. Calibration of built-in standards should be performed periodically and should be verified prior to use. History from measurement control programs (surveillance testing) may be used to determine calibration intervals.

7.2.5.8 Instruments used to monitor environmental conditions in the laboratory should be traceable to a suitable national laboratory (directly or via an accredited laboratory) and be recalibrated periodically unless defining standards are employed. Calibration periods will be documented by the laboratory.

7.2.6 Calibration Methods

7.2.6.1 The algorithm chosen for the measurement, the reference standard to be used, and the equipment to be used for a particular calibration should provide acceptable levels of uncertainty for

that calibration. A documented procedure should be available in the laboratory to determine the correct algorithm. Note Table 8 for guidelines.

7.2.6.2 Computer programs should have passed software quality analysis. Computer programs should be tested, using standard data sets designed to magnify errors, as an effective way of showing that program errors do not effect some measurements but cause others to be incorrect. Computer programs should be documented in detail. The documentation should include technical references that provide the basis for the algorithm, the weighing equation, and the data set used to test the program for errors.

7.2.7 Handling of Calibration Items

7.2.7.1 The laboratory should have documented procedures to ensure adequate chain-of-custody of calibration items if required by law.

7.2.7.2 The laboratory will document appropriate procedures to ensure that cleaning, if performed, ensures the integrity of the standards, and to provide for thermal conditioning, where appropriate.

7.2.7.3 Documented procedures to ensure adequate tracking of calibration items should be appropriate to the class of mass standard. Strings, tags, or labels fastened to the standard are inappropriate.

7.2.8 Certificates and Reports

7.2.8.1 Certificates and reports should describe the mass standards mentioned in the report with sufficient detail to avoid any ambiguity. For Echelons I and II, additional items to be included on a test report, are: mass (true mass) values, conventional (apparent) mass values versus appropriate reference density, reference density, uncertainties, material, thermal coefficient of expansion (if used in calculations), construction, density (measured or assumed), and any identifying markings.

7.2.8.2 Environmental parameters measured during the test should be provided on certificates and reports if appropriate. These include laboratory temperature, barometric pressure and relative humidity.

7.2.8.3 Information regarding cleaning methods (if requested) should be provided on the test report.

7.2.8.4 Reports may include reference to OIML or ASTM classification schemes and tolerances. Calibration items being tested should meet appropriate specifications for evaluation as well as tolerances. It is the responsibility of the requestor of the calibration to select classifications acceptable for their needs.

7.2.8.5 The weight surface of a mass standard should be free of any sign of abuse or damage. Signs of abuse or misuse include the placement of labels, tags, wires or other material on mass standards. In addition, visible dirt and fingerprints are a sign of misuse for Echelons I and II. It is recommended that the calibration laboratory establish appropriate means for notifying customers regarding any

unusual factors such as signs of abuse regarding the mass standard being tested should be included on the report. Out of tolerance conditions should be reported when significant or when requested.

Table 8. Summary of technical criteria for mass calibration

Echelon	Minimum Measurement Control	Minimum Reference Standards	Minimum Traceability	Minimum Calibration Methods
I (Extra Fine)	• Process control charts • Check standards for each decade, with long term standard deviation • Surveillance of all standards • Proficiency Testing -on-site assessment -round robin participation	• OIML Class E_1, or E_2 or • ASTM Class 1, 1.1, Type 1, Grade S; or • single piece, highly polished	• NIST, or other national level calibration every 2-5 years based on measurement process data and independent verification, or • NIST Mass MAP, or • User operated mass calibration package, on-site to verify traceability (when	• Documented weighing designs consisting of redundant comparisons, with built-in process controls such as those used at the national level. For example: • Technical Notes, 952 and 844
II (Fine)	• Process control charts • Check standards for each decade, with long term standard deviation • Surveillance of selected standards • Proficiency Testing -on-site assessment -round robin participation	• OIML Class E_1, or E_2 • ASTM Class 1, 1.1; or • single piece, highly polished	• NIST calibration every 2 - 5 years based on measurement process data and independent verification, or • Calibration by accredited Echelon I laboratory, if uncertainty requirements can be met.	• Documented comparison calibration procedure For example: • NIST Handbook 145, double substitution, or 3-1 weighing design, or equivalent
III (Medium)	• Process control charts • Check standards for each balance • Proficiency Testing -on-site assessment -round robin participation	Working standards such as: • ASTM Class 2, 3 or • OIML Class F_1 • two piece acceptable, fine finish	• Calibration of all working standards by NIST every 2 - 5 years based on measurement process data and independent verification, or • Calibration of all working standards by an Echelon I or II accredited labs every 2 - 5 years based on measurement process data and independent	• Use of annually calibrated balance with documented verification procedure prior to each use • Use of modified substitution (NIST Handbook 145) • Other documented and verified procedure

7.3 Technical Criteria for Volume Laboratories (NVLAP Calibration Laboratories Technical Guide with OWM modifications)

7.3.1 Scope

The purpose of this section is to specify the specific technical criteria needed to meaningfully assess the competence of a calibration laboratory that performs volume calibrations. It should be noted that the procedures affect the achievable uncertainty.

Table 9. Recommended "Scope of Accreditation" for volumetric calibration

Procedure Types	Scope of Accreditation - Nominal Value Range		
Gravimetric	Glassware		Metal Test Measures or Provers
	Standard	Pipets & Syringes	
	≥ 1 L		≥ 2 000 L **or** ≥ 500 gal
	1 L to 100 mL		100 L < V < 2 000 L **or** 25 < V < 500 gal
	100 mL to 1 µL	100 mL to 1 µL	≤ 100 L **or** ≤ 25 gal
Volume Transfer	Glassware		Metal Test Measures or Provers
	≥ 1 L **or** 1 qt		≥ 2 000 L **or** ≥ 500 gal
	100 mL < V < 1 L **or** 1 gill < V < 1 qt		100 L < V < 2 000 L **or** 25 < V < 500 gal
	...		≤ 100 L **or** ≤ 25 gal

7.3.1.1 Volumetric units are derived from mass units. Volume calibrations may be determined by either a gravimetric (weighing procedure) or a volume transfer (comparative) method. The two methods require different technical requirements and both are defined here. The measurement of volume by metering methods (and meter calibration) is outside the scope of this document.

7.3.1.2 The gravimetric procedure is based on the conservation of mass principle where a determination of the mass of water contained in or delivered from the vessel that is being calibrated is used to define volume. The mass values are determined in air, are corrected for air buoyancy effects, and are corrected to appropriate reference temperatures. The accuracy and precision will vary depending on balances used, the purity of the water, the ability to make accurate temperature measurements, the nominal value of the volume standard being tested, and the ability to make adequate mass measurements.

7.3.1.3 In the volume transfer procedure, water is delivered from a primary volume standard to the vessel under test. Temperature corrections are made to compensate for the cubical coefficients of

thermal expansion of the standard, test vessel, and water to a specified reference temperature. The accuracy and precision will vary considerably depending on the presence of a meniscus, the cleanliness and drain characteristics of the container, the cleanliness and purity of the water, and the ability to make adequate temperature measurements.

7.3.2 References

[1] ANSI/ASTM E 287, Standard Specification for Burets.

[2] ANSI/ASTM E 288, Standard Specification for Volumetric Flasks.

[3] ANSI/ASTM E 438, Standard Specification for Glasses in Laboratory Apparatus.

[4] ANSI/ASTM E 542, Standard Practice for Calibration of Volumetric Ware.

[5] ANSI/ASTM E 694, Standard Specification for Volumetric Ware.

[6] ANSI/ASTM E 969, Standard Specification for Volumetric (Transfer) Pipets.

[7] OIML IR #4, Volumetric Flasks.

[8] OIML IR #40, Graduated Pipettes for Verification Officers.

[9] OIML IR #41, Standard Burettes for Verification Officers.

[10] OIML IR #43, Standard Graduated Glass Flasks for Verification Officers.

[11] NIST Handbook 105-2, 105-3, 105-4 Specifications and Tolerances for Reference Standards and Field Standard Weights and Measures; Specifications and Tolerances for Field Standard Glass Flasks, Open-neck Provers, and LPG Volumetric Provers.

[12] API Manual of Petroleum Measurement Standards, Chapter 4 - Proving Systems (Field Standards, Tank Provers).

7.3.3 Statistical Process Control

7.3.3.1 Appropriate measurement control programs should be in place and available for review for each measurement type (based on procedures) and nominal volume range for which calibration data is provided. Note Table 12 for appropriate measurement control programs for each measurement type. Appropriate data includes standard deviations and range values that represent process variation and well characterized check standard values.

7.3.3.2 Measurement control techniques should exhibit results consistent with the procedures used to perform calibrations and should be integrated into the measurement to accurately reflect the

measurement process. For those situations where statistical information is not inherent to the process, i.e., simple measurements without built-in redundancy checks, additional measurements should be made to provide experimental characterization of the measurement sufficient for an adequate estimation of the process uncertainty. Those data should be available for review.

7.3.4 Accommodation and Environment

7.3.4.1 To be deemed capable of making adequate measurements, calibration laboratories should provide a facility with adequate environmental controls appropriate for the level of measurements to be made, according to procedure types as shown in Table 10. Lower relative humidity may increase measurement error due to evaporation.

Table 10. Environmental facility guidelines for volumetric calibration

Procedure	Temperature	Relative Humidity
I Gravimetric	20 °C to 23 °C, set point ± 2 °C maximum change 1.0°C/h	30% to 55%
II Volume Transfer	18 °C to 25 °C, maximum change 1.0 °C/h	20% to 60%

7.3.4.2 The environment in which testing activities are undertaken should not invalidate the results or adversely affect the required accuracy. Particular care should be taken when such calibration practices are undertaken at sites other than the permanent laboratory facility to minimize the effects of uncontrolled environments.

7.3.4.3 Vibration, air currents, rapid temperature fluctuations, and other environmental concerns should not diminish the accuracy and precision of volume transfer methods or the performance of precision balances or scales when gravimetric methods are used.

7.3.4.4 The quality of water used as a calibration medium should be of adequate purity (potable) and cleanliness, and should be free from excess air entrapment. For gravimetric procedures the density should be calculated/measured to the nearest 0.00001 g/cm^3.

7.3.5 Equipment and Reference Materials

7.3.5.1 Mass standards used as reference standards should be traceable to a national laboratory (such as NIST) and be available at each class and range, for which the laboratory is accredited, as recommended in Table 12. Sufficient historical data and uncertainty analysis should be available to support the standards used.

7.3.5.2 Volume standards used as reference standards in the laboratory should be traceable to a national laboratory (such as NIST) and the laboratory should have appropriate procedures in place for verification and recalibration. The accuracy of the primary volume standards of the laboratory should be appropriate for the accuracy class of services provided.

7.3.5.3 Gravimetric methods, which generally use water as calibration media, require the verification of an adequate supply of deionized or distilled water.

7.3.5.4 Gravimetric methods require the use of weighing equipment with adequate accuracy and precision for the uncertainty of the measurement procedure. Appropriate control charts or range charts should be maintained to verify the measurement process.

7.3.5.5 Gravimetric methods require the means to adequately measure barometric air pressure, air temperature, water temperature, and relative humidity of the laboratory environment. Volumetric methods require temperature measurements. Environmental measuring equipment should be available with the accuracy indicated in Table 11. Relative humidity may need to be monitored more closely if evaporation is a concern.

Table 11. Environmental equipment accuracy

Procedure Type	Barometric Pressure	Temperature water/air	Relative Humidity
Gravimetric	± 135 Pa (1.0 mm Hg)	± 0.1 °C / ± 0.5 °C	± 10%
Volume Transfer	Not essential	± 0.5 °C	Not essential

7.3.6 Calibration Methods

7.3.6.1 The algorithm chosen for the measurement, the reference standard to be used, and the equipment to be used for a particular calibration should be correct for that calibration. A documented procedure should be available in the laboratory to determine the correct algorithm. (Examples are provided in NIST Handbook 145 Standard Operating Procedures, SOPs.)

7.3.6.2 Computer programs should have passed software quality analysis. Computer programs should be documented in detail. The documentation should include technical references that provided the basis for the algorithm, any weighing equations, and data set used to test the program for errors.

7.3.7 Handling of Calibration Items

7.3.7.1 The laboratory should have documented procedures to ensure adequate chain-of-custody of calibration items if required by law.

7.3.7.2 Appropriate procedures should be documented to ensure adequate tracking of calibration items that are appropriate for glass or metal volumetric standards.

7.3.8 Certificates and Reports

7.3.8.1 Calibration reports should describe the volume standards mentioned in the report with sufficient detail to avoid any ambiguity. Additional items to be included on a test report are: volume, uncertainty, reference temperature, material, thermal coefficient of expansion (assumed or measured), construction, any identifying markings, and any tolerances if appropriate.

7.3.8.2 Environmental parameters measured during the test should be provided on the test report as appropriate. These include laboratory temperature, volume standard temperature, barometric pressure and relative humidity.

7.3.8.3 Volume standards being tested should meet the appropriate classifications such as NIST, ASTM, API, or OIML, if required by laboratory customers. It is the responsibility of laboratory customers to determine acceptable accuracy levels for their needs.

7.3.8.4 The calibration item (volume standard) should be free of any sign of abuse or damage. Signs of abuse or misuse include dents, chips, improper draining due to lack of cleanliness, and dirty sight gages. Out of tolerance conditions should be reported.

Table 12. Summary of technical criteria for volume calibration

Procedure	Minimum Measurement Control	Minimum Reference Standard	Minimum Traceability	Minimum Calibration Methods
I Gravimetric	• Process control charts • Check standards • Surveillance of all standards used to provide measurement services • Proficiency testing -On site assessment -Round robin participation	Appropriate mass standards • ASTM Class 2 or 3; or • OIML Class F1 or F2; or • Calibrated Balance	• NIST, or national level calibration periodically, based on independent historical data verification or • Test of weighing equipment using correct methods of calibration and adjustment with traceable mass standards	• Documented comparison calibration procedure or • NIST Handbook 145, double substitution (for example) or • Use of calibrated balance
II Volume Transfer	• Process control charts • Check standards • Surveillance of selected standards • Proficiency testing -On site assessment -Round robin participation	Primary volume standards with accuracy and repeatability characteristics acceptable for the type of service provided	• Original NIST calibration and periodic independent verification or • Calibration by accredited Echelon I laboratory, if uncertainty requirements can be met	Documented volume transfer (or water draw) procedure recognized by NIST, OIML, ASTM, or API

7.4 Technical Criteria for Hydrometer Laboratories (NVLAP Calibration Laboratories Technical Guide)

7.4.1 Scope

This section outlines the specific technical requirements in accordance with which a laboratory should demonstrate that it operates, if it is to be recognized as competent to carry out calibrations of hydrometers.

7.4.2 References

[1] ASTM E 100: Standard Specification for ASTM Hydrometers.

[2] ASTM E 126: Standard Method for Inspection and Verification of Hydrometers.

7.4.3 Statistical Process Control

7.4.3.1 All sources of variability for the hydrometer calibration should be monitored. Check standards should be used to ensure that the calibrations are carried out under controlled conditions. The laboratory should maintain statistical process control (SPC) commensurate with the accuracy levels needed for the calibration. The SPC control parameters should be based on measurements of check standards (or closure parameters) and the repeatability of multiple measurements. The frequency and number of process control checks should be appropriate for the level of uncertainty claimed for the calibration.

7.4.3.2 The laboratory should have control hydrometers which adequately span the range of materials and sizes normally calibrated by the laboratory. Every measured value of each control should be recorded and compared to its historic value to determine whether or not the process is in control. These values should be plotted on a control chart (may be done on a computer and stored electronically) that has upper and lower control limits.

7.4.4 Accommodation and Environment

7.4.4.1 The environmental conditions (i.e., temperature, atmospheric pressure and relative humidity) in the hydrometer calibration area should have no more than the maximum variations permitted, depending on the materials and the accuracy level needed for the calibration. The reference temperature for a particular hydrometer scale may vary from 15.56 °C (15.56 °C ≈ 60 °F, which is the reference temperature for petroleum products in the United States) to 20 °C. The laboratory should have the appropriate instrumentation required to measure the environmental conditions.

7.4.4.2 The density of the water used in hydrometer calibrations should be known to within 0.000005 g/cm^3. Specific gravity is expressed as the ratio of the density of a liquid to the density of water at a specified temperature.

7.4.4.3 Vibration of equipment used in the hydrometer calibrations should be reduced to non-influential levels. If an obvious source of vibration exists, it should not adversely affect the laboratory's claimed uncertainty level.

7.4.4.4 Any laboratory that makes hydrometer comparisons should have an appropriate supply of calibration fluids with suitable surface tensions. Hydrometers should be calibrated in the liquids in which they are to be used.

7.4.4.5 Calibration liquids should be stored in an approved safety cabinet. Laboratories that make hydrometer comparisons should abide by all safety requirements set forth by a regulatory counsel, (e.g., chemical labeling, EPA and OSHA guidelines, etc.).

7.4.5 Equipment and Reference Materials

7.4.5.1 The laboratory should have the appropriate equipment required to perform hydrometer calibrations at the accredited level. All equipment should be properly maintained.

7.4.5.2 The laboratory that performs hydrometer comparisons should have master hydrometers for which the calibrations are directly traceable to the appropriate national standards laboratory. The appropriate calibration corrections to these master hydrometers should be applied.

7.4.5.3 The laboratory should have the equipment needed to make auxiliary measurements of hydrometers, (e.g., balances, mass standards, knowledge of water density, etc.).

7.4.5.4 Any laboratory that makes hydrometer comparisons should abide by all safety requirements set forth by a regulatory counsel, (e.g., chemical labeling, EPA and OSHA guidelines, etc.).

7.4.5.5 The laboratory should have temperature measuring capabilities suitable to the calibration procedure. In the case of measuring the specific gravity of a liquid with a master hydrometer, temperature measurement of the liquid accurate to ±0.01 °C is required.

7.4.5.6 A laboratory that makes hydrometer comparisons should have a ventilated chemical hood to exhaust any harmful fumes from the working area.

7.4.6 Calibration Methods

7.4.6.1 The wide use of hydrometers for many different purposes has led to various stem scales for unique applications (e.g., specific gravity, percentage alcohol, degrees API, degrees Baume and Brix).

7.4.6.2 Ideally, hydrometers under test are compared directly to master hydrometers in the kinds of liquids in which they are to be used. This comparison is performed in a clear, smooth glass cylinder

of suitable size. The calibration liquid should be well stirred before each comparison to minimize temperature gradient in the liquid.

7.4.6.3 The laboratory should have a manual detailing the procedures to follow for each type of hydrometers being calibrated. This manual should contain all pertinent information needed for calibration at a given accreditation level.

7.4.7 Handling of Calibration Items

7.4.7.1 Hydrometers should be cleaned and stored in a manner that prevents accidental contact with material which could damage the calibration surfaces. Since hydrometers are made of glass and can be easily broken, they should be handled only by an experienced operator.

7.4.7.2 Inspection should be made of all hydrometers for calibration for bent stems, twisted scales, and loose material inside the body of the hydrometer.

7.4.7.3 The hydrometer should be wiped with alcohol and dried to ensure a clean surface before it is immersed in the calibration liquid.

7.4.8 Certificates and Reports

7.4.8.1 Summary sheets and data sheets should be used to document all calibrations. This documentation should be dated and initialed by the operator. A historical registry should be kept.

7.4.8.2 The uncertainty reported for the hydrometer should be derived from a model of the measurement system which includes, as applicable, the uncertainties due to:

a. master hydrometer;
b. long term reproducibility of measurement system;
c. thermal expansion; and
d. other appropriate factors.

7.5 Technical Criteria for Thermometer Laboratories (NVLAP Calibration Laboratories Technical Guide with OWM modifications)

7.5.1 Scope

7.5.1.1 This section contains the specific technical criteria in accordance with which a laboratory should demonstrate that it operates, if it is to be recognized as competent to carry out thermometer calibrations.

7.5.1.2. This section may also be used as a guide by thermometer calibration laboratories in the development and implementation of their quality systems.

Echelon: Level of performance associated with the level of total uncertainty, according to the following table:

Echelon	Total Uncertainty
I	≤ ±0.005 °C
II	> ±0.005 °C to ≤ ± 0.05 °C
III	> ±0.05 °C to ≤ ± 0.20 °C
IV	> ±0.20 °C to ≤ ± 1.0 °C
V	> ±1.0 °C to ≤ ± 5.0 °C

NOTE: The uncertainty of thermometers calibrated by the laboratory will vary depending upon the temperature range of application, even for the same thermometer. Thus, a laboratory may perform calibrations at Echelon II in some cases and Echelon III or IV in other cases because of the temperature ranges involved. Also, the echelon assigned is dependent on the types of thermometers calibrated.

7.5.2 References

[1] ASTM Annual Book of Standards, Volume 14.03, Standards Relating to Temperature Measurement.

[2] NIST Handbook 105-6, Specifications and Tolerances for Field Standard Thermometers.

[3] NIST SP 250-23, Liquid-In-Glass Thermometer Calibration Service.

[4] NBS Monograph 174, Thermometer Calibration, A Model for State Calibration Laboratories (Appendix A: NBS Monograph 150, Liquid-In-Glass Thermometry).

7.5.3 Statistical Process Control

7.5.3.1 Fixed-point cell and triple point of water as the reference standards

When the reference standard used by the laboratory is a fixed-point cell, the three action items described below are required as indicated by the application table that follows their description.

7.5.3.1.1 Records of complete phase equilibrium plateaus obtained for each cell upon receipt and every 6 months thereafter should be maintained.

7.5.3.1.2 A separate check thermometer should be used for each cell and control charts maintained.

7.5.3.1.3 The triple point of water should be measured after every measurement at another temperature.

Item	Echelon				
	I	II	III	IV	V
7.5.3.1.1	x	x	x	x	
7.5.3.1.2	x	x	x	x	
7.5.3.1.3	x				

7.5.3.2 SPRT or RIRT as the reference standard

When the reference standard used by the laboratory is a standard platinum resistance thermometer (SPRT) or a rhodium-iron resistance thermometer (RIRT), the two action items described below are recommended as indicated by the application table that follows them.

7.5.3.2.1 There should be documentation (i.e., control charts) to show that the resistance of the instrument at the triple point of water has not changed since its last calibration by more than the equivalent shown in the table below.

7.5.3.2.2 If a DVM, DMM, or digital temperature indicator is used, its calibration should be checked periodically at the ice point.

Item	Echelon				
	I	II	III	IV	V
7.5.3.2.1	2 mK	2 mK	5 mK	10 mK	10 mK*
7.5.3.2.2	x	x	x	x	x

7.5.3.3 Thermistor thermometer as the reference standard

When the reference standard used by the laboratory is a thermistor thermometer, the two action items described below are recommended as indicated by the application table that follows them.

7.5.3.3.1 The calibration of the thermistor thermometer should be checked frequently (monthly or weekly) depending on the particular application, and control charts should be kept.

7.5.3.3.2 If, since the last calibration, the resistance of the thermistor thermometer has changed at a reference check point (fixed-point, preferably) by the equivalent shown in the next table, a new calibration should be done.

Item	Echelon				
	I	II	III	IV	V
7.5.3.3.1		x	x	x	x
7.5.3.3.2		2 mK	5 mK	10 mK	

7.5.3.4 Thermocouple as the reference standard

When the reference standard used by the laboratory is a thermocouple, control charts should show the reproducibility at appropriate fixed points.

7.5.3.4.1 Liquid-in-glass thermometer as the reference standard

When the reference standard used by the laboratory is a liquid-in-glass thermometer, the two action items described below are recommended as indicated by the application table that follows them.

7.5.3.4.1.1 The total-immersion mercury-in-glass thermometer should be checked according to good laboratory practice. One method is to check at the ice point on a daily basis after use and maintain records.

7.5.3.4.1.2 The total-immersion liquid-in-glass thermometer should be checked according to good laboratory practice. One method is to check at the ice point weekly and maintain control charts.

Item	Echelon				
	I	II	III	IV	V
7.5.3.4.1.1			x	x	
7.5.3.4.1.2					x

7.5.4 Accommodation and Environment

7.5.4.1 For all echelons, the environmental conditions of the laboratory should be controlled.

7.5.4.2 The temperature of the laboratory should be controlled to ± 2 °C.

7.5.4.3 The relative humidity should be controlled between 30 percent and 55 percent.

7.5.4.4 Vibrations in the laboratory should be minimized.

7.5.5 Equipment and Reference Materials

7.5.5.1 Reference standards

The following table indicates which reference standard is acceptable for each echelon.

Acceptable reference standard	Echelon				
	I	II	III	IV	V
Fixed-point cell	x	x	x	x	
SPRT and/or RIRT	x	x	x	x	x
Thermistor thermometer		x	x	x	x
Gold/platinum thermocouple		x	x	x	x
Type S, R or B thermocouple			x	x	x
Total-immersion liquid-in-glass			x	x	x

7.5.5.2 Fixed-point cell as the reference standard

7.5.5.2.1 The purity of the fixed-point material should be ≥99.9999 percent and the other starting materials of construction of the cells should be of ultra-high purity also. If the cells are unsealed, they should be filled at all times with an inert gas such as argon.

7.5.5.2.2 The cells should be of the defining fixed points of the ITS-90, or well-characterized, stable and reproducible secondary fixed points.

7.5.5.3 SPRT or RIRT as the reference standard

7.5.5.3.1 A system having adequate resolution and uncertainty should be used to measure a reference SPRT or RIRT. Recommendations for specific situations are given below.

7.5.5.3.2 A resistance bridge having at least the resolution shown below, as a function of claimed total uncertainty, is recommended. A ratio bridge and standard resistors may also be used:

Echelon	Claimed total uncertainty	Minimum bridge resolution
I	≤±0.01 °C	10 μΩ
II	±0.05 °C	50 μΩ
III	near ±0.20 °C	200 μΩ
IV	near ±1.0 °C	1 mΩ

7.5.5.3.3 Alternatively, a DVM or DMM with the resolution shown below, and a constant-current source with provision for reversing the current, may be used. The current should be known to the same accuracy as the DVM or DMM.

Echelon	DVM or DMM resolution (digits)
I	6.5
II	6.5
III	6.5
IV	6.5

7.5.5.4 Thermocouple as the reference standard

If the reference standard is a noble metal thermocouple used with a scanner, a scanner with low-thermal switches should be used.

7.5.6 Measurement Traceability and Calibration

7.5.6.1 Fixed-point cell as the reference standard

When the reference standard is a fixed-point cell, the four action items described below are recommended as indicated by the application table that follows them.

7.5.6.1.1 The cell should be evaluated by NIST; or

7.5.6.1.2 The cell may have been evaluated by the supplier, if the supplier documented in detail the preparation and evaluation, showing direct traceability to NIST, or is NVLAP accredited; or

7.5.6.1.3 The cell should have been evaluated by a NVLAP accredited supplier.

7.5.6.1.4 The maximum uncertainty of the temperature of the cell should be as indicated in the next table:

Item	Echelon			
	I	II	III	IV
7.5.6.1.1	x	x*		
7.5.6.1.2		x**		
7.5.6.1.3			x	x
7.5.6.1.4	±l mK	≤±0.005 °C	0.01 °C	±0.02 °C

* for total uncertainties ≤±0.01 °C
** for total uncertainties in range ±0.01 °C to ±0.05 °C

7.5.6.2 SPRT or RIRT as the reference standard

When the reference standard is an SPRT or RIRT, the four action items described below are recommended as indicated by the application table that follows them.

7.5.6.2.1 The SPRT or RIRT should be calibrated by NIST or a NVLAP accredited laboratory every 2 years but may be calibrated by NIST every 2 to 5 years if adequate measurement process data is evident.

7.5.6.2.2 The SPRT or RIRT should be calibrated every 2 years but may be calibrated every 2 to 5 years if adequate measurement process data is evident.

7.5.6.2.3 If a bridge is used, it should be calibrated annually, and all reference resistors used with the bridge should be calibrated traceable to NIST.

7.5.6.2.4 If a DVM or DMM is used, it should be calibrated annually.

Item	Echelon				
	I	II	III	IV	V
7.5.6.2.1	x	x	x	x	
7.5.6.2.2					x
7.5.6.2.3	x	x	x	x	
7.5.6.2.4	x	x	x	x	x

7.5.6.3 If a **thermistor thermometer is the reference standard**, it should be calibrated traceable to NIST.

7.5.6.4 If a **thermocouple is the reference standard**, documentation should show that its calibration is traceable to NIST and indicate the annealing procedure used during the thermocouple's use.

7.5.6.5 If a **liquid-in-glass thermometer is the reference standard**, it should be calibrated traceable to NIST.

7.5.7 Calibration Methods

7.5.7.1 All computer programs used in data logging and analysis should be documented in detail. Also, all algorithms and equipment should be correct for the task.

7.5.7.2 When calibrations are performed by comparison against an SPRT or an RIRT, or a thermistor thermometer, or a liquid-in-glass thermometer, the five action items described below are recommended as indicated by the application table that follows them.

7.5.7.2.1 If a liquid medium is used, it should be stirred vigorously and a comparison block should be located in the bath to aid in improving the uniformity.

7.5.7.2.2 If a liquid medium is used, it should be adequately stirred and a comparison block should be located in the bath to aid in improving the uniformity.

7.5.7.2.3 If the comparison medium is a liquid, it should be adequately stirred.

7.5.7.2.4 The uniformity of the comparison medium should be measured by means of a fast-responding thermometer.

7.5.7.2.5 The temperature stability and uniformity of the comparison medium should be as shown in the next table.

Item	Echelon				
	I	II	III	IV	V
7.5.7.2.1	x	x			
7.5.7.2.2			x	x	
7.5.7.2.3					x
7.5.7.2.4			x	x	
7.5.7.2.5	±0.5 mK	±0.5 mK*	(a)	(a)	(a)

* For claimed uncertainty ≤±0.01 °C. For claimed uncertainty >±0.01 °C, at least 10 times better than the claimed uncertainty.

(a) At least 10 times better than the claimed uncertainty.

7.5.7.3 When the reference standard is a total-immersion mercury-in-glass thermometer, corrections obtained from measurements at the ice point should be made for all temperature measurements.

7.5.7.4 The ice-point bath should be made according to accepted procedures from ice made from distilled water. This applies to Echelons III, IV and V.

7.5.8 Handling of Calibration Items

In addition to the general requirements set forth for all calibration items, it should be noted that SPRT's are susceptible to and need protection from shock and vibration in shipping, handling, and storage.

7.6 Technical Criteria for Moisture Laboratories - Grain and/or Commodities (OWM Technical Guide)

7.6.1 Scope

7.61.1 The purpose of this section is to specify the specific technical criteria needed to meaningfully assess the competence of a testing laboratory that performs moisture analyses.

7.6.1.2 This document may also be used as a guide by moisture laboratories in the development and implementation of their quality systems.

7.6.1.3 Laboratories may be accredited based on procedures used to determine moisture. These four procedural categories identify the method of moisture determination and the reference methods. The scope of accreditation follows the categories as defined in Table 13. Laboratories may be accredited under two or more categories if they have the necessary equipment, skills, knowledge, measurement control and demonstrated competence to perform adequately in each category.

NOTE: The national laboratory for grain moisture in the United States is the Grain Inspection Packers and Stockyards Administration (GIPSA) formerly known as the Federal Grain Inspection Service (FGIS). The standard method recognized by the GIPSA laboratory is the Air Oven Method. Grain testing laboratories should reference the Air Oven Method and participate in interlaboratory comparisons to ensure comparability of measurements with the national laboratory.

Table 13. Moisture determination laboratory classifications

Procedural Category	Moisture Determination Method		Reference Methods
I Oven Methods	Ia	Air Oven	GIPSA (formerly FGIS) Moisture Handbook
	Ib	Vacuum Oven	AOAC Official Methods of Analysis, 15th ed. 1990, vacuum oven methods, Sec. 32
II Chemical Method	IIa	Karl Fischer chemical analysis	AOAC Official Methods of Analysis, 15th ed 1990, Karl Fischer methods AOAC, Automatic Karl Fischer Titration of Moisture in Grain, (Vol. 64, No. 6, 1981)
	IIb	Basic Reference Method	ISO 711, Cereals and Cereal Products-Determination of Moisture Content

7.6.1.4 Laboratories should document the grains and/or commodities tested and maintain replicate results within ± 0.2 percent. The scope of accreditation should indicate identified grains and/or commodities and the uncertainty limits. Uncertainty analysis should be completed according to the ISO Guide for the Expression of Uncertainty in Measurement.

7.6.1.5 Important definitions in this section follow:

Moisture content The loss in mass, expressed as a percentage, undergone by the product under the conditions specified in this document.

Air Oven A device which utilizes gravity convection or mechanical convection (forced-draft) to heat air in a chamber to its controlled temperature.

Vacuum Oven A device which utilizes a vacuum to alter the pressure within the oven chamber and maintain a temperature at that specific pressure.

Karl Fischer Titration A procedure that involves the simultaneous grinding of grain/commodity and extraction of the water with methanol and the subsequent titration of the extract with Karl Fisher reagent.

Basic Reference Method An ISO procedure (ISO Guide 711) utilizing oven and chemicals to determine moisture content of a product.

7.6.2 References

[1] United States Department of Agriculture, Grain Inspection Packers and Stockyards Administration, (GIPSA) Moisture Handbook, September, 1986.

[2] American Society for Testing and Materials (ASTM) E 145-68, Standard Specification for Gravity-Convection And Forced-Ventilation Ovens (reapproved 1987).

[3] Association of Official Analytical Chemists (AOAC), Official Methods of Analysis, 15th edition, Volume one and two, 1990.

[4] AOAC, Automatic Karl Fischer Titration of Moisture in Grain, Volume 64, No. 6, 1981.

[5] Anderson, J. E. "Storage of Cereal Grains and Their Products," Chapter 1, Moisture - Its Significance, Behavior, and Measurement. (Hunt, W. Haward and Pixton, S. W.).

[6] ISO 711, International Standard, Cereals and Cereal Products - Determination of Moisture Content (Basic Reference Method) Second edition, 1985.

[7] Scholz, Eugen "Karl Fischer Titration," 1984.

7.6.3 Statistical Process Control

7.6.3.1 An appropriate statistical process control system should be in place including procedures for measurement verification through participation in interlaboratory comparisons between the laboratory, GIPSA and other laboratories.

7.6.3.2 It is critical that testing results remain consistent with previous laboratory test results; repeated tests should remain within the laboratories documented uncertainties and be evaluated using statistical methods.

7.6.3.3 A laboratory should have an operating procedure to review data for trends and failures to indicate where failure has occurred. Records of corrective action, repair, or recalibration should also be maintained.

7.6.4 Accommodation and environment

7.6.4.1 To make adequate measurements, moisture determination laboratories should have a facility with adequate environmental controls appropriate for the laboratory classification.

7.6.4.2 Due to the extreme hygroscopic properties of ground grain (oven methods) and methanol (Karl Fischer chemical method), humidity and temperature should be controlled within the following parameters:

- Temperature: 20 °C to 23 °C, set point ±2 °C, maximum change of 1.0 °C/h; and
- Humidity: 30 percent to 55 percent.

NOTE: Sample exposure to the environment should be minimized throughout the collection, storage, and testing process.

7.6.4.3 To prevent contamination of test samples, from grain and/or commodity dust particles, adequate cleanliness should be maintained.

7.6.4.4 Adequate space should be available for sample storage, preparation and testing and be appropriately organized for efficient operation. Laboratory equipment should be logically placed to accommodate handling of samples, operation and maintenance of equipment and to prevent accidental sample substitution.

7.6.4.5 Laboratories should refrigerate storage areas for grain and/or commodities under test. Storage areas should be maintained between 1.5 °C and 7.0 °C.

7.6.4.6 Excess vibration may adversely affect the performance of precision analytical balances and mass comparators and should be prevented. Proximity to heavy machinery, railways, heavily traveled highways, or similar sources of known vibration is not recommended. Steps should be

taken to reduce vibration to an acceptable level of stability with methods such as isolated foundations for balances or elimination of the source.

7.6.4.7 Laboratories should ensure that electrical disturbances which affect moisture results are kept at a minimum.

7.6.4.8 Undesirable effects due to static electricity should be controlled as needed by maintaining appropriate laboratory humidity or with anti-static deionizing radiation devices. The grounding of balances or operators, or the use of special conductive flooring may also be used.

7.6.5 Equipment and Reference materials

7.6.5.1 Standard Reference Materials

7.6.5.1.1 Category Ia and Ib laboratories - The grains and/or commodities are prepared for use as reference standards according to documented procedures for oven testing. During preparation, storage and distribution, care should be taken to ensure reference sample integrity.

7.6.5.1.2 Category IIa and IIb laboratories - Specified reagents are used according to manufacturers' instructions for the specific type of Karl Fischer titration equipment in use. Category IIb laboratories generally should use chemicals specified in International Standard ISO 711, Sec. 7. During sample preparation, the integrity of the reagents and samples is critical.

7.6.5.2 Primary Equipment - Oven methods

7.6.5.2.1 Category Ia laboratories should have appropriate equipment for the moisture determination of grain and/or commodity moisture: mechanical (forced draft) or gravity convection ovens, desiccator, mill, moisture dishes, and analytical balance. Reference GIPSA Moisture Handbook, Chap. 4 for equipment specifications.

NOTE: The use of a mechanical convection (forced draft) oven is strongly recommended. Tests have shown that ovens of the forced-draft type have more uniform temperature due to heat circulation, the temperature recovery is more rapid after insertion of samples and will accommodate more samples than gravity convection ovens.

NOTE: Laboratories should have temperature monitoring devices with suitable accuracy and traceability to record oven temperatures during moisture testing.

7.6.5.2.2 Category Ib laboratories should have appropriate equipment for the moisture determination of grain and/or commodities: vacuum oven desiccator, mill, moisture dishes, and analytical balance with the same requirements as class Ia laboratories. Reference AOAC, Official Methods of Test for equipment specifications.

7.6.5.3 Primary Equipment - Karl Fischer chemical analysis

7.6.5.3.1 Category IIa laboratories should have appropriate equipment for the moisture determination of grain and/or commodities: Karl Fischer Titration Assembly (manual or automatic with a stirrer), mill, centrifuge, and analytical balance. Reference manufacturers' instructions and *Karl Fischer Titration*, Eugen Scholz, 1984.

7.6.5.3.2 Category IIb laboratories should have appropriate equipment for the moisture determination of grain and/or commodities: analytical balance, apparatus for reducing pressure, mill, dishes, cup, drying tube, oven, air-drying train, and desiccator. Reference International Standard ISO 711 for equipment specifications.

7.6.5.4 Secondary Equipment

7.6.5.4.1 Laboratories should measure air temperature and relative humidity of the laboratory environment. Instruments are used in close proximity to the grain and/or commodity tested. Laboratory ovens should be equipped with calibrated, accurate and traceable thermometers (accurate within $\pm$ 0.5 °C) to ensure the accuracy of the oven temperature.

7.6.5.4.2 Samples should be stored in clean, air-tight and moisture-proof glass containers or plastic bags to prevent the loss or gain of moisture in the product. Plastic bags should have a thickness of at least 0.1 mm (4 mil, 0.004 in). A thickness of 0.15 mm (6 mil, 0.006 in) is preferred due to greater durability.

7.6.6 Measurement traceability and calibration

7.6.6.1 Since direct traceability to a standard (national measurement unit) is not possible for moisture measurements of the type described here, and the Federal standard for grain moisture is defined by comparison to GIPSA results, it is critical for the laboratory to participate in interlaboratory comparison programs to establish "comparability" of the results between the laboratories.

7.6.6.2 It is essential that moisture testing equipment that affects the accuracy of the moisture measurement (e.g., to include thermometers and balances) be periodically calibrated or verified for accuracy and traceability.

7.6.6.3 Balances used in determining moisture content should be periodically verified or calibrated prior to use.

7.6.6.4 Instruments used to monitor environmental conditions in the laboratory should be periodically recalibrated. Appropriate calibration intervals should be established and documented by the laboratory.

7.6.7 Moisture determination methods

7.6.7.1 The types of moisture determination methods employed, and equipment used, should be appropriate for the grains and/or commodities being tested based on the procedural category. Measurement methods should provide acceptable repeatability. A documented procedure for each method should be available.

7.6.7.2 Computer programs used in the moisture determination of grains and/or commodities should have passed software quality analysis. Computer programs may be tested, using standard data sets designed to magnify errors, as an effective way of showing that program errors do not effect some measurements but cause others to be incorrect. Computer programs should be documented in detail. Documentation should include technical references that provide the basis for the algorithm, the moisture equations, and the data set used to test the program for errors.

7.6.8 Handling of grain and/or commodities for moisture determination

7.6.8.1 The laboratory should have documented procedures to ensure that all samples are properly and uniquely marked upon receipt to include: the type of sample and a nonrepetitive identification number to ensure adequate tracking of samples in laboratory and field.

7.6.8.2 The laboratory should document appropriate procedures for proper cleaning and storage of samples to ensure integrity.

7.6.8.3 Documented procedures should be maintained that ensure that subportions of the sample under test are representative of the whole.

NOTE: Care should be taken during sample collection and handling to prevent contamination of the sample with body oil or moisture, and to protect the sample from extreme environmental moisture and temperature.

7.6.9 Test Reports

7.6.9.1 Reports when necessary, should include: moisture determination results, sample type, condition and identification number, type of moisture determination used to ascertain the results, and the precision of measurement (repeatability between the dishes or duplicate runs.)

7.6.9.2 Environmental parameters measured during the test should be provided on reports. These include laboratory temperature and relative humidity.

7.6.9.3 Information regarding cleaning methods (if performed) should be provided on the test report.

Table 14. Summary of environmental facility guidelines (as described in Section 7)

Lab	Temperature range °C (set point)	± Temp variability °C	Max change per hour °C	Temp accuracy °C	RH percent range	RH percent accuracy	Pressure accuracy Pa
Mass I	20 - 23	1.0	0.5	0.1	30 - 55	5	65
Mass II	20 - 23	2.0	1.0	0.5	30 - 55	10	135
Mass III	18 - 25		1.0		30 - 60		
Volume - G	20 - 23	2.0	1.0	0.1/0.5 (H_2O, air)	30 - 55	10	
Volume - T	18 - 25	1.0		0.5	20 - 60		135
Dimensional	20 (18 - 22)	1.0		0.5			
Temperature		2.0			30 - 55		
Tuning Forks							
Hydrometers				0.01 (solution)			
Time							
Moisture	20 - 23	2.0	1.0	0.5	30 - 55		

8. References

ANSI/NCSL Z540-1-1994, American National Standards Institute, National Conference of Standards Laboratories, American National Standard, *General Requirements for Calibration Laboratories and Measuring and Test Equipment*, 1994.

ISO/IEC Guide 25, International Organization for Standardization, Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories*, 1990.

ISO/IEC Guide 38, International Organization for Standardization, Guide 38, *General Requirements for the Acceptance of Testing Laboratories*, 1983 (in course of revision).

ISO/IEC 10012-1, International Organization for Standardization, International Standard 10012-1, *Quality Assurance Requirements for Measuring Equipment, Part 1, Metrological Confirmation System for Measuring Equipment*, 1992.

NCSL Recommended Practice RP-11: *Reports and Certificates of Calibration,* October 1991.

NCSL Recommended Practice RP-7: *Laboratory Design,* July 1993.

NBS Handbook 145, *Handbook for the Quality Assurance of Metrological Measurements*, Oppermann, H.V., Taylor, J., 1985.

NIST Handbook 150, National Voluntary Laboratory Accreditation Program, NVLAP, *Procedures and General Requirements*, Cigler, J. L., and White, V. R., editors, March 1994.

Appendix A. List of NIST Services

Assistance Available from NIST

It is the objective of NIST to encourage all State laboratories to seek full accreditation. Technical assistance and consultation includes the following:

1. BASIC metrology training in mass, length, and volume (2-week seminar).

2. INTERMEDIATE metrology training in mass, length, and volume (1-week seminar). Prerequisite - completion of BASIC course and BASIC LAP problems or equivalent.

3. NIST Precision Measurement Seminars. Seminars on special measurement techniques (2 to 5 day duration). Examples - Precision Thermometry Seminar, Advanced Mass Seminar.

4. Recommended test procedures for:

   a. mass tolerance testing
   b. mass calibration weighing designs
   c. volume calibration
      - volume transfer
      - gravimetric
   d. length calibration
      - length bench
      - tape-to-tape
      - rigid rules
   e. temperature - NBS Monograph 150

5. Time and frequency information - NBS Special Publications 432 and 559.

6. Measurement assurance information - NBSIR 77-1240.

7. NIST evaluation of laboratory auditing problems.

8. NIST evaluation of laboratory facilities by on-site visit.

9. Measurement control programs in selected measurement areas.

For further details on any of the above, general information, or assistance in areas not listed above, or in the case of special measurement problems, contact:

Office of Weights and Measures
State Laboratory Program
National Institute of Standards and Technology
Gaithersburg, MD 20899
Phone: 301/975-4004
Fax: 301/926-0647

Appendix B. Request for Accreditation, Scope of Accreditation, Approved Signatories, Authorized Representative

Name of laboratory

_____

_____

_____

Address of laboratory

_____

_____

_____

Scope of Accreditation - complete Appendix D with uncertainty estimates included

_____

_____

_____

_____

_____

Approved Signatories - have assigned responsibility for validity of laboratory reports

_____

_____

_____

Authorized Representative - contact for administration of laboratory accreditation

_____

_____

Appendix C. Part 1, Internal Assessment and Management Review Outline for Laboratory Assessment

NOTE: This form must be completed as a part of an internal assessment and management review and submitted for evaluation each year. You can also use this form as an overview for a meeting between management and laboratory staff. A detailed internal assessment (in addition to this form) should be completed prior to the *management review*. This form provides a format for a management review but does not have adequate detail for a proper internal assessment. Comments should be submitted to OWM in addition to this form.

Date of *Management Review*:

Staff present:

Items reviewed (R) or reviewed/submitted (RS). Include any relevant comments in attached correspondence.

_____ Quality Manual - required if updated since last submission
_____ Internal Assessment (Appendix C) - required annually, Part II required if accreditation expires
_____ Control Charts and Measurement Control Data - completed annually, submitted as requested:
  _____Control charts for all measurement services provided by the laboratory
  _____LAP 26/27, analysis forms for evaluating traceability and "control" of mass standards
  _____Weighing Equipment Assessment Chart
  _____Proficiency Testing Results Chart
  _____Training Summary
  _____Measurement control charts for mass and volume tolerance testing
_____ Basic/Intermediate/Advanced Training - attendance or problems submitted as required
_____ Attendance at Regional Meetings - required annually

Internal Assessment Summary:

Please indicate any concerns, changes, goals, plans, or special needs since the last review period.

_____ Facilities
_____ Equipment
_____ Standards
_____ Staff
_____ Overall Operations
_____ Other/Miscellaneous

Signed by:

Weights and Measures Director _____
Metrologist(s) _____
_____

Appendix C. Part 2, Laboratory Assessment Checklist

(from NVLAP Technical Guide)

GENERAL OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, NVLAP Procedures and General Requirements and this Handbook 143, Program Handbook. As an aid to those laboratories wishing to comply with both OWM and NVLAP criteria, cross-referenced items in this section reference NVLAP Handbook 150. Sections 5 and 6 of Handbook 143 are nearly identical with Subpart D, section 285.33 Criteria for Accreditation. Items marked with other NVLAP cross references may not apply to OWM accreditation - in that case, indicate "NA" for not applicable. A checklist for specific technical criteria is not included in this handbook at this time.

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

SEC. 285.33 CRITERIA FOR ACCREDITATION

(b) ***Organization and management***

(1) The laboratory shall be:

_____ (i) legally identifiable;

Legal name of laboratory ownership: _____

_____ (ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

_____ (iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

_____ (i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

_____ (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;

Name of person: _____

_____ (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;

Name of person: _____

_____ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;

Name(s): _____

_____ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];

_____ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];

_____ (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:

_____ (i) have an established and maintained quality system appropriate to the type, range, and volume of calibration and testing activities it undertakes;

_____ (ii) have the elements of the quality system documented;

_____ (iii) ensure that the quality documentation is available for use by the laboratory personnel;

_____ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;

_____ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;

_____ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: _____

Date of latest update: _____

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall 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 [see also (c)(1)(vi), (j)(1)];

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

_____ (vi) identification of the laboratory's approved signatories (list here or in the comments section): _____

_____

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

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

_____ (ix) written procedures 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 [see also (b)(2)(x), (c)(6)(ii), (g)(3)];

_____ (xv) procedures to be followed for feedback and corrective action whenever:

_____ a) testing discrepancies are detected, or

_____ b) 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 [see also (n)];

_____ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];

_____ (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. Where 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 NVLAP requirements shall be reviewed at least once a 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 time scale.

(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, such as control charts and other available 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 [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

_____ (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*** [see also (c)(2)(v)]

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

_____ (2) The testing 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 (facilities) and environment*** [see also (i)(3)]

_____ (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: While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

(f) ***Equipment and reference materials***

(1) The laboratory shall:

_____ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;

_____ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.

_____ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the 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 labeled, 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, software, or reference material;

_____ (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;

_____ (x) measured value observed for each parameter found to be out of tolerance during calibration/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 applicable, 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 [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

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 percent 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, these 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 [see also (k)(2)(x)].

_____ (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 [see also (k)(2)(ix)].

_____ (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 have written procedures which ensure that:

_____ (i) the NVLAP requirements are complied with;

_____ (ii) computer software, computers or automated equipment 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 [see also (f)(1)];

_____ (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 [see also (m)(2)].

(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 [see also (k)(2)(v)].

_____ (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 [see also (e)].

_____ (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 [see also (c)(2)(iv)].

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 (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

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

Record retention time specified: _____

(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 [see also (k)(4)(i)].

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 [see also (i)(1)];

_____ (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 [see also (h)(5)];

_____ (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 [see also (c)(2)(xv), (h)(4)];

_____ (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 [see also (c)(2)(vi)];

_____ (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 [see also (l)].

_____ (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 [see also (k)(1)].

_____ (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 item (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 NVLAP requirements 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*** [see also (k)(3)]

_____ (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 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 [see also (h)(8)].

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

(n) ***Complaints*** [see also (c)(2)(xvii)]

_____ (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 NVLAP requirements 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 item (c)(3).

(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 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 sections 285.33(b) through (n).

____ (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 because of mishandling, misuse, or unusual results.

____ (iv) All operations performed by the supplier in compliance with these requirements 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 these requirements.

- 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 section 285.33(o) 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 items (f)(1), (g)(1), and (h)(2).

____ (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 items (h)(1) and (h)(2).

_____ (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 these requirements.

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

_____ (ix) Records: These requirements 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 section 285.33 (i) 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.

GENERAL OPERATIONS CHECKLIST
COMMENTS AND DEFICIENCIES

Instructions to the Assessor or Internal Auditor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

SPECIFIC OPERATIONS CHECKLIST
COMMENTS AND DEFICIENCIES

Instructions to the Assessor or Internal Auditor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	*Comments and/or Deficiencies*

Appendix D. Summary of Services for Laboratory Directory

State

Accreditation Period:

Laboratory Staff & Titles	Address	Communications
		Phone: Fax: e-mail:

Services Available		
Parameter	Range	Uncertainty*
Mass, I		
Mass, II		
Mass, III		
Length, Tapes - Bench		
Length, Tapes - Tape		
Length, Rigid Rules		
Volume, Gravimetric		
Volume, Transfer		
Temperature, I		
Temperature, II		
Temperature, III		
Temperature, IV		
Temperature, V		
Tuning Forks		
Hydrometers		
Time		
Moisture		

* Uncertainties Chart (p. 104) must be completed for each measurement parameter listed.

Fees

National Type Evaluation Program (NTEP)	
Address	Telephone Number

Commercial Measuring Device Testing (non-NTEP)	
Address	Telephone Number

Grain Moisture Testing	
Address	Telephone Number

Petroleum Quality Testing	
Address	Telephone Number

Uncertainties Chart for Measurement Parameter_____
Laboratory_____

Range	Type A Uncertainty	Type B Uncertainty	Combined Uncertainty	Expanded Standard Uncertainty (k = 2 or 3)	Comments

NIST Technical Publications

Periodical

Journal of Research of the National Institute of Standards and Technology—Reports NIST research and development in those disciplines of the physical and engineering sciences in which the Institute is active. These include physics, chemistry, engineering, mathematics, and computer sciences. Papers cover a broad range of subjects, with major emphasis on measurement methodology and the basic technology underlying standardization. Also included from time to time are survey articles on topics closely related to the Institute's technical and scientific programs. Issued six times a year.

Nonperiodicals

Monographs—Major contributions to the technical literature on various subjects related to the Institute's scientific and technical activities.

Handbooks—Recommended codes of engineering and industrial practice (including safety codes) developed in cooperation with interested industries, professional organizations, and regulatory bodies.

Special Publications—Include proceedings of conferences sponsored by NIST, NIST annual reports, and other special publications appropriate to this grouping such as wall charts, pocket cards, and bibliographies.

National Standard Reference Data Series—Provides quantitative data on the physical and chemical properties of materials, compiled from the world's literature and critically evaluated. Developed under a worldwide program coordinated by NIST under the authority of the National Standard Data Act (Public Law 90-396). NOTE: The Journal of Physical and Chemical Reference Data (JPCRD) is published bi-monthly for NIST by the American Chemical Society (ACS) and the American Institute of Physics (AIP). Subscriptions, reprints, and supplements are available from ACS, 1155 Sixteenth St., NW, Washington, DC 20056.

Building Science Series—Disseminates technical information developed at the Institute on building materials, components, systems, and whole structures. The series presents research results, test methods, and performance criteria related to the structural and environmental functions and the durability and safety characteristics of building elements and systems.

Technical Notes—Studies or reports which are complete in themselves but restrictive in their treatment of a subject. Analogous to monographs but not so comprehensive in scope or definitive in treatment of the subject area. Often serve as a vehicle for final reports of work performed at NIST under the sponsorship of other government agencies.

Voluntary Product Standards—Developed under procedures published by the Department of Commerce in Part 10, Title 15, of the Code of Federal Regulations. The standards establish nationally recognized requirements for products, and provide all concerned interests with a basis for common understanding of the characteristics of the products. NIST administers this program in support of the efforts of private-sector standardizing organizations.

Order the **following** *NIST publications—FIPS and NISTIRs—from the National Technical Information Service, Springfield, VA 22161.*

Federal Information Processing Standards Publications (FIPS PUB)—Publications in this series collectively constitute the Federal Information Processing Standards Register. The Register serves as the official source of information in the Federal Government regarding standards issued by NIST pursuant to the Federal Property and Administrative Services Act of 1949 as amended, Public Law 89-306 (79 Stat. 1127), and as implemented by Executive Order 11717 (38 FR 12315, dated May 11, 1973) and Part 6 of Title 15 CFR (Code of Federal Regulations).

NIST Interagency Reports (NISTIR)—A special series of interim or final reports on work performed by NIST for outside sponsors (both government and nongovernment). In general, initial distribution is handled by the sponsor; public distribution is by the National Technical Information Service, Springfield, VA 22161, in paper copy or microfiche form.

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